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Part II

Environmental Protection Agency

40 CFR Parts 9, 156 and 165
Pesticide Management and Disposal; Standards for Pesticide Containers and Containment; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 156 and 165

[EPA–HQ–OPP–2005–0327; FRL–8076–2]

RIN 2070–AB95

Pesticide Management and Disposal; Standards for Pesticide Containers and Containment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this final rule, EPA is establishing regulations for the safe storage and disposal of pesticides as a means of protecting human health and the environment pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act. This final rule establishes requirements for pesticide container design, and procedures, standards and label language to facilitate removal of pesticides from containers prior to disposal or recycling. This final rule also establishes requirements for containment of stationary pesticide containers and procedures for container refilling operations. In addition, in order to display the OMB control number for the information collection requirements contained in this final rule, EPA is amending the table of OMB approval numbers for EPA regulations that appears in 40 CFR part 9.

DATES: This final rule is effective on October 16, 2006. For purposes of judicial review, this rule shall be promulgated at 1pm eastern daylight/standard time on August 30, 2006 (See 40 CFR 23.6).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0327. Please note that the docket material for the proposed rule and supplemental notice, identified previously by docket ID number OPP–190001, is included as part of the official docket for this action, although the material in the legacy docket is available only in hard copy. All documents in the docket are listed on the regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Nancy Fitz, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7385; fax number: (703) 308–2962; e-mail address: *fitz.nancy@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a pesticide formulator, agrichemical dealer, or an independent commercial applicator. Potentially affected categories and entities may include, but are not limited to:

- Pesticide formulators (NAICS 35232, former SIC code 2879), e.g., establishments that formulate and prepare insecticides, fungicides, herbicides or other pesticides from technical chemicals or concentrates produced by pesticide manufacturing establishments. Some formulating establishments are owned by the large basic pesticide producers and others are independent.
- Agrichemical dealers (NAICS 44422, former SIC code 5191), e.g., retail dealers that distribute or sell pesticides to agricultural users.
- Independent commercial applicators (NAICS 115112, former SIC code 0721), e.g., businesses that apply pesticides for compensation (by aerial and/or ground application) and that are not affiliated with agrichemical dealers.
- Custom blenders (NAICS 44422, former SIC code 5191), e.g., most custom blenders are also dealers.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Units II.D., III., V.B., VI.C., VII.B., VIII.C. and IX.A. of this document. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. You may also access a frequently updated electronic version of the Code of Federal Regulations (CFR) through the Government Printing Offices pilot e-CFR site at *http://www.gpoaccess.gov/ecfr/*.

II. Background

A. Statutory Authority

These final regulations are issued pursuant to the authority given the Administrator of EPA in sections 3, 8, 19 and 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a, 136f, 136q and 136w.

Sections 19(e) and (f) of FIFRA grant EPA broad authority to establish standards and procedures to assure the safe use, reuse, storage, and disposal of pesticide containers. FIFRA section 19(e) requires EPA to promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides. The regulations must ensure, to the fullest extent practicable, that the containers:

(1) Accommodate procedures used for removal of pesticides from the containers and rinsing of the containers.

(2) Facilitate safe use of the containers, including elimination of splash and leakage.

(3) Facilitate safe disposal of the containers.

(4) Facilitate safe refill and reuse of the containers.

FIFRA section 19(f) requires EPA to promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal. The statute states that the regulations may:

(1) Specify, for each major type of pesticide container, procedures and standards for, at a minimum, triple rinsing or the equivalent degree of pesticide removal.

(2) Specify procedures that can be implemented promptly and easily in various circumstances and conditions.

(3) Provide for reuse, whenever practicable, or disposal of rinse water and residue.

(4) Be coordinated with requirements imposed under the Resource Conservation and Recovery Act (RCRA) for rinsing containers.

Section 19(f) provides that the EPA, at the discretion of the Administrator, may exempt products intended solely for household use.

Section 19(f)(2) states that after December 24, 1993, a State may not exercise primary enforcement responsibility under section 26, or certify an applicator under section 11, unless the Administrator determines that the State is carrying out an adequate program to ensure compliance with regulations promulgated under the authority of section 19(f)(1).

Section 19(h), titled Relationship to Solid Waste Disposal Act, specifies that nothing in section 19 shall diminish the authorities or requirements of RCRA. Also, the Food Quality Protection Act (FQPA) of 1996 amended section 19(h) of FIFRA to add an exemption for certain antimicrobial pesticides.

B. Regulatory Background

Prior to 1995, recommendations regarding procedures for storage and disposal of pesticides and pesticide containers were listed under 40 CFR part 165. On June 19, 1995, as part of the Federal government's initiative to streamline regulations, part 165 was deleted as unnecessary (60 FR 32094) because it contained recommendations rather than requirements. (Ref. 62) Subpart A of part 165 covered the scope and definitions in the recommendations. Subpart B dealt with EPA's disposal of suspended and canceled pesticides, and EPA has completed disposal of all pesticides for which it was responsible under those regulations. Subparts C and D contained recommended procedures for storage and disposal of pesticide containers. Subparts A, B, C, and D were superseded by the passage of the Resource Conservation and Recovery Act in 1976. FIFRA section 19, as revised in 1988 and 1996, contains authority for EPA in the area of pesticide storage and disposal, and the container and containment regulations promulgated today are being inserted into a newly established part 165.

In a Notice of Proposed Rulemaking (NPRM) issued on February 11, 1994 (59 FR 6712), EPA proposed standards for pesticide containers and containment structures. (Ref. 66) This proposal included requirements for nonrefillable and refillable containers that would ensure the safe use and disposal of the containers. The proposal also included standards for containment structures, which would promote safe storage by facilitating the safe use, refill, and reuse of refillable containers. Additionally, the proposed rule contained amendments to the labeling regulations in 40 CFR part 156 to ensure adequate levels of residue removal from containers.

The public comment period for the NPRM closed on July 11, 1994. EPA received about 1,900 pages of comments from more than 200 commenters, including many trade associations and individual companies from the pesticide manufacturing, pesticide retail, and container manufacturing industries as well as many State regulatory agencies.

EPA received numerous comments on a few particular issues; specifically the scope of the container standards and the relationship between the 1994 proposed rule and the U.S. Department of Transportation (DOT) standards for hazardous materials packaging. A third issue arose from the 1996 passage of the FQPA, which amended section 19(h) of FIFRA to add an exemption for certain antimicrobial pesticides. To solicit comment on EPA's interpretation of the new statutory language on exempting antimicrobial pesticides and to reopen comment on the scope of the container regulations and an approach for incorporating DOT's standards, EPA published a supplemental notice in the **Federal Register** on October 21, 1999 (64 FR 56918). (Ref. 53) The supplemental notice also provided an alternative definition of small business for certain sectors of the pesticide industry for use in analyzing the potential impacts to small businesses that were presented as part of the economic analysis.

The public comment period for the supplemental notice closed on March 20, 2000. EPA received comments from about 70 respondents, including many trade associations and individual companies from the pesticide manufacturing, pesticide retail, and container manufacturing industries as well as many State regulatory agencies.

On June 30, 2004 (69 FR 39392), EPA reopened the public comment period for this rulemaking for 45 days because significant time had passed since the proposed rule in 1994 and supplemental notice in 1999. (Ref. 33) The purpose of the reopening was to solicit public input on any policies, market practices, technology or other issues relating to this rule's requirements which would not have been available or could not have been addressed at the time of either the proposal or supplemental notice. On August 13, 2004 (69 FR 50114), the comment period was extended for 30 days. (Ref. 32) The public comment period closed on September 15, 2004. EPA received about 50 comments, mainly from individual entities or trade associations representing pesticide manufacturers, agricultural pesticide retailers and State regulatory agencies.

On December 17, 1993 (58 FR 65989), EPA published an interim determination of adequacy for States with primary enforcement responsibility and/or certification programs because EPA had not promulgated regulations under section 19(f)(1) by December 24, 1993. (Ref. 69) To avoid having the provisions of section 19(f)(2) adversely impact the States and EPA, the Agency published a policy in the **Federal Register** on August 18, 1993 (58 FR 43994), which set forth a process for EPA to make such an interim determination. (Ref. 68) EPA's interim determination of adequacy was based on an initial commitment by a State to conduct a number of activities which will position the State to have an adequate program in place by the time compliance with the regulations promulgated under section 19(f)(1) is required. The December 17 notice stated that the determination of adequacy is temporary and will expire 2 years after promulgation of a final rule issued under section 19(f)(1). Thereafter, States must have a program to ensure compliance with the section 19(f) regulations. Related **Federal Register** notices were published on February 25, 1994 (59 FR 9214) regarding New Mexico and May 10, 1995 (60 FR 24855) regarding the Virgin Islands. (Refs. 60 and 67) The criteria and process for evaluating State programs to ensure that they have adequate compliance programs for regulations promulgated under section 19(f) will be published in a separate **Federal Register** notice.

C. Additional Container Issues Under Consideration for Potential Regulation

Since the 2004 public comment period closed, EPA has gathered information from a variety of sources about the status and robustness of existing pesticide container recycling programs. Over the past decade, the Ag Container Recycling Council (ACRC) has demonstrated that pesticide containers can be safely and efficiently recycled, and their success in recycling more than 80 million pounds of plastic since 1992 is commendable. However, the current voluntary container recycling system is showing signs of instability and non-sustainability, largely because it is financially

supported by only a portion of the pesticide industry.

EPA has an interest in promoting recycling to minimize the use of less environmentally-sound methods of disposing of these containers, such as by landfill or burning, and to reduce the amount of solid waste produced annually. After considering and evaluating a number of alternatives to sustain and increase the current level of container recycling, EPA has initiated development of proposed regulations for the recycling of plastic pesticide containers to ensure equitable, safe, effective and robust implementation of recycling programs. We are exploring a range of regulatory options for requiring participation in pesticide recycling programs and we will work with stakeholders to evaluate and pursue the most efficacious of these approaches.

D. Summary of the Final Rule

The Container and Containment Rule is composed of the following five specific sets of requirements or standards:

- Nonrefillable containers (container design and residue removal);
- Refillable containers (container design and residue removal);
- Repackaging pesticide products;
- Containment structures; and
- Container labeling.

Table 1 provides a brief overview of each portion of today's final rule. For each section of the regulations, the table identifies the types of businesses that must comply, the major requirements and the compliance date. The regulations, along with a summary of comments on major issues and comments that led to changes to the final regulations and EPA's responses, are discussed in later units of this preamble. EPA has also prepared a Response to Comment document that provides additional details with regard to the comments and EPA's responses (Ref. 19).

Each portion of the regulations applies to a different subset of pesticide products. The criteria that define which pesticide products are subject to which regulations (and which ones are exempt from them) are relatively complex, but some key points are:

- The new *label* standards apply to all pesticide products.
- The *containment* regulations apply to agricultural pesticides only.
- The *nonrefillable container, refillable container and repackaging* regulations apply to the same subset of pesticide products. These products are described in Table 2 below.
- For the *refillable container and repackaging* regulations, antimicrobial products that are used only in swimming pools (and closely related sites like hot tubs, spas and/or whirl pools) are subject to a reduced set of the requirements.
- For the *nonrefillable container* regulations, some products are subject to all of the regulations, while others must comply only with the basic Department of Transportation packaging requirements in 49 CFR 173.24.

TABLE 1.—OVERVIEW OF THE PESTICIDE CONTAINER AND CONTAINMENT STRUCTURE REGULATIONS

Category	Nonrefillable Containers	Refillable Containers	Repackaging Pesticide Products	Container Labeling	Containment Structures
Who must comply	Registrants	Registrants Refillers (retailers, distributors)	Registrants Refillers (retailers, distributors)	Registrants Pesticide users (must follow new directions)	Ag retailers Ag commercial applicators Ag custom blenders
Major Requirements	DOT container design, construction and marking standards Container dispensing capability Standardized closures Residue removal Recordkeeping	DOT container design, construction and marking standards Serial number marking One-way valves or tamper-evident devices Stationary container requirements	Registrants develop information Registrants and others comply with specified conditions Refillers (registrants and others) obtain and follow registrant information, and clean, inspect and label containers before refilling them	Identify container as nonrefillable or refillable (all) Statements to prohibit reuse and offer for recycling; batch code (all nonrefillables) Cleaning instructions (some nonrefillables) Cleaning instructions before final disposal (all refillables)	Secondary containment structures (dikes) around stationary tanks Containment pads for pesticide dispensing areas Good operating procedures Monthly inspections of tanks and structures Recordkeeping Provisions for States with existing programs
Compliance Date	August 17, 2009	August 16, 2011	August 16, 2011	August 17, 2009	August 17, 2009

TABLE 2.—PRODUCTS THAT ARE SUBJECT TO THE NONREFILLABLE CONTAINER, REFILLABLE CONTAINER AND REPACKAGING REGULATIONS

Category	Nonrefillable Containers	Refillable Containers	Repackaging Pesticide Products
Products that are not subject to the regulations.	(1) Manufacturing use products, (2) Plant-incorporated protectants, and (3) Antimicrobial pesticide products that satisfy all four of these criteria: The product is an antimicrobial pesticide (as defined in FIFRA section 2(mm)) or it has antimicrobial properties (as defined in FIFRA section 2(mm)(1)(A)) and is subject to a tolerance or a food additive regulation. Its label includes directions for use on a site in at least one of the 10 antimicrobial product use categories identified as household, industrial or institutional. It is not a hazardous waste when it is intended to be disposed, as defined in 40 CFR part 261. EPA has not specifically found that the product must be subject to these provisions to prevent an unreasonable adverse effect on the environment.	(1) Manufacturing use products, (2) Plant-incorporated protectants, and (3) Antimicrobial pesticide products that satisfy all four of the criteria listed in the nonrefillable container column.	(1) Manufacturing use products, (2) Plant-incorporated protectants, and (3) Antimicrobial pesticide products that satisfy all four of the criteria listed in the nonrefillable container column.
Products that are subject to the regulations	A product is subject to ALL nonrefillable container requirements if it satisfies at least one of the following criteria: It meets the criteria of Toxicity Category I in 40 CFR 156.62. It meets the criteria of Toxicity Category II in 40 CFR 156.62. It is a restricted use product.	All products not listed above.	All products not listed above.
	If a product does not meet any of these criteria, the product is subject to only the basic Department of Transportation requirements in the nonrefillable container regulations.		

E. Summary of the Major Changes Since Proposal

1. *Plain language format.* Many of the comments on the proposed rule and the supplemental notice made clear that the scope of parties and products subject to the rule was complex and potentially confusing. We have rewritten the Container and Containment rule in a plain language format to make it clearer and easier to use. A plain language format includes maximum use of the active voice; short, clear sentences; questions and answers; use of ''you'' to identify the person who must comply; use of ''we'' to identify EPA; and ''must'' rather than ''shall.'' This new format, which minimizes the layers of subparagraphs, should also allow the reader to easily locate specific provisions of the regulation. While we have made substantive changes in some provisions, the plain language changes are only editorial. The legal implications of plain English regulations are the same as traditional regulatory text. The word ''must'' indicates a requirement. Words like ''should,'' ''could,'' or ''encourage'' indicate a recommendation or guidance.

In this preamble, as in the rule text, we often use the pronoun ''he'' as a generic term. ''He'' does not necessarily mean a man; it may be a woman, or in some cases, a business organization when referring to an owner or operator.

The plain language approach also leads to more separate sections than traditional regulatory language.

Therefore, we had to reorganize and renumber the regulations to accommodate the increased number of separate sections. The changes are shown in Table 3.

Some sections of today's regulation are presented in the traditional language or format because these sections are amending or changing existing regulations. The plain language format was not used in these existing provisions in an attempt to avoid any possible confusion or disruption in the flow of the regulations.

TABLE 3.—COMPARISON OF PROPOSED RULE AND FINAL RULE SECTION NUMBERS

Format in Proposed Rule		Format in Final Rule	
Subpart	Section Numbers	Subpart	Section Numbers
Part 156			
Subpart H: Container Labeling	§§ 156.140 - 156.144	Subpart H: Container Labeling	§§ 156.140 - 156.159
Part 165			
Subpart A: General	§§ 165.1 - 165.16	Subpart A: General	§§ 165.1 - 165.3
Subpart B	Reserved	Subpart B: Nonrefillable Containers	§§ 165.20 - 165.27
Subpart C	Reserved	Subpart C: Refillable Containers	§§ 165.40 - 165.47
Subpart D	Reserved	Subpart D: Repackaging	§§ 165.60 - 165.70
Subpart E	Reserved	Subpart E: Containment Structures	§§ 165.80 - 165.97
Subpart F: Nonrefillable Containers	§§ 165.100 - 165.119	Subpart F	Reserved
Subpart G: Refillable Containers	§§ 165.120 - 165.139	Subpart G	Reserved
Subpart H: Containment Structures	§§ 165.140 - 165.157	Subpart H	Reserved

2. *Reorganization of the rule.* In the final rule, we split the refillable container standards and the repackaging standards into two separate subparts to reinforce and clarify the differences between these requirements. The refillable container regulations are mostly technical and apply mostly to pesticide registrants. On the other hand, the repackaging requirements are mostly procedural and apply to registrants and refillers (who could be registrants, distributors or retailers). EPA believes that separating these regulations into different subparts will better illustrate the differences and make it easier for the regulated parties to understand.

3. *Scope of products subject to container-related regulations.* In the February 1994 NPRM, EPA proposed that the container standards would generally apply to all pesticides and all containers except for manufacturing use products (MUPs). The 1999 supplemental notice proposed several options for exempting specific subsets of products from the container standards. Today's final rule exempts MUPs, plant-incorporated protectants and certain antimicrobial products from the nonrefillable container, refillable container and repackaging regulations. All other products are subject to the container-related regulations, although the number of applicable standards is greatly reduced for some products. These changes apply only to the container-related sections of the rule. As we proposed, all pesticide products are subject to the container labeling requirements in today's final rule and only agricultural pesticide products are subject to the containment requirements.

4. *Exemption from container-related regulations for certain antimicrobial products.* The FQPA amended section 19 of FIFRA to exempt certain types of antimicrobial pesticides from the pesticide container provisions. The amendment exempted household, industrial, or institutional antimicrobial products which are not subject to the Solid Waste Disposal Act (SWDA) from the container regulations unless the EPA Administrator determines that the product causes an unreasonable adverse effect on the environment. Because the definition of an antimicrobial product is complex, the phrase ''subject to the SWDA'' is unclear and ''unreasonable adverse effects on the environment'' from pesticide containers need to be clarified, EPA conducted many analyses based on the comments received. According to today's final rule, an antimicrobial product is exempt from the container standards if meets all four of the following criteria:

- The product is an antimicrobial pesticide as defined in FIFRA section 2(mm) or it has antimicrobial properties (as defined in FIFRA section 2(mm)(1)(A)) and is subject to a tolerance or a food additive regulation.
- The product includes directions for use on a site in one of the antimicrobial product use categories identified as household, industrial or institutional.
- The product is not a hazardous waste when it is intended to be disposed.
- EPA has not specifically determined that the product must be subject to the container regulations to prevent an unreasonable adverse effect on the environment.

In addition, antimicrobial products that would not otherwise be exempt from the regulations and that are used only in swimming pools (and closely related sites like hot tubs, spas and/or whirl pools) are subject to a reduced set of the refillable container and repackaging requirements.

5. *Scope of container-related regulations for products other than antimicrobial products.* As proposed in 1994, MUPs are exempt from the

container regulations. Plant-incorporated protectants, which were not discussed in the proposed rule, are also exempt from the container regulations. According to today's final rule, all other pesticide products, except antimicrobial pesticides that are exempt, are subject to the nonrefillable container, refillable container and repackaging regulations. For the nonrefillable container regulations, a product is subject to all of the requirements if it classified in at least one of the following categories:

- Toxicity Category I;
- Toxicity Category II;
- Restricted use pesticide.

Products that do not meet at least one of these criteria (i.e., products that are classified in Toxicity Category III or IV and that are not restricted use pesticides) are excluded from all of the nonrefillable container standards except the basic DOT requirements.

In general, products other than MUPs, plant-incorporated protectants and exempt antimicrobial products are subject to all of the refillable container and repackaging regulations. One exception is that antimicrobial products that are used only in swimming pools and closely related sites are subject to a reduced set of the refillable container and repackaging requirements.

6. *Referring to and adopting some Department of Transportation regulations*. In the 1994 proposed rule, EPA clarified that compliance with EPA's container regulations would not exempt registrants from complying with applicable DOT Hazardous Materials Regulations, and that compliance with DOT's marking and drop test requirements would satisfy the corresponding EPA requirement for refillable containers. Also, the preamble of the proposed rule requested comment on several options for determining who would be responsible for ensuring that containers meet the standards. In the 1999 supplemental notice, we discussed the comments on the proposal and discussed a new approach, namely to adopt and refer to the DOT Packing Group III criteria for both nonrefillable and refillable containers. Today's final rule includes the same basic approach as described in the supplemental notice. Specifically:

- Pesticide products that are DOT hazardous materials must be packaged as required by DOT.
- Pesticide products that are not DOT hazardous materials must be packaged in containers that are designed, constructed, and marked to comply with the cross-referenced and adopted requirements of DOT regulations, as applicable to a Packing Group III material or the limited quantity/consumer commodity exception.
- All pesticide products must comply with the pesticide-specific requirements in the nonrefillable and refillable container regulations.
- EPA may modify or waive these requirements under certain, limited conditions.
- If DOT proposes to change any of the regulations that are incorporated by these regulations, EPA will provide notice to the public in the **Federal Register**.

7. *Residue removal standard for nonrefillable containers*. The 1994 NPRM required that registrants demonstrate at least 99.9999 (six 9's) percent residue removal using a prescribed testing methodology for dilutable products in rigid containers. Testing would have been required on 19 representative samples in accordance with Good Laboratory Practice (GLP) standards in 40 CFR part 160. We received many comments opposing virtually every aspect of this proposed requirement. Today's final rule requires rigid containers of dilutable liquid formulations to be capable of achieving at least 99.99 percent (four 9's) residue removal using a defined laboratory triple rinse method conducted on three representative containers. In addition, testing and recordkeeping is only required for flowable concentrate formulations or if EPA requests the tests on a case-by-case basis.

8. *Consistency with existing State containment regulations*. At least 19 States have already promulgated and implemented State bulk containment regulations. EPA's proposed rule included basic standards generally similar to State standards, although some were more rigorous and others less stringent than certain State standards. Today's containment standards are intended to introduce substantial safeguards in States that currently lack containment regulations and to harmonize with containment requirements in States where adequate containment safety programs already exist. While EPA believes a national standard must provide substantial environmental protection, a mechanism is being provided to accommodate States that have successfully implemented bulk containment programs.

9. *Hydraulic conductivity standard for containment structures*. The proposed rule would have required that existing and new structures demonstrate compliance with a hydraulic conductivity standard of 1×10^{-6} cm/sec and 1×10^{-7} cm/sec, respectively. EPA received many comments opposed to the hydraulic conductivity standard which was perceived to be too restrictive, not achievable and too costly. The requirement for a numeric hydraulic conductivity standard was dropped from the final rule, but all existing and new structures are required to be liquid-tight, with cracks and seams sealed.

10. *Scope of products subject to label regulations*. The final labeling regulations in today's rule cover the same statements and topics that were included in the proposed rule. Unlike the container-related regulations, all products must comply with the container labeling requirements — the labeling regulations do not exempt MUPs or certain antimicrobial products. One exception is that plant-incorporated protectant container-related labeling instructions will be determined by EPA on a case-by-case basis until specific labeling guidance for plant-incorporated protectants are promulgated under 40 CFR part 174.

While today's label requirements generally apply to all pesticide products, the specific label requirements apply to different groups of products and containers. In particular:

- A statement identifying a container as nonrefillable or refillable is required on the labels of all products and all containers.
- Statements to prohibit reuse and offer for recycling and a batch code are required on the labels or container of all products distributed or sold in nonrefillable containers.
- Rinsing instructions are required on the labels of some products distributed or sold in nonrefillable containers. Specifically, the requirement for rinsing instructions applies to dilutable products in rigid nonrefillable containers. Residential/household use pesticide products are exempt from this requirement.
- Instructions for cleaning before final disposal (not before refilling) are required on the labels of all products distributed or sold in refillable containers.

III. Container Regulations—Scope

The purpose of Unit III. is to describe the scope of the container-related regulations, including the standards for nonrefillable containers in 40 CFR part 165, subpart B, refillable containers in subpart C and repackaging pesticide products in subpart D. The regulations themselves are discussed in more detail in Units V., VI. and VII. for nonrefillable containers, refillable containers and repackaging, respectively. Unit IV. discusses the relationship between

EPA's container-related regulations and the Department of Transportation's Hazardous Materials Regulations.

EPA is exempting some pesticides and containers from today's rule based on the statutory language and the relative risk posed by the pesticides and containers. The 1994 NPRM proposed that the container regulations would generally apply to all end use pesticides and all containers, regardless of the pesticide market sector. The NPRM proposed to exempt MUPs from the container requirements. Many commenters opposed the broad scope of the regulations and requested EPA to exempt one or more subsets of pesticides from the container requirements.

The 1996 FQPA amended section 19 of FIFRA to exempt certain types of antimicrobial pesticides from the container provisions under certain circumstances. In the October 1999 Supplemental Notice, EPA proposed a regulatory option for exempting certain pesticides, and requested comment on the applicability and interpretation of the antimicrobial exemption to FIFRA.

As described in this unit, the container-related provisions in the final rule apply only to a subset of end use pesticide products. All MUPs and plant-incorporated protectants are exempt from the container-related requirements. The container regulations define criteria for antimicrobial products that are subject to the container-related standards. Other than MUPs, plant-incorporated protectants and exempt antimicrobial products, all products are subject to the nonrefillable container, refillable container and repackaging regulations. However, some products are subject to a reduced number of requirements. The discussion in Unit III. applies only to the nonrefillable container, refillable container and repackaging regulations. The containment and labeling regulations have different scopes, as described in Units VIII. and IX.

A. Exempt Manufacturing Use Products (§§ 165.23(a), 165.43(a) and 165.63(a))

1. *Final regulations*. MUPs, as defined in 40 CFR 158.153(h), are exempt from the container regulations. As described in the preamble to the proposed rule, this exemption applies to technical grade products and formulation intermediates intended only for formulation into other pesticide products and labeled for formulation use only.

2. *Changes*. This exemption is identical to the exemption in the 1994 proposed rule and the 1999 Supplemental Notice.

B. Exempt Plant-Incorporated Protectants (§§ 165.23(b), 165.43(b) and 165.63(b))

1. *Final regulations*. Plant-incorporated protectants, as defined in 40 CFR 174.3, are exempt from the container regulations.

2. *Changes*. EPA did not specifically mention plant-incorporated protectants in either the proposed rule or the supplemental notice because there were either no registrations for these products or they were uncommon at that time; these types of products are relatively new to the marketplace. In the June 30, 2004 **Federal Register** notice (69 FR 39393), EPA cited plant-incorporated protectants as an example of a topic that would be appropriate to comment on during the 2004 reopening of the comment period. (Ref. 33) As explained below, EPA believes it is appropriate to exempt plant-incorporated protectants from the container requirements in the final rule.

In comments on the 2004 **Federal Register** notice, two registrant groups and five registrants urged EPA to exempt plant-incorporated protectants from the container and containment regulations. These commenters stated that plant-incorporated protectants fit the three conditions of EPA's treated article policy and therefore should be exempt from all provisions of FIFRA when used in the manner described. They also concurred with EPA's assessment in the 2004 **Federal Register** notice that plant-incorporated protectants are not sold and distributed in containers like other pesticides; they are distributed as parts of seeds or plants.

The regulations for plant-incorporated protectants in 40 CFR parts 152 and 174 were finalized in the **Federal Register** on July 19, 2001 (66 FR 37771). (Ref. 50) A plant-incorporated protectant is a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. As explained in the preamble to the final rule for plant-incorporated protectants (66 FR 37774), ''[p]lant-incorporated protectants are primarily distinguished from other types of pesticides because they are intended to be produced and used in a living plant. This difference in use pattern dictates in some instances differences in approach.'' (Ref. 50) Plant-incorporated protectants are not sold and distributed in containers as distinct substances (e.g., liquids, solids or gels) like other pesticides; they are distributed as part of the seeds or plants. In other words, plant-incorporated protectants do not have containers like most pesticides. Therefore, EPA believes it is appropriate to exempt plant-incorporated protectants from the requirements of the container-related regulations.

C. Exempt Certain Antimicrobial Products (§§ 165.23(c), 165.43(c) and 165.63(c))

The 1996 FQPA amended section 19 of FIFRA to exempt certain types of antimicrobial pesticide products from the pesticide container provisions under certain circumstances. Specifically, FQPA added the following to FIFRA section 19(h):

> A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act (42 U.S.C. 6901 *et seq*.) shall not be subject to the provisions of subsections (a), (e), and (f), unless the Administrator determines that such product must be subject to such provisions to prevent an unreasonable adverse effect on the environment.

Because this language was added after the pesticide container and containment rule was proposed in 1994, EPA solicited public comment on the applicability of this provision to the proposed container regulations in the 1999 supplemental **Federal Register** notice. In addition, the supplemental notice described EPA's interpretation and response to the following two broad questions relating to the antimicrobial exemption provision:

- What is the scope of household, industrial, or institutional antimicrobial products that are not subject to regulation under the Solid Waste Disposal Act?
- Which products must be subject to the container provisions to prevent an unreasonable adverse effect on the environment?

Based on comments on the proposed rule and supplemental notice and on several additional analyses, EPA is making a number of changes in the approach for regulating antimicrobial products in the final regulations. The approach in the final rule is briefly described here and the details are provided in the issue-by-issue sections below.

- All four of the following criteria must be met for a product to be exempt from the container regulations:

(1) The product is an antimicrobial pesticide as defined in FIFRA section 2(mm) or it has antimicrobial properties (as defined in FIFRA section 2(mm)(1)(A)) and is subject to a tolerance or a food additive regulation.

(2) The product includes directions for use on a site in one of the

antimicrobial product use categories identified as household, industrial or institutional.

(3) The product is not a hazardous waste when it is intended to be disposed.

(4) EPA has not specifically determined that the product must be subject to the container regulations to prevent an unreasonable adverse effect on the environment.

• EPA will determine which products must be subject to the container provisions to prevent an unreasonable adverse effect on the environment on a case-by-case basis as described in the regulations.

• The final rule exempts refillable containers used to distribute antimicrobials used in swimming pools (and that are subject to the regulations because they do not meet all of the exemption criteria) from some of the refillable container and repackaging standards (including, but not limited to, serial number markings, one-way valves or tamper-evident devices, and some recordkeeping).

The four criteria that identify which antimicrobial products are exempt from the container regulations are discussed in greater detail in Units III.C.1. - III.C.4. The other aspects of the approach toward regulating antimicrobials are discussed in Units III.D. - III.F.

Throughout the preamble, the term ''antimicrobial'' is intended to be interpreted broadly with the property of destroying or inhibiting the growth of microorganisms (and as identified in FIFRA section 2(mm)(1)(A)) unless specified otherwise. In other words, we specify ''FIFRA 2(mm) antimicrobial pesticides'' if we are referring to the more limited definition of antimicrobial pesticides in FIFRA section 2(mm).

1. *Exemption criteria: definition of an antimicrobial pesticide*—i. *Final regulations.* The first of the four criteria that must be met for an antimicrobial product to be exempt from the container regulations is:

The pesticide product meets one of the following two criteria:

(1) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(2) The pesticide product:

(i) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(ii) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

ii. *Changes.* In the supplemental notice, this criterion was limited to ''The product meets the definition of an antimicrobial pesticide in FIFRA section 2(mm).'' EPA continues to believe that the most straightforward approach for defining antimicrobial products is to use the FIFRA definition of antimicrobial pesticide. The second criterion was added because, after thorough analysis of the definition of antimicrobial pesticide, EPA believes that some pesticides that are excluded from the definition should be eligible for exemption from the container regulations. Specifically, FIFRA section 2(mm)(1)(B) explicitly excludes pesticides with antimicrobial properties as identified in section 2(mm)(1)(A) from being FIFRA section 2(mm) antimicrobial pesticides if they are subject to a tolerance or a food additive regulation in their intended use. EPA believes that these pesticides should be eligible for exemption from the container regulations along with pesticides that are FIFRA section 2(mm)-defined antimicrobial pesticides.

Although there is no official legislative history documenting the intent of the definition of antimicrobial pesticide in FQPA, EPA acknowledges that FQPA also established time periods in FIFRA section 3 for registration review and action for various kinds of antimicrobial pesticides. EPA believes it is reasonable to conclude that pesticides subject to a tolerance or food additive regulation were excluded from the FIFRA section 2(mm) definition of antimicrobial pesticide at least partly because these pesticides require more data and analysis than other antimicrobial pesticides and, therefore, should not be subject to the registration time periods established in FIFRA section 3.

More importantly, EPA believes that the containers of pesticides with antimicrobial properties that are subject to a tolerance or food additive regulation generally pose a limited risk to human health and the environment. If either EPA or the Food and Drug Administration (FDA) determine that a pesticide with antimicrobial properties can be safely used on food or on food contact surfaces, the containers holding these pesticides are unlikely to pose a significant risk or even a risk greater than the pesticides that are FIFRA 2(mm) antimicrobial pesticides. EPA believes that these pesticides should also be eligible for exemption from the pesticide container regulations and that exempting these pesticides should not significantly increase the risk posed by containers of these pesticides. Therefore, it is very unlikely that such an exemption would pose an unreasonable adverse effect on the environment. We believe the provisions of FIFRA sections 19 and 25 authorize such an exemption.

While EPA is identifying pesticides with antimicrobial properties that are subject to a tolerance or food additive regulation as being *eligible* for exemption from the container regulations, they are not automatically exempt. Pesticides with antimicrobial properties that are subject to a tolerance or food additive regulation must also meet the other criteria identified by Congress in the FIFRA section 19(h) language: (1) It is a household, industrial or institutional product; (2) it is not a hazardous waste when disposed; and (3) EPA has not determined it must be subject to the regulations to prevent an unreasonable adverse effect. While EPA believes it is reasonable to make pesticides with antimicrobial properties that are subject to a tolerance or food additive regulation eligible for exemption from the pesticide container regulations, we see no reason that these pesticides shouldn't be subject to the other criteria that Congress established for antimicrobial pesticides.

EPA is not implementing similar exemption provisions for the other pesticide types excluded from the definition of antimicrobial pesticide in FIFRA section 2(mm), which include:

• Wood preservatives with claims for pests other than micro-organisms;

• Antifouling paint products with claims for pesticides other than micro-organisms;

• Agricultural fungicide products; and

• Aquatic herbicide products.

EPA does not believe that the pesticides in this list generally pose a limited risk to human health and the environment, as is the case with pesticides with antimicrobial properties that are subject to a tolerance or food additive regulation. EPA analyzed one of its pesticide data bases (Reference File System or REFS) and identified the wood preservative and antifouling paint products that claim to control pests other than micro-organisms. Many of the wood preservative products that claim to control pests other than micro-organisms also would be hazardous wastes when they are disposed and many of these are also restricted use products, such as those containing arsenic acid, arsenic pentoxide, chromic

acid, coal tar, creosote and pentachlorophenol. Many of the antifouling paint products that claim to control pests other than micro-organisms are also restricted use pesticides, such as products containing copper (I) oxide, bis(tributyltin oxide) and tributyltin methacrylate. EPA does not believe that products containing these active ingredients meet the criterion of generally posing a limited risk to human health and the environment, as is the case with pesticides with antimicrobial properties that are subject to a tolerance or food additive regulation.

2. *Exemption criteria: household, institutional or industrial products*—i. *Final regulations.* The second of four criteria that must be met for an antimicrobial product to be exempt from the container regulations is:

The product includes directions for use on a site in one of the following 10 antimicrobial product use categories identified as ''household, industrial or institutional:''

(1) Food handling/storage establishments premises and equipment.

(2) Commercial, institutional, and industrial premises and equipment.

(3) Residential and public access premises.

(4) Medical premises and equipment.

(5) Human drinking water systems.

(6) Materials preservatives.

(7) Industrial processes and water systems.

(8) Antifouling coatings.

(9) Wood preservatives.

(10) Swimming pools.

ii. *Changes.* Prompted by comments and after re-evaluating the antimicrobial product use categories, EPA is modifying the approach in the supplemental notice by adding a tenth category, *human drinking water systems*, to the list of ''household, industrial or institutional'' uses. EPA agrees with commenters that the category of human drinking water systems includes use in individual water systems, which could be used in homes. Additionally, human drinking water systems include use in public water systems and the drinking water treatment facilities that use the pesticides for this purpose fit into a reasonable understanding of industrial use. Therefore, 10 of the 12 antimicrobial product use categories will be ''household, industrial or institutional'' uses, compared to the nine categories identified in the supplemental notice. The two antimicrobial product use categories that are not identified as ''household, industrial or institutional'' are ''agricultural premises and equipment'' and ''aquatic areas.'' Multiple-use products with labels that include directions for use on a site in one of the excluded categories (''agricultural premises and equipment'' and ''aquatic areas'') and in at least one of the ten antimicrobial use product categories identified as ''household, industrial and institutional'' would be eligible for exemption.

3. *Exemption criteria: not subject to RCRA*—i. *Final regulations.* The third of four criteria that must be met for an antimicrobial product to be exempt from the container regulations is:

The pesticide product is not a hazardous waste as set out in 40 CFR part 261 when the pesticide product is intended to be disposed.

ii. *Changes.* This criterion is nearly the same as in the supplemental notice, but EPA modified the language slightly in response to a few comments to clarify that antimicrobials that are household waste are eligible for exemption. Rather than specifying that ''the pesticide product does not meet the criteria for hazardous waste as set out in part 261...'' as discussed in the supplemental notice, the final rule uses broader language (''the pesticide product is not a hazardous waste as set out in part 261...'') that clearly includes all of the criteria, exclusions and other provisions in 40 CFR part 261.

4. *Exemption criteria: EPA has not specifically determined the product must be subject to the regulations*—i. *Final regulations.* The fourth of four criteria that must be met for an antimicrobial product to be exempt from the container regulations is that EPA has not specifically determined that the pesticide product must be subject to the regulations to prevent an unreasonable adverse effect on the environment according to the provisions discussed in Unit III.F.

ii. *Changes.* This criterion is necessary to implement Option 1 in the supplemental notice. The sample regulatory text in the supplemental notice did not specifically have a provision for subjecting antimicrobial products to the container regulations on a case-by-case basis because the sample regulatory text reflected Option 3. As discussed in Unit III.F, the final rule must define conditions and procedures for EPA to determine that an antimicrobial product or group of products must be subject to the container regulations to prevent an unreasonable adverse effect on the environment. Because EPA may subject certain antimicrobial products to the container regulations in the future, a fourth criterion is necessary for the list of criteria for the antimicrobial products that are exempt from the container regulations. Respondents provided extensive comments (described in Unit III.E.) about how EPA should make these determinations.

D. Antimicrobial Swimming Pool Products That Are Not Exempt (§§ 165.43(d), 165.63(d))

1. *Final regulations.* An antimicrobial swimming pool product that is not otherwise exempt (because it is a manufacturing use product, plant-incorporated product or an exempt antimicrobial product) is subject to a reduced set of the refillable container and repackaging regulations. Comments on the supplemental notice and an analysis of antimicrobial products indicated that some antimicrobial swimming pool products are hazardous wastes when they are disposed and, therefore, would be subject to the pesticide container regulations because they do not meet all four criteria for exemption.

For the purposes of subparts C and D, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

- The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.
- The labeling of the pesticide product includes directions for use only on a site or sites in the antimicrobial product use category of swimming pools.

Antimicrobial swimming pool products that are not exempt must comply with all of the refillable container regulations in subpart C except for:

- § 165.45(d) regarding marking; and
- § 165.45(e) regarding openings.

Antimicrobial swimming pool products that are not exempt must comply with all of the repackaging regulations in subpart D except for the following requirements:

Requirement	Requirement for registrants who distribute or sell directly in refillable containers	Requirement for refillers who are not registrants
Recordkeeping specific to each instance of repackaging	§ 165.65(i)(2)	§ 165.70(j)(2)
Container inspection: criteria regarding a serial number or other identifying code	§ 165.65(e)(3)	§ 165.70(f)(3)
Container inspection: criteria regarding one-way valve or tamper-evident device	§ 165.65(e)(4)	§ 165.70(f)(4)
Cleaning requirement: criteria regarding one-way valve or tamper-evident device	§ 165.65(f)(1)	§ 165.70(g)(1)
Cleaning if the one-way valve or tamper-evident device is not intact	§ 165.65(g)	§ 165.70(h)

2. *Changes*. The supplemental notice included a similar provision, but it would have applied only to products eligible for exemption. Based on the comments and further analysis, EPA realized that the products for which relief was intended (those with sodium hypochlorite) may be hazardous wastes when disposed and, therefore, would not be eligible for either full or partial exemption according to the approach in the supplemental notice. Today's final rule subjects antimicrobial swimming pool products to a reduced set of the refillable container and repackaging requirements if they are sold and distributed in refillable containers. Specifically, antimicrobial swimming pool products would not have to comply with some of the standards, including, but not limited to, serial number markings, one-way valves or tamper-evident devices, and some recordkeeping. Currently, EPA is aware of sodium hypochlorite products that fit these criteria and that are sold and distributed in refillable containers. However, the partial exemption was drafted to be general so it would apply to any products that fit the criteria.

A description of an antimicrobial swimming pool product was added to subparts C and D for clarity. The regulatory text was modified to clarify that the reduced set of requirements applies to products labeled for use on a site or sites *only* in the antimicrobial product use category of swimming pools (which includes swimming pools, spas, hot tubs, and whirlpools). In other words, a product that is labeled for use in swimming pools (and/or spas, hot tubs and whirlpools) and another site, such as human drinking water systems, would have to comply with the full set of refillable container and repackaging requirements. Alternatively, the registrant of such a product could remove the use site(s) other than those in the antimicrobial product use category of swimming pools from the label, in which case the product would be subject to the reduced set of refillable container and repackaging requirements.

Many antimicrobial swimming pool products are completely exempt from the nonrefillable container, refillable container and repackaging regulations by §§ 165.23(c), 165.43(c) and 165.63(c). However, some antimicrobial swimming pool products are subject to the container-related regulations because they do not meet all of the criteria in these sections, for example, because they are hazardous wastes when they are disposed. The partial exemption in §§ 165.43(d) and 165.63(d) provides some regulatory relief from the refillable container and repackaging requirements for such antimicrobial swimming pool products. Antimicrobial swimming pool products that are not completely exempt must comply with all of the nonrefillable container requirements.

E. EPA Determinations that Products Must be Subject to the Container Regulations to Prevent an Unreasonable Adverse Effect on the Environment

1. *Final regulations*. The final regulations exempt all antimicrobial products that are eligible for exemption according to the criteria described in Unit III.C. from needing to comply with the nonrefillable container, refillable container and repackaging regulations. The final regulations also include a provision that allows EPA to determine, on a case-by-case basis, that a specific product or group of products must be subject to the regulations to prevent an unreasonable adverse effect on the environment if a problem becomes evident. The specifics of this provision are discussed in Unit III.F.

2. *Changes*. The approach in the final rule is a change from the approach that was identified as our preferred approach (Option 3) in the supplemental notice, which would have subjected all antimicrobials eligible for exemption that were classified in Toxicity Category I to a subset of the container regulations. In the supplemental notice, EPA described four options for determining which antimicrobial products that are eligible for exemption would be subject to the container provisions to prevent an unreasonable adverse effect on the environment. Today's final rule establishes Option 1 as the procedure to be implemented, which exempts all eligible antimicrobials, but includes a provision to require a specific product or group of products to comply with the container regulations if a problem becomes evident. The four options in the supplemental notice were:

- Option 1: Exempt all eligible antimicrobials, but include a provision to require a specific product or group of products to comply with the container regulations if a problem becomes evident.
- Option 2: Subject eligible antimicrobials classified in Toxicity Category I to all of the container regulations.
- Option 3: Subject eligible antimicrobials classified in Toxicity

Category I to a subset of the container regulations.

• Option 4: Apply the scope criteria being considered for other pesticides to eligible antimicrobials.

3. *Comments*. Two state agencies supported EPA's approach in the supplemental notice (Option 3). Eighteen commenters, representing the antimicrobial and/or the swimming pool/spa industries, strongly opposed EPA's approach, and most supported Option 1. An agricultural registrant stated that the language in section 19(h) is not a blanket exemption, and that focusing on only Toxicity Category I (as opposed to Toxicity Categories I and II in the applicability for all other products) is unfair and inconsistent.

Many commenters opposed EPA's approach and supported Option 1, either by specifically identifying it as the option EPA should adopt or by describing and supporting an approach that is consistent with Option 1. These commenters supported their positions with the following claims:

i. *Statutory intent*. Some commenters stated that only Option 1 is consistent with the statutory language. Several respondents specifically disagreed with EPA's general criteria approach, saying it was unnecessary, inappropriate and inconsistent with the statutory language.

ii. *Congress's intent*. Similarly, many commenters stated that only Option 1 is consistent with Congress's intent. The commenters generally argued that Congress's clear intent was to exempt nearly all eligible antimicrobials. One commenter referred to testimony received and comments made at various committee hearings to support its interpretation of the congressional intent. Several commenters stated that EPA's approach is contrary to the position of EPA negotiators during pre-FQPA discussions, which was that the provision constituted essentially a complete exemption.

iii. *No information about unreasonable adverse effects*. Many respondents pointed out that EPA does not have concrete information, such as documented incidents, of unreasonable adverse effects (UAEs) caused by antimicrobial pesticides. In addition, several pool supply companies said that there are no reports of accidents with refillable containers used for pool chemicals and mentioned that they have used these containers safely for many years and for large volumes of sodium hypochlorite.

iv. *Standard of unreasonable adverse effect on the environment*. Several commenters stated that the process of registration is intended to ensure that the pesticide will not cause an UAE, and therefore all registered products, including those in Toxicity Category I, have been determined to meet a standard of no UAE. These commenters further argued that information on specific exposures, leakage or other problems is needed to overturn the registration decision of no UAE and to determine that an UAE must be prevented. Another respondent commented that Congress didn't provide additional insight into what constitutes an UAE in the context of section 19, so it must have the same meaning as in the FIFRA registration standard in section 3(c)(5) and the obligation to report information on UAE in section 6(a)(2).

v. *FIFRA section 6(a)(2) reporting*. Several commenters stated that the section 6(a)(2) obligation for registrants to submit factual information regarding UAE to EPA provides an adequate mechanism for EPA to identify UAEs caused by antimicrobials eligible for exemption. A few of these respondents pointed out that the UAE standard in section 6(a)(2) is exactly the same as the standard in section 19(h)(2).

vi. *Minimal threat to the environment*. Several commenters specifically addressed sodium hypochlorite and commented that it is not a threat to the environment because: it has a short half life; it's final fate is sodium chloride (table salt); it is used widely without evidence that it is problematic; it's only in Toxicity Category I for eye effects, unlike the toxic and persistent agricultural pesticides; it's an inorganic chemical; the institutional/industrial formulation is only slightly more concentrated than common household bleach; it's less toxic than many automotive and household chemicals; and the resultant liquid from hosing down a spill is indistinguishable from drinking water. An industry association argued that many of these claims apply to institutional and industrial sanitizers and disinfectants in general.

vii. *No need for additional regulations*. Several commenters stated that there is no need for EPA to regulate institutional and industrial disinfectants because these products are already adequately regulated by EPA waste regulations, DOT's packaging requirements, and OSHA's health and safety standards. One commenter stated that most manufacturers and formulators of antimicrobial products use containers that meet at least the DOT Packing Group III standards for all materials, because it's not feasible to use certain containers for DOT hazardous materials and other containers for products that aren't DOT hazardous materials.

4. *EPA response*. EPA has decided to change its approach for determining which antimicrobial products that are eligible for exemption must be subject to the container regulations to prevent an unreasonable adverse effect. The final rule will implement Option 1 rather than Option 3.

EPA believes that Option 1 is acceptable because it is a legitimate, reasonable interpretation of the statutory language. In addition, making determinations for subjecting products to the container regulations based on specific information, data or other evidence of a problem to prevent unreasonable adverse effects on the environment is more straightforward than making such a determination based on arguments supporting the fact that there *could* be unreasonable effects.

In changing the approach to Option 1, EPA was partly convinced by the comments and observations relating to the standard of unreasonable adverse effect. The process of registration (including the submission and review of data plus establishing label restrictions) is intended to ensure that the pesticide will not cause UAEs on the environment. In other words, all registered products have been determined to meet a standard of not causing UAEs on the environment. This determination can be re-visited and changed by EPA if UAEs are identified during the process of reregistration or other review, under the ongoing mechanisms of FIFRA section 6(a)(2) (as implemented by 40 CFR part 159) or when other relevant information is received by EPA.

If all eligible Toxicity Category I antimicrobial products needed to be subject to the container regulations to prevent UAEs on the environment (according to options 2 and 3 in the supplemental notice), then currently we should be seeing UAEs from the containers of these products. This is especially true given the relatively large quantities of antimicrobial pesticides used annually. As described in the supplemental notice, in 1995 approximately 3,290 million pounds of antimicrobial active ingredients were used in the United States, compared to 1,222 million pounds of non-antimicrobial active ingredients.

However, EPA is unaware of a substantial number of UAEs resulting from the containers of antimicrobial pesticides. Data from the California Pesticide Illness Surveillance Program indicate only a limited number of cases where exposure to antimicrobial pesticides was very likely to be prevented if the container regulations had been in place. (Ref.22) Given the

limited number of incidents, we do not believe it is appropriate to require all eligible Toxicity Category 1 antimicrobial products to be subject to the container regulations, and we believe that a case-by-case approach is better suited to the issue.

Because Congress didn't provide additional insight into what constitutes an unreasonable adverse effect in the context of section 19, EPA agrees with the comment that it should have the same meaning as in the FIFRA registration standard in section 3(c)(5) and the obligation for registrants to report information about UAEs on the environment in FIFRA section 6(a)(2).

While some of the public comments were persuasive, EPA does not agree with all of the comments submitted in support of Option 1. For example, EPA stands by the statements in the supplemental notice that the statutory language ''unless the Administrator determines that [an eligible antimicrobial] product must be subject to [the container] provisions to prevent an unreasonable adverse effect on the environment'' provides considerable flexibility for EPA to implement it by establishing general criteria or by product-specific decisions. In addition, the lack of significant documented legislative or statutory history on the FQPA amendment to FIFRA section 19(h) makes it impossible to identify Congress's intent one way or another on this issue. Moreover, the fact that this language was added toward the end of the legislation's adoption indicates that commenters' statements regarding the intent of section 19(h) may not be an altogether accurate depiction of how Congress intended this portion of section 19(h) to be interpreted. EPA believes that some antimicrobial products may need to be subject to the container regulations to protect human health and the environment. These products will be identified and regulated by the process described in Unit III.F. below. Finally, EPA believes that the other regulations cited by commenters including EPA waste regulations, DOT's packaging requirements, and the OSHA health and safety standards overlap to some degree with the pesticide container regulations but generally address different stages of a container's life cycle. Also, these regulations apply to other pesticides and therefore do not uniquely affect antimicrobials.

F. Process for EPA to Make These Determinations (§§ 165.23(d),165.43(e) and 165.63(e))

1. *Final regulations*. The final regulations describe the process and standards by which EPA may determine that an antimicrobial pesticide product that would otherwise be exempt must be subject to the container regulations to prevent an unreasonable adverse effect on the environment. EPA may make this determination if all of the following conditions exist:

- EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.
- The information, data or other evidence is reliable and factual.
- The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.
- Complying with the container regulations could reasonably be expected to eliminate the problem.

The process in the final rule for making these determinations is based on the regulations in 40 CFR 152.164 for classifying products as restricted use pesticides. If EPA determines that an antimicrobial pesticide product that would otherwise be exempt must be subject to the container regulations to prevent an unreasonable adverse effect on the environment, EPA may:

- Require, by rule, that the product be repackaged (if applicable) and distributed or sold in containers that comply with all or some of the requirements in these regulations; or
- Notify the applicant or registrant of EPA's intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be repackaged (if applicable) and distributed or sold in containers that comply with all or some of the requirements in these regulations.

For the purposes of notification, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. This process allows EPA to apply all of the requirements in the nonrefillable container, refillable container and repackaging subparts to the product. Alternatively, EPA could apply a subset of the container-related requirements to the product if compliance with some but not necessarily all of the requirements would eliminate the problem.

EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the container and, if appropriate, the repackaging regulations within the time frames established by EPA in the rule or in its notification.

2. *Changes*. Because we are finalizing Option 1 rather than Option 3 in the supplemental notice, the final rule provides more specific criteria and a better-defined process for EPA to make determinations to prevent an unreasonable adverse effect on the environment. The criteria and process are outgrowths of comments on the supplemental notice and the following potential regulatory provision from the supplemental notice:

> EPA may determine that an antimicrobial product or products must comply with the container standards. EPA may consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product must comply with the container standards to prevent an unreasonable adverse effect on the environment.

3. *Comments*. Many commenters provided suggestions and information about how they believe the case-by-case determinations should be made. While the actual language varied among commenters, the respondents agreed that EPA needs specific evidence of a problem related to containers before EPA can determine a product must be subject to the container regulations to prevent an unreasonable adverse effect.

4. *EPA response*. EPA believes that the criteria and process in the final regulations for making determinations to prevent an UAE represent a legitimate, reasonable, straightforward interpretation of the statutory language. In addition, we think these criteria and the process for making determinations are similar to EPA's current systems. EPA has the ability to re-visit a product's registration standard of not causing UAEs and change it if UAEs are identified during the process of reregistration or other review, under the ongoing mechanisms of FIFRA section 6(a)(2) (as implemented by 40 CFR part 159, PR Notice 98–3 (Ref. 55), PR Notice 98–4 (Ref. 54) and other guidance documents) or when other relevant information is received by EPA. The criteria and process included in the final rule are consistent with most comments received on the supplemental notice.

It is difficult to precisely identify the kind of information that EPA would consider sufficient and to characterize in great detail the problems that could trigger this regulatory provision, because we cannot anticipate every situation that might arise in the future. However, the following items are intended to provide some guidance on the different factors that EPA will consider in making determinations about whether an antimicrobial product

or products must be subject to the container regulations:

- What kind of information, data or other evidence of a problem with containers has EPA obtained? This could be descriptions of cases, incidents or examples of problems or it could be some other kind of information.
- How severe are the problems identified in the information, data or other evidence obtained by EPA? The 6(a)(2) regulations in 40 CFR part 159 define severity categories assigned to incidents and PR Notice 98–3 (Ref. 55) expands the definitions for incidents involving humans and domestic animals.
- How prevalent are the problems identified in the information, data or other evidence obtained by EPA? Are the problems isolated or are they widespread? EPA will evaluate the prevalence of the problems and the severity of the problems before taking any action to subject the product or products to the container regulations.
- Where do the problems occur in the distribution chain? In other words, whether the incidents occur predominantly at the facilities of manufacturers, retailers or end users may affect our decision. Also, this information may allow EPA to trace a problem back to a certain facility or a limited number of facilities.
- What is the company's history in terms of reacting to problems of concern?
- Do the problems cause an unreasonable adverse effect on the environment?
- Could the problems reasonably be expected to cause an unreasonable adverse effect on the environment if they continue to occur? For example, about a decade ago, EPA received a significant number of reports of a household pesticide that exploded over time. While these initial incidents may not have directly led to a severe human injury or illness, it is reasonable to expect that someone could have been injured or become ill if they were in a garage or storage area when a container exploded.
- Would complying with the container regulations reasonably be expected to eliminate the problem? If the container regulations don't address the problem or would not mitigate the problem, then EPA could consider other approaches (such as establishing conditions specific to that registration) to mitigate the problem. As an example, it is possible that a problem could be caused by a problem with a specific kind of container material. In this case, the solution may be to require the product to be distributed in a certain container material or a container material that has been treated, e.g., fluorinated high density polyethylene. It is possible that some of these alternative approaches may have other impacts with respect to the container regulations. For example, requiring a product to be distributed in a nonrefillable container that is rigid rather than non-rigid would increase the number of nonrefillable container standards the product must comply with.

G. Summary Table of the Scope for Antimicrobial Products

The following tables compare the approach for regulating antimicrobial products in the final regulations and the supplemental notice. Table 4 compares the exemption criteria in the final rule with the criteria discussed in the supplemental notice. Table 5 compares whether certain kinds of products (assuming they would otherwise be exempt) are exempt from or subject to the container standards in the final regulations and the supplemental notice approach.

TABLE 4.—EXEMPTION CRITERIA FOR ANTIMICROBIAL PRODUCTS IN THE FINAL RULE COMPARED TO THE SUPPLEMENTAL NOTICE

Criterion for Exemption	Approach in the Final Rule	Approach in the Supplemental Notice
FIFRA section 2(mm) antimicrobial pesticide	As defined in FIFRA section 2(mm)	As defined in FIFRA section 2(mm)
Antimicrobial products that are not FIFRA 2(mm) antimicrobial pesticides because they are subject to a tolerance or food additive regulation	Criterion is included as an additional criterion allowing exemption	Criterion wasn't included; these would have been subject to the container regulations
Antimicrobial product use categories that are considered household, industrial, or institutional	10 antimicrobial product use categories are household, institutional or industrial. The additional antimicrobial product use categories are: • aquatic areas; and • agricultural premises and equipment	9 antimicrobial product use categories were identified as household, institutional or industrial. The additional antimicrobial product use categories were: • aquatic areas; • agricultural premises and equipment; and • human drinking water systems
Is not a hazardous waste when it is intended to be disposed	Is not a hazardous waste as set out in 40 CFR part 261 when intended to be disposed	Does not meet the criteria for hazardous waste in 40 CFR part 261 when intended to be disposed
EPA has not specifically determined product must be subject to container regulations to prevent an unreasonable adverse effect	Criteria and a process for making the determination are included in the final rule	Making case-by-case determinations was discussed as an option, but was not specifically included in the potential regulatory language

TABLE 5.—ANALYSIS OF WHETHER CERTAIN TYPES OF ANTIMICROBIAL PRODUCTS[1] WOULD BE SUBJECT TO OR EXEMPT FROM THE CONTAINER REGULATIONS - COMPARING THE FINAL RULE TO THE SUPPLEMENTAL NOTICE[2]

Antimicrobial Product Description	Final Rule	Supplemental Notice(Option 3)
Products that are subject to a tolerance or food additive regulation	Exempt from the regulations[3]	Subject to the regulations according to 2(mm) definition
Products that are exempt from, or otherwise not subject to a tolerance or food additive regulation	Exempt from the regulations according to 2(mm) definition[3]	Exempt from the regulations according to 2(mm) definition[3]
Wood preservative or antifouling paint intended to control only micro-organisms	Exempt from the regulations according to 2(mm) definition[3]	Exempt from the regulations according to 2(mm) definition[3]
Wood preservative or antifouling paint intended to control macro-organisms as well as micro-organisms	Subject to the regulations according to 2(mm) definition	Subject to the regulations according to 2(mm) definition
Agricultural fungicide or aquatic herbicide	Subject to the regulations according to 2(mm) definition	Subject to the regulations according to 2(mm) definition
Product in Toxicity Category I	Exempt from the regulations[3]	Subject to all nonrefillable container requirements except the residue removal standard; subject to all refillable container requirements unless used in swimming pools according to determination to prevent UAE
Product in Toxicity Category II, III or IV	Exempt from the regulations[3]	Exempt from the regulations[3]
Product used only in swimming pools and closely related sites	Exempt from some refillable container and repackaging requirements if subject to the regulations for any reason	Exempt from some refillable container and repackaging requirements if it met all of the exemption criteria and is in Toxicity Category I

[1] In this table, the term antimicrobial has a broad interpretation, i.e., as described in FIFRA section 2(mm)(1)(A).
[2] All antimicrobial products must comply with the new labeling requirements. (See Unit IX. for more details about the label regulations.) This table refers only to complying with the container-related regulations, i.e., standards for nonrefillable containers, refillable containers and repackaging.
[3] The product is exempt from the regulations unless it would be subject because of other triggers, such as it is a hazardous waste when intended to be disposed.

H. Other Pesticide Products Subject to These Regulations (§§ 165.23 (e), 165.43(f) and 165.63(f))

1. *Overview*—i. *Final regulations.* For nonrefillable containers, all pesticide products other than MUPs, plant-incorporated protectants and exempt antimicrobial products are subject to the nonrefillable container standards. However, only the ''higher risk'' products are subject to all of the nonrefillable container requirements. The ''lower-risk'' products are subject only to the basic DOT requirements. In particular:

- A product must comply with all of the nonrefillable container requirements if it is classified in at least one of the following categories: (1) Toxicity Category I; (2) Toxicity Category II; or (3) Restricted use product.
- All other products (those in Toxicity Category III or IV that are not restricted use products) must comply only with the basic DOT requirements in 49 CFR 173.24. If the pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires it to be packaged according to 49 CFR parts 171–180.

The final rule does not distinguish between higher risk and lower risk products for the refillable container and repackaging regulations. In other words, pesticide products other than MUPs, plant-incorporated protectants and exempt antimicrobial products must comply with all of the refillable container and repackaging standards. The only exception is that antimicrobial products that are used in swimming pools and closely related sites are subject to a reduced number of the requirements, as described in Unit III.D.

ii. *Changes.* The 1994 NPRM proposed that the container regulations would generally apply to all end use pesticide products and all containers, regardless of the pesticide market sector. The proposed container regulations included requirements that are equivalent to some DOT requirements, such as marking, container integrity, reclosing securely and a drop test, and some requirements that are pesticide-specific, such as standard closures, one-way valves, and the residue removal standard. Many commenters opposed the broad scope of the regulations and requested EPA to exempt one or more subsets of pesticides from the container requirements.

In the 1999 supplemental notice, EPA described a potential regulatory option for products other than antimicrobials that would exempt some pesticides and containers from the final rule. Rather than exempt products based on the pesticide market sector or the type of pesticide (as specified by the commenters on the proposal), EPA's approach was to exempt pesticides based on the relative risk they posed.

The regulatory approach in the supplemental notice would have exempted manufacturing use products, as we proposed in 1994, and included a previously described set of standards for antimicrobial products that would be eligible for exemption. For all other

products, a product would be subject to the regulations if it met any one of the following criteria:

- The product is classified in Toxicity Category I or II;
- The capacity of the container is equal to or larger than 5 liters (1.3 gal) for liquids or 5 kilograms (11.0 lbs) for solids;
- The product's labeling permits outdoor use and includes at least one of the specified environmental hazard statements.

The container size and environmental hazard label statement criteria would have captured many products in Toxicity Category III and IV so they would have been subject to the regulations.

About 18 respondents provided comments on these general (non-antimicrobial) scope criteria in the supplemental notice, consisting largely of individual registrants and registrant groups. The commenters generally agreed that it was appropriate to differentiate the stringency of the regulations based on the relative risk posed by the products and containers. None of the commenters wholly supported the approach in the supplemental notice and there was no general agreement in an approach among the suggestions provided by the respondents. Some commenters stated that certain standards (either the DOT Packing Group III standards or the standards in a DOT limited quantity exception) should apply to all products. Many commenters suggested changes to the Toxicity Category and container size criteria. None of the commenters supported the environmental hazard statement criteria. A few commenters suggested other exemptions that should be included, such as exempting all residential use products.

After carefully reviewing these comments and conducting an analysis of the products that would be regulated using the supplemental notice criteria, EPA decided to revise the approach in the final rule for regulating pesticide products other than MUPs, plant-incorporated protectants and antimicrobials that are exempt. As described above, the approach for the nonrefillable container standards, which differentiates between ''higher risk'' and ''lower risk'' products, is different from the approach for the refillable container and repackaging requirements, which do not make that distinction.

iii.*Refillable container and repackaging regulations.* Pesticide products other than MUPs, plant-incorporated protectants and exempt antimicrobial products must comply with all of the refillable container and repackaging standards. One exception is that antimicrobial products that are used in swimming pools and closely related sites are subject to a reduced number of the requirements.

2. *Alternative approach and rationale for changes.* The final rule approach for regulating pesticide products that are not otherwise exempt was developed based on the comments on the supplemental notice and on an analysis conducted by EPA. The broad comments related to substantial changes in the approach are described in this subunit, while comments on the specific criteria in the supplemental notice are discussed individually in subunits below.

i. *Comments - overall approach.* EPA posed six questions in the supplemental notice related to the scope of products subject to the container regulations. The first question was ''Is it appropriate to apply the container standards only to the higher-risk pesticides?'' Eight respondents specifically addressed this question and seven of them generally agreed with EPA that it is reasonable to apply different levels of regulation to higher-risk and lower-risk pesticides. However, the commenters differed in their recommendations for regulating the lower-risk pesticides. Only one of the eight commenters, a non-agricultural registrant group, specifically supported a complete exemption for the lower-risk pesticides. Some commenters took a middle ground. In particular, the comments from a registrant group and three registrants were a bit vague, stating that it is appropriate to apply the container standards only to the higher risk pesticides and that lower-risk pesticides should not be subject to the same requirements. Several commenters opposed the approach of completely exempting some products. Two registrant groups explicitly supported an option where lower risk pesticides would be subject to some regulations, although different standards would be appropriate. Also, the commenter who didn't support distinguishing between risk levels was a registrant who stated that the requirements for DOT Class 9 materials should apply to all pesticides that are not DOT hazardous materials.

The second question was ''Are the criteria being considered by EPA to distinguish between higher-risk and lower-risk pesticides appropriate?'' The same eight commenters addressed this question and none of them believed that the criteria in the supplemental notice were appropriate for distinguishing between higher-risk and lower-risk pesticides. An agricultural registrant group commented that toxicity and container size are generally appropriate criteria, but questioned the viability of using these criteria because of the wide range of combinations of toxicity (human health and environmental), container sizes and distribution and handling practices. This commenter supports establishing the DOT Packing Group III standards as a minimum for agricultural pesticides in nonrefillable containers. A registrant group and a registrant stated that DOT limited quantity provisions should be authorized for pesticides that are not DOT hazardous materials. The regulatory language recommended by one of these commenters would require pesticide products to comply with all nonrefillable container standards unless they were specifically exempt or subject to a limited quantity exception. Four commenters--a registrant group and three registrants--strongly opposed the environmental hazard statement criterion because they don't believe the environmental hazard statements on the label are appropriate indicators of risk. One of them said that toxicity category alone should be used to distinguish between higher-risk and lower-risk pesticides. A non-agricultural registrant group questioned the appropriateness of human toxicity characteristics for packaging regulations that, it claims, deal primarily with storage and disposal. This commenter urged EPA to develop alternate criteria, such as the potential for the product to leak from containers and/or to persist in the environment.

In addition, a registrant group and a registrant who addressed the above question provided more detailed comments on an alternate approach. These commenters stated that all agricultural pesticides distributed in nonrefillable containers should comply with the DOT packaging standards. Under this option, pesticides that are not DOT hazardous materials would comply with the Packing Group III standards or, if appropriate, one of the limited quantity exceptions. The registrant group stated that having minimum requirements on pesticide integrity is in the best interest of agriculture, the public and our industry.

Another registrant provided a detailed description of an alternate approach. This commenter split the regulations into two primary issues - (1) container design and integrity testing and (2) container residue removal standards and others - based on the goals of the rule and their financial impact. This agricultural registrant strongly believes that all pesticides in nonrefillable containers should be required to use DOT Packing Group III containers as a minimum safety standard. On the other

hand, this respondent believes that it may be reasonable and appropriate to consider exempting lower-risk pesticides from some standards, such as the residue removal requirement.

ii. *EPA response - overall approach*. These comments prompted EPA to reconsider the approach discussed in the supplemental notice where lower-risk pesticides would be completely exempt from the nonrefillable container standards. EPA agrees with the point made by some commenters that all containers should meet standards for integrity and compatibility and is modifying the final rule accordingly. However, EPA believes that the minimum standards for integrity are different between nonrefillable and refillable containers.

In general, DOT has two different sets of package integrity standards. The most thorough set of requirements are the performance-oriented packaging standards, which include drop, leakproofness, hydrostatic pressure, stacking and vibration tests. These tests may vary in stringency depending on the packing group of the material. For example, a Packing Group I test involves a drop from 1.8 meters (5.9 feet) while a Packing Group III test has a drop from 0.8 meters (2.6 feet). The other set of requirements are the packaging standards in 49 CFR part 173 subpart B, which are referenced in DOT limited quantity exceptions. In other words, packages that are subject to a limited quantity exception must comply with the standards in subpart B of part 173, even though they are exempt from the full array of performance-oriented packaging tests and other standards.

The requirements in 49 CFR part 173 subpart B include many different standards related to ''Preparation of Hazardous Materials for Transportation.'' Some of these requirements address aspects of transportation other than packaging, such as the loading and unloading of transport vehicles, or establish requirements for specific modes of transportation, such as general requirements for transportation by aircraft. Therefore, it would not be appropriate for EPA to reference all of part 173 subpart B, because we are only interested in incorporating the DOT standards that address packaging design, construction and marking. After analyzing the subpart B regulations, EPA believes that the general requirements for packagings and packages in 49 CFR 173.24 are appropriate basic standards that all nonrefillable containers must meet. The standards in 49 CFR 173.24 address container integrity, compatibility, closures and outage/filling limits. These DOT standards cover the same areas as the proposed requirements for nonrefillable container integrity/compatibility in § 165.102(b) and reclosing containers securely in § 165.102(d)(3). EPA believes that all nonrefillable containers should easily be able to comply with these requirements, yet they provide a standard that we could enforce in situations where container problems may arise. Therefore, the final rule references the general requirements for packagings and packages in 49 CFR 173.24 as the basic standards for all nonrefillable containers, unless the pesticide product is exempt from the regulations.

On the other hand, EPA believes that the DOT Packing Group III standards, including the performance-oriented packaging tests, are an appropriate minimum standard for refillable containers. Refillable containers need to be sturdier, stronger and able to withstand more stress than nonrefillables because they spend more time in use (i.e., full of pesticide) and in the lanes of transportation. Because refillable containers are returned to the refiller and/or registrant repeatedly over the useful life of the containers, they are subject to more wear and tear than containers that are used once. Therefore, EPA believes that it is appropriate to require refillable containers to be capable of meeting DOT's packaging standards at the Packing Group III level, if the pesticide product is not a DOT hazardous material. If the pesticide product is a DOT hazardous material, it must comply with the relevant DOT standards.

3. *Nonrefillable containers: human toxicity criterion*—i. *Final regulations*. For pesticide products other than MUPs, plant-incorporated protectants, and exempt antimicrobial products, a pesticide product must comply with all the nonrefillable container requirements if it is classified in Toxicity Category I or II, as set out in 40 CFR 156.62.

ii. *Changes*. For pesticide products in nonrefillable containers, this criterion is identical to the one set forth in the potential alternative regulatory text in the 1999 supplemental notice. EPA continues to believe that the most hazardous groups of pesticides in terms of human toxicity - those in Toxicity Category I and Toxicity Category II - should be subject to the nonrefillable container standards. Most problems with handling containers will lead to human exposure, as a result of dripping, glugging, leaking, or container failures, so EPA believes that human toxicity is an appropriate criterion. Furthermore, EPA believes that products in Toxicity Category I and II pose a significant enough risk in these situations that these products should be subject to the nonrefillable container requirements.

EPA is participating in a global effort to harmonize the classification and labeling of chemicals for human and environmental hazards, which is being led by international agencies such as the Organization for Economic Co-operation and Development (OECD), the International Labor Organization and the UN Committee of Experts on the Transportation of Dangerous Goods. The global harmonization effort resulted in new definitions for toxicity characteristics and a new Category V. The categories and rationale were described in *OECD Series on Testing and Assessment Number 33, Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures*. That document has since been superceded by a consolidated document published by the United Nations Economic Commission for Europe (UNECE) entitled *Globally Harmonized System of Classification and Labeling of Chemicals (GHS)* and is available at the following Web site: *http://www.unece.org/trans/danger/publi/ghs/ghs__rev01/01files__e.html*. (Ref. 16) Each country will select elements of the system deemed appropriate for regulating transport, worker and environmental protection. When EPA modifies its definitions of toxicity categories in 40 CFR part 156 to harmonize with the OECD guidelines, EPA plans to revise the toxicity category criteria in § 165.23(e) to incorporate the new toxicity categories. The criteria and signal words associated with the GHS toxicity categories are different than EPA's existing criteria and signal words. Therefore, the universe of products subject to the full set of nonrefillable container standards and the universe of products subject only to the basic DOT packaging requirements will likely change.

4. *Nonrefillable containers: other toxicity criterion*—i. *Final regulations*. For pesticide products other than MUPs, plant-incorporated protectants, and exempt antimicrobial products, a pesticide product must comply with all the nonrefillable container requirements if it is classified by EPA as a restricted use product.

ii. *Changes*. This criterion is different than the criterion described in the supplemental notice that would have required a product to comply with the nonrefillable container regulations if its labeling allowed outdoor use and included at least one of the specified

environmental hazard statements. Rather than relying on the environmental hazard statements on pesticide labels, such as ''This pesticide is toxic to birds,'' EPA decided to change this criterion to products that are classified as restricted use products, which was discussed as an option in the supplemental notice. According to an EPA analysis, fewer than 250 restricted use products are in Toxicity Category III or IV (i.e., that are not already captured by the human toxicity criteria). (Ref. 45)

iii. *Comments*. Many commenters--all registrant groups and registrants--commented on the environmental toxicity criterion in the supplemental notice. One non-agricultural registrant group stated that some of the criteria covered by the hazard statements, such as whether a pesticide leaches through the soil to groundwater, are appropriate and should be substituted for the human toxicity criteria. A registrant group and a registrant opposed any environmental criteria. A registrant group and two registrants opposed the environmental hazard criterion because they did not agree that the actual use (indoor or outdoor) of a pesticide is a realistic basis for determining exemptions from the container regulations. These commenters said that a spill or release could happen at any point during transportation, storage or handling and that all pesticide products share the same lanes of transportation. Therefore, these commenters believe the distinction between whether the pesticide is used indoors or outdoors is irrelevant. Several commenters opposed the environmental hazard criterion because they don't believe the environmental hazard statements on the label are appropriate indicators of risk.

Several commenters addressed the option discussed in the supplemental notice for including a criterion for pesticides that are classified as restricted use for environmental or ecological reasons. In particular, a registrant group and several registrants commented that ''while it is true that compounds that are restricted in their use for ecological reasons would have some of the specified environmental hazard statements ..., it is also true that many compounds with little or no potential for risk could easily contain such language.'' This statement implies that these respondents distinguish between the risks posed by pesticides that are restricted in their use for ecological reasons - which are higher - and the risks posed by other pesticides.

iv. *EPA response*. As stated in the supplemental notice, EPA continues to believe that it is important and necessary to account for environmental factors when evaluating the risks posed by pesticide containers. After considering the comments and re-evaluating the environmental hazard statement approach described in the supplemental notice, EPA is changing the approach in the final regulations. EPA believes that the environmental hazard statement option, as described in the supplemental notice, would be difficult to implement because each label would have to be evaluated and because the ''catch-all'' standard included in the supplemental notice (''Any environmental hazard statement pertaining to wildlife, fish, birds or groundwater'') raises some ambiguity about which products would be included by this criterion. Also, while EPA doesn't necessarily agree with all of the comments, an EPA analysis (Ref. 78) raised questions about whether using the environmental hazard statements on the label would capture the highest-risk pesticides. Finally, the final rule uses the criterion of restricted use classification to distinguish between levels of regulation (subject to all of the nonrefillable container standards versus subject to the basic DOT standards) rather than to distinguish between whether the product is regulated or exempt. Therefore, we can afford to set the criterion at a level that would focus on the most environmentally risky products, because the other products will be subject to basic container integrity and compatibility standards, rather than being completely exempt.

The criteria that EPA utilizes to restrict an end use product to use by certified applicators (or persons under their direct supervision) are described in 40 CFR 152.170. The general criteria for restricting the use of a product are that EPA determines that:

- The product's toxicity exceeds one or more of the specific hazard criteria in 152.170, or evidence substantiates that the product or use poses a serious hazard that may be mitigated by restricting its use;
- The product's labeling is not adequate to mitigate these hazards;
- Restriction of the product would decrease the risk of adverse effects; and
- The decrease in risks of the pesticide as a result of restriction would exceed the decrease in benefits.

Section 152.170 lists specific human and ecological toxicity endpoints that cause a product to be considered for restricted use classification. In addition, the regulations state that EPA may consider evidence such as field studies, use history, accident data, monitoring data or other pertinent evidence in deciding whether the product or use may pose a serious hazard that could be mitigated by restricted use classification.

An analysis of products in EPA's REFS data base shows that many restricted use products are also classified in Toxicity Category I or II. However, there are about 225 restricted use products in Toxicity Category III or IV and all of these products were restricted at least partly for environmental/ecological reasons. (Ref. 45) In particular, the criteria for restricting the Toxicity Category III/IV products include ground water contamination; toxicity to fish, birds, or aquatic organisms; and hazard to wildlife or non-target organisms.

5. *Nonrefillable containers: container size criterion*—i. *Final regulations*. Container size is not a criterion in the final regulations for determining whether a pesticide product is subject to the nonrefillable container regulations.

ii. *Changes*. The approach in the supplemental notice included a container size limit as one of the criteria for being subject to the nonrefillable container regulations. Specifically, a product would have been subject to the nonrefillable container regulations if the container's capacity was equal to or larger than 5.0 liters (1.3 gallons) for liquid formulations or 5.0 kilograms (11.0 pounds) for solid formulations. EPA decided not to incorporate the container size criterion into the final rule for nonrefillable containers because of other changes in the structure of the final regulations. In particular, the final rule uses the scope criteria to distinguish between levels of regulation (subject to all of the nonrefillable container standards versus subject to the basic DOT standards) rather than to distinguish between whether the product is regulated or exempt. The criteria in the final rule subject the most toxic and most risky pesticides — those in Toxicity Categories I and II and any others that are restricted use products — to the full set of nonrefillable container requirements. All other products that are not specifically exempt are subject to basic container integrity and compatibility standards, rather than being completely exempt. EPA believes the basic DOT packaging standards offer an acceptable level of protection for the products that are in Toxicity Categories III and IV and that are not restricted use products. Therefore, a container size criterion is not necessary for nonrefillable containers.

6. *Refillable containers and repackaging*—i. *Final regulations*. Pesticide products other than MUPs, plant-incorporated protectants and exempt antimicrobial products must comply with all of the refillable

container and repackaging standards. One exception is that antimicrobial products that are used in swimming pools and closely related sites are subject to a reduced number of the requirements.

ii. *Changes*. The regulatory language is different than the approach described in the supplemental notice, which described the criteria of Toxicity Category I or II, container size and environmental hazard statements for subjecting a pesticide product to the refillable container and repackaging regulations. However, the net effect of the scope language in the supplemental notice is very similar to the scope of the final rule. Because nearly all, if not all, refillable containers are larger than the container size identified in the supplemental notice of 5 liters (1.3 gallons) or 5 kilograms (11 pounds), the supplemental notice criteria would have subjected nearly all, if not all, products in refillable containers to the regulations.

iii. *Comments*. Respondents did not specifically address how the general scope criteria should apply to refillable containers. A few commenters specifically limited some points to nonrefillable containers, although most did not. Therefore, EPA believes that the comments described in Units III.H.1. though III.H.5. generally also apply to refillable containers.

iv. *EPA response*. Under the supplemental notice approach, nearly all refillable containers would have been subject to the refillable container and repackaging regulations because of the container size criterion of 5 liters for liquids and 5 kilograms for solids. Although the container size criterion is not being incorporated into the final regulations, EPA believes it is necessary for products that are not specifically exempt to comply with the refillable container and repackaging regulations.

First, one of the goals of the refillable container and repackaging regulations is to minimize cross-contamination in refillable containers. The regulatory standards in the final rule - including one-way valves, tamper-evident devices, having registrants develop cleaning procedures, and requiring refillers to clean containers if necessary - are necessary for preventing cross-contamination in all products. All products that are distributed or sold must have the composition as stated in their confidential statements of formula and not be adulterated. This standard does not differ based on the toxicity of the product, the container size or any other factor. Therefore, minimizing the chance of cross-contamination is one reason that the final regulations were changed so that the refillable container and repackaging regulations apply to all products that are not specifically exempt. Note that certain antimicrobial products are subject to a reduced number of requirements, as described in Unit III.D.

Second, the repackaging regulations assign responsibility for certain requirements to registrants and to refillers, in addition to setting out the procedures that both parties must follow for pesticide products to be repackaged into refillable containers. EPA believes that it is important for all products that are not specifically exempt to be handled consistently under the repackaging regulations. We think that this consistency will facilitate compliance by both the registrants and refillers.

Third, as stated earlier, the final rule takes the approach that all containers should meet standards for integrity and compatibility. EPA believes that the DOT Packing Group III standards, including the performance-oriented packaging tests, are an appropriate minimum standard for refillable containers. Refillable containers need to be sturdier, stronger and able to withstand more stress than nonrefillables because they spend more time in use (i.e., full of pesticide) and in the lanes of transportation. Because refillable containers are returned to the refiller and/or registrant repeatedly over the useful life of the containers, they are subject to more wear and tear than containers that are used once. Therefore, EPA believes that it is appropriate to require refillable containers to be capable of meeting DOT's packaging standards at the Packing Group III level, if the pesticide product is not a DOT hazardous material. If the pesticide product is a DOT hazardous material, it must comply with the relevant DOT standards.

7. *Changes to the container vs. label regulations*—i. *Final regulations*. In general, all products must comply with the container labeling requirements — the labeling regulations do not exempt MUPs or certain antimicrobial products. One exception is that plant-incorporated protectant container-related labeling instructions will be determined by EPA on a case-by-case basis until specific labeling guidance for plant-incorporated protectants are promulgated under 40 CFR part 174. This approach is discussed in more detail in Unit IX.

ii. *Changes*. This is the same approach described in the 1999 supplemental notice except for the case-by-case handling of plant-incorporated protectants.

I. Flow Chart/Summary

The full scope of the final pesticide container and containment rule is summarized in this section. Different sections of the final rule apply to different subsets of products:

- The *label* requirements apply to all products.
- The *containment structure* requirements apply to agricultural products (stored in stationary pesticide containers by retailers, custom applicators and custom blenders).
- The *nonrefillable container*, *refillable container* and *repackaging* requirements apply to products other than MUPs, plant-incorporated protectants and certain antimicrobial products, as shown in Figure 1.

Within Figure 1, there is a box with the question ''Is it an antimicrobial product that meets all four criteria?'' This box represents a placeholder for the flow chart in Figure 2.

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Figure 1. Scope of the Nonrefillable Container, Refillable Container and Repackaging Regulations

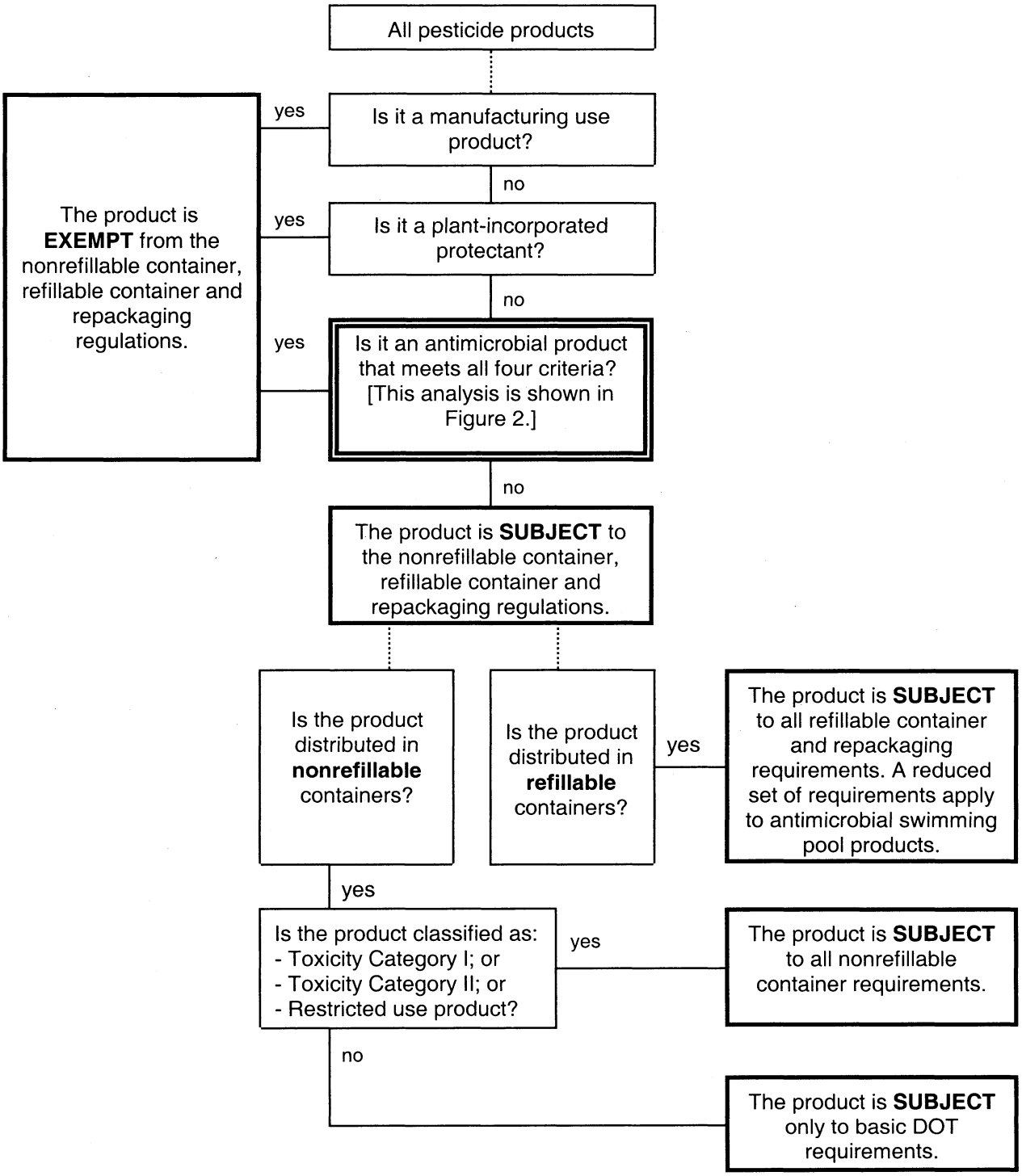
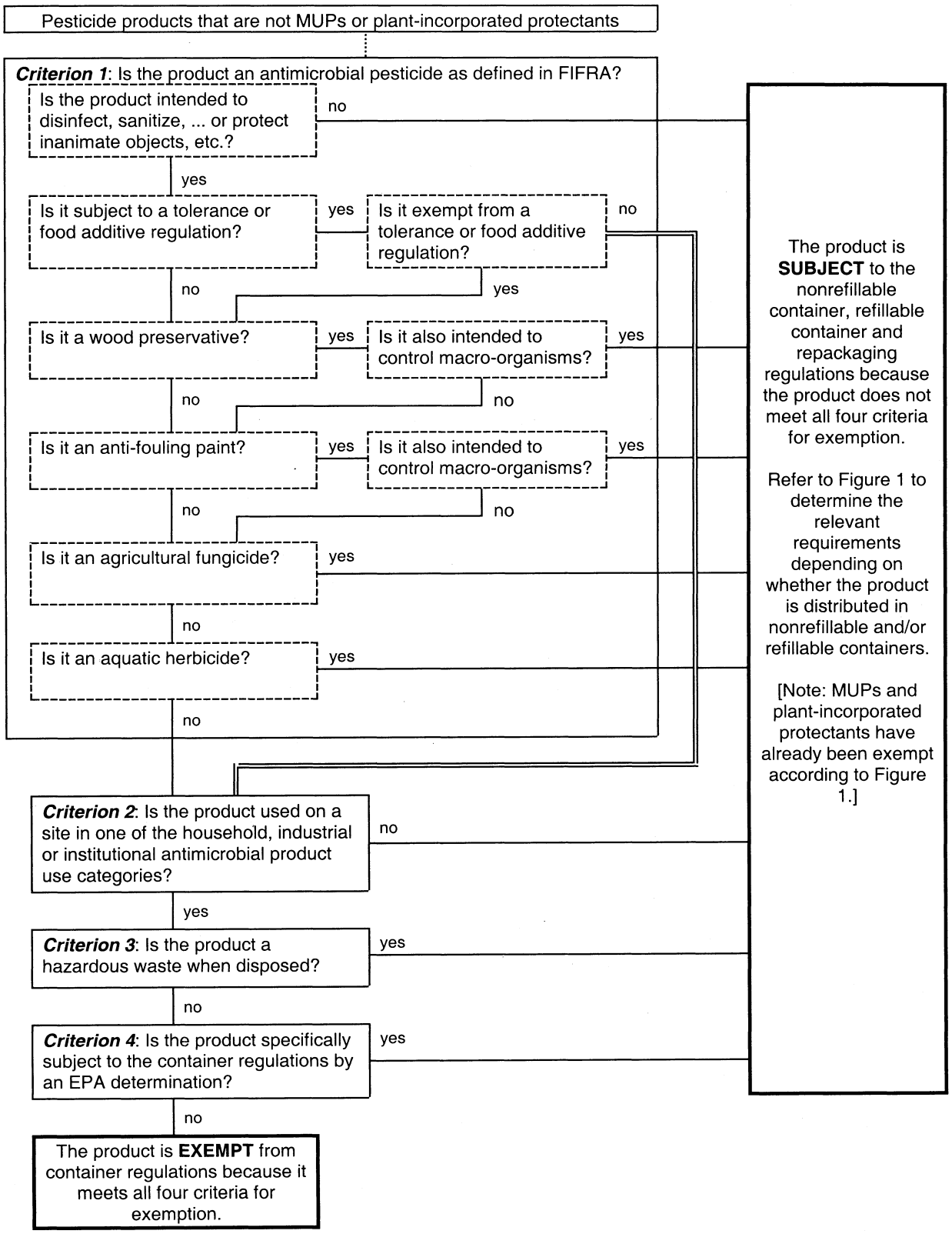


Figure 2. Determining Whether Antimicrobial Products are Exempt from or Subject to the Nonrefillable Container, Refillable Container and Repackaging Regulations



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IV. Container Regulations—Relationship with the Department of Transportation Regulations

A. Background

1. *Department of Transportation Hazardous Materials Regulations.* The U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR) are based on the authority in the Federal hazardous materials transportation law, the Hazardous Materials Transportation Act, and are found in 49 CFR parts 171 through 180. The HMR establish standards governing a wide range of the safety aspects of transportation, including requirements for the classification of materials, packaging (including manufacture, continuing qualification and maintenance), hazard communication (i.e., package marking, labeling, placarding, and shipping documentation), transportation, handling and incident reporting.

Some, but not all, pesticide products are defined as DOT hazardous materials by 49 CFR 171.8. A pesticide product may be classified as a DOT hazardous material for displaying any of the hazards identified in the DOT regulations, which are defined in nine different classes. Some DOT hazard classes include several different divisions. The most common hazard classes and divisions for pesticide products include:

- Class 3: flammable or combustible liquids;
- Division 6.1: poisonous materials;
- Class 8: corrosive materials; and
- Class 9: miscellaneous hazardous materials, such as marine pollutants.

Pesticide products that are DOT hazardous materials are required under existing DOT regulations to comply with all applicable regulations in all of the safety areas mentioned above - classification, packaging, hazard communication, transportation and handling. For pesticide products that are not DOT hazardous materials, EPA has focused on the DOT requirements for package design (and manufacture, continuing qualification, and maintenance) and package marking, because these are the areas that overlap with the proposed pesticide container regulations. In other words, EPA is not adopting the HMR standards for DOT labeling, placarding, shipping documentation, transportation and handling, and incident reporting because these areas are generally outside the scope of the pesticide container regulations.

The DOT HMR include general packaging requirements that address areas such as compatibility, closures, venting, and filling limits. The HMR also set out performance standards and related tests that packaging must meet, including drop, leakproofness, hydrostatic pressure, stacking, and vibration tests. The stringency of these tests varies according to the packing group (PG) of the material being transported. The packing group represents a measure of the relative hazards, where PG I includes materials that pose a relatively great hazard and PG III includes materials that pose a relatively minor hazard. Within a given hazard class or division, the DOT HMR assign packing groups based on the materials characteristics, or the regulations refer to the hazardous materials table in 49 CFR 172.101 for substance-specific assignments of packing groups. Most pesticide products that are classified as DOT hazardous materials are in Packing Group III, although some are in PG II and a few are in PG I.

The HMR include exceptions from some portions of the overall regulatory scheme in certain situations, e.g., for damaged packages placed in salvage drums (49 CFR 173.3), for small quantities of hazardous materials (49 CFR 173.4) and for the shipment of waste materials (49 CFR 173.12). Also, the regulations in 49 CFR 173.150 through 173.156 set out limited quantity and consumer commodity exceptions for different hazard classes. The limited quantity exceptions provide relief from some of the HMR requirements, specifically the labeling requirements (unless the package is transported by aircraft), the placarding provisions, and the testing standards in 49 CFR part 178. Also, if a limited quantity meets the definition of consumer commodity, relief from the shipping paper requirements is provided in many cases.

Pesticide products that are classified as DOT hazardous materials must continue to be packaged in accordance with the DOT HMR. Nothing in the pesticide container regulations changes the specific requirements in the HMR that apply to pesticide products based on the criteria in the DOT regulations. Additionally, the pesticide container regulations do not change the stringency of the DOT HMR. If a pesticide product is categorized as a PG II material, it would continue to have to meet the PG II standards and likewise for products in PG I or PG III.

2. *Final regulations (§§ 165.25(a), (b) and (c), and 165.45(a), (b) and (c)).* The final regulations adopt and refer to some of the HMR for pesticides that are subject to this final rule. The approach in the final rule is closely tied to the changes in scope described in Unit III. Some products, including MUPs, plant-incorporated protectants, and some antimicrobial products are completely exempt from the container regulations and are not included in the following discussion because they are exempt. All other products are subject to the final regulations.

For pesticide products that are lower risk (in Toxicity Category III or IV and not restricted use products) in nonrefillable containers, the nonrefillable containers must comply only with the general requirements for packagings and packages in 49 CFR 173.24. No other requirements in EPA's pesticide container regulations apply to these lower risk products. Of course, if any of these products are DOT hazardous materials, they must comply with all applicable DOT regulations. For the purpose of enforcing the pesticide container regulations, however, EPA is only referring to and adopting 49 CFR 173.24 for any lower risk products that are subject to the regulations, regardless of whether or not they are classified as DOT hazardous materials.

Pesticide products that are higher risk (in Toxicity Category I or II or a restricted use product) in nonrefillable containers and all products in refillable containers must be packaged in a container that is designed, constructed, and marked to comply with the requirements of 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178 and part 180 that apply to a Packing Group III material. These portions of the DOT regulations, which are described in more detail in later sections of this preamble unit, include:

- General requirements for packagings and packages (§§ 173.24, 173.24a, 173.24b);
- Reuse, reconditioning and remanufacture of packagings (§ 173.28), except for the leakproofness test specified in § 173.28(b)(2);
- Exceptions for Class 9 materials, miscellaneous hazardous materials (§ 173.155);
- Non-bulk packagings for hazardous materials in Packing Group III (§ 173.203 for liquids and § 173.213 for solids);
- Portable tanks, closed bulk bins and intermediate bulk containers for certain low hazard materials (§§ 173.240(c) and 173.240(d) for low hazard solid materials and §§ 173.241(c) and 173.241(d) for low hazard liquid and solid materials);
- Specifications for Packagings (part 178), including non-bulk performance-oriented packaging standards (subpart

L), testing of non-bulk packagings and packages (subpart M), intermediate bulk container (IBC) performance-oriented standards (subpart N), and testing of IBCs (subpart O); and

• Continuing qualification and maintenance of packagings (part 180)

Again, products that are DOT hazardous materials must comply with all applicable DOT regulations. For the purposes of enforcing the pesticide container regulations, the final rule states that a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a container that is ''designed, constructed and marked'' to comply with the requirements of 49 CFR parts 171–180. Including the phrase ''designed, constructed and marked'' allows EPA to focus on the DOT requirements for package design (and manufacture, continuing qualification, and maintenance) and package marking, as described above, rather than the HMR standards for DOT labeling, placarding, shipping documentation, transportation and handling, and incident reporting.

Because the pesticide container regulations refer to and adopt certain DOT requirements, these requirements also are EPA standards that can be enforced by EPA and the State agencies that implement EPA's pesticide programs. However, EPA and the State pesticide programs will enforce only the 49 CFR requirements that are referred to and adopted in the pesticide container regulations; not the full DOT HMR. Clearly, DOT maintains authority to enforce all of its regulations against parties that are subject to the HMR.

The final rule includes two other provisions related to the DOT standards. These provisions are discussed in more detail in Units IV.E. and IV.F. First, if DOT proposes to change any of the regulations that are incorporated into the pesticide container regulations, EPA will provide notice of the proposed changes and an opportunity to comment in the **Federal Register**. Following notice and comment, EPA will take final action regarding whether or not to revise its rules and the extent to which any such revision will correspond with revised DOT regulation. Second, the regulations include a provision for modifying or waiving the adopted standards if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the adopted requirements.

3. *Changes*. The same general approach that was described in the 1999 supplemental notice is included in the final regulations. The final rule refers to and adopts some DOT standards for pesticide products that are not DOT hazardous materials and requires that these products be packaged in containers that are designed, constructed, and marked to comply with the adopted requirements for Packing Group III materials. However, a number of changes are made in the final rule approach:

• The biggest change is related to the changes in the scope of the nonrefillable container standards. Rather than completely exempt the lower risk pesticide products (e.g., lower toxicity in small containers without an environmental hazard statement on the label), the final rule mandates that the lower risk products must comply with the general packaging requirements in 49 CFR 173.24.

• Some of the specific 49 CFR standards that are adopted for the higher risk products in nonrefillable containers and for all products in refillable containers are different in the final rule than in the supplemental notice approach. In particular, the final regulations include an exception from 49 CFR 173.28(b)(2), which requires leakproofness testing every time a non-bulk packaging is refilled. The final regulations specify that this leakproofness testing is not required for products that are not DOT hazardous materials if containers comply with the 40 CFR part 165, subpart C regulations and the repackaging is done in compliance with the 40 CFR part 165, subpart D regulations. Also, the final rule refers to and adopts only portions of 49 CFR 173.240 and 173.241 (bulk packaging for certain low hazard materials) to clarify that the pesticide container regulations do not regulate transport vehicles. By referring to and adopting only paragraphs (c) and (d) in both sections, the final rule incorporates the standards for portable tanks, bulk bins and intermediate bulk containers, but not for rail cars, motor vehicles or cargo tanks.

• The final regulations specifically refer to and adopt the terms of the exceptions for Class 9 miscellaneous materials in 49 CFR 173.155 instead of incorporating the relevant text from that section into the pesticide container regulations, as discussed in the supplemental notice.

4. *Comments on the overall approach*. More than 20 respondents commented on the approach of adopting some DOT requirements at the Packing Group III level in the supplemental notice. The comments can be split into two categories according to the type of commenter. State regulatory agencies and agricultural pesticide registrants and registrant groups generally supported the overall approach, while registrants and registrant groups from the non-agricultural pesticide sector generally opposed the overall approach.

i. *Support*. Several State regulatory agencies and an agricultural registrant group supported EPA's approach of adopting some DOT requirements for pesticide products that are not DOT hazardous materials. These commenters stated that consistency with DOT should facilitate compliance and minimize confusion in the regulated community and will avoid conflicting regulations.

In addition, a few agricultural registrant groups and some agricultural registrants supported EPA's overall approach, if EPA incorporates the changes included in their comments on the supplemental notice. These comments recommended changing several sections of the DOT regulations that are adopted and extending the compliance period for refillable containers. One of the registrants commented that all pesticides in nonrefillable containers should meet the DOT PG III standards at a minimum to provide an updated level of protection for the environment and for all who use, store, display, buy or distribute pesticide products.

ii. *Oppose*. About 10 respondents clearly opposed the supplemental notice approach of adopting some DOT Packing Group III standards for products that are not DOT hazardous materials, including several nonagricultural registrant groups, a group representing agricultural formulators and distributors, an institutional formulator/distributor group and some non-agricultural registrants. These respondents opposed EPA's approach because they claim that:

• There is no need to regulate pesticides that are not DOT hazardous materials. Several commenters stated that DOT requirements take into consideration the seriousness of transporting the substances and that DOT chose not to regulate these substances. Several others questioned whether there is evidence of a problem with shipping non-DOT hazardous pesticides.

• Costs of packaging would increase, which respondents state would be burdensome for small businesses. Costs mentioned were $2,500 for design plate changes and about the same amount per package type to maintain the required certification files.

• This approach would be burdensome for EPA to monitor DOT regulatory changes and to render exemption decisions. A commenter also

questioned whether EPA had the expertise to make exemption decisions.

• EPA's approach would be confusing because it incorporates some, but not all, of DOT's standards.

• EPA's regulations could be different than DOT's. Several commenters cited the waiver provision and the lack of a consumer commodity exemption in EPA's approach as examples.

iii. *EPA response*. EPA continues to believe that the general approach of referring to and adopting the DOT Packing Group III packaging design, construction and marking requirements is the best approach for regulating pesticide containers.

Commenters who opposed this approach in the supplemental notice must recognize that the alternative to the supplemental notice approach of referring to and adopting some of DOT's standards is not an option of declining to establish regulations for container integrity and construction. Instead, as described in the supplemental notice, the alternative is to finalize the standards from the 1994 proposed rule that address container integrity and construction. These standards include container integrity and compatibility, marking, and reclosing securely for nonrefillable containers and container integrity, marking and a drop test for refillable containers. EPA is separately required under FIFRA to promulgate such regulations for all pesticides. If Congress had believed that existing Federal requirements promulgated by DOT were sufficient, or that EPA should restrict its regulation to pesticides covered as DOT hazardous materials, Congress could have restricted FIFRA section 19 to that extent. Instead, it appears that, with limited exceptions, Congress intended all pesticides to be regulated under section 19.

In fact, the approach to refer to and adopt the DOT Packing Group III packaging design, construction and marking requirements was based on suggestions from commenters on the proposed rule, who urged EPA to be consistent with the DOT regulations. More than 20 respondents, including individual companies and trade groups from the pesticide registrant and container manufacturing industries, provided commentary on the DOT HMR and the United Nations (UN) Recommendations on the Transport of Dangerous Goods. All of the commenters agreed that EPA should be consistent with the DOT HMR and the UN standards in terms of definitions, requirements, and testing. Respondents argued that such consistency would: (1) Facilitate compliance because the industry is already familiar with the DOT and UN standards; (2) eliminate the potential burden of complying with two different, overlapping regulatory schemes; and (3) not establish additional trade barriers. Most of the commenters on the DOT issue in the proposed rule specifically favored the use of DOT's Packing Group III criteria as the minimum standard for pesticide products not regulated by DOT as hazardous materials.

B. Leakproofness Testing Before Reuse (49 CFR 173.28(b)(2))

1. *Final regulations*. The final regulations retain the reference to 49 CFR 173.28, which establishes standards for the reuse, reconditioning and remanufacture of packagings. Also, the final rule adds a provision that exempts refillers from the leakproofness test requirement in 49 CFR 173.28(b)(2) for products that are not DOT hazardous materials if the refillable container complies with the refillable container regulations and the refilling is done in compliance with the repackaging regulations.

2. *Changes*. The major change to this part of the approach is that the final regulations add a provision that exempts refillers (which includes registrants and independent refillers) from the leakproofness test requirement in 49 CFR 173.28(b)(2) for products that are not DOT hazardous materials if the refillable container is in compliance with the subpart C refillable container regulations and the refilling is done in compliance with the subpart D repackaging regulations. This exception was added in response to comments on the supplemental notice.

3. *Comments*. Some commenters - including several registrant groups and several registrants - opposed the requirement in 49 CFR 173.28(b)(2) for non-bulk packaging to pass a leakproofness test before every time it is refilled. The test involves applying a raised internal air pressure to the container and ensuring that no air leaks from it. The test method for the leakproofness test described in 49 CFR 178.604 specifies restraining the container under water to determine if air leaks from the container, although alternatives are provided in an appendix to part 178. The commenters generally requested EPA to delete the reference to 49 CFR 173.28, although they did not point out problems with any other provisions of 49 CFR 173.28. One of the registrants provided the most precise and detailed description of the potential problems that could result from requiring leakproofness testing before every refill, including:

• It would pose practical problems and increased costs because refillers and possibly farmers would have to obtain the training and equipment required to do the leakproofness test.

• Due to the logistical and cost problems, the registrant believes that many non-bulk refillable containers would be replaced by nonrefillable containers, contrary to EPA's stated goals of pollution prevention.

• This commenter believes that the general packaging requirements in 49 CFR 173.24 and the container inspection provisions in subpart D of EPA's regulations are sufficient to ensure the integrity of non-bulk refillable containers.

• In addition to a leakproofness test, 49 CFR 173.28(b)(2) specifies a marking requirement, which could be interpreted to impose a testing requirement because of other DOT provisions (such as 49 CFR 171.2(c)), even if the packaging is used to transport only non-hazardous materials. The commenter stated that DOT provided a verbal interpretation that 49 CFR 171.2(c) does not require such testing of non-bulk containers used to transport only non-hazardous materials. The registrant recommended that EPA consult with DOT to confirm the approach on this topic. This commenter and a few registrant groups recommended deleting the reference to 49 CFR 173.28 to avoid confusion about whether a container must be leakproofness tested before it is refilled.

4. *EPA response*. EPA agrees with the commenter's concerns about the problems that might be caused by requiring a leakproofness test each time a non-bulk refillable container is refilled with a pesticide product that is not a DOT hazardous material. However, EPA disagrees with the commenters that the solution is to delete the reference to 49 CFR 173.28. EPA believes that § 173.28 includes useful provisions that will help ensure the safe reuse of pesticide containers. In addition, § 173.28 includes provisions for reconditioning and remanufacturing containers, which will clarify and allow the reconditioning of certain kinds of packaging, such as drums. Many commenters on the proposed rule and supplemental notice identified the lack of a regulatory option for reconditionable containers as an issue. Including the reference to § 173.28 solves this problem and allows drums to be reconditioned and then reused under the pesticide container regulations.

Rather than deleting the reference to 49 CFR 173.28, EPA is modifying the final regulations to exempt refillers from the leakproofness test requirement in 49 CFR 173.28(b)(2) for products that are

not DOT hazardous materials if the refillable container complies with the refillable container regulations and the refilling is done in compliance with the repackaging regulations. This provision is similar to one in DOT's regulations, specifically 49 CFR 173.28(b)(7), which allows a package to be reused without being leakproofness tested with air if four criteria are met, including being refilled and offered for transportation by the original filler. EPA believes that the refillable container requirements in subpart C, including the adopted DOT standards, and the repackaging requirements in subpart D, including the container inspection standards, provide for the safe refill and reuse of refillable pesticide containers without requiring leakproofness testing before each refill.

C. Regulating DOT Intermediate Bulk and Bulk Containers (49 CFR 173.240 and 173.241)

1. *Final regulations*. The final regulations refer to and adopt only certain paragraphs of the DOT regulations that authorize bulk packagings for certain low hazard materials. In particular, the final container rule refers to and adopts 49 CFR 173.240(c), 173.240(d), 173.241(c), and 173.241(d), so it incorporates standards for portable tanks, bulk bins and intermediate bulk containers, but not for rail cars, motor vehicles or cargo tanks. DOT defines bulk packagings to be larger than 119 gallons for liquids and 882 pounds for solids.

2. *Changes*. The approach described in the supplemental notice would have incorporated all of 49 CFR 173.240 and 173.241. The final regulations were changed to refer to and adopt only the portions of those sections that authorize portable tanks, closed bulk bins and intermediate bulk containers (IBCs). The portions of 49 CFR 173.240 and 173.241 that are not included in the final regulations authorize rail cars, motor vehicles and cargo tanks, which are not regulated by the container regulations.

3. *Comments - supplemental notice*. The comments from eight respondents (registrants and registrant groups) were split fairly evenly on this topic, even though these commenters tended to provide similar comments on other parts of the approach to incorporate some DOT regulations.

A few registrant groups and a registrant (all from the agricultural pesticide sector) supported the reference to 49 CFR 173.240 and 173.241. These respondents supported authorizing bulk packagings by adopting these sections for the following reasons:

- DOT provides greater latitude on the construction and less frequent testing requirements for bulk packages because of their size and sturdier construction. EPA should follow the same approach and authorize the same standards for bulk containers used to distribute pesticides that are not DOT hazardous materials.
- These sections of the DOT regulations authorize the use of certain non-DOT specification bulk packaging, including portable tanks and bulk bins. A few of these commenters stated that non-DOT specification packagings that are authorized for DOT Class 9 materials should also be acceptable for pesticides that are not DOT hazardous materials. The non-specification packagings must comply with the general packaging requirements in 49 CFR part 173, but not all of the testing and marking standards in other portions of the HMR.

In addition, the registrant explained that the HMR do not require non-DOT specification packagings (which are authorized by 49 CFR 173.240 and 173.241) to have the UN symbol marked on them. This commenter requested EPA to confirm that the pesticide container regulations authorize the use of these non-DOT specification packagings.

On the other hand, a non-agricultural registrant group and several agricultural registrants opposed the reference to 49 CFR 173.240 and 173.241. Several of the registrants stated that the intent of their comments on the proposed rule was for EPA to adopt the DOT Packing Group III standards for non-bulk packagings, not for bulk containers (which includes intermediate bulk containers by definition). The registrant group stated that the requirements in §§ 173.240 and §§ 173.241 would be burdensome and are not necessary from a safety standpoint. This commenter also believes that adopting these requirements would lead to a decrease in the use of refillable containers.

A registrant requested that EPA re-evaluate the reference to these sections because they authorize bulk and intermediate bulk containers and the definitions of these kinds of containers are very different than the ones customarily used within the agricultural pesticide industry. A few other commenters also addressed the definition issue by pointing out that the term minibulk (used in the agricultural pesticide industry and in the proposed regulations) has no DOT regulatory definition.

4. *EPA response - supplemental notice*. EPA is aware that the DOT regulations do not include a definition of minibulk container. However, the proposed definitions for dry and liquid minibulks were developed to intentionally include container sizes in both DOT's non-bulk and intermediate bulk container categories. As mentioned above, under the DOT regulations, intermediate bulk containers are a subset of bulk containers. EPA is not finalizing the definitions of dry and liquid minibulk (and bulk) containers in the final rule, as described in Unit V.

EPA intended to refer to and adopt DOT Packing Group III packaging standards for DOT non-bulk containers and intermediate bulk containers. EPA disagrees with the commenters who support the DOT standards for non-bulk containers (less than 119 gallons for liquids or 882 pounds for solids) but not for the next largest size, intermediate bulk containers. Minibulk containers used for pesticides include ones with capacities in the non-bulk classification, e.g., 60 to 110 gallons, and containers in the intermediate bulk container sizes, e.g., 150 to 250 gallons. EPA believes that it is not logical to require smaller minibulks to comply with the DOT Packing Group III testing standards, and to not specify any testing standards for larger minibulks, which could lead to a bigger spill. EPA believes strongly that both non-bulk and intermediate bulk containers holding pesticides that are not DOT hazardous materials should comply with the applicable Packing Group III packaging construction, testing and marking requirements.

Upon re-evaluation of the reference to 40 CFR 173.240 and 173.241, however, EPA realized that there may be some confusion caused by the paragraphs that authorize rail cars, motor vehicles and cargo tanks. EPA has never intended to regulate transport vehicles. The proposed rule (in § 165.122(b)(2)) and the final rule (in § 165.43(h)) state that the pesticide container regulations 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. To eliminate potential confusion, EPA changed the final rule to only include the portions of 49 CFR 173.240 and 173.241 that authorize portable tanks, bulk bins and intermediate bulk containers.

5. *Comments - UN marking*. In response to the 2004 reopening of the comment period, some commenters provided new information and comments regarding the approach of referring to and adopting a subset of DOT's hazardous materials packaging regulations. A registrant group and two registrants commented that, since the supplemental notice was published in

1999, several manufacturers have voluntarily changed their packaging specifications for all products, hazardous materials and nonhazardous materials, to meet DOT Packing Group III standards.

These three respondents and two other commenters (a registrant group and a registrant) supported the marking that would be required by adopting the DOT standards. One registrant group stated that ''It is important to have the UN marks to provide a minimum performance standard to those in the channels of distribution that purchase, fill, and sell crop protection products in refillable containers.'' The other commenters also supported adopting the DOT marking, but asked for clarification about which containers would need the UN mark. The DOT regulations do not require UN markings on certain kinds of containers, such as non-DOT specification portable tanks and containers holding limited quantities or consumer commodities. One of the registrants stated that their understanding of the DOT reference is that EPA is proposing UN markings only for those kinds of containers that require UN markings for DOT Packing Group III hazardous materials. In other words, when DOT regulations require UN marking for a container holding a DOT hazardous material, that same marking would also be required for the same kind of containers that hold pesticides that are not DOT hazardous materials. Most of the respondents recommended adding a statement to the regulatory text referring to the DOT regulations such as ''This includes certain containers which require UN markings (e.g., 2 x 2.5 gallon cartons, 50 pound multiwall paper bags, 5, 30 and 55 gallon drums) and certain other containers which do not require UN markings (e.g., limited quantities, consumer commodities and non-DOT specification portable tanks).''

On the other hand, a registrant group and two registrants stated that the marking size and location requirements of 49 CFR 178.3 should not apply to non-hazardous materials, claiming that placing the UN mark on the containers of these materials could create confusion among carriers and emergency responders. They expressed concern that non-certified transporters may refuse entire loads of non-hazardous materials marked with the circle UN mark since this is an indication of a DOT regulated material. These commenters also said that emergency responders may assume the cargo is a hazardous material and handle the situation accordingly if there was an accident involving such materials. These respondents suggested a certification process similar to Child Resistant Packaging approval or placing the specification packaging designation for non-hazardous materials on the product label (like the EPA Registration Number) rather than the large and prominent marking required by 49 CFR part 178.

6. *Response - UN marking*. EPA wants to clarify that the approach of referring to and adopting a subset of the DOT requirements would require the marking that is specified in the DOT regulations. UN markings would be required only for those containers that require UN markings for DOT Packing Group III hazardous materials. If DOT does not require the UN marking but allows the use of the packaging for Packing Group III materials (e.g., limited quantities, consumer commodities and non-DOT specification portable tanks), the EPA regulations would allow the use of these packagings and would not require the UN marking. However, EPA is not modifying the final regulations to add the suggested additional sentence because we do not believe it provides additional clarification. In addition, EPA believes that the preamble and guidance documents are the proper vehicles for providing this kind of clarification. EPA disagrees with the commenters who opposed using containers with the UN mark for non-DOT hazardous materials. As other commenters stated, several companies have voluntarily switched to use DOT Packing Group III (presumably with the UN mark) since 1999 and have not reported any of the potential problems described by the respondents who oppose using the UN mark. Further, EPA clarifies that the UN mark would only be required if required by the DOT regulations.

D. Limited Quantity/Consumer Commodity Exception (49 CFR 173.155)

1. *Final regulations*. The final regulations refer to and adopt 49 CFR 173.155, which establish limited quantity and consumer commodity exceptions for Class 9 materials (miscellaneous hazardous materials).

2. *Changes*. The potential alternative regulatory text in the supplemental notice would have incorporated the relevant portions of the limited quantity exception in 49 CFR 173.155 into the text of the pesticide container regulations. After reviewing the comments and re-evaluating the regulations, EPA believes it is more straightforward to simply refer to and adopt the entire section of the DOT regulatory exceptions for Class 9 materials in 49 CFR 173.155.

3. *Comments*. About 11 commenters addressed the idea of including a provision such as a limited quantity exception in the pesticide container regulations and all but one strongly supported this kind of provision. The opposing commenter, a registrant, stated that it did not believe that incorporating the Class 9 limited quantity exception was appropriate. The other commenters, mainly registrant groups and registrants, varied a bit in the specific approach they recommended, but all supported the idea of including this kind of exception in the pesticide container regulations.

Several commenters specifically requested that EPA add a reference to 49 CFR 173.155, the limited quantity and consumer commodity exceptions for Class 9 materials, to the pesticide container regulations to be more consistent with the DOT regulations. Several respondents supported the limited quantity exception as described in the supplemental notice. Several other commenters recommended that EPA incorporate both the limited quantity exception and the consumer commodity exception in 49 CFR 173.155. As defined in the HMR, consumer commodity means a material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. This term also includes drugs and medicines. Two registrant groups who urged EPA to also adopt the consumer commodity exception said that the consumer commodity exception is necessary to prevent increased costs and unnecessary complications caused by complying with EPA and DOT regulations that would be different.

4. *EPA response*. As stated in the supplemental notice, EPA continues to believe that it is necessary to incorporate a DOT limited quantity exception to maintain consistency with the HMR and to provide regulatory relief for relatively small quantities of pesticides. However, after reviewing the comments and re-evaluating the regulations, EPA believes it is better to simply refer to and adopt 49 CFR 173.155 in its entirety because it is more straightforward. In addition, the final rule approach adds the benefit of including the consumer commodity exception for Class 9 materials, which will provide clarity and consistency for registrants of products that are not DOT hazardous materials and that meet DOT's definition of consumer commodity.

E. Waiving or Modifying the Requirement to Comply with Some DOT Regulations (§§ 165.25(g) and 165.45(g))

1. *Final regulations.* The final regulations include provisions that would allow EPA to modify or waive the requirements of the regulatory sections that refer to and adopt the DOT requirements if EPA determines that the alternative (partial or modified) set of standards or pre-existing conditions achieves a level of safety that is at least equal to that specified in the requirements of this section. Section 165.25(g) establishes the waiver/modification standard for nonrefillable containers and § 165.45(g) provides it for refillable containers.

2. *Changes.* This is the same basic approach that was described in the supplemental notice. EPA made a few adjustments in the final regulations, such as clarifying that EPA must determine that the alternative set of standards achieves an acceptable level of safety before a waiver is granted (rather than being based on the registrant submitting information.) In addition, EPA reorganized the final regulations so all of the waiver requests are grouped together to simplify the process of applying for a waiver from any of the container standards. Finally, EPA changed the wording of the regulations to clarify that, for pesticide products that are DOT hazardous materials, we will modify or waive the requirements regarding the DOT standards only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

3. *Comments - DOT regulations.* Some commenters (registrant groups and registrants) supported the DOT waiver provision set out in the potential alternative regulatory text in the 1999 supplemental notice, stating they believed it was sufficient. A few registrant groups opposed the suggested DOT waiver provision in the supplemental notice. In particular, these commenters opposed EPA modifying DOT's standards for pesticides subject to DOT standards, because these pesticides could be rendered out of compliance with DOT standards and could not be transported legally. One of these commenters also expressed concern about EPA's ability to make waiver decisions, questioning EPA's resources, lack of expertise similar to DOT's, and the absence of the kinds of relationships that DOT has with transportation-related standard setting organizations.

4. *EPA response - DOT regulations.* EPA understands some of the concerns expressed by commenters regarding pesticides that are DOT hazardous materials. It is possible that EPA modifications to the adopted DOT requirements for a pesticide that is a DOT hazardous material could create a set of requirements that conflict with DOT's regulations. In this case, it would not be possible to package a pesticide such that it could meet both EPA's and DOT's standards. To prevent this kind of situation, EPA modified the final regulation in several ways. First, a separate waiver provision is included for pesticides that are DOT hazardous materials and for pesticides that are not DOT hazardous materials. Second, the waiver provision for pesticides that are DOT hazardous materials specifies that EPA will modify or waive the requirements only after consulting with DOT to ensure consistency with DOT regulations and exemptions. A similar provision is not necessary for pesticides that are not DOT hazardous materials, because these pesticides aren't subject to DOT's requirements, so there won't be a conflict.

EPA plans to coordinate with DOT as much as possible and hopes to benefit from their great experience in regulating packaging and their relationships with other organizations. EPA is very familiar with regulating pesticides. Through our authority in FIFRA to regulate pesticide products (which includes the pesticides, the labeling and the containers), we have directly or indirectly set packaging standards for a number of pesticide products. We also have established relationships with pesticide manufacturers and have developed expertise with pesticide handling and use practices. It is possible that at some point, compliance with one of the adopted DOT standards may conflict with safe use and handling practices for pesticides. For pesticides that are not DOT hazardous materials, EPA believes we should have the ability to modify or waive the adopted DOT standards if we determine (based on information provided) that an alternative set of standards achieves a level of safety that is at least equal to that specified in the adopted DOT standards.

F. Providing Public Notice of Changes in the Adopted DOT Regulations (§§ 165.25(c) and 165.45(c))

1. *Final regulations.* The final regulations include a provision that says EPA will provide notice to the public in the **Federal Register**, and an opportunity to comment, if DOT proposes to change any of the regulations that are referred to and adopted in EPA's pesticide container regulations. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.

2. *Changes.* This is similar to the approach described in the supplemental notice.

3. *Comments.* A registrant group questioned whether OPP has the resources for the on-going effort of monitoring DOT's regulatory changes and constantly proposing and promulgating its own revisions to mirror the DOT actions. This respondent also expressed concern that there would be lag times between DOT's and EPA's regulatory changes, creating confusion and putting registrants in the position of being subject to conflicting Federal standards.

4. *EPA response.* EPA does not believe that the notification process in the pesticide container regulations will be overly burdensome. An OPP staff member currently monitors the DOT regulatory changes. Increased communication with DOT resulting from these final regulations should provide advanced notice of any changes, which would make any monitoring efforts even easier. In addition, EPA believes the commenter misunderstood the point of this notification provision. EPA does not anticipate changing its regulations based on proposed changes by DOT in most situations. Instead, the purpose of EPA's notifications will be to let EPA's regulated community know that DOT has proposed to modify the DOT regulations adopted by the pesticide container regulations. Therefore, pesticide registrants and related parties will be able to monitor the DOT rule process themselves and can provide comments to DOT if they believe it is warranted. If a DOT rule change creates a significant obstacle to compliance or another substantial problem for pesticide containers, EPA would consider changing the pesticide container regulations that refer to and adopt the DOT requirements. However, EPA believes the chances of this happening are very small because it defeats the purpose of referring to and adopting the DOT requirements to provide a consistent set of packaging requirements.

V. Nonrefillable Container Standards

A. Purpose (§ 165.20(a))

1. *Final regulations.* The purpose of the nonrefillable container standards is to establish design and construction requirements for nonrefillable containers used for the distribution or sale of some pesticide products.

2. *Changes*. This is nearly the same as the proposed purpose (in § 165.100). One minor change was to acknowledge the reduced number of products that are subject to the final regulations by stating that the rule applies only to the distribution or sale of *some* pesticide products. The proposed regulations would have applied to all products. Another modification was to delete the term ''standards'' from the phrase ''establish standards and requirements'' because it is redundant.

B. Who Must Comply (§ 165.20(b))

1. *Final regulations*. You must comply with the nonrefillable container regulations if you are a registrant who distributes or sells a pesticide product in nonrefillable containers. If your product is subject to the nonrefillable container regulations as described in Unit V.D., the product must be distributed or sold in nonrefillable containers that comply with these regulations. This statement applies to each and every nonrefillable container used to sell or distribute the product.

2. *Changes*. This is the same approach that we proposed in § 165.100. As described in Unit V.D., the final rule exempts some products from the final rule and subjects some products to only the basic DOT general packaging standards. However, the approach of registrants being responsible for complying with the nonrefillable container standards is unchanged.

C. Compliance Date (§ 165.20(c))

1. *Final regulations*. The final regulations provide a 3–year period after the date of publication of the final rule in the **Federal Register** before compliance with the nonrefillable container standards is required. Specifically, within 3 years from today's date, registrants must distribute or sell all subject pesticide products in nonrefillable containers in compliance with these regulations.

2. *Changes*. EPA made several significant changes to the compliance date for nonrefillable containers in the final rule. First, the final regulations provide a 3–year period after today's date before compliance is required, compared to the 2–year period in the proposed rule. Second, the proposed rule specified (in § 165.117(b)) that 5 years after the date of publication of the final rule, all products distributed or sold in nonrefillable containers by persons other than the registrant would have had to comply with these standards. This ''channels of trade'' date affecting persons other than the registrant is not being finalized in today's final regulations. Third, the compliance date for registrants to submit certifications is not being finalized because the certification requirement from the proposal is not being finalized, as described in Unit V.M.

3. *Comments - length of compliance period*. About 15 commenters, including registrants, registrant groups, a dealer group, and a State regulatory agency, stated that 2 years would not be enough time to comply with the proposed standards, especially the nonrefillable container residue removal standard. Many of the respondents commented that 2 years is not long enough to test containers initially and, for containers that fail the residue removal standard, to redesign containers, reformulate the product, or obtain EPA approval for a waiver. Also, many commenters expressed concerns about delays caused by EPA in providing necessary implementation information, processing waiver requests, and reviewing reformulated products.

4. *EPA response - length of compliance period*. EPA agrees with some of the commenters that a longer compliance period will make it easier for registrants to comply with the nonrefillable container standards. To facilitate compliance while trying to minimize the impact on companies, EPA lengthened the compliance period for the nonrefillable container requirements to 3 years. EPA believes a 3–year period is sufficient based on the results of the economic analysis and because some of the changes made to the regulations facilitate compliance. These changes include: (1) Some products are completely exempt from the nonrefillable container requirements; (2) many products must comply only with basic DOT requirements, not the full set of nonrefillable container requirements; and (3) changes in the residue removal requirement, discussed in Unit V.H., which reduce the burden of that requirement.

5. *Comments - channels of trade*. Some commenters — registrant groups and registrants — urged EPA to delete the channels of trade provision, generally stating that current products/containers don't pose a large enough hazard to justify the costs of a recall. A few State regulatory agencies and a container manufacturer requested clarification of this requirement, i.e., who would be included and who would be responsible for compliance and/or disposition of ''expired'' products.

6. *EPA response - channels of trade*. 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 costs of recalling them from retailers and distributors to either repackage or dispose of them. EPA believes that setting a date for when 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.

D. Pesticide Products Included (§ 165.23)

1. *Final regulations*. As described in detail in Unit III., only certain products have to comply with the nonrefillable container standards. MUPs, plant-incorporated protectants, and certain antimicrobial products are completely exempt from the nonrefillable container requirements. All other pesticide products are subject to the nonrefillable container regulations.

There are different tiers of regulation for products that are subject to the nonrefillable container regulations. A product is subject to *all* of the nonrefillable container requirements if it satisfies *at least one* of the following criteria:

- It meets the criteria of Toxicity Category I.
- It meets the criteria of Toxicity Category II.
- It is classified for restricted use as set out in 40 CFR 152.160 - 152.175.

If a product does not satisfy any of these criteria (and it is not an MUP, plant-incorporated protectant or an exempt antimicrobial), it must be packaged in accordance with 49 CFR 173.24. These products do not have to comply with any other nonrefillable container requirements. However, if any of these products are DOT hazardous materials, they are separately obligated under DOT regulations to comply with all applicable DOT requirements. In other words, nothing in EPA's regulations changes the requirements in the DOT HMR for products that meet DOT's criteria for hazardous materials.

2. *Changes*. In the proposal, only MUPs would have been exempt from the nonrefillable container regulations (in § 165.100). All other products would have been subject to the standards. The 1999 supplemental notice discussed regulatory options for exempting some products (antimicrobials and non-antimicrobials) from the full set of refillable container regulations and for exempting certain antimicrobial products from specific requirements.

The criteria in the final rule for exempting antimicrobials are somewhat different from those we indicated as our preferred approach in the supplemental notice. The final rule exempts plant-incorporated protectants. Also, the final rule uses toxicity category and restricted use product status to determine the level of regulation subject to all nonrefillable container requirements compared to the basic DOT packaging requirements rather than to determine whether the product is subject to or exempt from the nonrefillable container regulations.

Table 6 describes the provisions for determining which pesticide products are subject to which nonrefillable container regulations and a brief explanation of how (or if) this provision changed from the proposal and/or the supplemental notice.

TABLE 6.—CHANGES TO THE SCOPE OF THE NONREFILLABLE CONTAINER REGULATIONS

Regulatory Provision in the Final Rule	Changes
Manufacturing use products are exempt.	No change from proposed rule or supplemental notice.
Plant-incorporated protectants are exempt.	Plant-incorporated protectants would have been subject to the proposed rule. The regulations for plant-incorporated protectants were finalized in 2001. We are exempting them from the final rule because of their unique nature.
Certain antimicrobial products are exempt.	Antimicrobial products would have been subject to the proposed rule. The final rule implements an approach similar to option 1 in the supplemental notice, although some of the details are different.
All other products are subject to the regulations as follows:[1]	
Products in Toxicity Category I or II are subject to all of the nonrefillable container requirements.	No change from the supplemental notice approach.
Restricted use products are subject to all of the nonrefillable container requirements.	This is different from the other two criteria discussed most thoroughly in the supplemental notice, which were: (1) container capacity equal to or larger than 5 liters or 5 kilograms and (2) having a specified environmental hazard statement on the label of an outdoor use product.
All other products (those in Toxicity Category III or IV and that are not restricted use products) must comply only with the basic DOT packaging requirements in 49 CFR 173.24.	This category of lowest regulation is different from the supplemental notice in two ways. First, these products are subject to the basic DOT requirements rather than being completely exempt from the nonrefillable container regulations. Second, more products are in this category of lowest regulation because there are fewer Toxicity Category III or IV products subject to all of the nonrefillable container requirements in the final rule (restricted use products) than under the supplemental notice (products in small containers and outdoor use products with a specified environmental hazard statement on the label).

[1]The rest of the changes focus on changes from the supplemental notice. All of these products would have been subject to the proposed rule because the proposed rule would have applied to all products except for manufacturing use products.

E. DOT Standards (§ 165.25(a) - (c))

1. *Final regulations.* As discussed in detail in Unit IV., nonrefillable containers must comply with the DOT Hazardous Materials Regulations that are referred to and adopted into EPA's regulations. These incorporated regulations establish requirements for container design, construction and marking.

2. *Changes.* This is a significant change from the proposed regulation, although the approach of referring to and adopting a subset of the DOT standards was discussed in detail in the 1999 supplemental notice. See Unit IV. for a detailed discussion. As discussed in Unit V.M., three of the proposed requirements for nonrefillable containers (container integrity, marking the material of construction and ensuring that the container recloses securely) are not being finalized in the final rule because they were replaced by equivalent DOT requirements.

F. Closures (§ 165.25(d))

1. *Final regulations.* A nonrefillable container must have at least one of the four closures listed below if it meets all of the following criteria:

- The container is used to distribute or sell a liquid, agricultural pesticide;
- The container is rigid;
- The capacity of the container is equal to or greater than 3.0 liters (0.79 gal); and
- The container is not an aerosol container or a pressurized container.

The four closures specified in the regulations are:

- Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5 threads per inch, National Pipe Straight (NPS) standard.
- Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.
- Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch.
- Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch. The cap may fit on a separate rigid spout or on a flexible pull-out plastic spout.

2. *Changes.* The scope of the requirement for standardized closures is unchanged from the proposal; it applies to liquid agricultural pesticides in rigid containers with capacities equal to or greater than 3.0 liters. The closure standard does not apply to aerosol or pressurized containers. The final regulation made several changes in the dimensions and other specifications of the closures based on comments and additional research to accurately reflect

the closures that are most commonly used in the agricultural pesticide industry. Also, the proposed provision that would allow the use of non-standard closures was moved to a separate section of the final rule (§ 165.25(g)) along with the other waiver and modification provisions, as described in Unit V.I.

G. Dispensing Capability - Glugging and Dripping (§ 165.25(e))

1. *Final regulations.* A nonrefillable container with a capacity of 5 gallons (18.9 liters) or less, that is not an aerosol or pressurized container or a spray bottle, and that holds a liquid pesticide must do both of the following:

- Allow the contents of the nonrefillable container to pour in a continuous, coherent stream.
- Allow the contents of the nonrefillable container to be poured with a minimum amount of dripping down the outside of the container.

2. *Changes.* The final rule includes several substantial changes from the proposal. First, the dispensing requirements in the proposed rule would have applied to all nonrefillable containers for liquid pesticides, regardless of the size of the container. The final rule only applies the dispensing requirements to containers that are less than 5 gallons (18.9 liters) in size. This change was made in response to the comments that said large containers should not be subject to the dispensing standards. Because these standards are intended to minimize exposure to pesticides when they are poured from containers, EPA agrees that the requirements should not apply to containers that are too large to allow their contents to be poured from them. The dispensing requirements in the final rule apply only to containers with capacities of 5 gallons (18.93 liters) or less, which we believe are the containers that can be picked up and the contents poured out.

Second, the final rule clarifies that, like the nonrefillable container closure requirement, the glugging and dripping standards do not apply to aerosol containers or pressurized containers. The proposed dispensing requirements would have applied only to liquid pesticides, and the final rule maintains this approach. EPA did not intend that these requirements would apply to aerosol or pressurized containers. The proposed closure regulation specifically excluded aerosols and pressurized containers, so the lack of similar language in the dispensing requirements led some commenters to believe that aerosol and pressurized containers are subject to the dripping and glugging standards. To clarify our intent, EPA modified the final rule to clearly state that the dispensing standards do not apply to aerosol containers and pressurized containers. As mentioned above, the dispensing standard is intended to minimize exposure to pesticides when they are poured from containers, which is not how pesticides are dispensed from aerosol or pressurized containers.

Third, the requirement in the final rule was modified to also exclude spray bottles. During a review of products that would be subject to the final regulation, EPA realized that spray bottles should also be exempt from the dispensing requirements because the container contents are sprayed out by a trigger mechanism, rather than poured.

Fourth, the requirement regarding dripping in the final rule specifies that the contents of a container must be poured with a minimum amount of dripping, rather than no dripping as proposed. Fifth, the dripping standard was clarified to specify ''dripping down the outside of the container'' to distinguish this from when the pesticide drips out of the container into its target when the material is poured from the container. Many commenters (registrants, registrant groups, a grower group, a container manufacturer, and a State regulatory agency) supported modifying this standard from ''eliminating'' dripping to ''minimizing'' dripping. Most of these respondents commented that completely eliminating dripping is impractical or impossible and that the amount of pesticide on the outside of the container is largely a function of user care. EPA agrees with the commenters that the proposed standard of eliminating dripping is not practical, particularly without a specific testing procedure and considering the significant role of user handling practices in whether the containers drip. Therefore, EPA is modifying the dripping standard to minimize rather than eliminate dripping. The structure of the standard was revised to be similar to the glugging standard so it would be clear that the dripping standard applies when the contents are poured from the container. Finally, the requirement refers to minimizing the amount of ''dripping down the outside of the container.'' EPA believes this phrase clarifies that the dripping that should be minimized is the trickle or drops of liquid on the container exterior; not the last few drops of material or rinsate that leave the container when the contents are poured.

Lastly, the proposed standard for reclosing securely is not being finalized in the final rule, because there is an equivalent DOT standard that is being adopted, as explained in Unit V.M.

H. Residue Removal (§ 165.25(f))

1. *Overview*—i. *Final rule.* Rigid containers with capacities less than or equal to 5 gallons for liquid formulations or 50 pounds for solid formulations holding dilutable formulations must be capable of attaining at least 99.99 percent removal for each active ingredient when tested using the EPA testing methodology. Percent removal represents the percent of the original concentration of an active ingredient in the pesticide product formulation when compared to the concentration of that active ingredient in an extra rinse following administration of the triple rinse procedure specified in the testing methodology, i.e., in the fourth rinse. All dilutable products in these smaller rigid containers must be capable of meeting the 99.99 percent removal standard, although the testing must be done only if products are flowable concentrate formulations or if EPA requests the test data on a case-by-case basis.

ii. *Changes.* EPA made many substantive changes to the nonrefillable container residue removal standard in the final rule based on public comments and a re-evaluation of currently available data. The significant changes are listed briefly in this subsection and are described in more detail below in the response to comment summaries. The major changes in the residue removal standard are:

- The performance standard was changed from 99.9999 percent removal (''six 9's'') in the proposal to 99.99 percent removal (''four 9's'') in the final rule.
- The wording was changed from ''The registrant shall demonstrate for each container/formulation combination that the standard is achieved'' in the proposal to ''Each container/formulation combination must be capable of attaining the standard.'' The language in the final rule provides more flexibility in showing compliance with the standard, while still placing the responsibility of meeting the standard on the registrant.
- Testing (and the corresponding recordkeeping in § 165.27(b)(5)) is only required for flowable concentrate formulations or if EPA specifically requests the records on a case by case basis.
- The test procedure will be established as an OPP test procedure titled ''Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers,'' which is incorporated into the

regulations. (Ref. 20) The proposed regulatory language provided some details of the test procedure, which EPA intended to supplement with guidance. The final rule does not include the specific testing requirements because we believe it is more appropriate to provide these detailed procedures in a test protocol rather than in the regulations.

- The residue removal standard only applies to containers that are small enough to be shaken because the final test procedure and the supporting data involved shaking the containers during triple rinsing. As stated in Unit IX.I., EPA generally believes that the largest containers that users can shake during a triple rinse are those with capacities of 5 gallons for liquids and 50 pounds for solids.

In addition, the final residue removal test procedures, incorporated in ''Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers,'' (Ref. 20) contain several key changes.

- In the final test procedure, the test must be conducted on three containers, rather than the proposed approach of a minimum of 19 containers.
- Rather than the proposed statistical standard (at least 95 percent confidence that at least 85 percent of containers tested will meet the standard), the final test procedure specifies that all three containers tested must meet the four 9's standard in the final rule. The final rule approach is similar to the standards for complying with DOT's drop tests and other performance tests.
- The final rule does not specify that the testing must be conducted in compliance with the full set of Good Laboratory Practice Standards in 40 CFR part 160. While registrants may comply with the GLP standards, it is not required. However, some key GLP requirements are specified in the final test procedure to accomplish the goals of ensuring adequate quality of the testing and the resulting data.

iii. *Comments*. Several State regulatory agencies and a container manufacturer group supported EPA's proposal to require a laboratory standard for removing residue from nonrefillable containers. These commenters stated that such a standard would enhance safe use and recycling, facilitate management of empty containers and provide flexibility to registrants.

A registrant and a registrant group supported consideration of a residue removal performance standard but opposed the stringency of EPA's proposal. Additionally, a few registrants commented that encouraging the use of containers and formulations that facilitate residue removal is reasonable, but did not support the proposed standard.

Many respondents (from nearly all commenter categories, but mostly the pesticide registrant industry) opposed the establishment of any numeric standard for residue removal for the following reasons (which are described in more depth in the Response to Comment document (Ref. 19)):

- EPA doesn't demonstrate a problem;
- Much of the information cited by EPA isn't relevant/applicable;
- The problem is that users don't rinse containers; not the container designs; and
- The solution is educating users and enforcing rinsing standards.

Many commenters specifically opposed the six 9's standard as too stringent. These comments claimed that the six 9's standard is overly ambitious and that the standard would be too costly for the benefit obtained. In many cases, commenters said the standard would be impossible to achieve. While some respondents acknowledged that the six 9's standard is technologically feasible, they said it would not be practical in application.

iv. *EPA response*. EPA believes that ensuring adequate residue removal at the user level to achieve the goal of containers that can be safely managed for disposal or recycling involves the following steps:

(1) The use of container designs and formulations that facilitate effective residue removal;

(2) Defining proper cleaning procedures;

(3) Educating users about proper cleaning procedures;

(4) Motivating users to properly clean containers; and

(5) Enforcing proper cleaning in the field.

Problems and breakdowns can occur with any of these steps. If problems do occur, containers will not be adequately clean when they are offered for disposal or recycling. EPA acknowledges the commenters' point that much of the problem with inadequately cleaned containers lies with the fact that the users don't rinse them properly, implying a breakdown in items 2, 3, and/or 4. EPA believes that the label standards associated with these regulations establish proper and clear cleaning procedures, as described in Units IX.F. - IX.K. EPA agrees that it is important and appropriate to dedicate adequate resources to user education and motivation and to enforcing the rinsing standards. Additional efforts on these points will be discussed in Unit V.H.5.

However, EPA still believes that the first step in adequate container cleaning - and a responsibility of the registrant - is making sure that the containers can come clean. Therefore, EPA is retaining a residue removal performance standard in the final regulations for rigid nonrefillable containers with dilutable formulations. Additional information about the many variables observed in more than 20 rinsing studies and about the FIFRA Section 19 mandates is in the Response to Comment document. (Ref. 19)

2. *Numeric residue removal standard*. EPA decided to change the performance standard from 99.9999 percent removal (''six 9's'') in the proposal to 99.99 percent removal (''four 9's'') in the final rule.

i. *Comments*. Several State regulatory agencies and an environmental group specifically expressed support for the ''six 9's'' standard. One State regulatory agency said their data show that 99.9999 percent removal is achievable under field conditions. Another said that the standard is achievable for most containers, but not for flat-topped metal cans — a container type it feels is not suited for use with pesticides.

On the other hand, many commenters opposed the proposed six 9's standard, stating that it was overly ambitious and too burdensome. Specific comments include:

- Almost 20 commenters, mostly registrants and registrant groups, objected to EPA's interpretation of the residue removal data and particularly opposed EPA's assessment that a level of six 9's was technologically practicable.
- About 20 commenters (mostly registrants and registrant groups) urged EPA to base the standard on the risks involved. Many of these respondents commented that there is no risk analysis showing that residues in existing containers pose a theoretical or real threat or that reaching a six 9's standard would substantially reduce this risk.
- Many commenters, including registrants, registrant groups, State regulatory agencies, a dealer and a dealer group, questioned the cost-effectiveness of the six 9's standard.
- Some registrants who opposed the six 9's standard favored adopting a less stringent four 9's requirement. They termed it more practical, in line with industry expectations, and the only achievable level of removal.

One registrant group provided comprehensive comments during the 2004 reopening of the comment period based on the Ag Container Recycling

Council's (ACRC's) experience over the past 10 years. This commenter described ACRC's efforts to assess and control the risk from using the recycled plastic and noted that, since ACRC's inception in 1992, there have been no reports of incidents where public health or safety has been compromised as a result of exposure to the minimal residues found in recycled plastic pesticide containers. Further, ACRC's study indicated that the risk to human health and the environment from recycling emptied pesticide containers that remove 99.99 percent of residue from containers is within acceptable levels for recycling.

This registrant group also stated that ACRC's experience with recycling clean, rinsed one way pesticide containers for more than a decade leads them to believe that residue removal is an issue of instructing applicators to triple or pressure rinse containers immediately after use. A registrant expanded on this idea by stating that recent experience with pesticide container collection programs has shown substantial improvement in the cleanliness of incoming containers and that it has become obvious that problems with dirty containers are not caused by product that is not able to be rinsed, but by users who do not rinse, or do not rinse in a timely manner. The registrant contrasted this experience with EPA's focus in the proposed rule on ensuring that products will rinse easily from their containers, which seems to have been based the reports of poorly rinsed containers from early container collection programs. The registrant said that great strides have been made in the growth of State container return/recycle programs and in grower, applicator, and user education since that period.

ii. *EPA response.* After considering the comments, re-evaluating the residue removal data and factoring in the experiences of pesticide container collection and recycling programs over the past decade, EPA believes the residue removal standard should be revised from 99.9999 percent to 99.99 percent removal.

Of the many rinsing studies, four sets of data were developed using a standard testing procedure (similar to the final test procedure) to test currently used formulations and container designs. Two sets of data focused on containers and formulations typical of the agricultural pesticide market and the other two were intended to represent containers and formulations in the household, institutional and industrial market. Table 7 summarizes the results of these studies in terms of the standard that the container/formulation would meet based on the concentration of active ingredient in the rinsate from the fourth rinse.

TABLE 7.—ANALYSIS OF RESIDUE REMOVAL DATA

Study Name	Total Cntr/Form Combinations Tested	Number of Container/Formulations That Meet*		
		Four 9's	Five 9's	Six 9's
Formulogics (agricultural) (Refs. 8 and 36)	19	19	17	13
NACA (triple rinse) (Refs. 15 and 39)	24	24	19	12
Subtotal: agricultural market	43	43 (100%)	36 (84%)	25 (58%)
Formulogics (nonagricultural) (Refs. 6 and 37)	29	29	26	16
CSMA (Refs. 35 and 77)	7	6	4	1
Subtotal: nonagricultural market	36	35 (97%)	30 (83%)	17 (47%)
Total	79	78 (99%)	66 (84%)	42 (53%)

*Note: Some container/formulation combinations were tested on one container; others on two or three (identical) containers for that formulation. Formulations tested on more than one container were classified in the highest standard that all of the containers met. For example, a container/formulation would be classified as four 9's if the results for the formulation in three containers were 99.9988, 99.9996 and 99.9995. For reference, the structure of the studies were: (1) Formulogics (ag): all 19 tests on 1 container; (2) NACA (triple rinse): 9 tests on 1 container, 15 tests on 3 containers; (3) Formulogics (nonag): 3 tests on 2 containers, 6 tests on 3 containers but the rinsates had to be composited to provide adequate volume, and 21 tests on 3 containers; and (4) CSMA: all 7 tests on 1 container.

While a more thorough discussion of these data and the comments regarding them is included in the next section, EPA believes that the data show that a standard of four 9's adequately represents the results from a careful laboratory triple rinse. Of the 79 container/formulations tested, only one did not meet a 99.99 percent removal standard. The Consumer Specialties Manufacturers Association (CSMA, now the Consumer Products Manufacturers Association) provided information indicating that the container/formulation that failed was an agricultural pesticide product in a household pesticide container. Therefore, EPA does not believe that this data point represents a formulation/container that is actually distributed in the marketplace. After reconsidering the available data, EPA believes that the proposed standard of six 9's would be a ''technology-forcing standard,'' whereas the final standard of four 9's accomplishes the goal stated in the preamble of the proposed rule and mandated in FIFRA section 19(f)(1)(B) to establish a standard that is equivalent to triple rinsing.

EPA also considered the experiences and results of pesticide container and recycling programs over the past decade. When the regulations were proposed, the experiences and observations of some of the earliest container collection and recycling programs were available. This information led to the statement in the preamble of the proposed rule that ''Pesticide container recycling programs and municipal waste facilities report the frequent rejection of certain pesticide formulation and container combinations because of unacceptable pesticide residues.'' The data from some of the earliest container collections are shown in Table 8.

TABLE 8.—RESULTS FROM EARLY PESTICIDE CONTAINER COLLECTION PROGRAMS (REF. 43)

State	Year	Number of Containers			Rejection Rate (percent)	Reference
		Accepted	Rejected	Brought In		
Florida (South Florida)	1991	1,594	231	1,825	12.7	(Ref. 4)
Florida (Jackson County)	1991	991	113	1,104	10.2	(Ref. 3)
Illinois	1993	57,086	3,451	60,537	5.7	(Ref. 2)
Iowa	1990	64,000	ND	ND	50	(Ref. 9)
Michigan	1992	18,959	2,990	21,949	13.6	(Ref. 12)
Minnesota	1990	9,192	2,136	11,328	18.9	(Ref. 17)
Minnesota	1991	56,928	4,646	61,574	7.5	(Ref. 17)

However, more recent information provided by several States shows that the container rejection rate decreases over time. This is generally attributed to pesticide users becoming more aware of proper rinsing procedures and the container cleanliness standards because of outreach, training and education efforts. One example is the decrease in the rejection rate experienced in Minnesota from 1990 (18.9 percent) to 1991 (7.5 percent) despite a large increase in the number of containers collected, as shown in Table 8. Out of the five Minnesota counties that had programs both years and for which data are available (Ref. 17), the rejection rate in four of them decreased substantially in 1991 while one stayed constant:

- Isanti County: The rejection rate decreased from 20.9 percent in 1990 to 12.9 percent in 1991;
- Polk, Pennington and Red Lake Counties: 9.5 percent in 1990 to 2.3 percent in 1991;
- Pope County: 13.8 percent in 1990 to 14.1 percent in 1991;
- Stevens County: 25.0 percent in 1990 to 0.2 percent in 1991; and
- Swift County: 14.6 percent in 1990 to 2.7 percent in 1991. (Ref. 17)

A 1996 report from the Minnesota Department of Agriculture confirms that this trend continued over time. (Ref. 13) From 1990 through 1995, the container rejection rate in Minnesota ranged from 10 percent to 20 percent, with a high of 35 percent. The report stated that ''Pesticide users had a difficult time rinsing containers to acceptable standards. Timing of the rinse, poor equipment for rinsing and inadequate rinsing techniques resulted in many containers not being accepted.'' The rejection rate for 1996 ranged from 0 percent to 2 percent.

Before 1995, a county in North Carolina collected about 2,500 containers per year and had a container rejection rate around 28 percent. After receiving a grant in 1995 which allowed the county to expand the program to 12 convenient sites and to provide additional training on proper rinsing, the county collected about 21,000 containers and the rejection rate dropped to 3 percent. (Ref. 10) Nebraska and South Carolina report current rejection rates of 2 percent on their web sites. Virginia reported a rejection rate of 0.5 percent in 2002, which was higher than the 2000 rate but still deemed to be acceptable. (Ref. 43)

EPA believes this information shows that the main reason containers are rejected from pesticide container collection programs is because they were not rinsed properly. EPA agrees with the States that the container rejection rates decreased substantially over time as pesticide users improved their rinsing techniques, rinsed the containers before residue dried, and gained understanding of the cleanliness criteria used by the Ag Container Recycling Council (ACRC) recycling contractors. The ACRC contractors have a strong incentive to carefully inspect containers to ensure they are clean because contamination increases the risk to the contractor's workers and reduces the value of the collected plastic. Therefore, we think it is accurate to conclude that the lower rejection rates in recent years are not a reflection of relaxed or reduced inspection standards.

EPA also believes that the container rejection rates from the container collection and recycling programs show that containers do not have to meet a standard of six 9's to be adequately cleaned. Table 7 shows that almost 60 percent of the agricultural formulations and containers tested met a standard of six 9's. Assuming that the tested formulations/containers are representative of the agricultural market, we would expect to find a rejection rate of over 40 percent if a six 9's standard was necessary for adequate cleaning. Data from several States show that currently a maximum of 2 percent of containers are rejected, which is much lower than 40 percent. EPA interprets this to indicate that meeting a standard of six 9's is not necessary to ensure that a container is clean enough to be recycled safely.

EPA disagrees with commenters who stated that the residue removal standard should be based solely on toxicological significance, because establishing and proving compliance with such a standard would be very complex. In addition, any amount of residue in a container could cause a disruption to its proper disposal or recycling because of the perception of risk the concentration of active ingredient may not be relevant in such a situation. However, toxicity and relative risk are indirectly taken into account for the nonrefillable residue removal standard in the final rule because of the changes in the scope of the container regulations. The less toxic/risky pesticide products (those in Toxicity Categories III and IV and that are not restricted use pesticides) are subject only to the basic DOT standards, and are exempt from some of the container requirements, including this one. Only products that are in Toxicity Category I and II and others that are restricted use products are subject to the residue removal standard in the final rule.

Setting the residue removal standard at four 9's in the final rule will reduce the costs of implementing the regulations because a higher percentage of existing container/formulations will comply with the standard. Therefore, fewer container design changes, re-formulations, and modification or

waiver requests will be needed. Reducing the stringency of the residue removal standard does not reduce the testing costs. However, the testing costs attributed to the final rule are reduced from those in the proposal because fewer containers/formulations are subject to the standard (due to the changes in the scope). In addition, changes in the final test procedure (see Unit V.H.4.) and the final implementation approach (discussed in Unit V.H.5.) of only requiring testing for flowable concentrate formulations and if requested on a case-by-case basis will greatly reduce testing costs.

EPA believes that a 99.99 percent removal standard is consistent with the results from triple rinsing current containers/formulations, which we generally believe can be adequately cleaned if they are properly rinsed.

In summary, EPA believes that most containers/formulations can meet a four 9's standard. However, we do believe that a standard is necessary and appropriate for several reasons. First, the initial step in ensuring clean containers is to use container designs and formulations that facilitate residue removal. This is a responsibility of the registrant and a standard ensures that the registrants appropriately facilitate safe and proper residue removal. Second, the rinsing data show that there is a difference in how easily residues can be removed from containers, based on the formulation and container characteristics, meaning that there is the potential for problems in removing residues. Third, observations from State pesticide container collection programs have noted a problem over time (i.e., not just when collections were initiated) with certain pesticide formulations as discussed in more detail in Unit V.H.5. Lastly, a four 9's standard maintains the current level of rinsability and prevents the use of formulations or containers that retain more residue or are harder to rinse than currently used containers and formulations.

3. *Rinsing data*—i. *Comments*. Some commenters specifically addressed the triple rinsing data discussed in the preamble of the proposed rule. A registrant group and a registrant questioned the relevancy of some of the container cleaning data cited by EPA. These respondents pointed out that some of the data were 6 to 10 years old, and cited a widespread move to plastic jugs, making data on metal pails obsolete.

Several commenters expressed the following specific concerns about the residue removal data that EPA cited to support the proposed six 9's standard:

- A registrant group and a registrant commented that several transcription errors were made in constructing Table 1 (triple rinsing data for agricultural containers/formulations) in the preamble of the proposed rule. One of the respondents added that these errors undermine the credibility of the data and the arguments developed that use the data as their basis.
- A registrant questioned whether the research data were generated under GLPs.
- Two registrants questioned whether the data are truly representative of containers/formulations that are subject to the regulations.
- A registrant commented that data other than EPA's (Formulogics), NACA's and CSMA's are not relevant because they are not generated from the same test procedures.

A registrant group and a few registrants expressed concerns that the EPA data for non-agricultural pesticide markets (in Table 2 of the preamble of the proposal) are not representative of the household, industrial and institutional markets. All of these commenters pointed out that the EPA data do not include tests on dilutable antimicrobial products or similar formulations. In addition, the registrant group stated that EPA (Formulogics) did not test formulations containing active ingredient concentrations lower than 38 percent by weight. This respondent also added that the data provided by CSMA cover a small but representative number of nonagricultural container/formulation combinations and that most of them (10 out of 12) would not meet the six 9's standard.

ii. *EPA response*. EPA agrees that residue removal data produced using a rinsing procedure other than the one identified in the EPA standard methodology are not relevant to supporting or changing a regulatory standard. As stated in Unit V.H.2., four sets of data were developed using a standard testing procedure (that is very similar to the final test procedure) to test currently used formulations and container designs. Two sets of data focused on containers and formulations typical in the agricultural pesticide market and the other two were intended to represent containers and formulations in the household, institutional and industrial market. Even though the testing to develop these four sets of data was done in the early 1990's, EPA believes that the formulations and containers tested are still commonly used.

Table 7 presents the results of these studies in terms of the standard that the container/formulation would meet based on the concentration of active ingredient in the rinsate from the fourth rinse. The following table presents the information in a somewhat different format. In Table 9, each container/formulation combination is included only once per row in the column for the most stringent standard it would meet. For example, if the percent removal for a container/formulation combination was 99.9992 percent, it would be listed only in the five 9's column (even though it also meets a standard of four 9's).

TABLE 9.—ANALYSIS OF RESIDUE REMOVAL DATA

Study Name	Total Cntr/Form Combinations Tested	Number of Container/Formulation Combinations That:[1]			
		Don't meet Four 9's	Meet Four 9's	Meet Five 9's	Meet Six 9's
Formulogics (agricultural)	19	0 (0%)	2 (11%)	4 (21%)	13 (68%)
NACA (triple rinse)	24	0 (0%)	5 (21%)	7 (29%)	12 (50%)
Formulogics (nonagricultural)	29	0 (0%)	3 (10%)	10 (34%)	16 (55%)
CSMA	7	1 (14%)	2 (29%)	3 (43%)	1 (14%)
Total	79	1 (1%)	12 (15%)	24 (30%)	42 (53%)

[1] Same note as Table 7.

Looking at the presentation of the results of the four studies in Tables 7 and 9, it can be seen that a higher percentage of the container/formulations tested by Formulogics for EPA meet a standard of six 9's than the containers/formulations tested by the industry associations. This is especially true for the tests of nonagricultural products. However, there is no difference or minimal difference in the results between EPA's data and industry's data in terms of whether the containers/formulations meet a standard of four 9's. As described earlier, only one container-formulation combination (which isn't actually distributed in the marketplace) did not meet a four 9's standard.

EPA acknowledges that there were discrepancies between the data in the Report to Congress and the data in Table 1 in the proposed rule's preamble. These discrepancies were due to corrections made to the NACA data reported to EPA; the earlier (and incorrect) data were presented in the Report to Congress and the more recent, correct data (which should have been cited) were included in the preamble for the proposal. Reference 42 explains these discrepancies in more detail. Tables 7 and 9 present the correct data.

EPA acknowledges that the sample size of 79 container/formulation combinations is relatively small, but we believe that the formulation types and container designs tested to produce the data in Tables 7 and 9 are representative of the formulations and containers that are currently used. Some formulations (such as dilutable sanitizers and disinfectants) may be under-represented numerically, since only the CSMA testing included these kinds of formulations. However, the CSMA tests done on the dilutable sanitizers and disinfectants show that these kinds of products can attain a standard of four 9's. Also, only a limited number of antimicrobial products will be subject to the container regulations (and therefore the residue removal standard) based on the revised scope of the final rule. Therefore, the proportion of antimicrobial product formulation types that were tested may be similar to the proportion that are subject to the residue removal standard in the final regulation.

The supporting data were not generated according to GLPs. Additionally, the supporting studies were conducted on one, two or three containers per formulation; not 19 containers. As described in Unit V.H.4., the methodology in the final rule was changed to be consistent with the supporting data.

4. *Final test protocol.* Many respondents commented on the proposed testing methodology and particularly its relationship to the protocol developed for EPA by Formulogics prior to proposing the rule. Most of these comments are addressed in the Response to Comment document, although the comments regarding GLP standards and the number of containers tested are summarized below.

i. *Comments - GLP standards.* Many commenters (registrants, registrant groups, and a consultant) objected to the GLP testing requirement as unnecessarily burdensome, substantially increasing the cost of testing without increasing the validity of the data. However, one respondent (a consultant) commented that all studies should be done under GLPs in some form to ensure data quality. A registrant group and a registrant suggested that it would be sufficient to require a company official to certify the data. Several registrants commented that GLP testing would force them to have outside labs conduct the testing and claimed that this would dramatically increase the costs. One registrant said that many container testing labs are not familiar with EPA's GLP regulations. Another stated that because labs cannot dispose of rinsate properly, they will send it back to the registrants, increasing costs and waste generation. A registrant group and a registrant pointed out that the data used to develop EPA's proposal were not generated under GLP and asked that the GLP requirement be dropped from the final rule.

ii. *EPA response - GLP standards.* EPA changed the test protocol for the final rule in several ways to address some of the problems described by commenters. First, the final rule does not specify that the testing must be conducted in compliance with the full set of GLP standards in 40 CFR part 160. While registrants may comply with the GLP standards, it is not required. EPA believes that the container residue removal testing can adequately be accomplished by registrants at their facilities; the intent was not to have this testing contracted to outside labs, although a registrant may choose that option.

While EPA does not believe that compliance with the full GLP standards in 40 CFR part 160 is necessary, we think that it is necessary to incorporate some of the key GLP requirements to ensure that the data are of sufficient quality. EPA reviewed the part 160 regulations and particularly the subset of requirements specified in 40 CFR 160.135 for certain studies to determine physical and chemical characteristics of pesticides. Of the subset of requirements identified in 160.135, we identified some requirements that residue removal testing must meet. These GLP requirements are identified in the final test protocol. (Ref. 20)

iii. *Comments - number of containers.* All of the many (nearly 20) commenters (registrants, registrant groups and a container manufacturer group) who addressed this issue were opposed to testing 19 containers per formulation/container combination. Many registrants and a registrant group urged EPA to require testing of only three replicates of each container/formulation combination, rather than the proposed 19. A registrant group and a few registrants suggested starting with three and testing more if necessary to achieve a predetermined level of statistical significance. Commenters said testing of 19 containers is not statistically justified, not cost effective, and not necessary for achieving the data requirements. Some of these commenters pointed out that EPA used only three containers to generate the preamble data and asked why the same standard is not sufficient for registrants.

iv. *EPA response - number of containers.* EPA changed the test protocol for the final rule to specify that the test must be conducted on a minimum of three containers, rather than the proposed approach of a minimum of 19 containers. The main reason for changing the number of containers that must be tested is that the testing conducted to produce the data supporting the residue removal standard was conducted on three containers. The supporting data was not conducted on 19 containers, so it is unclear whether the available data could support a standard based on testing 19 containers. Upon re-evaluation, EPA agrees that the test procedure used to produce the supporting data and the test procedure for the regulatory standard should be very similar if not identical. In addition, EPA believes that testing three containers offers cost reduction benefits including less time to actually conduct the testing with one-sixth the number of containers to be rinsed, one-sixth the number of analyses that need to be conducted, and one-sixth the amount of rinsate that needs to be managed or disposed. The final rule approach of testing three containers is similar to the standards for complying with DOT's drop tests and other performance tests.

5. *Implementation*—i. *Comments.* In the preamble of the proposed rule, EPA requested comments on the circumstances under which submission of residue removal data from pesticide products with substantially similar

container/formulation characteristics would be sufficient in lieu of data generation for every pesticide product. EPA also requested comments on the factors to be considered in determining when container and formulation characteristics should be considered ''substantially similar'' for the purposes of this requirement. The following comments address these issues:

- Too many tests required: Some respondents, including registrants, registrant groups, and a container manufacturer group, expressed concern that the proposed residue removal standard and the interpretation of design type as expressed in the proposed rule would necessitate testing for virtually every container/formulation combination in every size and variation. They said the costs to registrants would be crippling and asked EPA to consider alternatives.
- Design type clarification: Several commenters asked for clarification of EPA's criteria for determining whether containers are the same or different. They urged a broad definition of design type to reduce the testing burden.
- Formulation similarities: Several commenters suggested ways to eliminate duplicative testing on the basis of formulation, such as granting waivers to products that meet certain physical property criteria or to formulations similar to ones that have already passed.
- Industry task force: Some agricultural registrants and a registrant group voiced support for a plan to establish an industry task force that would conduct studies to determine the physical properties of formulations and containers that meet the four 9's standard. Combinations matching those criteria would be exempted from testing; necessary testing would be limited to broad categories of product/container combinations developed by the studies.

ii. *EPA response*. Many of the changes in the residue removal standard discussed in the previous sections reduce the cost of complying with this standard, including:

- Changing the scope of the nonrefillable container regulations so only dilutable products in Toxicity Category I or II or that are restricted use products have to comply with the residue removal standard;
- Reducing the standard from 99.9999 percent to 99.99 percent removal; and
- Changing the testing protocol.

Despite these changes, the estimated costs of complying with the residue removal standard were still a fairly large percentage of the overall annual costs and costs per facility. Rather than trying to minimize the burden to registrants by trying to identify and define substantially similar containers and formulations, EPA believes it is better to require testing only for formulations and containers that have shown to be difficult to clean. As stated earlier, EPA believes the data show that most containers/formulations can meet a four 9's standard although practical experience with container recycling programs shows that there are problems with certain formulations. Because a universal approach (testing all products subject to the regulations) to identify the exceptions (the problematic formulations) is inefficient, EPA believes there is a more efficient yet effective way to implement the residue removal standard in the final regulations.

In particular, the final rule takes the following approach:

- All dilutable liquid products in rigid containers must be capable of meeting the 99.99 percent removal standard. This sets a minimum standard for all products.
- On the basis of the Formulogics and NACA data, EPA is making the assumption that nearly all products meet a standard of 99.99 percent removal, and therefore is requiring testing only in limited circumstances. In particular, registrants only have to conduct the residue removal testing if the products are flowable concentrate formulations or if EPA requests the test data on a case-by-case basis.
- Accordingly, the recordkeeping standards in § 165.27(b)(5) were changed so recordkeeping of test results is only required for flowable concentrate formulations or if EPA specifically requests the records on a case-by-case basis.

EPA chose to require testing of flowable concentrate formulations for several reasons. First, the results of the four studies in Table 7 show that there is a difference in rinsing efficiency between the formulation types that were tested, specifically flowable concentrates, emulsifiable concentrates, aqueous solutions, and encapsulated formulations. Tables 10, 11, and 12 show the data from the studies in Table 7 with the residue removal performance broken down by formulation type. The results - particularly for the studies with the most testing - show that flowable concentrate formulations had the biggest difference between meeting four 9's and five 9's, which suggests that these kinds of products may generally be a little more difficult to remove from containers due to characteristics of the formulation type in general. The emulsifiable concentrates tested generally reached a five 9's level of residue removal but showed a similar difficulty as flowable concentrates in reaching the six 9's level of residue removal in the Formulogics study of agricultural formulations and containers. While not completely conclusive, EPA believes these data support the observation that flowable concentrates may generally be more difficult to remove from containers than other kinds of formulations.

TABLE 10.—ANALYSIS OF RESIDUE REMOVAL DATA BY FORMULATION TYPE - AGRICULTURAL FORMULATIONS AND CONTAINERS (FORMULOGICS & NACA)

Formulation	Total Cntr/Form Combinations Tested	Number of Containers/Formulations That Meet:		
		Four 9's	Five 9's	Six 9's
Flowable concentrate	15	15	11	10
Emulsifiable concentrate	20	20	18	12
Encapsulated	4	4	3	1
Aqueous Solution	3	3	3	1
Dry Flowable	1	1	1	1
Total	43	43	36	25

TABLE 11.—ANALYSIS OF RESIDUE REMOVAL DATA BY FORMULATION TYPE—HOUSEHOLD, INDUSTRIAL AND INSTITUTIONAL CONTAINERS (FORMULOGICS)

Formulation	Total Cntr/Form Combinations Tested	Number of Containers/Formulations That Meet:		
		Four 9's	Five 9's	Six 9's
Flowable concentrate	10	10	7	1
Emulsifiable concentrate	9	9	9	8
Encapsulated	10	10	10	7
Total	29	29	26	16

TABLE 12.—ANALYSIS OF RESIDUE REMOVAL DATA BY FORMULATION TYPE—HOUSEHOLD CONTAINERS (CSMA)

Formulation	Total Cntr/Form Combinations Tested	Number of Containers/Formulations That Meet:		
		Four 9's	Five 9's	Six 9's
Flowable concentrate[1]	1	1	1	0
Emulsifiable concentrate[1] [2]	2	1	0	0
Aqueous solution[1]	4	4	3	1
Total	7	6	4	1

[1] Based on the description of the formulations, we assumed that the CSMA data included one flowable concentrate, two emulsifiable concentrates and four aqueous solutions.
[2] The container/formulation that did not meet four 9's was an agricultural emulsifiable concentrate in a small (16 ounce) container.

Second, the Minnesota Department of Agriculture (DOA) developed a report that summarized the observations of inspectors and the experiences of pesticide users regarding rinsing containers that held pesticide products formulated as flowable concentrates. (Ref. 18) These containers tended to be rejected at a higher rate than other types of formulations. The Minnesota DOA observed that about 60 percent of the containers of one specific flowable concentrate formulation contained pesticide residue, even when the overall container rejection rate at the collection site was less than 1 percent. To make the containers holding the studied formulation come clean, users had to take extra measures beyond triple rinsing, such as power rinsing for a long time, using hot water, cutting the containers open to allow access to hard-to-reach areas, soaking the containers, using soap or another material and conducting extra rinses. While we do not have laboratory triple rinsing data on this product to confirm whether or not it meets a 99.99 percent standard, the description in Minnesota's report clearly documents a problem with cleaning the containers used for this product, which was a flowable concentrate. The Minnesota DOA report mentioned several other products that it also categorizes as more difficult to rinse.

Third, recent conversations with people active in pesticide container recycling confirmed commenters' assertions that the main reasons for unclean containers at recycling programs are lack of effort by the end users when rinsing containers and because of pesticide product drying along the inside of the container if the material in the container is not used all at once. (Ref. 26) Neither of these problems would be addressed by the residue removal standard. Based on their observations, these people believe that any container with any formulation type can be adequately cleaned if the container is emptied completely at one time (all contents are used initially), if the end user rinses the container promptly after emptying it and if the end user rinses it properly (either pressure or triple rinsing). On the other hand, these people also commented that specific products may need a little extra effort into rinsing (more time in a pressure rinse or an extra rinse after the triple rinse procedure) to completely clean the container.

Based on this information, EPA believes the final regulations should be implemented in a way that minimizes the required testing because the laboratory data and field observations do not support a widespread problem with residue removal that could be solved by the residue removal standard. Therefore, EPA decided to only require residue removal testing for flowable concentrates, which showed the most difficulty in being removed in the laboratory testing. EPA believes that the field observations indicated that specific products - in any formulation type - may be more difficult to remove by rinsing than other products. Therefore, the final regulations also provide EPA the option to require residue removal testing (and keeping records of it) on a case-by-case basis. EPA anticipates using this option if we receive credible information about a wide-spread problem with a specific container/formulation combination being difficult to clean.

I. Waiver and Modification Criteria (§ 165.25(g))

1. *Final regulations.* Section 165.25(g) of the final rule explains that registrants may request waivers from or modifications to the nonrefillable container standards. This section sets out the criteria that must be met for EPA to approve a waiver/modification request. The criteria are different for each of the nonrefillable container requirements, as described below.

• *§ 165.25(a): DOT standards for pesticide products that are not DOT hazardous materials.* EPA may waive or modify the requirements of § 165.25(a) if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of § 165.25(a).

• *§ 165.25(b): DOT standards for pesticide products that are DOT*

hazardous materials. EPA may waive or modify the requirements of § 165.25(b) if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of § 165.25(b). EPA will modify or waive the requirements of § 165.25(b) only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

• *§ 165.25(d): Container closures*. EPA may approve a non-standard closure (that is, a closure not listed in § 165.25(d)) if EPA determines that both of the following conditions are satisfied:

(1) The non-standard closure is necessary for the proper mixing, loading, or application of the pesticide product.

(2) The non-standard closure offers exposure protection to handlers during mixing and loading that is the same or greater than that provided by the standard closures.

• *§ 165.25(e): Container dispensing capability*. EPA may waive or modify the standards in § 165.25(e) if EPA determines that at least one of the following conditions is satisfied:

(1) The product is typically removed from the container by a method other than pouring.

(2) Compliance with the container dispensing capability standards would increase exposure to the pesticide container handler.

• *§ 165.25(f): Residue removal standard*. EPA may waive or modify the requirements of § 165.25(f) if EPA determines that both of the following conditions are satisfied:

(1) The residue remaining in the container would not cause an unreasonable adverse effect on the environment; and

(2) The product offers significant benefits and cannot be economically reformulated or repackaged.

2. *Changes*. The final rule is significantly different than the proposal. Additional waiver/modification provisions were added and all of the criteria were consolidated into one section. The proposed rule included waiver/modification provisions only for the standard closure and residue removal requirements. The waiver/modification criteria for the standard closure requirement in the final rule are similar to the proposed regulations, although a few minor editorial changes were made. Also, the final rule clarifies that both criteria must be met before EPA will approve the use of an alternative closure, which was the intent of the proposed rule. The waiver/modification provision for the residue removal requirement was modified to add specific criteria that must be met. This change was made partly because the proposed criterion for waiving or modifying the residue removal standard was very broad and partly because a more specific and limited waiver/modification standard is appropriate with the less stringent residue removal standard in the final rule. The final rule incorporates a DOT waiver provision similar to the one set out in the potential alternative regulatory text in the 1999 supplemental notice. EPA modified the DOT waiver provision in several ways to address a few comments about the problems that could be caused if EPA changed the adopted DOT requirements for pesticides that are DOT hazardous materials. First, a separate waiver/modification provision is included for pesticides that are not DOT hazardous materials and for pesticides that are DOT hazardous materials. Second, the waiver/modification provision for pesticides that are DOT hazardous materials specifies that EPA will modify or waive the requirements in § 165.25(b) only after consulting with DOT to ensure consistency with DOT regulations and exemptions. The final rule also adds waiver/modification provisions for the container dispensing standards.

The waiver/modification provisions are included to address situations where the nonrefillable container requirements might compromise the success, safety and effectiveness of currently used containers or those developed in the future. While EPA has attempted to focus each nonrefillable container requirement on containers and pesticides for which it is appropriate, we are not familiar with every container used for every product. It is likely that there are some problematic situations where existing containers that are specifically designed for a certain use or adaptation may have difficulty complying with the final regulations. We may not be aware of these situations and they may not have been mentioned by commenters. In general, waivers or modifications are intended to provide relief for a limited number of situations, and we wanted to provide a mechanism to account for these situations without having to amend the regulations. Waivers and modifications are appropriate in a limited number of situations, such as the use of non-standard closures, since the point of the requirement is to limit the number of closures (and therefore adapters) to encourage the use of closed transfer systems.

J. Procedure for Applying for a Waiver or Modification (§ 165.25(h))

1. *Final regulations*. Section 165.25(h) describes the procedure for registrants to follow if they want to obtain a waiver from or a modification to any of the nonrefillable container standards. The regulations specify that a registrant cannot distribute or sell a pesticide product in a nonrefillable container that does not comply with all of the nonrefillable container standards unless and until EPA approves the request for the waiver or modification in writing.

To obtain a waiver or modification, a registrant must submit a written request for a waiver or a modification to the EPA's Office of Pesticide Programs at the address provided in the regulations. Two copies of the following information (which may be part of an application for registration or amended registration) must be included with the request:

• The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

• The name and EPA registration number of the relevant pesticide product.

• A statement specifying the requirement(s) from which the waiver or a modification is requested.

• A description of the relevant nonrefillable container(s).

• Documentation or justification to demonstrate that the applicable waiver or modification criteria in § 165.25(g) are satisfied.

2. *Changes*. The procedure for obtaining all waivers and modifications is essentially the same as the procedure proposed (in § 165.119) for obtaining a waiver of the standard closure requirement. No specific procedure was identified for the residue removal waiver in the proposed rule or for the waiver from DOT requirements in the 1999 supplemental notice. Consolidating all of the waiver criteria in § 165.25(g) and using the same procedure for all waivers requests should facilitate the process for registrants and EPA. Therefore, the significant change to the waiver procedure requirements in the final rule is that they clearly apply to all waiver requests. Several additional minor modifications were made to the final rule, including updating the address, clarifying the statement requiring EPA approval before a pesticide product can be sold or distributed in containers with waived or modified requirements, broadening several of the information items to accommodate the additional waiver provisions, and clarifying that a waiver request could apply to more than

one nonrefillable container design for the identified pesticide product. Because the waiver and modification requests are part of an application for registration or amended registration, each waiver request must apply to only one product.

K. Reporting (§ 165.27(a))

1. *Final regulations.* This section clarifies that the pesticide container regulations do not require registrants to report to EPA with information about their nonrefillable containers. It refers registrants to the reporting standards in 40 CFR part 159 to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2).

2. *Changes.* The intent and substance of this standard is the same as in the proposal. However, the wording was changed to clarify that this is simply a reference to the existing 6(a)(2) standards and that it does not add any new requirements.

L. Recordkeeping (§ 165.27(b))

1. *Final regulations.* For each product that is subject to the full set of nonrefillable container regulations and is distributed and sold in nonrefillable containers, registrants must keep the following records for as long as a nonrefillable container is used for the product and for 3 years thereafter:

- The name and EPA registration number of the product.
- A description of the container(s) used to distribute or sell the product.
- Documentation of compliance with the closure requirement, if applicable.
- Documentation of compliance with the dispensing requirement, if applicable.
- Documentation of compliance with the residue removal requirement, if applicable.

The registrant must make these records available for inspection or copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

2. *Changes.* The requirements are substantially the same as proposed. Several minor modifications were made in the final rule to improve the clarity of the recordkeeping requirements, including:

- Deleting ''design type'' in several places to clarify that the requirements apply to the containers used to distribute or sell the product. However, the specific records for the dispensing and residue removal recordkeeping allow information for different containers and products to be used to document compliance, under the specified conditions.
- The first sentence in the recordkeeping requirement in the final rule was revised to clarify that the recordkeeping applies to pesticide products distributed or sold in nonrefillable containers and that are subject to the full set of nonrefillable container regulations in §§ 165.25 - 165.27. In other words, products that are completely exempt and products that must comply only with the standards in 49 CFR 173.24 do not have any recordkeeping requirements. This change was necessary because of the changes in the scope of products that are subject to the nonrefillable container standards.
- Because the requirement for registrants to submit a certification is not being finalized, the need to keep a record of the certification is no longer necessary.
- For the closure-related records, several minor changes were made to further describe the kinds of documentation that would be acceptable.

M. Proposed Standards That Are Not Being Finalized

1. *Final regulation/changes.* The following requirements relating to container design from the proposed regulation are not being finalized in the final rule:

- § 165.102(b): Container integrity and compatibility;
- § 165.102(c)(1): Permanently marking the EPA registration number;
- § 165.102(c)(2): Permanently marking the container's material of construction;
- § 165.102(d)(3): Requiring the container to reclose securely; and
- § 165.106: Residue removal methodology for dilutable products in rigid containers
- § 165.111: Certification.

Three of these proposed requirements for nonrefillable containers are not being finalized because they were replaced by equivalent DOT requirements. The following table lists the non-finalized requirements from the proposed rule and the DOT equivalent regulations:

TABLE 13.—PROPOSED NONREFILLABLE CONTAINER STANDARDS THAT WERE NOT FINALIZED AND THEIR DOT EQUIVALENTS

Proposed Pesticide Container Requirement	Proposed 40 CFR Cite	Equivalent 49 CFR Cite
Container integrity and compatibility	§ 165.102(b)	§§ 173.24(b), 173.24(e)
Permanently marking the material of construction	§ 165.102(c)(2)	§§ 178.3(a), 178.503(a)
Requiring the container to reclose securely	§ 165.102(d)(3)	§ 173.24(f)

As discussed in Units V.H.1. and V.H.4., the residue removal testing methodology that was proposed in § 165.106 is not being finalized in the regulatory language and will be incorporated into EPA's testing guidelines. The test procedure is established as an OPP test procedure titled ''Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers.'' (Ref. 20) The proposed regulatory language provided some details of the test procedure, which EPA intended to supplement with guidance. The final rule does not include the specific testing requirements because we believe it is more appropriate to provide these details in a test protocol than in the regulations.

EPA decided not to finalize the proposed requirement in § 165.102(c)(1) that each nonrefillable container be permanently marked with the EPA registration number of the pesticide in the final rule. Also, EPA is not finalizing the proposed requirement in § 165.111 for registrants to certify that their nonrefillable containers meet the standards and to submit the certifications to EPA.

2. *Comments - EPA registration number.* Several State regulatory agencies supported requiring the EPA

registration number, saying it would help in the identification and disposal of unwanted and/or abandoned pesticides. One acknowledged that the container might not hold its original contents, but that the benefits outweigh the disadvantages. One commenter suggested imbedding identification stripes in bags to identify the contents and another recommended requiring the year the pesticide was manufactured in addition to the EPA registration number.

Almost 30 commenters, including almost 20 registrants, some registrant groups, a few container manufacturer groups, and a State regulatory agency, opposed requiring the EPA registration number to be permanently marked on the container because the container may not hold its original contents, the number is already on the pesticide label, it would be too expensive, and it would create inventory and container ordering problems.

3. *EPA response - EPA Registration Number*. This requirement was intended to help the managers of State pesticide collection and disposal programs (often called Clean Sweep programs) identify unknown pesticides when they receive containers without labels. However, based on the comments, we no longer believe that the benefits of this standard would outweigh the costs. EPA believes that many commenters misunderstood the intent of the proposed interpretation of permanent marking because the comments implied that the EPA registration number would have to be embossed in the container. This was not the intent of the proposal, which would have allowed ink jetting, so the comments regarding inventory problems and some of the costs are not relevant. However, even the estimates for ink jet printing and the costs to alter a filling line are substantial when extrapolated to all of the formulators, particularly when the actual benefits are unclear. EPA doesn't question the benefit of helping State pesticide disposal programs identify pesticides to facilitate and minimize the cost of disposing of unwanted pesticides. However, there are many legitimate questions about how often this might happen and how much confidence a pesticide disposal program manager would have that the container holds its original contents. (See the discussion of good stewardship for service containers in Unit VII.L. of this preamble.) Also, the EPA registration number is required on the pesticide's label. Therefore, EPA is not finalizing this requirement in today's final nonrefillable container regulations. EPA continues to believe that durably marking a product's EPA registration number on its nonrefillable containers is a good practice and we encourage registrants to do this (or continue doing it), although it is not required.

4. *Comments - certification*. A registrant group commented that registrants would be able to certify compliance if appropriate standards are established. Another registrant group commented that current registration guidelines make the certification redundant and claimed that the requirement to certify was not in compliance with the Paperwork Reduction Act. A registrant group and a registrant urged EPA to develop guidance to define what registrants should certify, because it is unclear what must be certified and when. A registrant group and a registrant/distributor said that formulators and subregistrants should be allowed to meet this requirement by a data certification process.

5. *EPA response - certification*. EPA considered modifying the certification requirement to clarify the intent. However, EPA decided not to finalize the certification requirement because, in this case, we believe that the benefits of having registrants certify compliance are outweighed by the paperwork burden on industry and EPA. EPA believes that having a high level official certify compliance with the regulations generally facilitates compliance by having companies focus on the regulations up-front and by creating an incentive for that official to ensure compliance because of the responsibility of signing such a statement. However, the registrants will already be sending in a submission with an official's signature because of the changes to the pesticide storage and disposal label statements. Therefore, we believe that some of the benefits of the label submissions will carry over onto the container standards. Also, this approach should eliminate potential confusion about submitting label changes and certifications if a product must comply with the label changes in this rule but not the nonrefillable container standards (because of different scopes). Lastly, the container regulations, promulgated under the authority of FIFRA section 19, are directly enforceable by section 12(a)(2)(S) of FIFRA, which states that it is unlawful to violate any regulation issued under section 3(a) or 19. In other words, the certifications are not necessary to enforce these regulations. For all of these reasons, EPA decided not to finalize the certification requirement in today's final rule.

VI. Refillable Containers

A. Key Terms

1. *Overview*. The following terms, defined in § 165.3 of subpart A, are key to understanding the refillable container standards in subpart C.

(1) Dry pesticide
(2) One-way valve
(3) Portable pesticide container
(4) Refillable container
(5) Stationary pesticide container
(6) Tamper-evident device
(7) Transport vehicle.

Three of these definitions--dry pesticide, tamper-evident device, and transport vehicle--are identical to the proposed definitions. The definition of refillable container was slightly modified to clarify that refillable containers are used for sale or distribution. As discussed below, a definition of portable pesticide container has been added to the final rule and the other two definitions were changed substantively.

The following proposed definitions that were relevant to the proposed refillable container standards are not being finalized: dry bulk container; dry minibulk container; liquid bulk container; and liquid minibulk container. These are discussed below in conjunction with stationary pesticide container.

2. *One-way valve*—i. *Final regulation*. One-way valve means a valve that is designed and constructed to allow virtually unrestricted flow in one direction and no flow in the opposition direction, thus allowing the withdrawal of material from, but not the introduction of material into a container.

ii. *Changes*. EPA incorporated the following phrase, as suggested by a registrant: ''to allow virtually unrestricted flow in one direction and no flow in the opposition direction.'' EPA believes this improves the definition by clarifying what we mean by one-way.

3. *Stationary pesticide container*—i. *Final regulation*. Stationary pesticide container means a refillable container that is fixed at a single facility or establishment or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

ii. *Changes*. The proposed definition for ''stationary bulk container'' was revised in several ways, as discussed in detail in Unit VIII.E. of this preamble, which describes the containers that are subject to the containment requirements. The final rule changes the term from ''stationary bulk container'' to ''stationary pesticide container'' because

the changes to the final containment regulations eliminated the need for the proposed definitions of minibulk and bulk containers.

The proposed containment regulations would have required each stationary bulk container to be protected by a secondary containment unit. The proposed rule defined stationary bulk container to be ''a liquid bulk container or a dry bulk container that is fixed at a single facility or establishment...'' The proposed rule also defined liquid bulk and dry bulk containers by size. For example, liquid bulk container was defined as ''a refillable container designed and constructed to hold liquid pesticide formulations with the capacity to hold undivided quantities of greater than 3,000 liters (793 gallons).''

The final containment regulations take a different approach of delineating the containers that must be within secondary containment units. Section 165.81(b) states that ''Stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide are subject to the regulations in this subpart and must have a secondary containment unit that complies with the provisions of this subpart ...'' Because the container sizes are a regulatory criterion in § 165.81(b), the definitions of liquid bulk container and dry bulk container are no longer necessary and are not being finalized. The definition of dry minibulk container was not used in the proposed or final regulations and is also not being finalized.

4. *Portable pesticide container*—i. *Final regulation*. Portable pesticide container means a refillable container that is not a stationary pesticide container.

ii. *Changes*. The proposed regulations did not define portable pesticide container. However, this definition is necessary in the final rule to replace the term liquid minibulk container in the refillable container regulations. As described above, EPA is not finalizing the definitions for liquid bulk, dry bulk and dry minibulk containers because they are not necessary. Similarly, EPA believes that it is logical to not finalize the definition for liquid minibulk container. In the proposal, the only time the term liquid minibulk container was used in the regulatory language was to define the kinds of refillable containers that had to comply with the one-way valve/tamper-evident device requirement. In the final rule, EPA partially describes the containers that must comply with the one-way valve/tamper-evident requirement in § 165.45(e) as ''a refillable container that is a portable pesticide container that is designed to hold liquid pesticide formulations...''

B. Purpose (§ 165.40(a))

1. *Final regulations*. The purpose of the refillable container standards is to establish design and construction requirements for refillable containers used for the distribution or sale of some pesticide products.

2. *Changes*. This is nearly the same as the proposed purpose (in § 165.120(a)). One minor change was to acknowledge the reduced number of products that are subject to the final regulations by stating that the rule applies only to the distribution or sale of *some* pesticide products. The proposed regulations would have applied to all products. Another insignificant modification was to delete the term ''standards'' from the phrase ''establish standards and requirements'' because it is redundant.

C. Who Must Comply (§ 165.40(b))?

1. *Final regulations*. You must comply with all of the refillable container regulations if you are a registrant who distributes or sells a pesticide product in refillable containers. If your product is subject to the refillable container regulations as described in Unit VI.E., the product must be distributed or sold in refillable containers that comply with these regulations. This is true regardless of whether you repackage the product into the container yourself or whether you sell or distribute the product to an independent refiller, who repackages your product into refillable containers.

In addition, you must comply with the regulations in § 165.45(f) for stationary pesticide containers if you are a refiller of a pesticide product and you are not the registrant of the pesticide product.

2. *Changes*. For registrants, this is the same approach that we proposed in §§ 165.122(a)(1)(i) and 165.122(a)(2)(i). However, the wording is more straightforward because the regulations for refillable containers were separated from the repackaging regulations in the final rule. This subpart includes only the refillable container standards, which apply to all registrants that use refillable containers to distribute or sell their products. The standards for repackaging were placed in a separate subpart, because those regulations must distinguish between registrants who repackage product directly into the containers and registrants who allow independent refillers to repackage their product into refillable containers.

The final rule clarifies that refillers must comply with the requirements for stationary pesticide containers in § 165.45(f). EPA believes it is reasonable to hold both the registrants and refillers responsible for meeting the stationary pesticide container standards in § 165.45(f) because they are both selling and distributing the pesticide that is held in those containers.

D. Compliance Dates (§ 165.40(c))

1. *Final regulations*. The final regulations provide a 5–year period after the date of publication of the final rule in the **Federal Register** before compliance with the refillable container standards is required. Specifically, within 5 years from today's date, registrants must distribute or sell all pesticide products in refillable containers in compliance with these regulations.

2. *Changes*. Based on the comments, EPA decided to extend the compliance period from the 2–year time frame that was proposed in § 165.139. Also, the compliance date for registrants to submit certifications is not being finalized because the certification requirement from the proposal is not being finalized, as described in Unit VI.M.

3. *Comments*. A few commenters (registrant groups, a registrant and a State) on the proposed rule supported a 2–year compliance period if EPA adopts a grandfather clause or references the DOT regulations rather than the proposed regulations. However, many commenters (mostly registrants, but also a dealer group and a few States) argued for a longer compliance period to allow the continued use of sound containers and to minimize the burden of retrofitting containers or replacing the containers in inventory. Because refillable containers can be used for many years (the average life span is 5 years for plastic minibulks and 15 years for steel minibulks), a 2–year phase-in period would require companies to dispose of good containers or to retrofit them. Several of the commenters mentioned that it would take longer than 2 years to come into compliance.

In addition, many commenters (registrants and registrant groups) on the supplemental notice stressed the need for an adequate transition period regarding the option of adopting the DOT Packing Group III standards in the final rule. The main points made by the commenters included:

- An adequate transition period is required to design and obtain new packaging, finish using existing supplies of previously authorized packaging, allow existing nonrefillable packaging to

work its way through the distribution system and let refillable packaging complete its useful life.

- An inadequate transition period would significantly increase the cost of compliance with this rule. Major costs would be avoided as long as it is not necessary to dispose of packaging which has not yet reached the end of its useful life or to recall packaging which is still in the distribution channels and has not yet reached its final destination. The suggested transition periods would minimize the cost impact of the EPA container regulation.
- Pesticide products change hands several times as they move down the distribution chain from the basic producer to the end user (basic producers, formulators, distributors, retail dealers, brokers, custom applicators and end users). In many cases, the movement of materials is reversed when products are not consumed.
- The distribution process normally is completed in a given sales year. However, when materials are not consumed, inventories build at all levels of the distribution chain. Quite often materials may be held in inventory for multiple years before re-entering the distribution network. During periods when materials are being held in inventory, the pesticide formulators and others are negatively impacted when regulatory changes are imposed on products in the distribution chain (rather than on products that will be sold or distributed at some future date), which involves substantial expenses to producers with, in most cases, no justifiable gain in safety.

4. *EPA response*. As described above, EPA is extending the compliance period for refillable containers to 5 years to provide for a smoother and less burdensome transition for companies. 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 container standards will allow existing refillable containers that meet the DOT Packing Group III standards to be retrofitted relatively easily (by durably marking each container with a serial number and having a one-way valve and/or tamper-evident device on each opening of liquid minibulk containers) 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.

E. Pesticide Products Included (§ 165.43(a) - (g))

1. *Final regulations*. As described in detail in Unit III., only certain products have to comply with the refillable container standards. MUPs, plant-incorporated protectants, and certain antimicrobial products are completely exempt from the refillable container requirements. All other pesticide products are subject to the refillable container regulations.

Some of the antimicrobial pesticides that are subject to the refillable container regulations are subject to a reduced set of regulations. In particular, antimicrobial pesticides that are used in swimming pools and closely related sites (such as hot tubs, spas and whirlpools) are exempt from the requirements for marking the serial number and having a one-way valve and/or tamper-evident device on each opening.

2. *Changes*. In the proposed rule, only MUPs were exempt from the refillable container regulations (in § 165.122(b)(1)). All other products would have been subject to the standards. The 1999 supplemental notice discussed regulatory options for exempting some products (antimicrobials and non-antimicrobials) from the full set of refillable container regulations and for exempting certain antimicrobial products from specific requirements.

The criteria in the final rule for exempting antimicrobials are different than those discussed in the supplemental notice and the final rule exempts plant-incorporated protectants. The final refillable container regulations do not incorporate the toxicity category, container size or environmental hazard criteria from the supplemental notice. Also, the final rule changes some aspects of the supplemental notice approach of subjecting antimicrobial swimming pool products to a reduced set of requirements.

Table 14 describes the provisions for determining which pesticide products are subject to which refillable container regulations and a brief explanation of how (or if) this provision changed from the proposal and/or the supplemental notice.

TABLE 14.—CHANGES TO THE SCOPE OF THE REFILLABLE CONTAINER REGULATIONS

Regulatory Provision	Changes
Manufacturing use products are exempt.	No change from proposed rule or supplemental notice.
Plant-incorporated protectants are exempt.	Plant-incorporated protectants would have been subject to the proposed rule. The regulations for plant-incorporated protectants were finalized in 2001. We are exempting them from the final rule because of their unique nature.
Certain antimicrobial products are exempt.	Antimicrobial products would have been subject to the proposed rule. The final rule implements an approach similar to option 1 in the supplemental notice, although some of the details are different.
All other products are subject to the refillable container requirements, except for certain antimicrobial swimming pool products.	All products other than manufacturing products would have been subject to the proposed rule. The final rule is different than the approach discussed in the supplemental notice, which would have exempted products in Toxicity Category III or IV in small containers and outdoor use products without the specified environmental hazard statements on their label.
Antimicrobial products used in swimming pools and closely related sites are subject to a reduced set of refillable container requirements.	Antimicrobial products used in swimming pools would have been subject to the proposed rule. The final rule is the result that was intended in the supplemental notice, although the specifics of how it is implemented in the final rule are different than in the supplemental notice.

F. Other Exemptions (§ 165.43(h))

Final regulations and changes. The refillable container regulations 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. This is identical to the exemption proposed in § 165.122(b)(2). In addition, the final rule includes a specific exemption for gaseous pesticides, which is necessary to implement our intent from the proposal because the final rule does not use the proposed terms liquid minibulk, dry minibulk, liquid bulk and dry bulk containers, which would have excluded gaseous pesticides.

G. DOT Standards (§ 165.45(a) - (c))

1. *Final regulations.* As discussed in detail in Unit IV., refillable containers must comply with the DOT Hazardous Materials Regulations that are referred to and adopted into EPA's regulations. These incorporated regulations establish requirements for container design, construction and marking.

2. *Changes.* This is a change from the proposed regulation, although the approach of referring to and adopting a subset of the DOT standards was discussed in detail in the 1999 supplemental notice. See Unit IV. for a detailed discussion. As discussed in Unit VI.M., some of the proposed requirements for refillable containers are not being finalized in the final rule because they were replaced by equivalent DOT requirements.

H. Serial Number Marking (§ 165.45(d))

1. *Final regulations.* Each refillable container 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. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, and marking with durable ink. The serial number or other identifying code must be located on the outside part of the container except on a closure. Placement on the label or labeling is not sufficient unless the label is an integral, permanent part of or permanently stamped on the container. Antimicrobial products used in swimming pools and closely related sites (that are subject to the regulations) are exempt from this requirement.

2. *Changes.* The marking requirement was changed significantly from the proposal to the final rule. First, the proposed rule included seven pieces of information that would have been marked on the containers and the final rule only includes one piece of data, the serial number (or other identifying code). Some of the proposed items--the container manufacturer, date of manufacture, rated capacity, and material of construction--were deleted because this information is required in the DOT standards. The other pieces of information--the model number and the phrase ''Meets EPA standards for refillable containers''--were deleted from the regulations because they are no longer necessary for implementing the refillable container and repackaging requirements due to the change to refer to and adopt the DOT regulations and because commenters raised some legitimate problems with them.

Second, the regulatory text was changed to clarify that the serial number (or identifying code) must be durably marked on the container, rather than permanently marked as stated in the proposed regulations. EPA's intent for permanent marking in the proposal was described in the preamble as ''Permanent marking includes, but is not limited to, etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.'' EPA believes that durable marking is a more accurate term to describe our intent. The text in the final regulation-- ''must be marked in a durable and clearly visible manner''--is based on the DOT marking standards for intermediate bulk containers in 49 CFR 178.703(a)(1).

Third, the proposal included a provision that allowed compliance with a similar DOT marking requirement to satisfy the corresponding EPA pesticide container standard. This provision is no longer necessary because the final regulation refers to and adopts some of the DOT standards.

3. *Comments - permanent marking.* The proposal for the container marking drew a large number of comments. About 20 commenters, consisting mainly of registrants, registrant groups, and container manufacturer groups, addressed EPA's interpretation of permanent marking. These comments focused on the proposed permanent marking requirements for nonrefillable containers, but are applicable to the refillable container and label regulations as well. These comments are included in the refillable container section because the marking requirements for nonrefillable containers are not being finalized.

One registrant supported the list of different techniques that would qualify for permanent marking. Some respondents (registrants and registrant groups) specifically supported including ink jetting as a means of permanent marking and one suggested adding rubber-stamping to the list. A few registrants commented that many inks can be removed with solvent-based products.

Some commenters (registrants and registrant groups) urged EPA to move the list of acceptable forms of permanent marking from the preamble to the regulations if permanent marking is required. Respondents said this would prevent confusion and misunderstanding during enforcement.

One container manufacturer group discussed the difference between the UN/DOT terms ''permanent'' and ''durable'' and suggested that EPA's purposes would be met by requiring durable marking. A registrant provided similar comments and supported marks that are ''long-lasting and persistent through the life of the pesticide.'' This registrant also commented that permanent marking is best performed by container manufacturers, although registrants can add durable marking, such as ink jetting and stenciling with paint. A container manufacturer group supported providing options because different types of markings are suitable for different container types, but opposed mechanically attaching a plate to plastic containers and expressed concern about some of the other alternatives.

Some respondents (registrants and registrant groups) urged EPA to allow the use of pressure-sensitive labels and/or labels attached with permanent adhesive as alternative ways to comply with the permanent marking requirement. A container manufacturer group recommended requiring the containers to be marked in a manner ''that at least some of the material from which the container is made must be destroyed to remove the marking.'' A pesticide user commented that the marking should be legible after the third water rinse and dry cycles.

4. *EPA response - permanent marking.* EPA modified the approach toward permanent marking several ways in the final rule to eliminate confusion about the intent and to facilitate compliance. First, EPA changed the description of marking from ''permanent'' to ''durable'' marking. EPA believes that durable marking is a more accurate term to describe our intent because the description of ''permanent'' marking in the preamble of the proposal included marking methods, such as ink jetting, stamping and marking with durable ink, that are durable but not permanent. Second, the final rule clarifies that ink jetting and stamping are allowable

methods of marking the required information on the containers. Third, the allowable methods of marking are listed in the regulations, rather than only in the preamble or guidance material, to enhance the understanding of the intent.

5. *Comments - serial numbers.* Serial numbers were uniformly opposed by several registrants, several registrant groups, and a container manufacturer because these commenters claimed requiring serial numbers would greatly increase the cost of compliance. Several commenters focused on the potential impact on plastic and steel drums and flexible intermediate bulk containers, and said it would be very burdensome to permanently mark a serial number on each container. Three respondents specifically addressed swimming pool chemicals. These commenters stated that the requirement for serial numbers and the associated recordkeeping requirements would be completely unworkable for refillable pool chemicals because millions of refillable containers (from 1 to 55 gallons) are used each year and a single shipment can contain 4,000 to 5,000 bottles. This increased cost would make refillable containers uneconomical for swimming pool chemicals, which would lead to the registrants switching to nonrefillable plastic jugs.

6. *EPA response - serial numbers.* EPA disagrees with commenters that the cost of complying with the serial number requirement (for products other than swimming pool chemicals) would be overly burdensome. First, the final regulation clarifies that the serial number must only be durably marked, not permanently marked. Therefore, it would not have to be done by an automatic marking device capable of changing each time a new container is made. Second, this standard only applies to containers that are refilled. It does not apply to containers that are being reconditioned, remanufactured or repaired according to the DOT standards in 49 CFR 173.28 or 180.352. In other words, it does not apply to drums that are used once and reconditioned according to DOT standards and then filled with pesticide or another substance. See the discussion in Unit IV.B. that states that the reference to 49 CFR 173.28 is included in the final regulations to allow drums to be reconditioned and then reused under the pesticide container regulations.

EPA agrees with the commenters that applying serial numbers (and some other requirements) to refillable containers used for swimming pool pesticides would disrupt the current refillable container system for swimming pool chemicals and would quite likely cause the refillables to be replaced by millions of single-use, nonrefillable containers. Therefore, the final rule exempts antimicrobial products used in swimming pools and closely related sites (and that are subject to the regulations) from the serial number requirement.

I. Openings - One-Way Valves or Tamper-Evident Devices (§ 165.45(e))

1. *Final regulations.* Like the proposed rule, this standard applies only to *portable pesticide (refillable) containers designed to hold liquids*--not portable pesticide containers for dry pesticides or stationary pesticide containers. Also, this standard does not apply to cylinders that comply with the DOT HMR. Each opening of a portable pesticide container for liquid materials (except for DOT cylinders) other than a vent must have a one-way valve, a tamper-evident device or both. A one-way valve may be located in a device or system separate from the container if the device or system is the only reasonably foreseeable way to withdraw pesticide from the container. A vent must be designed to minimize the amount of material that could be introduced into the container through it.

2. *Changes.* EPA made several modifications to this requirement. First, the description of the containers that must comply was changed to portable pesticide containers that are designed to hold liquid formulations because the definition of liquid minibulk container is not being finalized. Second, we changed the word ''aperture'' in the proposal to ''opening'' in the final rule because it is a more common term that should facilitate understanding and therefore compliance with the regulations. Third, the standard was changed so vents do not need to have tamper-evident devices or one-way valves. Instead, a sentence was added to ensure that vents are designed to minimize the amount of material that could be introduced into containers through them. Fourth, the requirement was amended to clarify that a one-way valve may be located in a separate device or system, such as a coupler, if that device or system is the only reasonably foreseeable way to withdraw pesticide from the container. This was the intent of the proposed standard, as described in the 1994 preamble, but we are adding it to the regulations for clarity. Fifth, the final rule was amended to state that this requirement does not apply to cylinders that comply with DOT's Hazardous Materials Regulations. Sixth, antimicrobial products used in swimming pools and closely related sites (that are subject to the regulations) are exempt from this requirement.

3. *Comments - vents.* A container manufacturer group pointed out that vents are needed to provide air flow and that a person could introduce a material through a vent if they tried hard enough. This commenter recommended requiring vents to be designed to minimize the introduction of material through them. Similarly, a State regulatory agency urged EPA to modify the requirement to acknowledge that vents are required on refillables and are not one-way.

4. *EPA response - vents.* EPA agrees with the commenters that vents are needed to provide air flow when unloading material from a container and that vents do not meet the definitions of either one-way valves or tamper-evident devices. Therefore, EPA modified the regulations to clarify that vents do not need one-way valves or tamper-evident devices, but that they must be designed to minimize the introduction of material through them.

5. *Comments - chloropicrin.* A group of chloropicrin manufacturers and users cited several reasons why that product should be exempt from the opening requirement. This commenter provided the following information:

- Chloropicrin is a highly volatile liquid that is shipped and handled essentially like a gas.
- End-use formulations containing chloropicrin are shipped in refillable steel containers manufactured under the same DOT specifications as propane cylinders.
- Chloropicrin containers typically have only one specialized valve for filling and emptying the cylinder and specialized connections are required to fill them.
- Chloropicrin cylinders contain screw-on valve protections known as bonnets. The commenter stated that adding external one-way valves is not possible due to space limitations and increasing the size of the bonnets would reduce the ability of the bonnet to protect the valve.

In addition, the commenter claimed that:

- The specialized valve and refilling connections minimize the chance of contamination or unauthorized filling.
- No valves were available in 1994 that were compatible with chloropicrin and that allow filling and emptying the container through a one-way valve.
- Installing one-way valves on thousands of existing cylinders could cause unnecessary worker exposure.

6. *EPA response - chloropicrin.* EPA agrees that the one-way valve/tamper-

evident device requirement could be problematic for cylinders, such as those used to distribute chloropicrin end-use products and propane. The one-way valve/tamper-evident device requirement applies to portable pesticide containers for liquid materials, which we envisioned as DOT portable tanks, IBCs and the non-bulk refillable containers designed to hold liquids. As explained by the commenter, chloropicrin is unusual in the sense that it is a liquid, but it is shipped and handled essentially like a gas. DOT classifies chloropicrin as hazard division 6.1 (poisonous material). EPA believes that the DOT specifications for cylinders are extremely detailed and extensive and we do not want to add requirements to them that would compromise the safety and protection provided by the DOT cylinder requirements. Note that cylinders holding gases would not be subject to the one-way valve/tamper-evident device requirement because they are exempt from the refillable container regulations by § 165.43(h)(2).

EPA believes that the chloropicrin cylinders described by the commenter should not have to comply with the one-way valve/tamper-evident device requirement. However, rather than specifically exempt containers holding chloropicrin, the final regulations take a more general approach and exclude cylinders that comply with the DOT HMR. The more general approach was taken because there may be other highly volatile liquid pesticides that are distributed in DOT cylinders that would face the same difficulties in complying with this requirement.

7. *Comments - sodium hypochlorite*. In comments on the proposed rule, a registrant group stated that the one-way valves identified in their research cost several times more than the refillable containers used to distribute sodium hypochlorite. According to this commenter, the one-way valve costs (in 1994) ranged from $10 for a 1–gallon container to $45 for a 55–gallon container. Another registrant group identified one-way valves as one aspect of the proposed regulations that would make refillable containers economically unfeasible for sodium hypochlorite in the swimming pool industry. A trade group representing all aspects of the swimming pool industry explained that sodium hypochlorite is a relatively low value product that sold for as little as $1.00 per gallon in 1994. At the time, purchasers would pay a deposit of $0.50 to $1.00 per refillable container. This commenter believes that the proposed regulations would make the refillable jugs used to distribute sodium hypochlorite for swimming pool use prohibitively expensive. All of these commenters favored exempting sodium hypochlorite from the pesticide container rule.

The comments on the supplemental notice were similar. The trade group representing all aspects of the swimming pool industry stated that the proposal to exempt eligible Toxicity Category I antimicrobial products used in swimming pools from most of the refillable container standards is laudable, but that it does not go far enough. A pool supply company commented that using one-way valves and serial numbers on its returnable bottles would increase the cost to the point where it could no longer compete in the marketplace. A sodium hypochlorite manufacturer stated that the relatively low value of the product makes the use of one-way valves unaffordable. This commenter stated that one-way valves for drums cost about $75 container, not including the connectors/adaptors that the applicators would need. This manufacturer identified a one-way valve device that could be added to the refillable jugs for about $3 per container, which is more reasonable, but noted that these devices could not be produced in large enough quantities to account for all refillable jugs currently in use.

8. *EPA response - sodium hypochlorite*. EPA modified the regulation to exempt antimicrobial products (that are subject to the regulations) used in swimming pools and closely related sites from this requirement for one-way valves or tamper-evident devices. As stated in the supplemental notice, EPA acknowledges that applying some of the refillable container standards, including this one, to sodium hypochlorite used in swimming pools would disrupt the current refillable container system for these products. This disruption would probably cause the refillables to be replaced by millions of single-use, nonrefillable containers, which is inconsistent with the goals of pollution prevention and of facilitating the safe refill and reuse of containers (FIFRA section 19(e)). Therefore, the 1999 supplemental notice described a regulatory option intended to exempt swimming pool chemicals from some of the refillable container requirements. Based on comments and further analysis, EPA realized that the products for which relief was intended (sodium hypochlorite) may be hazardous wastes when disposed and, therefore, would not be eligible for exemption as described in the supplemental notice. Therefore, the final rule was revised to clarify that swimming pool products are exempt from the problematic requirements. Currently, EPA is aware of sodium hypochlorite products that fit the exemption criteria and that are distributed and sold in refillable containers, although the partial exemption was drafted to be general so it would apply to any products that fit the criteria. See Unit III.D. for a more detailed discussion.

J. Stationary Pesticide Container Standards (§ 165.45(f))

1. *Final regulation*. Stationary pesticide containers that are designed to hold undivided quantities of pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide and are located at the refilling establishment of a refiller operating under written contract to a registrant must meet certain standards. As discussed in Unit VI.C., both registrants and refillers are responsible for ensuring that these requirements for stationary pesticide containers are met. First, all of these stationary pesticide containers (for liquid and dry pesticides) must be:

- Resistant to extreme changes in temperature,
- Constructed of materials that are adequately thick and that are resistant to corrosion, puncture, or cracking, and
- Capable of withstanding all operating stresses.

As proposed, these requirements do not apply during a civil emergency or any unanticipated grave natural disaster or other natural phenomenon of an exceptional, inevitable and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight.

Second, several other standards apply only to liquid bulk containers. Specifically,

- They must be equipped with a vent or other device designed to relieve excess pressure, prevent losses by evaporation, and exclude precipitation.
- External sight gauges are prohibited.
- Each container connection below the normal liquid level must be equipped with a shutoff valve, which is capable of being locked closed.
- Shutoff valves must be located within a secondary containment unit (if secondary containment is required).

2. *Changes*. There were several changes in this section from the proposed rule. First, the description of containers that must comply with these requirements was changed to be consistent with the quantities for secondary containment structures

because the definitions of liquid and dry bulk containers are not being finalized. Second, the requirement for shutoff valves on liquid bulk containers was amended to specify that a shutoff valve: (1) Is only required for container connections that are below the normal liquid level; and (2) must be located within a secondary containment unit, if secondary containment is required by subpart E. Third, the text for the shutoff valve requirement was adjusted to make it clear that the valves must be capable of being locked closed. Fourth, the proposed phrase ''act of God'' is not included in the final rule. The language in § 165.45(f)--''any unanticipated grave natural disaster or other natural phenomenon of an exceptional, inevitable and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight''--sufficiently describes the kinds of events that would be considered ''acts of God,'' so that phrase is not necessary.

3. *Comments - shutoff valve*. Some commenters addressed the need for requiring shutoff valves and there were few common themes among the respondents. A few registrants and a registrant group supported having all connections on stationary liquid pesticide containers (except for vents) equipped with a lockable valve. A container manufacturer group asked to change the language to: ''Each liquid bulk container connection below the normal liquid level...,'' stating that requiring valves above that level serves no purpose on bulk tanks.

4. *EPA response - shutoff valve*. EPA agrees with the container manufacturer group and will amend the final rule so the shutoff valve requirement applies to liquid pesticide container connections below the normal liquid level. Vents and other openings on the top of the container are above the normal liquid level, so the phrase ''except for vents'' is no longer necessary and is not in the final regulation.

5. *Comments - location of shutoff valve*. EPA requested comments on whether it is necessary to regulate the location of shutoff valves, and if so, what the location should be. Some commenters (registrants, registrant groups, dealer groups, and a State regulatory agency) supported a general guideline that would allow placement of the valve anywhere within the secondary containment. These commenters believed that fine-tuning the valve location wouldn't increase overall release protection as long as the valve was in secondary containment. Only one commenter, a State regulatory agency, stated a preference for locating the valve close to the storage vessel, saying that field experience has demonstrated that valves are subject to incidental spillage due to factors such as ''pipe chatter.''

6. *EPA response - location of shutoff valve*. EPA agrees with the majority of the commenters that shutoff valves should be located within a secondary containment unit. Therefore, this part of the standard will be amended to specify that the shutoff valve be located within a secondary containment unit, if secondary containment is required by subpart E. EPA believes that nearly all, if not all, stationary pesticide containers that are subject to § 165.45(f) will be required to be within a secondary containment unit by subpart E. However, subpart E applies only to agricultural pesticides, so it is possible that a container holding a nonagricultural pesticide could be subject to the stationary pesticide container standards, but not the containment standards.

K. Waivers and Modifications (§ 165.45(g) - (h))

1. *Final regulation*. Section 165.45(g) of the final rule explains that registrants may request waivers from or modifications to some of the refillable container regulations and sets out the criteria that must be met for EPA to approve a waiver/modification request. Section 165.45(g) regulations are identical to the corresponding portion of the waiver/modification provisions regarding the DOT provisions for nonrefillable containers in § 165.25(g).

Section 165.45(h) describes the procedure for registrants to follow if they want to obtain a waiver from or modification to the specified refillable container regulations. The procedure in § 165.45(h) is identical to the procedure for obtaining waivers from or modifications to the nonrefillable container regulations in § 165.25(h).

2. *Changes, comments and EPA responses*. The proposed rule did not include any waiver or modification provisions for the refillable container regulations. The supplemental notice discussed an approach for incorporating a waiver from or modification to the referenced and adopted DOT requirements. EPA made several changes to the supplemental approach before incorporating the waiver/modification provisions into the final regulations. See Unit V.I. (on nonrefillable containers) for changes, comments and EPA responses regarding the waivers from and modifications to the pesticide container regulations that refer to and adopt the DOT requirements, which apply to both nonrefillable and refillable containers. Unit V.J. provides more details on the process for applying for waivers and modifications, which is the same for nonrefillable and refillable containers.

L. Reporting (§ 165.47)

1. *Final regulation*. This section clarifies that the pesticide container regulations do not require registrants to report to EPA with information about their refillable containers. However, it refers registrants to the reporting standards in 40 CFR part 159 to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2).

2. *Changes*. The intent and substance of this standard is the same as in the proposal. However, the wording was changed to clarify that this is simply a reference to the existing 6(a)(2) standards and that it does not add any new requirements.

M. Proposed Standards That Are Not Being Finalized

Final regulation/changes. The following requirements relating to refillable container design from the proposed regulation are not being finalized in today's final rule:

- § 165.124(b)(1)(i) - (v) and (vii): Permanent marking other than serial numbers
- § 165.124(b)(2): Compliance with DOT's marking satisfies the corresponding EPA permanent marking requirement
- § 165.124(c): General minibulk integrity standard
- § 165.124(d): Drop test for minibulk containers (requirement)
- § 165.125: Minibulk container drop test methodology (test procedure)
- § 165.128(a) & (b): Keep records of container descriptions, minibulk drop test results and the GLP statement specified for the drop test.
- § 165.126: Certification
- § 165.128(c): Keep records of the certification.

The first six proposed standards are not being finalized in the refillable container regulations because the approach of referring to and adopting a subset of the DOT standards makes them unnecessary. In particular:

- Some of the items for permanent marking in proposed § 165.124(b)(1)--the container manufacturer, date of manufacture, rated capacity, and material of construction--are not being finalized because this information is required in the DOT standards that specify marking. Two other proposed pieces of information--the model number and the phrase ''Meets EPA

standards for refillable containers''--are not being finalized because they are no longer necessary due to the change to refer to and adopt the DOT regulations. See Unit VI.H. for more detail about the proposed marking requirements.

- The statement proposed in § 165.124(b)(2) is not being finalized because the final rule specifically refers to the DOT marking, so it is no longer necessary to include a provision stating that compliance with DOT's marking satisfies the corresponding EPA marking requirement.
- The proposed general minibulk integrity standard in § 165.124(c) is not being finalized because the DOT regulations address container integrity in 49 CFR 173.24.
- The proposed drop test requirement for minibulks in § 165.124(d) and the proposed minibulk container drop test in § 165.125 are not being finalized because the DOT regulations include a drop test requirement. The drop test procedure for nonbulk packagings is defined in 49 CFR 178.603 and the drop test procedure for intermediate bulk containers is defined in 49 CFR 178.810.
- The proposed recordkeeping requirements in § 165.128(a) and (b) for container descriptions, drop test results and a GLP statement for the drop test are not being finalized because they are no longer necessary because compliance with the DOT requirements can be ensured by the structure and certification standards in the DOT HMR. Because we can rely on the DOT or UN marking to ensure compliance with the applicable DOT requirements, EPA no longer needs to see records of the testing to confirm compliance with the drop test (and in the final rule) and other test requirements.

The final two proposed items listed above--having registrants certify compliance with the regulations and the associated recordkeeping--are not being finalized for the same reasons that the nonrefillable container certification and recordkeeping are not being finalized, as described in Unit V.M.

N. Options for Implementing the Rule

1. *Final regulations.* In the preamble to the proposed rule, EPA discussed three options for implementing the refillable container and repackaging standards, which were all in one subpart in the proposed rule. These options covered different approaches for determining who would be held responsible for ensuring that the refillable containers meet the refillable container standards. EPA considered several options because the pesticide products distributed or sold in refillable containers and the containers themselves often enter the pesticide distribution chain separately, so identifying responsibility for compliance is not as straightforward as it is for nonrefillables, which the registrants fill at their establishments.

In evaluating the options for container design responsibility, EPA considered the differences among the options in terms of seeking the least burdensome approach that is also effective, practicable, and easily enforceable. In the proposal, we identified Option 1 as our preferred option (as indicated in the proposed regulatory text) because we thought it was more effective, more practicable, and significantly more easily enforceable than the other two options. The three options are described below.

- Option 1. Registrants would be responsible for containers meeting the design standards. The containers would be marked ''Meets EPA standards for refillable pesticide containers'' and registrants would maintain records for their containers. The registrants would develop a list of acceptable containers for each product, identified by manufacturer and model number, and provide the list to refillers. Refillers could repackage pesticide only in containers identified on the registrants list.
- Option 2. Anyone could produce containers, certify to EPA that the containers meet EPA design standards, and receive permission to mark containers with EPA certification seal. This could be container manufacturers, but it could also be registrants, refillers, or even end users. EPA would compile a list of certified container models. Registrants and refillers could repackage products only into certified containers. Registrants would develop a list of acceptable container construction materials for each product and provide the list to refillers, who could refill only into certified containers made from materials identified as acceptable by the registrant.
- Option 3. Container manufacturers would be responsible for containers meeting EPA's design standards and would mark containers with a certification seal. Container manufacturers would keep records for containers. Registrants would develop a list of acceptable container materials for each product and provide the list to refillers. Registrants and refillers would repackage only into containers marked with the seal and made of materials identified as acceptable by the registrant.

As discussed in the 1999 supplemental notice, EPA is implementing a combination of Option 1 and Option 3 in the final rule.

2. *Changes.* The key change from the proposed rule is that the final regulations adopt and refer to the DOT standards for container design, construction and marking, as discussed in Unit IV. Therefore, registrants only have to ensure that they use containers that meet the cross-referenced DOT standards for container integrity, construction and testing, rather than being responsible for the testing themselves. Registrants must also ensure compliance with the permanent marking (serial number) and opening (one-way valve/tamper-evident device) requirements. Because containers will be identifiable by the UN/DOT marking, some of the repackaging standards can be adjusted to be more flexible. Specifically, rather than requiring the registrants to identify acceptable containers by the model numbers and container manufacturers, they will be able to identify acceptable containers by the appropriate level of DOT testing (Packing Group I, II or III) and the container materials that are compatible with the product. The general structure of the repackaging standards, though, remains as proposed: (1) Registrants are responsible for developing certain information and providing it to the refillers; (2) refillers have certain responsibilities for inspecting, cleaning, and labeling the container since they are the ones actually handling the containers; and (3) both registrants and independent refillers have certain responsibilities if an independent refiller repackages a registrant's product. The changes to the repackaging regulations are discussed in more detail in Unit VII.

VII. Repackaging Standards

A. Format Changes

Final regulation and changes. In the proposed regulation, the refillable container design standards and the repackaging requirements were included in the same subpart of the regulations. In the final rule, EPA moved the repackaging requirements into a separate subpart because we think separating the two kinds of requirements will make the regulations easier to understand. The container design requirements are mostly technical and apply mostly to registrants. The repackaging requirements are mostly procedural and apply to registrants and to anyone who repackages pesticide products into refillable containers, which could be registrants, distributors, retailers, or other kinds of companies.

In addition, the repackaging requirements were reorganized so all of the requirements that apply to a certain kind of business are listed together. Specifically, the requirements are listed for: (1) Registrants who distribute or sell pesticide products directly in refillable containers; (2) registrants who distribute or sell pesticide products to independent refillers for repackaging; and (3) independent refillers. The term ''independent refiller'' is used to identify a refiller that is not part of the registrant's company. The differences between these categories are described in more detail below in Unit VII.C. This format requires some standards to be repeated. For example, the container inspection requirement applies to registrants who distribute or sell pesticide products directly in refillable containers and to independent refillers, so the inspection requirement is repeated. Despite the repetition, EPA believes this regulatory structure is more clear and easier to understand.

B. Purpose (§ 165.60(a))

1. *Final regulations.* The purpose of the repackaging standards is to establish requirements for repackaging some pesticide products into refillable containers for distribution or sale.

2. *Changes.* This is nearly the same as the proposed purpose (in § 165.120(b)). One minor change was to acknowledge the reduced number of products that are subject to the final regulations by stating that the rule applies only to repackaging *some* pesticide products. The proposed regulations would have applied to all products. Another insignificant modification was to delete the term ''standards'' from the phrase ''establish standards and requirements'' because it is redundant.

C. Who Must Comply (§§ 165.60(b), 165.65(a), 165.67(a), and 165.70(a))

1. *Final regulation.* You must comply with the repackaging regulations if you are a:

- Registrant who distributes or sells a pesticide product in refillable containers. This means that you conduct all of the repackaging for a pesticide product and that you do not distribute or sell your pesticide product to a refiller that is not part of your company for repackaging into refillable containers.
- Registrant who distributes or sells a pesticide product to a refiller that is not part of your company for repackaging into refillable containers.
- Refiller of a pesticide product and you are not the registrant of the pesticide product.

As explained in Units VII.J. and VII.K., a registrant may repackage a product directly into refillable containers for sale or distribution *and* distribute or sell that same product to an independent refiller for repackaging. In this case, the registrant must comply with both sets of requirements.

2. *Changes.* The same kinds of businesses that were included in the proposed rule (in § 165.122(a)(1), (2) and (3)) are subject to the final rule. One minor modification was to clarify that refillers in the last two categories are refillers that are not part of the registrant's company. Registrants can also be refillers, which is the situation described in the first category; the registrant conducts all of the packaging and repackaging. Therefore, the changes are intended to clarify that the second and third category refer to independent refillers, i.e., refillers that are not part of the registrant's company.

D. Compliance Dates (§ 165.60(c))

1. *Final regulations.* The final regulations provide a 5–year period after the date of publication of the final rule in the **Federal Register** before compliance with the repackaging standards is required. Specifically, within 5 years from today's date, all products sold in refillable containers must be distributed or sold in compliance with these regulations.

2. *Changes.* Based on the comments relating to refillable container design as described in Unit VI.D., EPA decided to extend the compliance period for the refillable container regulations from the 2–year time frame that was proposed in § 165.139. The longer time frame is to provide for a smoother and less burdensome transition for companies. Because the repackaging regulations require pesticide product to be repackaged only into containers that meet the refillable container standards, the compliance date for these regulations needed to be changed for consistency.

E. Pesticide Products Included (§ 165.63(a) - (g))

1. *Final regulations.* As described in detail in Unit III., only certain products have to comply with the repackaging standards. MUPs, plant-incorporated protectants, and certain antimicrobial products are completely exempt from the repackaging requirements. All other pesticide products are subject to the repackaging regulations. This is identical to the scope of the refillable container regulations.

Some of the antimicrobial pesticides that are subject to the repackaging regulations are subject to a reduced set of regulations. In particular, antimicrobial pesticides that are used in swimming pools and closely related sites (such as hot tubs, spas and whirlpools) are exempt from certain recordkeeping requirements, as well as the parts of the standards for inspecting and cleaning containers that relate to serial numbers, one-way valves, and tamper-evident devices.

2. *Changes.* In the proposed rule, only MUPs were exempt from the repackaging requirements, which were included in the refillable container regulations (see § 165.122(b)(1)). All other products would have been subject to the standards. The 1999 supplemental notice discussed regulatory options for exempting some products (antimicrobials and non-antimicrobials) from the full set of refillable container regulations including the repackaging requirements and for exempting certain antimicrobial products from specific requirements.

The criteria in the final rule for exempting antimicrobials are different than those discussed in the supplemental notice and the final rule exempts plant-incorporated protectants. The final repackaging regulations do not incorporate the toxicity category, container size or environmental hazard criteria from the supplemental notice. Also, the final rule changes some aspects of the supplemental notice approach of subjecting antimicrobial swimming pool products to a reduced set of requirements.

The following table describes the provisions for determining which pesticide products are subject to the repackaging regulations and a brief explanation of how (or if) this provision changed from the proposal and/or the supplemental notice.

TABLE 15.—CHANGES TO THE SCOPE OF THE REPACKAGING REGULATIONS

Regulatory Provision	Changes
Manufacturing use products are exempt.	No change from proposed rule or supplemental notice.

TABLE 15.—CHANGES TO THE SCOPE OF THE REPACKAGING REGULATIONS—Continued

Regulatory Provision	Changes
Plant-incorporated protectants are exempt.	Plant-incorporated protectants would have been subject to the proposed rule. The regulations for plant-incorporated protectants were finalized in 2001. We are exempting them from the final rule because of their unique nature.
Certain antimicrobial products are exempt.	Antimicrobial products would have been subject to the proposed rule. The final rule implements an approach similar to option 1 in the supplemental notice, although some of the details are different.
All other products are subject to all of the repackaging requirements, except for certain antimicrobial swimming pool products.	All products other than manufacturing use products would have been subject to the proposed rule. The final rule is different than the approach discussed in the supplemental notice, which would have exempted products in Toxicity Category III or IV in small containers and outdoor use products without the specified environmental hazard statements on their label.
Antimicrobial products used in swimming pools and closely related sites are subject to a reduced set of repackaging requirements.	Antimicrobial products used in swimming pools would have been subject to the proposed rule. The final rule is the result that was intended in the supplemental notice, although the specifics of how it is implemented in the final rule are different than in the supplemental notice.

F. Other Exemptions (§ 165.63(h))

1. *Final regulations.* The repackaging regulations 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 or to containers that hold gaseous pesticides. In addition, the final rule includes a statement that clearly exempts custom blending from the repackaging requirements.

2. *Changes.* The exemption for transport vehicles is identical to the exemption proposed in § 165.122(b)(2) and the exemption included in the final refillable container regulations. The exemption for custom blending was not included in the proposed regulatory text. It is discussed in Unit VII.L. In addition, the final rule includes a specific exemption for gaseous pesticides, which is necessary to implement our intent from the proposal because the final rule does not use the proposed terms liquid minibulk, dry minibulk, liquid bulk and dry bulk containers, which would have excluded gaseous pesticides.

G. Legal Basis for Repackaging Pesticide Products for Distribution or Sale

Before continuing with a section-by-section analysis of the regulations, EPA believes it is necessary to address three broad issues regarding repackaging pesticide products into refillable containers: (1) The legal basis for repackaging pesticide products (and the related Bulk Pesticides Enforcement Policy); (2) the integrity and purity of products sold or distributed in refillable containers; and (3) whether pesticides can be repackaged at locations other than registered establishments.

1. *Background.* FIFRA section 3(a) provides in pertinent part that ''no person in any State may distribute or sell to any person any pesticide which is not registered under this Act.'' Registration is the principal means of ensuring that a product is brought under the FIFRA regulatory scheme. The registrant must demonstrate to EPA's satisfaction that the product meets the statutory criteria for registration with respect to composition, labeling, and the lack of unreasonable adverse effects. The registrant must take responsibility for quality control of the product's composition and for adequate labeling describing the product, its hazards, and its uses. Repackaging a pesticide produces a new pesticide product that must be registered before it can be distributed or sold.

Before a pesticide product that is not included within the terms of an existing registration enters the channels of trade, a separate registration must be obtained. Changes in the formulation of a registered product, changes in accepted labeling, as well as any repackaging of a pesticide into another container activate the registration requirement, unless the purposes of product registration would be fully met by carrying forward the Federal registration of the constituent product.

In 1977, EPA issued an enforcement policy for bulk shipments of pesticides. (Ref. 75) The policy describes certain conditions in which EPA allows the transfer and repackaging of bulk pesticides to occur without requiring registration of the repackaged pesticides. The 1977 Bulk Pesticides Enforcement Policy (the Policy) defined ''bulk'' for the purposes of the Policy as ''any volume of pesticide greater than 55 gallons or 100 pounds held in an individual container.'' EPA developed the Policy to accommodate business practices of manufacturers and distributors who handle pesticides in large undivided quantities rather than in small individual containers because of the environmental and logistical benefits associated with refillable containers.

In the Policy, EPA determined that repackaging of bulk pesticides could occur without a separate registration if certain conditions were met that would assure that the purposes of registration would be satisfied. The conditions are that repackaging of the registered bulk pesticides could involve nothing more than changing the product container; i.e., no change in: (1) The pesticide formulation, (2) the pesticide's labeling except to add an appropriate statement of net contents and a registered establishment number, and (3) the identity of the party accountable for the product's integrity.

The Policy elaborated on the accountability requirement and set out that the pesticide had to be: (1) transferred at an establishment owned by the registrant; or (2) transferred at a registered establishment operated by a person under contract with the registrant; or (3) transferred at a registered establishment owned by a party not under contract to the product registrant, but who had been furnished written authorization for use of the product label by the registrant. The requirement for written authorization assures that the registrant remains responsible for quality control of the product's composition and adequate labeling describing the product, its hazards, and its uses.

The 1977 Policy only addressed the transfer of a volume of pesticide greater

than 55 gallons or 100 pounds held in an individual container. In March 1991, the Policy was amended (Ref. 71) to allow repackaging of any quantity of pesticides into refillable containers, provided that all three conditions below are met:

(1) The container is designed and constructed to accommodate the return and refill of greater than 55 gallons of liquid or 100 pounds of dry material.

(2) Either: (a) The containers are dedicated to and refilled with one specific active ingredient in a compatible formulation; or (b) the container is thoroughly cleaned according to written instructions provided by the registrant to the dealer prior to introducing another chemical into the container, in order to avoid cross-contamination.

(3) All other conditions of the July 11, 1977 Policy are met.

As discussed in the preamble of the proposed rule, EPA is replacing the Bulk Pesticides Enforcement Policy with these regulations, specifically §§ 165.67(b) - (c) and 165.70(b) - (c). These regulations provide that a registrant may allow an independent refiller to repackage the registrant's pesticide product into any size refillable container and to distribute or sell such repackaged product under the registrant's registration (i.e., the product's EPA registration number stays the same), provided all conditions set out in the rule are met.

These regulations do not change the existing law; the Bulk Pesticides Enforcement Policy would be replaced by a regulation. The registrant remains responsible for the integrity, labeling, and packaging of the repackaged product. Both the registrant and independent refiller may be held liable for violations pertaining to the repackaged product. The repackaging regulations set out the requirements for both registrants and independent refillers, because they have different roles and responsibilities in distributing pesticide products in refillable containers.

The conditions set out in §§ 165.67(b) - (c) and 165.70(b) - (c) do not apply to registrants repackaging their own pesticide products solely at their own establishments. As described in Pesticide Registration (PR) Notice 98–10 ''Notifications, Non-notifications and Minor Formulation Amendments,'' the registrant generally can modify the package size and label net contents statement without notifying EPA. (Ref. 56) This would be an amendment to the registration not requiring EPA notification or approval.

2. *Final regulations*. The regulations implementing the legal basis for repackaging are similar to the provisions in the proposed rule with two significant changes, described in the next section, and some minor formatting modifications. Specifically, §§ 165.67(b) and 165.70(b) specify that a registrant may allow a refiller to repackage a pesticide product into refillable containers and to distribute or sell such repackaged product under the existing registration if all of the following conditions are satisfied:

- The repackaging results in no change to the pesticide formulation.
- One of the following conditions regarding a registered refilling establishment is satisfied:

(1) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(2) 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 as required by § 167.20.

- The registrant has entered into a written contract with the refiller to repackage the pesticide product and to use the label of the pesticide product.
- The pesticide product is repackaged only into refillable containers that meet the standards of subpart C.
- The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refiller's EPA establishment number.

In addition, the regulations (§§ 165.67(c) and 165.70(c)) state that repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions listed above is a violation of section 12 of FIFRA. Both the registrant of the product and the refiller that is repackaging the pesticide product under contract to the registrant may be liable for violations pertaining to the repackaged product.

3. *Changes*. One significant change to these conditions for repackaging pesticide products for distribution or sale is to add the specification that the pesticide product can be repackaged by a registered refilling establishment at the site of a user who intends to use or apply the product as an acceptable alternative to the condition that the product must be repackaged at a registered refilling establishment. This change is discussed in detail in Unit VII.I. below. Another change is that the final rule specifies that the registrant must enter into a written contract with the refiller. The proposed option for the registrant to enter into a ''written authorization'' with the refiller is not being finalized for several reasons. First, EPA believes it is not necessary to have two different mechanisms. It is more straightforward to specify one method, which should facilitate compliance and minimize confusion. Second, EPA believes that a ''written contract'' is more familiar to the regulated community and more defined in law than a ''written authorization,'' which is why we chose to specify contracts as the mechanism for establishing a repackaging relationship between the registrant and refiller in the final rule. Third, in the years since the Bulk Pesticides Enforcement Policy was issued, the ''written authorizations'' have become virtually indistinguishable from ''written contracts'' in format, length and level of detail. Therefore, EPA anticipates that specifying a contract (and not an authorization) in the final rule should not cause a substantial impact to the way repackaging is currently being conducted, particularly considering the 5–year implementation period for the refillable container and repackaging regulations. The other modifications were minor formatting changes that were needed to accommodate: (1) the revision to plain language; (2) needing to include the conditions in the requirements for registrants who distribute or sell to independent refillers and in the requirements for independent refillers; and (3) clarifying that the EPA establishment number added to the label is the refiller's EPA establishment number.

4. *Comments - implementation*. One registrant urged EPA not to eliminate the ability of manufacturers and distributors that are not registrants of an MUP to repackage that product for distribution and sale.

5. *EPA response - implementation*. In the preamble to the proposed regulations, EPA stated that the Bulk Pesticides Enforcement Policy would remain in effect until the date specified for compliance with the refillable container and repackaging regulations, at which point it would be rescinded. EPA will implement this as discussed in the preamble to the proposal. The refillable container and repackaging regulations will supersede the Bulk Policy for products that are subject to these regulations. Pesticide products that are exempt from the refillable container and repackaging regulations--MUPs, plant-incorporated protectants, and some antimicrobials--can only be repackaged under the limitations established by FIFRA, the registration requirements in 40 CFR part 152, and the applicable OPP policies. A key

limitation is that the products that are exempt from the refillable container and repackaging regulations must be repackaged by the registrant or a person under written contract to the registrant. EPA believes this constraint will not be a problem for MUPs and exempt antimicrobials because we have received information that these products are repackaged by the registrants if they are sold or distributed in refillable containers. In addition, refillable containers are not appropriate for distributing plant-incorporated protectants, so these products will also not be adversely affected.

One issue that has been raised is whether registrants and independent refillers can comply with the regulations (and specifically the conditions for repackaging pesticide products for distribution or sale) before the compliance date. This is appealing to registrants and independent refillers because the regulations allow pesticides to be repackaged under written contracts into refillable containers of any size (compared to the 55 gallon container size limit established in the Bulk Policy and maintained in the 1991 amendment). EPA believes that it is acceptable for registrants and independent refillers to repackage pesticide products under the regulations before the 5 year compliance date as long as they are in full compliance with the refillable container and repackaging regulations. In other words, registrants can enter into contracts with independent refillers to refill containers only if: (1) The containers comply with the refillable container regulations, i.e., they meet the specified DOT standards, have a durable serial number or other identifying code, and have one-way valves and/or tamper-evident devices; (2) the registrant meets the repackaging conditions and develops and provides the necessary information, including a description of acceptable containers and a cleaning procedure; (3) the refillers meet the repackaging conditions and comply with the operational procedures, including inspecting, cleaning (if necessary), and labeling the containers; and (4) all other requirements specified in the refillable container and repackaging regulations are followed.

H. Product Integrity

1. *Background.* The Bulk Pesticides Enforcement Policy and both the proposed and final rules hold the registrant and the refiller (if different than the registrant) responsible for product integrity of the pesticide product repackaged by the refiller. ''Product integrity'' means that the pesticide product is not adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3. This requirement reflects current law. Under FIFRA section 12(a)(1), it is unlawful for any person to distribute or sell to any person a pesticide which is adulterated or whose composition differs from the composition described in its confidential statement of formula.

FIFRA Section 12(a)(1) applies to pesticide distributed or sold in nonrefillable containers and in refillable containers. For pesticides distributed or sold in nonrefillable containers, it is clear that the registrants are responsible for product integrity because there are no other parties involved (except for supplemental registrants, as regulated by 40 CFR 152.132, and parties acting as agents under contract to the registrant). Similarly, when a registrant repackages a product directly into a refillable container for distribution or sale, it is also clear that the registrant is responsible for product integrity.

The situation is less clear when a registrant distributes or sells a product to an independent refiller for repackaging into refillable containers. Both the registrants and the independent refillers are selling or distributing the product, so both parties are responsible for product integrity. The registrant is responsible because the registrant has authorized the independent refiller to repackage the registrant's pesticide product and to use the registrant's label according to the terms of the written contract (or authorization under the Bulk Policy). The registrant remains accountable for its repackaged product which is distributed or sold in the refillable container. EPA believes it is appropriate for registrants to be held responsible for acts by independent refillers because the repackaging is being done under the registrant's registration and the independent refillers are agents of the registrants for purposes of carrying out the written contract. The independent refiller is responsible for product integrity because the refiller is the person who physically places the product into the container for sale or distribution.

In 1996, EPA established a policy on ''Toxicologically Significant Levels of Pesticide Active Ingredients'' in PR Notice 96–8. (Ref. 58) This document describes EPA's interpretation of the term ''toxicologically significant'' as it applies to contaminants in pesticide products that are also active ingredients. The policy provides risk-based concentration levels of such contaminants that are generally considered to be toxicologically significant (and therefore must be reported and accepted as part of product registration according to 40 CFR 158.167). The concentrations are defined according to the type of pesticide that is contaminated (insecticide, herbicide, low dose herbicide, etc.) and the pesticide category of the contaminant. While PR Notice 96–8 applies to all pesticide products in nonrefillable and refillable containers, a driving force in developing the policy was the cross-contamination found in refillable containers in the early 1990's.

2. *Final regulations.* The repackaging regulations clearly hold all parties subject to the repackaging standards to be responsible for product integrity. This includes:

(1) Registrants who distribute or sell a pesticide product in refillable containers (in § 165.65(b));

(2) Registrants who distribute or sell pesticide products to independent refillers for repackaging into refillable containers (in § 165.67(e)); and

(3) Refillers of a pesticide product that are not the registrants of the pesticide product (in § 165.70(d)).

Specifically, all of these businesses are responsible for the pesticide product that they distribute or sell not being adulterated or different from the composition described in the product's confidential statement of formula that is required under FIFRA section 3.

3. *Changes.* The language in the final regulation is nearly identical to the text in the proposed regulation. One slight modification is that the phrase ''described in its confidential statement of formula that is required under FIFRA section 3'' is used in the final regulations because it is more straightforward than the proposed phrase ''described in the statement required in connection with registration under section 3 of the Act.'' EPA considers these two phrases to mean exactly the same thing.

However, one thing that has changed since the proposed rule is EPA's policy on toxicologically significant levels of pesticide active ingredients. PR Notice 96–8 defines risk-based concentration levels of contaminants that are generally considered to be toxicologically significant. Active ingredient contaminants that are present at lower concentrations do not have to be reported by registrants and accepted by EPA as part of product registration. For example, if an herbicide active ingredient is detected at less than 1,000 ppm in any pesticide where the contaminant is accepted for use on all

sites for which the product is labeled, the herbicide active ingredient is not considered to be toxicologically significant. As described in PR Notice 96–8, the purpose of this policy is to: (1) Recognize that cross-contamination is a reality, and that not all cross-contamination is problematic; (2) set a clear standard that can be readily applied by EPA, States and the regulated industry; (3) ensure that allowable cross-contamination does not pose unreasonable adverse effects; (4) minimize the paperwork burden for EPA and registrants; (5) maintain accountability for the product from the registrant to the end user; and (6) not preclude marketplace or private solutions to correct problems that do arise.

I. Delivery and Repackaging at End User Locations

1. *Background*. The 1977 Bulk Policy (Ref. 75) provided the following two examples of acceptable practices for shipping ''bulk'' pesticides to end users:

- A registrant ships a bulk pesticide directly to an end user (custom applicator, farmer, etc.). The label accompanies the shipment and is placed on the user's tank. No new establishment or product registration is needed for the bulk container since the labeled product is fully registered and has been sold intact to the user.
- A tank car of pesticide from which commercial applicators meter off into their own tanks, without being put into a dealer's holding tank, would be exempt from new producer establishment registration. It is considered that the original container has not been changed in delivery to the applicator and the tank car label (placard) will bear the producer's establishment number.

In the preamble to the 1994 proposed rule, EPA stated that repackaging by the registrant must be done at a registered establishment, as required by 40 CFR part 167. In addition, EPA stated that we saw no reason to continue the exemption from the registered establishment requirement described in the second bullet in Unit I.1., above. We requested comments on the effect of discontinuing this exception.

On February 3, 1994, EPA released the ''Bulk Pesticide Repackaging Question & Answer Document'' (Ref. 63) which included the following question and answer that address the issue of making a bulk delivery directly to an end user.

18. May a registrant deliver pesticides in bulk directly to a farm, even if the farm is not registered as a producing establishment? May someone other than the registrant do this?

Under the bulk pesticide repackaging policy, a registrant may deliver pesticides directly to a farm, even if the farm is not registered as a pesticide producing establishment. Someone other than the registrant could not deliver pesticides in bulk to a farm unless the farm was registered as a pesticide producing establishment and that person has received written authorization from the registrant to deliver the pesticide to the specific farm. The registrant of the establishment (i.e., the farmer) would also be required to submit annual production reports. Please note that some States and most registrants require containment structures for the storage of bulk pesticides. Most farmers do not have these containment structures and delivery to these farms may not be allowed under State law.

After discussion and debate on this question among the regulated community and regulatory agencies, EPA reconsidered and revised our position in a memo titled ''Bulk Pesticide Transfers'' dated March 22, 1995. (Ref. 59) The new question 18 supersedes the question in the 1994 Bulk Policy Question & Answer document and is:

18(a). May a registrant deliver pesticides in bulk directly to a farm, even if the farm is not registered as a producing establishment? May someone other than the registrant do this?

A registrant, dealer, or other authorized person pursuant to the ''Enforcement Policy Applicable to Bulk Shipments of Pesticides'' (July 11, 1977) may transfer pesticides in bulk at a farm, even if the farm is not registered as a pesticide producing establishment.

18(b). May a registrant deliver pesticides in bulk directly to end use sites other than a farm, even if such site is not registered as a producing establishment? May someone other than the registrant do this?

Yes. See answer to question 18(a) above. However, the Agency will continue to pursue enforcement actions against all end users that use any registered pesticide in a manner inconsistent with its labeling pursuant to FIFRA 12(a)(2)(G).

The March 22, 1995 memo explained that this revision was made because end users are not the persons repackaging shipments of bulk pesticides at the farm and other end use sites. The memo further stated that the terms and conditions of the 1977 Bulk Policy and 1991 amendment are unchanged. Since the pesticide that is transferred at the farm or other end use site is not being transferred and held for further sale, final accountability for meeting the terms of the Bulk Policy remains with the registrant and the last establishment making a transfer associated with a pesticide sale, the dealer. Registrant and dealer establishments are responsible for reporting repackaging as production pursuant to 40 CFR 167.85. In the memo, EPA recommended (but did not require) that pesticides be transferred into stationary bulk containers protected by a secondary containment structure at end user sites.

2. *Final Regulation*. One of the requirements specified in §§ 165.67(b) and 165.70(b) for when a registrant may allow a refiller to repackage its pesticide product into refillable containers and to distribute or sell such repackaged product under the existing registration is:

One of the following conditions regarding a registered refilling establishment is satisfied:

(1) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20.

(2) 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 as required by § 167.20.

3. *Changes*. The first condition listed above (Unit I.2.(1)) (the product is repackaged at a registered refilling establishment) is the same as the proposed regulation. The second condition--the product is repackaged at the site of a user who intends to use or apply the product by a registered refilling establishment--was added to the final rule to be consistent with EPA's revised policy as described in the March 22, 1995 ''Bulk Pesticide Transfers'' memo. The final regulation is consistent with EPA's 1995 position that final accountability for meeting the terms of the Bulk Policy remains with the registrant and the last establishment making a transfer associated with a pesticide sale (an independent refiller in this case), because the pesticide that is transferred at the farm or other end use site is not being transferred and held for further sale.

EPA has received anecdotal evidence that the practice of refilling containers (bulk containers, minibulks, application tanks, nurse tanks, etc.) at end user sites has increased over the past few years and may continue to increase in the future. Therefore, EPA is concerned about the potential for spills, leaks and other releases during transfers at end user sites to cause soil and water contamination. As described in the preamble to the proposed rule, EPA decided to require containment structures at dealers, commercial applicators and custom blenders with bulk storage tanks, largely because these were the kinds of sites where contamination had been documented. EPA did not and still does not have documentation of end user site contamination due to repackaging pesticide product. Therefore, the final pesticide container and containment

regulations do not require repackaging at end user sites to be done within a containment structure. However, EPA strongly recommends that repackaging at end user sites be conducted over some kind of containment--whether it is a permanent concrete containment pad or a portable containment structure. In the future, EPA may revise the repackaging regulations to require all repackaging (including at end user sites) to occur over a containment structure if we become aware of a pattern of end user site contamination being caused by repackaging.

J. Registrants Who Distribute or Sell Pesticide Products in Refillable Containers - Overview (§ 165.65)

1. *Final Regulation.* The regulations in § 165.65 apply to registrants who distribute or sell pesticide products in refillable containers. This means that the registrant conducts all of the repackaging for the product and does not distribute or sell the product to a refiller that is not part of its company for refilling.

Of course, a registrant may repackage a product directly into refillable containers for sale or distribution *and* distribute or sell that same product to an independent refiller for repackaging. In this case, the registrant must comply with both sets of requirements: the standards in § 165.65 for those quantities the registrant distributes or sells directly in refillable containers and the requirements in § 165.67 for those quantities that the registrant distributes or sells to independent refillers for repackaging.

A registrant who distributes or sells a pesticide product directly in refillable containers:

- Is responsible for the integrity of the product, as discussed in Unit VII.H.;
- Must develop a refilling residue removal procedure, as discussed in Unit VII.M.;
- Must develop a description of acceptable containers, as discussed in Unit VII.N.;
- Must comply with the requirements for refillers (including having certain information and inspecting, cleaning, and labeling the refillable containers), as discussed in Unit VII.O. through VII.R.;
- Must keep records, including copies of the refilling residue removal procedure and the description of acceptable containers and certain information about each instance of repackaging. The recordkeeping requirements are discussed in Unit VII.S.

2. *Changes.* All of these requirements for registrants who distribute or sell pesticide products directly in refillable containers were included in the proposed regulation. Some of the requirements were modified based on comments and the change to refer to and adopt some of the DOT standards. The specific changes to these requirements are discussed in other sections of Unit VII.

K. Registrants Who Distribute or Sell Pesticide Products to Refillers for Repackaging - Overview (§ 165.67)

1. *Final Regulation.* The regulations in § 165.67 apply to registrants who distribute or sell pesticide products to refillers that are not part of their companies for repackaging into refillable containers. This is the more common form of repackaging, where the registrant ships in bulk to a refiller (normally a retailer) who repackages the product into portable pesticide containers.

As mentioned above, a registrant may repackage a product directly into refillable containers for sale or distribution *and* distribute or sell that same product to an independent refiller for repackaging. In this case, the registrant must comply with both sets of requirements: the standards in § 165.65 for those quantities the registrant distributes or sells directly in refillable containers and the requirements in § 165.67 for those quantities that the registrant distributes or sells to independent refillers for repackaging.

A registrant who distributes or sells a pesticide product to an independent refiller for repackaging:

- Must comply with the conditions for allowing a refiller to repackage his product, as discussed in Unit VII.G.;
- Must provide the refiller with the written contract to repackage before distributing or selling the product to the refiller;
- Is responsible for the integrity of the product, as discussed in Unit VII.H.;
- Must develop a refilling residue removal procedure, as discussed in Unit VII.M.;
- Must develop a description of acceptable containers, as discussed in Unit VII.N.;
- Must provide the refilling residue removal procedure, description of acceptable containers, and the product's label and labeling to the refiller before or at the time of distribution or sale to the refiller;
- Must keep records of the contracts, the refilling residue removal procedure, and the description of acceptable containers. The recordkeeping requirements are discussed in Unit VII.S.

The requirements that are specific to registrants who distribute or sell pesticide products to independent refillers for repackaging are the two that establish standards for the timing of when the registrant provides documents to the refiller. Under § 165.67(d), the registrant must provide the written contract to repackage the product *before* selling or distributing the product to the refiller. Section 165.67(g) specifies that the other information (cleaning procedure, description of acceptable containers, and label/labeling) can be provided earlier but must be provided to the refiller at the time of sale or distribution at the latest. These two provisions are identical to the proposed regulations.

2. *Changes.* All of these requirements for registrants who distribute or sell pesticide products to refillers for repackaging were included in the proposed regulation. Some of the requirements were modified based on comments, modifications to some EPA policies, and the change to refer to and adopt some of the DOT standards. The specific changes to these requirements are discussed in other sections of Unit VII.

L. Refillers Who Are Not Registrants - Overview (§ 165.70)

1. *Final Regulation.* The regulations in § 165.70 apply to refillers who are not registrants of the products that they repackage for sale or distribution.

A refiller who repackages a product for distribution or sale and is not the registrant of the product:

- Must comply with the conditions for allowing him to repackage the registrant's product, as discussed in Unit VII.G.;
- Is responsible for the integrity of the product, as discussed in Unit VII.H.;
- Must comply with the requirements for refillers (including having certain information and inspecting, cleaning, and labeling the refillable containers), as discussed in Unit VII.O. through VII.R.;
- Must keep records, including copies of the contract from the registrant, refilling residue removal procedure, and description of acceptable containers, and certain information about each instance of repackaging. The recordkeeping requirements are discussed in Unit VII.S.

2. *Changes.* All of these requirements for independent refillers were included in the proposed regulation. Some of the requirements were modified based on comments, modifications to some EPA policies, and the change to refer to and adopt some of the DOT standards. The specific changes to these requirements are discussed in other sections of Unit VII.

3. *Comments - whether or not to include custom blending in this rule.* In the preamble to the proposed rule, EPA discussed whether or not the requirements for independent refillers should apply to custom blenders, who provide the service of mixing pesticides with fertilizer, feed, or another pesticide to a customer's specification. The preamble provided two options for the final rule: (1) Issue a regulation on refilling practices that is tailored specifically to custom blenders that distribute pesticide mixtures, or (2) exempt custom blenders from the repackaging requirements. EPA requested comments on these options.

A few commenters showed lukewarm support for applying the repackaging regulations to custom blenders. A registrant was unaware of pressing reasons to exclude custom blenders and pointed out that custom blenders are usually custom applicators. A State regulatory agency stated that custom blenders should be required to meet the refilling requirements if the criteria apply to them. This commenter also pointed out that custom blends are generally placed into a spreader, not a container.

A registrant group stated that custom blenders provide valuable service in reducing pesticide container use and applicator exposure. This respondent recommended developing standards that are specific to custom blenders and that address items such as container integrity and cleaning procedures.

A registrant distinguished between custom blending and selling a pesticide product in a refillable container with a registrant's label on it as two different activities. A few dealer groups strongly urged EPA to exclude custom applicators from the refiller requirements. The retailer-related commenters believe it is inappropriate to address custom blenders in a section that focuses on maintaining the original integrity of repackaged pesticides. They also described current custom blending practices in the Midwest, including the following points:

- Midwest dealers with bulk pesticides are mostly all custom blenders and custom applicators and have become repackagers recently.
- It is common for the volume of bulk pesticides that goes into custom blends to exceed the volume that is repackaged into refillable containers.
- Custom blends may be loaded into custom application and nurse vehicles of that dealer, another for-hire custom applicator, or a customer.
- On the other hand, registered bulk pesticides are: (1) Repackaged into minibulk containers; (2) moved in portable service containers from the bulk container to supply the dealer's custom application operation in the field; and (3) loaded into tanks that are an integral part of application or nurse vehicles for field nursing or to supply injection systems.

4. *EPA response - whether or not to include custom blending in this rule.* In the final rule, EPA decided to exempt custom blending from having to comply with the repackaging requirements. As stated by several of the commenters, EPA determined that there is an inherent difference between custom blending and repackaging pesticide products for sale or distribution. When a product is repackaged for sale or distribution, it must maintain the characteristics of the product and meet the ingredient contents identified on the label and in the product's registration. On the other hand, a custom blend intentionally mixes a pesticide with another substance. While the product's labeling must be consistent with the custom blend (i.e., the labeling directions do not prohibit the use of the product in such a blend) and the product's label must be delivered to the end-user, the material in the custom blend is no longer just the pesticide product identified on the label. In fact, the custom blender must deliver a statement specifying the composition of the mixture.

The exemption for custom blending was added to § 165.63(h) of the final regulation, which asks ''Are there any other exceptions?'' Paragraph (h) in § 165.63 was added to state that custom blending is exempt from the regulations in this subpart. In addition, § 165.3 of the regulations define custom blending as ''Custom blending means the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when:

(1) The blend is prepared to the order of the customer and is not held in inventory by the blender;

(2) The blend is to be used on the customer's property (including leased or rented property);

(3) The pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend;

(4) The blend is prepared from registered pesticides; and

(5) The blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.''

This description is based on the definition of ''custom blender'' in 40 CFR 167.3, but was modified to reflect the practice of custom blending rather than the establishment at which it takes place. The § 167.3 definition focuses on the establishment, because the part 167 regulations then exempt custom blenders from the requirements to register their establishments (in § 167.20(a)(1)) and to report production (in § 167.85(a)). The § 167.3 definition of custom blender includes a sixth condition--that no other pesticide production activity is performed at the establishment--because these other activities would subject a custom blender to the establishment registration and production reporting requirements. However, this sixth condition is not relevant to the pesticide product repackaging requirements in 40 CFR part 165 subpart D because the subpart D regulations are tied to the process or action of repackaging. As reported by several commenters, a facility may conduct several different activities, including repackaging pesticide products into refillable containers and custom blending. In this case, the repackaging must be conducted in accordance with the regulations in this subpart, while the custom blending is exempt from the regulations in this subpart.

It is worth noting that the containment regulations in subpart E apply to some custom blenders, specifically ''custom blenders of agricultural pesticides.''

5. *Comments - mixing diluent with pesticides.* Several commenters (dealer groups and a dealer) urged EPA to allow water as a blend component. One retailer described the awkwardness of the situation when such mixing is not permitted — a dealer can put pesticide in a farmer's application equipment at its facility (with a containment pad), but the farmer has to return to his own location to add water and finish preparing the application mixture. The two dealer groups suggested or stated that using water as a custom blend component is currently practiced in the Midwest. The two dealer groups also recommended deleting condition #6 in the § 167.3 definition of custom blender which specifies that ''no other pesticide production activity is performed at the establishment.''

6. *EPA response - mixing diluent with pesticides.* EPA disagrees with the comment to delete condition #6 in the § 167.3 definition of custom blender that specifies ''no other pesticide production activity is performed at the establishment.'' As described above, this condition is intended to distinguish between custom blenders - who are exempt from the part 167 establishment registration requirements - and

producing establishments, who are required to register their establishments. Condition #6 does not prevent a facility from conducting custom blending and repackaging (producing). These facilities must register as establishments because they are producing establishments. Instead, condition #6 is intended to describe the facilities that are exempt from the establishment registration requirements, i.e., facilities that custom blend and do not repackage or otherwise produce pesticides.

However, EPA considered the request from commenters to allow custom blends to be diluted with water. Various offices and Regions within EPA, as well as the States, have not had a consistent policy about whether custom blends can be diluted with water or another diluent. After reviewing this issue, it is appropriate to clarify our position on diluting custom blends. EPA believes that the definition of custom blender in § 167.3 provides flexibility. Custom blenders are defined as ''any establishment which provides the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when'' the six conditions described above are met. In particular, the word ''usually'' in this definition provides flexibility and allows water (or other diluents when specified by the labeling of the pesticide[s] in the blend) to be added to custom blends.

EPA believes that the language of § 167.3 allows custom blends to be diluted with water or a diluent specified on the labels of all pesticides in the blend. In many ways, it is more efficient and possibly more accurate for the facility that is measuring and blending pesticides, fertilizers and/or animal feed to also measure and blend the diluent into the custom blend. In addition, custom blends (with diluents) that are delivered to an end user as a use-dilution (usually in refillable containers) offer worker exposure and environmental protection benefits including eliminating the need for end users to mix, handle and potentially spill the pesticide in the field; eliminating the need for the end user to rinse containers in the field; allowing the use of closed systems; and reducing the number of nonrefillable containers that must be disposed or recycled. However, EPA wants to clarify that custom blends with a diluent added still must comply with all five conditions in the definition of custom blend in § 165.3: ''Custom blending means the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when:

(1) The blend is prepared to the order of the customer and is not held in inventory by the blender;

(2) The blend is to be used on the customer's property (including leased or rented property);

(3) The pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend;

(4) The blend is prepared from registered pesticides; and

(5) The blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.''

EPA will monitor the practices and procedures that develop and proliferate in the field with this interpretation. If problems develop, EPA will consider options, including revising its interpretation, adding protective conditions if diluents are added to custom blends, and subjecting custom blending to the repackaging requirements in part 165.

In addition, EPA does not view a difference between custom blending and custom mixing from a regulatory point of view. A custom mixer is a facility that stores materials previously purchased by end-users and that custom mixes the products just prior to application. A custom mixer does not own, sell or apply the product, although the conditions in the § 165.3 definition of custom blending are met. Over the years, there have been different interpretations of whether or not there is a difference between custom blending and custom mixing. At least a few businesses have been established as custom mixers under the determination that they are not custom blenders. This final rule does not distinguish between custom blenders and custom mixers. Similarly, the policy of allowing diluents to be added to custom blends applies to both custom blenders and custom mixers. As discussed above, custom blending is excluded from the subpart D repackaging requirements. However, custom blenders (including custom mixers) would be subject to the subpart E containment standards if they blend (mix) agricultural pesticides.

7. *Comments - service containers.* A few dealer groups noted that the proposed rule does not address service containers, which are used to move pesticides from bulk storage to end-use applications in the field, e.g., the tanks that are an integral part of application or nurse vehicles. These commenters pointed out some advantages of service containers including: reducing the number of nonrefillable containers used, keeping pesticides separate from water or fertilizers during transportation, accommodating on-board injection systems and allowing the applicator to adjust pesticides in the field. These commenters urged EPA and industry to consider providing for the expanded use of service containers, with some exclusions from the refillable container requirements, to increase the use of bulk pesticides. A State regulatory agency supported keeping the Bulk Policy because they don't want to register each facility where bulk pesticides are metered, such as where pest control operators place pesticides into service containers.start here

8. *EPA response - service containers.* The pesticide container and repackaging regulations do not regulate service containers, because the container and repackaging regulations only apply to containers that are used to sell or distribute pesticide products and to the repackaging of products for sale or distribution. For the purposes of this discussion, a service container is defined 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, the measuring device, or the application device.''

EPA does not currently regulate service containers. In 1976, EPA issued a Pesticide Enforcement Policy Statement (PEPS) on ''Structural Pest Control: Use and Labeling of Service Containers for the Transportation or Temporary Storage of Pesticides,'' which defined minimal labeling requirements and several other limitations for the acceptable use of service containers by structural pest control operators. (Ref. 76) However, this PEPS was later rescinded. EPA continues to believe that it is a good management practice to ensure that the contents of service containers are identified and that the label of a pesticide product that is in a service container is available to the person handling and/or applying the pesticide. EPA may consider developing a separate policy on service containers while the pesticide container and containment regulations are being phased in.

M. Registrant Refilling Residue Removal Procedure (§ 165.65(c)(1) and 165.67(f)(1))

1. *Final Regulation.* Registrants who sell or distribute pesticide products directly in refillable containers and registrants who sell or distribute products to independent refillers for repackaging must develop a refilling

residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled. Registrants must specify a cleaning procedure for each product sold or distributed in refillable containers, although the same procedure can be used for multiple products. The refilling residue removal procedure must provide instructions for removing residues from all refillable containers. The same procedure can apply to portable and stationary pesticide containers, or the registrant can describe different procedures if it is appropriate and necessary. Finally, the refilling residue removal procedure describes how to remove residue from a refillable container. While this generally involves rinsing the container with water, the regulations do not specifically require rinsing with water. If a different procedure is appropriate for a given formulation, it can be used as long as it meets the following performance standard.

The refilling residue removal procedure must meet the performance standard of being adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula. This standard ensures that the products distributed and sold in refillable containers meet the existing product integrity requirements, as described in Unit VII.H.

The refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations if: (1) The procedure requires the use of a solvent other than the diluent used for applying the pesticide, or (2) there is no diluent used for application. This information is necessary to help refillers manage rinsate that cannot easily be used as make-up water in future applications.

2. *Changes*. This requirement is the same as it was in the proposed rule. Several minor editing change have been made to improve the clarity and the different refillable containers are described as portable and stationary pesticide containers because the definitions of minibulk and bulk are not being finalized. These modifications have not changed the requirement or intent of the requirement.

N. Registrant Description of Acceptable Containers (§§ 165.65(c)(2) and 165.67(f)(2))

1. *Final regulation*. Registrants who sell or distribute pesticide products directly in refillable containers and registrants who sell or distribute products to independent refillers for repackaging must develop a description of acceptable refillable containers (portable and stationary pesticide containers) that can be used for distributing or selling that pesticide product. An acceptable container is one which the registrant has determined meets the refillable container standards in subpart C and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container. The registrant must identify the containers by specifying: (1) The container materials of construction that are compatible with the pesticide formulation; and (2) information necessary to confirm compliance with the refillable container requirements in subpart C. The refillable container requirements include the adopted DOT standards, being marked with a serial number or other identifying code, having a one-way valve or tamper-evident device on each opening (other than a vent) of a portable pesticide container designed for liquids, and the stationary pesticide container requirements.

Similar to the refilling residue removal procedure, registrants must specify a description of acceptable containers for each product sold or distributed in refillable containers, although the same description can be used for multiple products if it meets the standards.

2. *Changes*. This requirement was changed significantly from the proposed rule. The proposal would have required registrants to develop lists (not descriptions) of acceptable containers, which would have been identified by specifying the container manufacturer and model number of the container. This was proposed because registrants are responsible for ensuring that the refillable containers used to sell and distribute their products meet the requirements in the container regulations. When EPA proposed the rule, specifying the container manufacturer and model number seemed like a relatively easy way for registrants to identify acceptable containers for their refillers.

However, the final rule's approach of referring to and adopting some DOT requirements provides an even easier way for registrants to identify acceptable containers to the refillers. Rather than citing specific model numbers, the registrants can provide refillers with a much less prescriptive approach by identifying characteristics, such as the material of construction, how to determine if the container meets the applicable DOT standards, how to comply with the serial number requirement, how to obtain and apply one-way valves and/or tamper-evident devices to the openings of portable pesticide containers for liquids and information for complying with the stationary pesticide container standards.

3. *Comments*. Several commenters (registrants and a registrant group) recommended that instead of a list of acceptable containers, the registrants should identify acceptable containers by providing the compatible materials of construction and the necessary information to apply the DOT standards. The registrant group and a distributor commented that this requirement will be helpful to ensure that formulators and subregistrants know and obtain information about the proper packaging.

4. *EPA response*. In the final rule, EPA changed the requirement for identifying acceptable containers so registrants can describe acceptable containers by specifying compatible materials of construction and the information necessary to comply with the refillable container requirements. This includes information for complying with the adopted DOT standards, but also the other requirements in subpart C.

O. Requirements for All Refillers (§§ 165.65(d) and 165.70(e))

1. *Final regulation*. All refillers, including those at registrant's facilities and those who are not part of a registrant's company must comply with the following provisions regarding repackaging a pesticide product into refillable containers:

*(1) The establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.

*(2) The refiller must not change the pesticide formulation unless he has a registration for the new formulation.

(3) The refiller must repackage a pesticide product only into a refillable container that is identified on the description of acceptable containers for that pesticide product.

(4) The refiller may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that can be used.

(5) The refiller must have all of the following items at the establishment

before repackaging a pesticide product into any refillable container for distribution or sale:

*(A) The written contract from the pesticide product's registrant. [Subparagraph A applies only to independent refillers.]

*(B) The pesticide product's label and labeling.

(C) The written refilling residue removal procedure for the pesticide product.

(D) The written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, the refiller must identify the pesticide product previously contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with the cleaning requirements described in Unit VII.Q. The refiller may identify the previous pesticide product by referring to the label or labeling.

(7) The refiller must inspect each refillable container as discussed in Unit VII.P.

(8) The refiller must clean each refillable container, if required, as discussed in Unit VII.Q.

*(9) The refiller must ensure that each refillable container is properly labeled as discussed in Unit VII.R.

(10) The refiller's establishment must maintain records, as discussed in Unit VII.S.

*(11) The refiller's establishment must maintain records as required by 40 CFR part 169.

*(12) The refiller's establishment must report as required by 40 CFR part 167.

(13) Stationary pesticide containers (that meet the specified size criteria) at the establishments of independent refillers must meet the standards in § 165.45(f). [Paragraph 13 is only included in the regulations in § 165.70(e) for independent refillers. The refillable container regulations state that both the registrant and independent refillers are responsible for complying with the stationary pesticide container requirements.]

(14) Refillers may be required to comply with the containment standards in subpart E. [Paragraph 14 applies only to independent refillers.]

These requirements, except for items 5(A), 13 and 14 which apply only to independent refillers, apply to any refiller that repackages a product subject to the regulations regardless of the main business of the refiller (registrant, retailer, etc.). Some of these conditions (indicated by an asterisk) simply refer to or reinforce key requirements in existing regulations, including 40 CFR parts 156, 167 and 169 or incorporate existing standards of the Bulk Policy (having a copy of the registrant's contract). These provisions are included here for the sake of completeness and as a reference for refillers.

In other words, the new provisions for refillers are that each refiller:

- Must repackage a product only into a container identified on the registrant's description of acceptable containers;
- May repackage any quantity of a product into a refillable container (up to its rated capacity) and there are no general limits on the size of the refillable containers;
- Must have certain documents before repackaging;
- Must identify the product previously in the container by its label;
- Must inspect and, if necessary, clean the container; and
- Must maintain certain records.

EPA believes that these provisions are good management practices that are intended to ensure product and container integrity. The second provision actually removes a condition on container size from the bulk policy. In other words, it provides more flexibility to registrants and refillers than currently exists.

2. *Changes*. Regarding the list of requirements for refillers, the final regulations are very similar to the proposed rule. However, the structure and order of the final rule was revised to list these requirements in one section. EPA believes this makes the regulations more clear, which should facilitate compliance. The items that refer to existing requirements in 40 CFR parts 167 and 169 were added to the list to provide a more complete reference for refillers. However, these statements simply refer to existing requirements; they don't add new ones.

Adjustments were made to a few of the provisions. Specifically, the requirements in the proposed rule that referred to the registrant's list of acceptable containers were changed to refer to the registrant's description of acceptable containers (see items 3 and 5 above), to accommodate the changes described in Unit VII.N. Also, the proposed regulatory text did not explicitly allow any size refillable container to be used, although the preamble discussed removing the size limit in the Bulk Policy in some detail. Therefore, a sentence clarifying that there are no general limits for the size of refillable containers was added to the statement allowing any quantity of pesticide (up to the container's rated capacity) to be repackaged. (See item 4.)

Specific modifications made to the inspecting, cleaning, labeling and recordkeeping requirements and comments on these standards are discussed in detail in Units VII.P. - VII.S.

The refillable container regulations were modified to clarify that both registrants and refillers are responsible for complying with the stationary pesticide container requirements in § 165.45(f). The final repackaging rule includes this provision in the list of requirements as a reminder for independent refillers.

P. Inspecting Refillable Containers (§§ 165.65(e)and 165.70(f))

1. *Final regulation*. Before repackaging pesticide products into refillable containers, refillers must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings and openings (tamper-evident devices or one-way valves). As with the proposed regulations, inspecting the containers is the responsibility of the refillers, since they are the ones who are actually handling and refilling the containers. If any of the failure conditions in this section are observed during the inspection, the container cannot be refilled unless the problems are rectified and the associated acceptability criterion (either reconditioning according to DOT's requirements or coming into compliance with the refillable container standards in subpart C) is satisfied.

The container fails the inspection and must not be refilled (unless the applicable DOT standards for reconditioning are met) if the integrity of the container is compromised in any of the following ways:

- The container shows signs of rupture or other damage which reduces its structural integrity. [Based on the criterion in 49 CFR 173.28(a)]
- The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects. [Based on the criterion in 49 CFR 173.28(c)(1)(iii)]
- The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation. [Based on the criterion in 49 CFR 180.352(b)(2)(iii)]
- There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container. [Similar to the criterion in

49 CFR 180.352(b)(2)(ii) for service equipment.]

If either of the following conditions exists (or both), the container fails the inspection and must not be refilled until the container meets the refillable standards specified in subpart C. The conditions are:

- The container does not bear the markings required by subpart C or such markings are not legible.
- 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 that these two conditions are written so refillers of antimicrobial products used in swimming pools and related sites would not have to inspect for a serial number (because it's not a marking required by subpart C for these products) or for an intact and functioning one-way valve or tamper-evident device on each opening, because neither is required for these products.

2. *Changes.* The general obligation to inspect refillable containers before repackaging pesticide products into them is the same as the proposed rule. However, EPA made several changes to the details of the inspection. First, we based the conditions for failing the inspection on conditions specified in the DOT regulations in 49 CFR 173.28 and 180.352(b)(2). A commenter suggested this change and EPA believes it is an appropriate modification and is consistent with other changes in the regulation to refer to and adopt the DOT standards for container design, construction and marking. While we don't think the criteria in the final rule are necessarily more stringent than those in the proposed rule, we believe that consistency with DOT is beneficial. Second, the inspection requirement was modified to clarify that if problems found during the inspection are fixed and certain criteria are met, the container can be refilled. Under the proposed standard, it was not clear that a container could be reconditioned or brought into compliance with the refillable container standards and then refilled. Several other minor modifications were made to account for changes in the regulations, including: (1) removing the reference to a standard for the age of the container and (2) clarifying that vents do not need to have one-way valves or tamper-evident devices. Because the refillable container regulations in subpart C exempt antimicrobial products used in swimming pools and related sites from the serial number requirement and the standard requiring a one-way valve or tamper-evident device, the final rule was written so that refillers of these products are not subject to the failure criteria that address serial numbers, one-way valves, or tamper-evident devices.

Q. Cleaning Refillable Containers (§§ 165.65(f) - (g) and 165.70(g) - (h))

1. *Final regulation.* Refillers must clean refillable containers by conducting the pesticide product's refilling residue removal procedure before repackaging the product into the refillable container, unless condition #1 and either condition #2 or #3 are satisfied:

(1) Each tamper-evident device and one-way valve is intact (if required).

(2) The refillable container is being refilled with the same pesticide product.

(3) Both of the following conditions are satisfied.

(A) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.

(B) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container. If a tamper-evident device or one-way valve is not intact, the refiller must clean the container according to the product's refilling residue removal procedure. In addition, the final regulations state in § 165.65(g) for registrants who refill and in § 165.70(h) for independent refillers that other procedures may be necessary in this case to assure that product integrity is maintained.

The first condition is written so it would not apply to refillers of antimicrobial products used in swimming pools because neither a one-way valve or tamper-evident device is required.

2. *Changes.* The biggest change from the proposed regulations is adding the condition where the container is being refilled with the same pesticide product as a case for not needing to clean the container. Some commenters pointed out that the conditions in the proposed regulation and the 1991 amendment to the Bulk Pesticides Enforcement Policy (Ref. 71) would require a refillable container holding a product with multiple active ingredients to be cleaned even when it was refilled with that product. This is true because the proposed rule, based on the 1991 amendment to the Bulk Policy, specified a product with a single active ingredient in a compatible formulation as an acceptable condition for refilling without cleaning. EPA corrected this oversight in the final rule, because refilling with the same product (regardless of how many active ingredients there are) is certainly the most clear way to ensure product integrity and should be allowed (assuming any tamper-evident devices and one-way valves are intact).

Several other minor changes include:

(1) Changing the first condition so it includes one-way valves and not just tamper-evident devices like in the proposal;

(2) Adding ''if required'' to the first condition, since one-way valves or tamper-evident devices are only required on portable pesticide containers for liquids and are not required on the containers of antimicrobial products used in swimming pools;

(3) Using the phrase ''described in its confidential statement of formula that is required under FIFRA section 3'' because it is more straightforward than the proposed phrase as described in Unit VII.H.;

(4) The condition in criterion 3(B) was modified to be more general to account for situations other than reactions or interactions between the two products such as very different active ingredient concentrations that could cause the repackaged product to differ from the confidential statement of formula; and

(5) Splitting the situation of a broken tamper-evident device or one-way valve into a separate paragraph for clarity.

R. Labeling Refillable Containers (§§ 165.65(h) and 165.70(i))

1. *Final regulation.* Before distributing or selling a pesticide product in refillable containers, refillers must ensure that the label of the product is securely attached to the refillable containers such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of 40 CFR part 156. In particular, refillers must ensure that the net contents statement and EPA establishment number appear on the label. This part of the regulations simply re-states requirements from 40 CFR part 156 and FIFRA for clarity.

2. *Changes.* The major change to the labeling requirement was to change it

from an ''active'' standard (i.e., the refiller must securely attach the label) to a ''passive'' standard (i.e., the refiller must ensure that the label is securely attached). Also, the regulatory text was modified to state that the net contents and EPA establishment number appear on the label (rather than the new label as proposed). Both of these changes account for situations where the label is embossed on the container or the container already has an intact label that meets all the requirements. For example, a commenter said that 1–gallon refillable containers for the swimming pool market are embossed with label information because they are refilled automatically at a rate of 100–120 bottles per minute.

S. Recordkeeping (§§ 165.65(i), 165.67(h), 165.70(j))

1. *Final regulation.* All of the companies subject to the repackaging standards must keep certain records, although the specific records vary according to who the company is and what it does. These records must be furnished and made available for inspection and copying upon request of EPA or our designee, such as a State or Tribe. Informational records (listed in the first few rows of Table 16) must be maintained for the current operating year and for 3 years after that. The repackaging records (listed in the last three rows of Table 16) must be generated each time a product is repackaged into a refillable container for distribution or sale and must be maintained for at least 3 years after the date of repackaging. All of the records are product-specific. In other words, this information must be kept for each product distributed or sold in refillable containers. The same cleaning procedure or description of containers can be used for different products, but there must be a record documenting a procedure and a description for each product distributed or sold in refillables.

TABLE 16.—RECORDKEEPING REQUIREMENTS IN THE REPACKAGING REGULATIONS

Product-Specific Record	Registrants who d/s directly in refillables[1]		Registrants who d/s to refillers for repackaging into refillables [1]	Refillers who aren't registrants	
	Swim pool products[2]	All other products	All products	Swim pool products[2]	All other products
Informational Records					
Contract to repackage	No	No	Yes	Yes	Yes
Refilling residue removal procedure	Yes	Yes	Yes	Yes	Yes
Description of acceptable containers	Yes	Yes	Yes	Yes	Yes
Repackaging Records					
EPA registration number of the product distributed or sold in the container	No	Yes	No	No	Yes
Date of the repackaging	No	Yes	No	No	Yes
Serial number of the container	No	Yes	No	No	Yes

[1] ''d/s''= distributed or sold.
[2] Swim pool products = antimicrobial products used in swimming pools and closely related sites, that are subject to the pesticide container-related regulations.

EPA reminds registrants and refillers that the records identified in §§ 165.65(i), 165.6(h) and 165.70(j) of the repackaging regulations do not change other recordkeeping requirements that currently apply to them, such as restricted use product records or applicable records required in 40 CFR parts 167 and 169.

2. *Changes.* EPA made the following significant changes in the recordkeeping requirements in the final regulations:

- The informational records must be kept for the current operating year and for 3 years after that rather than the proposed time period of as long as the pesticide product is distributed or sold in refillable containers and for 3 years thereafter. The specific informational records kept by each of the three categories of businesses is the same in the final rule as in the proposal, although the list of acceptable containers was changed to the description of acceptable containers.
- The repackaging records in the final rule are a subset of what was included in the proposed rule. The final regulations do not include the name or quantity of the product, the name and address of the consignee, a record that the refiller has inspected the container (and the results), and a record of whether a refilling residue removal procedure was conducted (and, if not, why not). Additionally, the date of the distribution or sale (in the proposal) was changed to the date of the repackaging in the final rule.
- Refillers that repackage antimicrobial products used only in swimming pools or closely related sites would not have to comply with the repackaging recordkeeping. However, these refillers would have to comply with the informational recordkeeping.
- The proposed regulations would have required refillers to maintain certain records of containers that were received by them to be refilled, including the name and address of the person providing the container, its serial number, the date it was received and the name and EPA registration number of the product that was last distributed or sold in the refillable container. These records are not being finalized in today's final regulations.

3. *Comments - refiller records*. Many commenters (registrants, registrant groups, State regulatory agencies, a dealer, a dealer group, and an equipment manufacturer) opposed the recordkeeping requirements for refillers. Most of these respondents commented that the proposed recordkeeping requirements were too burdensome and several stated that these standards will discourage the use of refillable containers. A registrant group recommended requiring refillers to maintain records of the serial number, the amount of product placed in the container and the date the refilling took place.

4. *EPA response - refiller records*. EPA modified the refiller recordkeeping requirements to minimize the paperwork burden of maintaining these records. However, EPA believes that some records are necessary to ensure safe repackaging and compliance with these requirements. First, the refiller must have the informational records, including the registrant's contract (if applicable), the refilling residue removal procedure and the description of acceptable containers. These records are necessary so the refiller has the information needed to properly repackage a product into refillable containers and to ensure that an independent refiller has the proper approval from a registrant to repackage the product.

Second, certain information about when a product is repackaged into a refillable container is needed in case there is a problem with a product sold in refillable containers, i.e., it is adulterated or contaminated or it causes damage to the site after application. However, EPA pared the repackaging records down to the minimum amount of information that would allow the refiller and investigators to identify the product, the container, and the date of the repackaging. All of this information is readily available at the time the pesticide product is repackaged into the refillable container, unlike in the proposed rule where the information also included the name and address of the person receiving the container. EPA deleted the requirement to record the results of the inspection and whether the container was cleaned because these records would probably not be useful in enforcement cases. We will be able to determine that a container was not inspected if a container in poor condition (that did not just sustain recent damage) is found and, similarly, we'll be able to tell if a container was not properly cleaned if we find high levels of contamination in the product in that refillable container.

5. *Comments - sodium hypochlorite*. Several respondents from the sodium hypochlorite industry commented on the proposed rule and stated that the refiller recordkeeping requirements would be especially burdensome for this market. One registrant group described a typical sodium hypochlorite delivery, where a truck holding up to 4,000, 1–gallon refillable containers stops at several locations, delivers various volumes of product, and picks up empty containers. This commenter estimated all the recordkeeping standards could triple the time for deliveries and increase the cost of the product by 100 percent. An association representing many businesses involved with swimming pools commented that the requirement for individual serial numbers and the recordkeeping requirements attendant to the serial number marking would be completely unworkable for refillable pool chemical containers. These respondents and a swimming pool supply company stated that the recordkeeping would discourage the use of refillables in the pool chemical industry.

When commenting on the supplemental notice, the registrant group representing the sodium hypochlorite industry reiterated its estimate of the increase in time and costs that could be attributed to the proposed recordkeeping. In addition, a sodium hypochlorite manufacturer requested EPA to exempt all refillable plastic containers of sodium hypochlorite from the requirements for serial numbers, one-way valves, tamper-evident devices and burdensome recordkeeping that would negatively impact the currently used refillable container system.

6. *EPA response - sodium hypochlorite*. EPA was persuaded by the arguments from the companies who repackage sodium hypochlorite into refillable containers for use in swimming pools. Because of the huge number of small (1– and 2.5–gallon) refillable containers used in this market segment, EPA acknowledges that compliance with this recordkeeping would be burdensome. Therefore, the final rule exempts refillers of antimicrobials used in swimming pools and similar sites from the repackaging recordkeeping, although they must comply with the informational recordkeeping.

T. Proposed Standards That Are Not Being Finalized

Final regulation/changes. The following proposed requirements relating to repackaging are not being finalized in today's final rule:

- § 165.134(f): Age of plastic liquid minibulk containers; and
- § 165.136(b): Records on the return of refillable containers to refillers.

The proposed rule would have prohibited a refiller from repackaging a product into a plastic liquid minibulk container more than 6 years after the container's date of manufacture. EPA decided not to finalize this provision to be consistent with the DOT regulations, which do not establish a life limit for plastic nonbulk containers (which may be portable pesticide containers under our regulations) or for plastic intermediate bulk containers (which also may be portable pesticide containers under our regulations).

As discussed in Unit VII.S., EPA is not finalizing the requirement for refillers to keep records on the return of refillable containers to minimize the burden on refillers. Also, this information would have been of limited use because it would not have been sufficient to conclusively identify where a container had been and who had had possession of it.

VIII. Containment

A. Introduction

1. *Regulatory background*. In 1994, EPA proposed standards in subpart H of 40 CFR part 165 for containment of large pesticide containers and procedures for container refilling operations. Standards for pesticide containers, including large storage containers, are covered in Units III. through VII. of this notice, and apply to all pesticides unless specifically exempted. The requirements for a secondary containment unit (either a containment structure around a stationary container, or a containment pad under a container refilling operation) only apply to agricultural pesticides. The requirements are intended to protect human health and the environment from contamination by spills and leaks which may occur during container filling or when a stationary container fails. Affected facilities are required to have structures which intercept and contain spills and leaks of agricultural pesticides in areas where stationary containers are stored and agricultural containers are refilled or cleaned.

Secondary containment means a structure, such as rigid diking, berms or walls, designed to intercept and contain leaks and spills from the enclosed containers. Some States define bulk quantities as a pesticide container with a volume exceeding 55 gallons; others use 210, 300, or 500 gallon criteria. EPA's proposed definition of bulk quantities was 3,000 liters (793 gallons)

for liquid pesticides and 2,000 kilograms (4,409 pounds) for dry pesticides. The final rule establishes quantities of 500 gallons (1,890 liters) for liquids and 4,000 pounds (1,818 kilograms) as the threshold for requiring secondary containment. Thus, EPA's regulations cover only relatively large containers which pose the greatest risk of catastrophic contamination in case of failure.

EPA believes the Federal containment standards, together with requirements for container design and residue removal, are essential for ensuring the safe use, reuse and refill of containers as required by FIFRA section 19. The regulations promulgated today will be located in 40 CFR part 165 in § §165.80 - 165.97.

2. *Summary of proposed and final containment standards.* The proposed and final standards include criteria for design, maintenance and operation of containment structures (units and pads) at certain facilities. The design criteria include standards for material of construction, capacity, and protection from stormwater and precipitation. The facilities subject to the requirements are agricultural pesticide refilling establishments and custom blenders (as defined in § 167.3), and facilities of businesses that apply agricultural pesticides for compensation (also referred to as for-hire applicators in this preamble). In the preamble to the proposal, the Agency explained its rationale for choosing these facilities. Although spills can occur throughout the chain of pesticide commerce (from manufacturer to user), the accumulated evidence points to agrichemical dealerships, custom blenders, and for-hire applicators as facilities where pesticide contamination of soil and water is most frequently documented. (See 59 FR 6750 (Ref. 66) and Unit VIII.C. for a detailed discussion.) The agricultural chemical distribution system has the most potential for spills and a requirement for reporting spills, and is uniquely characterized by the use of large tanks and container refilling operations, often outdoors, while other sectors generally use smaller containers, pre-packaged indoors by a manufacturer.

Standards which are considered critical are required for all existing and new containment units and pads, and some additional criteria are imposed for new containment structures. For this final rule, the criteria identified as critical reflect the comments received and new information, and are not necessarily the same criteria used in the proposed rule. For example, hydraulic conductivity criteria were considered critical in the proposed rule, but, as a result of comments we received on hydraulic conductivity, are not being finalized in the final rule (see discussion in VIII.H).

Many respondents provided comments on specific provisions of the containment regulations. EPA has made certain revisions to the proposed regulations based on these comments. The following units of the preamble discuss the comments received on each of the major issues raised in the proposed rule, any differences between the proposal and the final rule, and the Agency's reasons for making the changes.

Costs and benefits of the rule have been revised from those projected at the time of the proposed rule. Total costs are predicted to be less than estimated in the proposal, due to the changes made as a result of comments and new information.

3. *State secondary containment regulations.* At least 19 States have already promulgated and begun implementing their own secondary containment regulations for bulk storage of pesticides. The 1992 State of the States Report (*Pesticide Storage, Disposal and Transportation*, Ref. 70) cited in the proposed rule showed the wide variety of containment regulations among States. There are variations in the facilities affected, the container volume triggering the requirement for secondary containment, etc. The economic assessment for the proposed rule estimated the number of facilities with bulk pesticide storage in each State based on commercial, State and government business census data. EPA estimated that a total of 5,214 agrichemical dealers in all States and the District of Columbia have containers of a size defined in the proposed rule as bulk (greater than 3,000 liters liquid or 2,000 kilograms dry). (Ref. 21) EPA has reviewed the secondary containment regulations in all 19 States and has found that they are generally comparable to or more stringent than the requirements in today's final rule. These 19 States contain 81 percent (4,220) of the agrichemical facilities regulated by this final rule.

EPA received many comments on the negative impact of the proposed regulations on facilities in States with preexisting regulations. Today's containment standards are intended to introduce basic safeguards in States that currently lack containment regulations and to harmonize with containment requirements in States where adequate containment safety programs already exist. While EPA believes a national standard must provide baseline environmental protection, a mechanism is being provided to accommodate States that are already successfully implementing pesticide containment programs.

4. *Key terms for understanding the requirements of subpart E.* The following terms, defined in § 165.3 of subpart A, are key to understanding the containment standards in subpart E:

(1) Agricultural pesticide.
(2) Appurtenances.
(3) Container.
(4) Containment pad.
(5) Containment structure.
(6) Dry pesticide.
(7) Establishment.
(8) Facility.
(9) Owner.
(10) Operator.
(11) Pesticide compatible.
(12) Pesticide dispensing area.
(13) Refillable container.
(14) Refilling establishment.
(15) Rinsate.
(16) Secondary containment unit.
(17) Stationary pesticide container.
(18) Transport vehicle.
(19) Washwater.

i. *Changes.* Based on commenters' suggestions and additional research, the definitions of the following terms were added to the final rule to clarify the requirements: facility, pesticide compatible, and rinsate.

ii. *Comments.* A regulatory agency in a State with many bulk containment facilities commented that the definition of a stationary bulk container uses the words ''facility'' and ''establishment,'' but only defines the latter. The State agency advised that those trying to avoid the costly container and containment requirements might choose to view this as a legal loophole, and that the term facility should also be defined.

Several State agencies requested that EPA clarify the phrase ''resistant to pesticide,'' because its meaning could be either compatible or unreactive and could be difficult or burdensome to enforce. Alternatives were proposed, including ''chemically compatible,'' defined as the ability of the containment structure materials to withstand anticipated exposure to stored or transferred materials without losing the ability to provide the required secondary containment of the same or other materials within the containment area.

Several State regulatory agencies commented that their regulations require containment of rinsate, and recommend containment for wash waters, because hazardous waste violations at pesticide facilities are often linked to problems with rinsate/wash waters. One State agency asked if a 300–

gallon spill mixed with 600 gallons of cleanup water can be considered rinsate. Another State agency has an expanded definition of rinsate to include recovered sedimentation, washwater, contaminated precipitation, or other contaminated debris.

iii. *EPA response*. The word facility has been added to the list of definitions. The Agency agrees that the phrase pesticide compatible is clearer than pesticide resistant and has changed the regulation accordingly. For the purpose of this regulation, rinsate is being defined as the liquid (usually water) used to rinse the interior of any equipment or container that has come in direct contact with any pesticide. The Agency agrees that it is a good management practice to place rinsate tanks within containment and is recommending that practice, but does not have information on the risks of storage of such dilute pesticides.

B. Purpose (§ 165.80(a))

1. *Final regulations*. The purpose of the containment standards is to protect people and the environment from exposure to agricultural pesticides from spills and leaks, and to reduce wastes produced during pesticide storage, handling or refilling of pesticide containers.

2. *Changes*. This is the same as the proposed purpose in § 165.140.

C. Who Must Comply (§ 165.80(b))

1. *Final regulations*. You must comply with these regulations if you are the owner or operator of a facility that stores pesticides in a stationary pesticide container or conducts any of the regulated pesticide transferring activities and if you are a retailer, for-hire applicator, or custom blender (as defined in 40 CFR 167.3) of agricultural pesticides.

2. *Changes*. This is the same approach and scope that we proposed in § 165.141. The proposed regulations included only retailers, for-hire applicators, and custom blenders because they are the three categories for which EPA has accumulated the most substantial evidence of soil and groundwater contamination by pesticides. The final rule maintains the same scope. These facilities represent only a subset of the realm of operations where containment requirements might be appropriate. The Agency may consider further containment rulemaking for other elements of the pesticide industry if further information indicates that such requirements are needed. In addition, the final rule revises the regulatory language to clarify that the containment regulations only apply to agricultural pesticides. (See Unit VII.L. for a discussion of custom blending and custom mixing.) Also, a description of ''principal business is retail sale'' — more than 50% of total annual revenue comes from retail operations — was added to the final regulation for clarity.

3. *Comments*. Many commenters (dealer groups, dealers, State regulatory agencies, and a distributor/registrant) responding to both the 1994 proposal and the 2004 reopening of the comment period argued for a level playing field and urged EPA to expand the scope of the containment standards to include manufacturing plants, distributors, farms, and non-agricultural facilities. Commenters argued that there are similar potential risks of environmental contamination at any facility that meets the volume, time or activity criteria, regardless of the location of the facility or the type of pesticide, Many commenters (State regulatory agencies, a dealer, a dealer group, an aerial applicator and an aerial applicator group) stated that there are some farms which store and handle more pesticides than some small retailers, and that the regulations should focus on the activity and/or the quantity stored, not the individual storing it.

Commenters to the 2004 **Federal Register** Notice reopening the comment period stated that there have been changes in pesticide use patterns in the 11 years since the regulations were proposed. They stated that equipment technology developments in the handling and application of bulk agricultural chemicals have advanced dramatically, and that these new technologies coupled with the increase in the number of farms with large acreage have led to end users becoming a dramatic growth sector of purchasers of commercial application equipment. A dealer association stated it had surveyed chemical equipment dealers in Kansas and that 20 to 25 percent of all new large commercial application rigs and 80 percent of all used application equipment is currently purchased by end users, most of whom are farmers. The commenter said that using such equipment requires large quantities of chemicals on site and concluded that on-farm bulk storage is growing.

Another dealer association commented in 2004 that by the end of 2006, 70 percent of all crop protection products, mainly herbicides, will be off-patent, creating a marketing opportunity for non-traditional suppliers and chemical brokers. They noted that end users could become direct crop protection customers without appropriate facilities, resulting in increased environmental incidents. The association also stated that at least 58 percent of U.S. farmland is not farmed by the landowner, countering the belief that farmers are better stewards because they have a vested interest in protecting their farmland from contamination. They commented that retailers are professionals trained in handling hazardous materials compared to end users, who tend to have less knowledge and training in safety, containment, and cleanup procedures. A dealer stated that some farmers have become tool shed dealers who store bulk without containment and repackage for neighboring farmers. This point was reinforced by retailers during a meeting in 2004 following the reopening of the comment period (Ref. 31), where the dealer associations and individual dealers reiterated their submitted written comments and cited a growing problem of cash and carry dealers who repackage product on farms illegally without a license.

Several commenters opposed expanding the scope to include farmers. In 2004, the Farm Bureau and associated grower groups opposed any change in the proposed scope. A registrant group recommended that EPA work jointly with State pesticide regulatory officials and industry to devise a method for obtaining reliable data on the number of farmers storing bulk nationwide. The Association of American Pest Control Officials recommended that EPA not expand the scope to farmers without first researching the number, volumes and other pertinent data regarding on-farm bulk practices, an assessment of the risks of on-farm operations, and an analysis of the costs and benefits of on-farm bulk containment.

Several commenters specifically supported requiring non-agricultural pesticides stored in bulk to be subject to the rule. They state that bulk pesticide storage presents potential hazards regardless of use or activity, and that risk may be even higher due to greater population density compared to rural agricultural settings.

EPA response. Due to the large number of commenters in 1994 and 2004 from all sectors who supported requiring farms to have containment for stationary container pesticide storage, the Agency considered the option of expanding the scope of the rule to include farms and other entities. Although the Agency had solicited data on bulk pesticide storage on farms and at non-agricultural facilities in both the 1994 proposed rule and the 1999 supplemental notice, only anecdotal information was received alleging an

increase of stationary container pesticide storage on farms. (Ref. 27)

The Agency therefore researched the issue of whether pesticide storage on farms is a significant problem. The Agency contacted several commenters to the rule for clarification and was unable to confirm that the use of larger spray equipment relates to increased bulk pesticide storage or only to fertilizer storage and application. In cases where bulk storage of pesticide most likely occurs on large farms, such as with metam-sodium, it is not clear that pesticide remains in the tank for 30 days or more. The Agency asked the USDA to contact its sources in the extension network, and Agency staff contacted regulatory representatives and dealers in several States, particularly those with large areas under field crops. In general, the persons contacted knew of few, if any, farms with bulk pesticide storage, with the definition of bulk as 500 gallon containers or greater.

USDA contacted Colorado, where less than 1 percent of farmers potentially store pesticides in bulk, and where minibulks up to 660 gallons are exempt from the requirement for containment if they are approved by DOT or MACA. USDA also contacted Illinois, Kansas and Nebraska. Illinois has implemented new regulations which require farmers to have secondary containment if they meet the volume criteria, so any farmers with large tanks are taking them out of service. They learned that Kansas has three to six farms with bulk pesticides, and most farmers are using 250 gallon minibulks. Nebraska representatives could not estimate how many farms have bulk pesticide, but the most commonly used containers are 85 to 250 gallon minibulks. The only State with hard data was Indiana, which has 65 farmers with bulk storage (defined as larger than 55 gallons), of which 31 reportedly had tanks larger than 500 gallons.

EPA has no data on the existence of bulk storage in non-agricultural facilities. EPA assumes that at such facilities, pesticides are often stored indoors, where the building itself affords some measure of containment. EPA is aware of some isolated mosquito-control facilities which may store pesticides in large stationary tanks during the treatment period, but does not have any way to estimate the existence of such facilities nationwide.

In short, EPA has not received sufficient evidence of contamination at manufacturing plants, distributors, farms and non-agricultural sites to justify regulating them. In the proposed rule, we outlined the data available to the Agency documenting contamination at agricultural retailers, refilling establishments and commercial applicator sites. At least 30 of the references to the proposed rule were State monitoring studies showing contamination at such sites. Data documenting widespread contamination at other facilities were not submitted, and have not been identified.

The consensus, even from commenters who support expansion of the scope to include farmers, is that on-farm bulk storage is still rare. The Agency does not wish to regulate in anticipation of a potential problem, particularly since it is questionable that such a regulation could be enforced on an equitable basis. We recognize the staff and resource restrictions of State agencies, and do not wish to add to their burden in anticipation of a problem which may or may not occur in the future.

The Agency recognizes that all large, stationary tanks have the potential to leak or burst, and considered requiring all stationary tanks, regardless of location, to conform to the containment standards. However, the Agency also believes that the volume through-put of tanks used for retail sale or commercial application of pesticides is higher than that expected for individual farms, resulting in a higher potential risk associated with their usage. The Agency further believes that an end-user who is not significantly involved in resale of product has less opportunity and motivation to finance the purchase of large tanks and the construction of secondary containment.

EPA added a description of the phrase ''principal business is retail sale'' to the final rule so § 165.180(b)(1) states that refilling establishments who repackage agricultural pesticides and whose principal business is retail sale (i.e., more than 50% of total annual revenue comes from retail operations) must comply with the containment regulations. EPA's intent of including the phrase principal business in the 1994 proposed rule was to distinguish between refilling establishments whose principal business is retail sale and refilling establishments whose primary function is formulation or manufacturing of pesticides. The description of principal business was added to the final rule to provide clarification on how to make this distinction. In addition, the information we received during the 2004 comment period about some farmers reportedly repackaging pesticides for sale further supported the need to clarify the meaning of principal business is retail sale. For the reasons discussed in this section, EPA decided not to apply the final containment regulations to farmers. We believe that adding the clarification of principal business to the final rule will help identify the retail facilities that we intend to regulate with § 165.180(b)(1). However, EPA wants to clarify that anyone including a farmer - who is repackaging pesticides for sale or distribution must comply with the existing requirements in 40 CFR part 167 to register their establishments and report their production (repackaging) to EPA and must also keep records of pesticide production according to 40 CFR part 169. In addition, such facilities would be regulated as refillers under this final rule and would have to comply with the refiller requirements in subpart D, Standards for Repackaging Pesticide Products into Refillable Containers. These facilities would have to comply with the containment requirements in subpart E if they repackage agricultural pesticides and if more than 50% of their total annual revenue comes from retail operations.

The Agency is willing to amend the regulation to include such sites if a pervasive pattern of contamination or other handling problems appear at other sites in the future. It is recommended that State and local agencies regulate such facilities at the local level as needed.

D. Compliance Dates (§ 165.80(c))

1. *Final regulations.* All containment structures subject to today's rule must comply with all applicable containment regulations for new and existing structures within 3 years of today's date.

2. *Changes.* The proposed rule required new structures to comply with the containment standards beginning 2 years after publication of the final rule. Existing structures would have been required to comply with interim standards for a period of 8 years, beginning 2 years after publication of the final rule, and then existing structures would have to comply with the same standards as new structures. The interim standards were defined as critical to safe containment, and considered readily implemented within 2 years. The interim period was intended to allow existing structures which have design or structural features not amenable to upgrading without major modification to phase in those modifications over time. The final rule has no provision for an interim period; the final rule applies only one set of requirements to existing structures over their life spans. Both new and existing structures must comply with applicable standards beginning 3 years after publication of the final rule.

3. *Comments.* Many commenters had objections or changes to propose on the interim period. Several respondents commented specifically on the length of the interim period. A registrant thought it should be longer and a State regulatory agency said it should be shortened to 5 years and be based on the structure's age and performance. A State regulatory agency said that the nine critical standards were sufficient and that the only distinction between new and existing facilities should be the compliance date. A dealer opposed the interim period because States already have containment standards and would have to learn two new sets of standards above and beyond existing State rule. Several respondents commented on the different possibilities for an interim period discussed in the preamble. A State regulatory agency supported an age-based approach of setting the compliance date on a formula using 20 years minus the existing containment facility's age. Many commenters (dealers, a dealer group and a State regulatory agency group) opposed setting any standards that are more stringent than existing State standards. A principal reason for opposition was that interim requirements would comprise an extra, unnecessary set of requirements to be learned by regulators and regulated parties, particularly in States with containment programs in place. It would also be costly for existing structures to have to retrofit, particularly in States where facilities had already been constructed to conform with State requirements. Several commenters (State regulatory agencies, a dealer, and a grower group) recommended that EPA grandfather existing containment facilities that are already in compliance with State standards. A State regulatory agency group requested EPA to seriously consider accepting small discrepancies in some standards due to differences in existing State rules and legislation. This commenter said that national uniformity in regulation is desirable, although progress toward this goal should not be at the expense of States that have already enacted rules and statutes that vary slightly from the proposed Federal regulations. A dealer group suggested that EPA set the Federal standards as a baseline, which would allow the proactive work of some States to stand. Many dealers recommended that EPA adopt the Iowa standards in lieu of those in the proposal. A dealer said that making States enforce standards different from their own would cause difficulties for enforcing agencies, distributors, retailers and end users, and a State regulatory agency elaborated, stating that States with containment requirements would have to reinitiate their compliance efforts and would lose credibility and trust of the regulated community. A few State regulatory agencies suggested adding a provision that would use the time during the interim period to collect data about the adequacy of State regulations. If the collected information indicated a State's requirements weren't adequate, EPA could justify compliance with the Federal standards.

4. *EPA response.* The interim period was intended to allow substandard facilities sufficient time to retrofit and come into full compliance with the regulations and for owners to recoup the benefits from the depreciation of their capital investment and financially prepare to upgrade their structure. EPA has maintained a dialogue and information exchange with States and the regulated community (facilities and their associations) since the rule was published in 1994. EPA has decided not to finalize the most onerous and contentious standards from the requirements for existing facilities, such as a hydraulic conductivity standard, thereby significantly reducing the effort and expense needed to comply. EPA believes that 33 months between the reference date for new structures (3 months after publication) and the compliance date (36 months after publication) would provide a reasonable period of time for new structures to be planned and built in compliance with the full requirements of subpart E. If an existing structure does not already comply with the standards for existing structures, EPA believes that the remaining modifications can be readily implemented at existing structures within 3 years. The proposed period of 2 years before compliance may not have provided ample time for facilities to meet the requirements, particularly facilities in locales with significant seasonal constraints on construction. In addition, allowing 3 years as a compliance date for both new and existing structures will allow one year for States with their own containment regulations to apply for an equivalency determination, and still avoid confusion by retaining the same compliance date for all facilities. EPA believes that allowing one more year before implementation will not have a significant adverse impact on the environment, particularly given the many State regulations that are already in effect. This is a shorter time frame than the 5–year phase-in period allowed for the refillable container and repackaging regulations, but given that most States with dealerships have already implemented containment regulations, the Agency considers 3 years sufficient time for facilities to comply. The Agency is allowing 5 years for compliance with the refillable container standards because registrants need to phase out existing containers without recalling them prior to the completion of their normal usable life. The transition period helps distribute costs over time and improve regulatory compliance.

The critical standards cited in the preamble of the proposed rule (59 FR 6765, February 11, 1994) for implementation during the interim period have been modified based on comments, additional research, and evaluation of existing State regulations. The modified standards for existing structures are considered crucial to safe containment and comprise the basic standards demonstrated to be effective for existing structures in States with containment regulations. The following table compares standards in the proposed rule to today's final standards for existing structures. New structures are subject to these standards plus additional standards representing further protectiveness.

TABLE 17.—COMPARISON OF STANDARDS FOR PROPOSED AND FINAL RULE

Standard in Proposed Rule for Existing Structures	Standard in Final Rule for Existing Structures	Additional Standard in Final Rule for New Structures
Construction with rigid materials.	Same.	NA
Use of pesticide-resistant materials.	Use of pesticide-compatible materials.	NA

TABLE 17.—COMPARISON OF STANDARDS FOR PROPOSED AND FINAL RULE—Continued

Standard in Proposed Rule for Existing Structures	Standard in Final Rule for Existing Structures	Additional Standard in Final Rule for New Structures
Hydraulic conductivity no greater than 1 x 10^{-6} cm/sec during interim, 1 x 10^{-7} cm/sec after 10 years.	None. Liquid-tight.	NA
Withstand full hydrostatic head.	Same.	NA
Stormwater run-on protection for a 25-year, 24-hour storm.	Sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it.	NA
Protection of appurtenances and containers.	Same.	Appurtenances configured so leaks can be observed.
Seal joints and cracks and repair any visible damage.	Same.	NA
Inventory reconciliation of liquid remaining in tank during interim only.	None.	NA
Pad capacity 1,000 gallons.	Pad capacity 750 gallons.	Sloped to liquid-tight sump.
Liquid stationary containers - unit capacity 100 percent/110 percent indoor/outdoor minimum during interim, 110 percent/125 percent indoor/outdoor after 10 years.	Liquid stationary containers - unit capacity 100 percent indoor/outdoor minimum.	Liquid stationary - outdoor capacity 110 percent minimum.
Anchoring liquid stationary containers.	Anchoring or elevating liquid stationary containers.	NA
Prevent pesticide-containing material from escaping from containment.	Seal appurtenances, discharge outlets and gravity drains through base or wall of containment unit, including sump. Containment pads may drain to a watertight sump with method of removing accumulated liquids, such as a pump, which transfers contents to aboveground container.	Appurtenances must be configured in such a way that spills or leaks are easy to see.
Dry product stationary container - no capacity requirement during interim, 100% after 10 years.	Dry product stationary container protected from wind/rain with 6-inch berm at least 2 feet from container.	NA
Attended transfers; locked valves; cleanup by the end of day of spill; monthly inspection.	Same.	NA

E. Stationary Containers Included (§ 165.81)

1. *Final regulations*. Stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide are subject to the containment regulations. Containers of less than these volume/weight capacities are not required to be protected with a secondary containment unit. The definition of stationary pesticide container includes transport vehicles that are fixed or remain at a facility for at least 30 consecutive days.

A stationary pesticide container is subject to the containment regulations and must have a secondary containment unit unless it satisfies any one of the following conditions:

- The container is empty, which means that it has been cleared of all pesticide that can be removed by customary methods such as draining, pumping, or aspirating (whether or not residues have been removed by washing or rinsing).
- The container holds pesticide rinsates or wash waters and is so labeled.
- The container holds only pesticides which would be gaseous when released at atmospheric temperature and pressure.
- The container is dedicated and labeled for non-pesticide use.

2. *Changes*. This is not the same subset of stationary containers proposed in § 165.142(a) as subject to, or exempt from, the standards. The three differences are that the: (1) Liquid container size subject to the rule is 500 gallons rather than 793 gallons; (2) dry container size subject to the rule is 4,000 pounds rather than 4,409 pounds; and (3) period of time that a container can remain fixed or at a single facility in order to be considered stationary is 30 days, rather than the 14–day period in the proposed rule.

3. *Comments - holding capacity*. Many commenters (State regulatory agencies, dealer groups, and another government agency) urged EPA to reduce the capacity threshold for containers for which secondary containment is required. Specific alternative suggestions included: (1) 300 gallons for liquids or 100 pounds for dry products; (2) 300 gallons for liquids or 500 pounds for dry products; (3) 500 gallons for liquids or 2,000 pounds for dry products. A registrant group commented in 2004 that packaging experts believe plastic containers larger than 330 gallons would not meet DOT

Packing Group III standards, which they cite as further evidence that containers that size and larger need secondary containment. A State agency stated that they are already seeing a shift in container size (below the regulatory cut-off) in order to be exempt from the State's containment regulations. Another State agency suggested that States have geographical differences and that perhaps EPA should allow individual States to mandate storage limits based on their individual situation. A dealer group and a registrant group jointly commented that containers with a liquid capacity of greater than 330 gallons should be protected by containment. There were no commenters who thought the container size of 793 gallons was appropriate or that it should be larger.

4. *EPA response - holding capacity - liquids*. The Agency recognized that the liquid capacity proposed was substantially greater than volume criteria adopted by many States with containment regulations. These States use lower limit ''bulk'' criteria ranging from 55 to 500 gallons to trigger secondary containment requirements for liquid pesticides. The reasoning for the proposed definition (793 gallons) of liquid bulk container was to be consistent with the DOT definitions in distinguishing between intermediate bulk containers and bulk containers. Since the final containment regulations do not use definitions of bulk or intermediate bulk, the DOT definitions are irrelevant here. As discussed in Unit VI.A., EPA is not finalizing the definitions of minibulk and bulk containers in the final rule. The Agency's intent for the secondary containment requirement is to prevent the most catastrophic spills, and the larger the container, the greater the risk of contamination. The Agency believes contamination from failure of a 500–gallon container would be significant, and agrees with commenters that a 330–gallon container is generally considered the largest size container that can be moved by a fork lift and can be considered mobile. The next most common size used in the field is 500 gallons. The Agency agrees with States that those 500 gallon tanks should be required to have secondary containment, and is lowering the size cut off to capture those tanks and harmonize with existing regulations. The Agency has confirmed by personal communication with some State regulators and extension staff (Ref. 28) that there are few, if any, containers between the sizes of 500 and 793 gallons, (the next most common size after 500 gallons is 1,000 gallons) and expects that today's rule will discourage demand for container sizes in that range in an attempt to be exempt from the containment regulations. The Agency confirmed that 500–gallon tanks are common in the field, and recognizes that the regulations may prompt some demand for tanks slightly smaller (e.g., 450 gallons) in order to be exempt from the Federal requirement. There may always be facilities which try to skirt the law in such ways, but the Agency intended the containment regulations to prevent the environmental consequences from the most catastrophic spills. The smaller the tank size, the less contamination will result from leaks or spills. The Agency also reviewed containment regulations in the 19 States which have them, and determined that the size cut-off which triggers the requirement for secondary containment varies from 55 to 550 gallons, with many states selecting 300– or 330–gallon tanks as the cut-off size. The Agency believes that selecting a volume cut off between 55 and 500 gallons would conflict with some State regulations at a cost to both States and facilities, with no measurable benefit to the environment (Ref. 25) and has therefore selected 500 gallons as a realistic, practical and protective size which triggers the need for secondary containment.

5. *EPA response - holding capacity - dry pesticides*. As with liquid pesticides, the Agency's goal in proposing larger weight criteria for dry pesticides, was to target containers that pose the greatest risk of catastrophic consequences in the event of failure. The proposed size criterion for dry pesticide containers was 4,409 pounds (2,000 kilograms). There were many comments on the size criterion for dry pesticide containers in 1994. Those comments objected specifically to the proposed standard for 100 percent containment capacity for such containers based on the physical nature of a dry spill. The Agency has confirmed with the packaging industry (Ref. 29) that dry pesticides are not packaged in containers between the sizes of 4,000 and 4,409 pounds. Therefore, EPA is lowering the size of the container for which containment is required to 4,000 pounds (1,818 kilograms) for simplicity and clarity, since 4,000 is an easier number to remember for compliance and enforcement purposes, and there is no functional difference between 4,000 and 4,409 pounds for refillable dry bulk containers, since neither size exists. In addition, EPA has replaced the requirement for 100 percent containment capacity for dry pesticides with a requirement for a 6–inch berm in the final rule.

6. *Comments - 14–day residence*. Several commenters suggested increasing the time criterion to 30 days to account for factors beyond the control of the facility. One commenter questioned the associated recordkeeping as burdensome and unclear as to what was required. A registrant requested that EPA exempt packaged product in nonrefillable containers from the 14–day time trigger because it would burden small facilities.

7. *EPA response - 14–day residence*. Although most large containers used at commercial agrichemical facilities are stationary, some containers are actually vehicles (such as tank trucks) used for prolonged storage or repeated on-site dispensing of pesticide at one location. In this case, the primary function of the vessels shifts from pesticide transport to pesticide storage or handling, and therefore containment is required. Since monthly inspection is required at such facilities, EPA believes that it would be reasonable to allow a 30–day maximum residence time without containment requirements, since any transport vehicles temporarily stored would have to be inspected by the owner or operator within that period. The recordkeeping required for stationary containers which do not have secondary containment could simply be a signature of the driver and/or facility owner/operator on a paper listing the driver's arrival date. The regulation is not intended to impose burdensome recordkeeping. The regulations will not affect packaged pesticide in small quantities used by small entities, since the quantities required that would trigger containment requirements are 500 gallons liquid or 4,000 pounds dry pesticide.

F. Pesticide Dispensing Areas Included (§ 165.82)

1. *Final regulations*. Dispensing areas are subject to the requirements for a containment pad if one of the following activities is conducted in the dispensing area:

- Emptying, cleaning, and rinsing of refillable containers that hold agricultural pesticides.
- Dispensing of an agricultural pesticide from a stationary pesticide container of a size holding 500 gallons or more of liquid or 4,000 pounds or more of dry pesticide for any purpose.
- Dispensing of an agricultural pesticide from a transport vehicle to fill a refillable container.
- Dispensing of an agricultural pesticide from any other container for

the purpose of refilling a refillable container for sale or distribution.

A dispensing area is exempt from subpart E requirements for a containment pad if it satisfies any of the following conditions:

(1) The only pesticides handled in the pesticide dispensing area are pesticides which would be gaseous if released at atmospheric temperature and pressure.

(2) The only pesticide containers refilled within the pesticide dispensing area are stationary pesticide containers protected by a secondary containment unit that complies with the requirements of this subpart.

(3) The pesticide dispensing area is used solely for dispensing pesticide from a rail car that is not a stationary pesticide container. However, if a rail car is used as a stationary pesticide container, secondary containment is required.

2. *Changes.* This is the same approach and scope that was proposed in § 165.142(b) for including and exempting pesticide dispensing areas from the requirement for a containment pad. The language in § 165.82(a)(2) has been slightly revised to reflect the lower container sizes, and all of the conditions have been slightly revised to be clearer.

3. *Comments.* As with the scope of facilities subject to the containment requirements above, many commenters responding to both the 1994 proposal and the 2004 Notice (State regulatory agencies, a few dealer groups and a registrant) urged EPA to expand the scope to all permanent areas where the transfer of pesticides from any container occurs, regardless of container size or pesticide type. In particular, they argued for requiring containment pads for mixer/loader activities by farmers or for-hire applicators, citing significant soil and groundwater contamination in agricultural States, and equivalent risk whenever large quantities of pesticides are handled. They noted the possibility that farmers are less well-trained in pesticide management than commercial dealers. State agencies supported including farmer mixer/loader pads in order to strengthen their own regulations.

Arguments by State regulatory agencies, user groups, a registrant, and a registrant group against including farmers in the scope cited the difficulty of monitoring numerous individual farms and lower quantities of pesticides used. Two user groups opposed including farmers because the costs would be significant to farmers and could not be passed on; the costs of monitoring the large number of farm sites would be burdensome; and farm sites generally handle less material, which should result in fewer spills.

4. *EPA response.* As discussed above in Unit VIII.C., *Who Must Comply*, EPA focused on commercial agrichemical facilities because these have the clearest pattern of soil and ground water contamination by pesticides. EPA did not include farms because farms conduct operations on an occasional basis and would not have the same environmental impacts as refilling establishments. Containment on a farm would also be expensive and require year-round maintenance but only be needed on a seasonal basis. EPA does not have a good estimate of the number of farms with stationary bulk storage, nor evidence that significant contamination is occurring at farm sites. Although it follows logically that any area where pesticides are transferred between containers and application equipment may become contaminated, the quantities transferred at dealer and commercial sites for sale to multiple customers are expected to far exceed quantities transferred at individual farms.

EPA noted that the language in § 165.82(a)(4) did not fit the plain-English standard for simplicity and revised it to clarify that the activity of refilling refillable containers for sale or distribution, even if the source container is smaller than the size requiring secondary containment, requires a secondary containment pad. For example, refilling a 15–gallon minibulk from a 400–gallon stationary tank would still require a containment pad if the product was intended to be sold or distributed.

G. Definition of New and Existing Structures (§ 165.83)

1. *Final regulations.* A new containment structure is one whose installation begins more than 3 months after the final rule is published. Installation is considered to have begun if:

(1) You, as the owner or operator, have obtained all Federal, State, and local approvals or permits necessary to begin physical construction of the containment structure; AND

(2) You have either begun a continuous on-site physical construction or installation program OR you have entered into contractual obligations for physical construction of the containment structure. The contract must be such that it cannot be canceled or modified without substantial loss, and must be for the physical construction or installation of the containment structure within a specific and reasonable time frame.

An existing containment structure is one whose installation began on or before the date 3 months after the final rule is published.

2. *Changes.* This is identical to the definitions of new and existing containment structures proposed in § 165.144. However, the general structure of the final rule is different from the proposal, as explained in more detail in Unit VIII.K. The proposed rule would have required existing structures to comply with interim standards for a period of 8 years, beginning 2 years after publication of the final rule, and then existing structures would have had to comply with the same standards as new structures. Instead, the final rule establishes critical design standards for both new and existing structures, and several additional standards for new structures. In other words, certain standards in the final rule apply to all existing structures for their lifetimes. Similar but slightly different standards apply to all new containment structures. As noted earlier, these standards would not apply in States that show that their regulations afford environmental protection at least equivalent to that provided by EPA's regulations.

Also, EPA reorganized the regulatory text so all the design and capacity standards for new structures are grouped together in § 165.85. (See Unit VIII.H.) All the design and capacity standards for existing structures are grouped together in § 165.87. (See Unit VIII.I.) The regulations that follow these two groupings of standards, including but not limited to operational, inspection, maintenance and recordkeeping requirements, apply to both new and existing structures. EPA believes this format is clearer and should facilitate compliance compared to the structure of the proposed rule, which intermingled requirements for the interim period and for new structures.

H. Design and Capacity Requirements for All New Structures (§ 165.85)

1. *Construction materials for new containment structures (§ 165.85(a))*—i. *Final regulations.* New containment structures must be made of steel, reinforced concrete or other rigid material which will withstand the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The construction material must not be natural earthen material, unfired clay, or asphalt, and must be compatible with the stored pesticide.

ii. *Changes.* The proposed rule stated that the construction material had to be

resistant to pesticide. The final rule states that the material must be compatible with the pesticide. The proposed rule also had the following additional requirement for new structures, which is not being finalized in the final rule:

Each new containment structure must have a hydraulic conductivity less than or equal to 1×10^{-7} centimeters per second. During the interim period, each existing structure must have a hydraulic conductivity standard less than or equal to 1×10^{-6} centimeters per second.

iii. *Comments - rigid structures.* A few State regulatory agencies supported requiring rigid structures. One recommended allowing flexible synthetic liners in the base. A university and a registrant supported the use of steel structures. A few State regulatory agencies and a containment materials supplier supported portable rigid or non-rigid structures.

iv. *EPA response - rigid structures.* EPA does not believe that flexible, portable, or non-rigid structures can adequately ensure the permanent and continuous liquid-tight containment of large quantities of agricultural pesticides or of areas where pesticides are transferred and handled regularly. Years of State experience with secondary containment has shown that structures of concrete, steel or other rigid material are effective in containing spills and leaks. Furthermore, as stated in the proposed rule, key technical guidance documents recommend that rigid materials, especially reinforced concrete, be used for structural support in pesticide containment facilities. Industry guidance (Ref. 11) indicates that water-tight concrete can be achieved with nonporous aggregate, high-quality cement paste, proper curing, etc., and that maintenance plays an important role in keeping the structure impermeable to liquids. Although flexible, portable containment structures may be appropriate in certain other situations, EPA believes that durable, rigid materials should be required for stationary pesticide containment at facilities covered in today's final rule.

v. *Comments - hydraulic conductivity.* Several State regulatory agencies supported the hydraulic conductivity standard as proposed. Many commenters (including State regulatory agencies, another agency, registrants, a registrant group, dealer groups, and a dealer) commented that a hydraulic conductivity standard would be difficult to implement, generally citing a lack of methods to verify compliance with such a standard. Some respondents (dealers, State regulatory agencies, registrants and a registrant group) commented that there are no on-site, non-destructive tests to verify hydraulic conductivity. Respondents from a variety of commenter categories opposed the standard as too restrictive, unnecessary, unachievable, and too costly. Some commenters (registrants, a registrant group, and State regulatory agencies) pointed out that RCRA-mandated wood preservative drip pads serve as primary containment, whereas the proposed regulations apply to secondary containment, arguing that the same standard should not apply in both cases. A few State regulatory agencies expressed concern that construction modifications of existing structures to comply with the capacity and hydraulic conductivity standards may not be technically feasible and could penalize proactive States. A few State regulatory agencies and a dealer group commented that there is no evidence of pesticide moving through concrete slabs or unsatisfactory performance by existing concrete structures, and one commenter observed that most releases from secondary containment are through unsealed cracks and installed drains.

Respondents commented on the methods needed to achieve a hydraulic conductivity standard, such as use of coatings, sealants, and liners. A State regulatory agency supported the use of sealants and coatings and a few dealer groups acknowledged that coatings on concrete would extend the useful life of the structure and make it less permeable. Many commenters expressed concerns about the use of coatings and sealants on containment structures, for reasons such as: coatings can cover cracks and problems that would not be visible (dealer, dealer association and a State regulatory agency); abrasion from traffic (State regulatory agency) and deterioration of sealants due to ultraviolet light (registrant group and several registrants) could prevent a structure from maintaining compliance; and high cost of maintenance and replacement. Some commenters (dealer groups, State regulatory agencies) suggested qualitative alternative ways to implement an impermeability standard: liquid-tight with cracks, seams and joints sealed; spill retention; leakproof, coupled with permit and other requirements; leakproof and constructed with materials resistant to pesticides. A State regulatory agency observed that most releases from secondary containment are through unsealed cracks or installed drains.

vi. *Comments - hydrostatic head.* A few State regulatory agencies argued that a requirement for construction to withstand full hydrostatic head would require dike walls to be unreasonably thick in order to withstand a very rare but not impossible tidal wave impact of a large tank rupture. A dealer group urged EPA to replace the standard with the following language from the Association of American Pest Control Officials (AAPCO) model rule: ''Secondary containment shall be constructed of sufficient thickness, density, and composition so as to contain any discharged material...''

vii. *EPA response - hydraulic conductivity and hydrostatic head.* Based on the comments and additional research, EPA agrees that the proposed hydraulic conductivity requirements would be unnecessarily burdensome, and that rigid walls of chemically compatible material have been proven effective in controlling accidental spills. The 1×10^{-7} cm/sec standard was based on the hydraulic conductivity requirement found in current RCRA requirements for wood preservative drip pads in subpart W of 40 CFR parts 264 and 265. EPA agrees that secondary containment structures are intended to catch and briefly retain spills and releases, not store them indefinitely, and recognizes the difficulty in verifying hydraulic conductivity. The Agency has therefore decided not to finalize the standards for hydraulic conductivity. The Agency disagrees that the requirement to withstand full hydrostatic head is unreasonable. It is a requirement in many State containment regulations. The final rule was modified slightly to delete the phrase (dynamic or static) because that phrase adds more confusion than clarity. However, EPA believes that the standard of being ''capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation...'' requires the secondary containment unit to be able to contain a catastrophic spill. EPA believes that using industry construction guidance on concrete quality and reinforcement bars will ensure that containment structure's integrity in the case of a catastrophic spill of a large tank.

2. *General design requirements for all new containment structures (§ 165.85(b))*—i. *Final regulations.* These are the general design requirements for new containment structures:

(1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

(2) Appurtenances, discharge outlets, or gravity drains must not be configured

through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart. Appurtenances must be configured in such a way that spills or leaks are easy to see.

(3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.

(4) Multiple stationary pesticide containers may be protected within a single secondary containment unit. The volume of the largest container determines the capacity requirement of the unit.

ii. *Changes*. Requirements in § 165.85(b)(1) and (2) are identical to those proposed in § 165.146(b). Paragraph (4) is added to clarify a statement in the proposed rule under § 165.152. The requirement in § 165.85(b)(3) has been changed. In the proposed rule, the requirement was to prevent storm water run-on from seeping into or flowing onto it from adjacent land or structures during a 25–year, 24–hour rainfall event.

iii. *Comments - storm protection*. Several respondents (a registrant and two State regulatory agencies) supported the stormwater control provision. Several others (a dealer group and two State regulatory agencies) suggested alternative language, such as diverts water, no discharge, or constructed to prevent any surface water from moving onto or across the structure. Several commenters (a dealer group, a registrant group and two State regulatory agencies) noted that it would be difficult to comply because (1) a watershed runoff study would be needed; (2) the 25–year, 24–hour criterion would be difficult to determine at different sites; (3) rainfall varies substantially from year to year. A few State regulatory agencies commented that the stormwater control standard doesn't adequately address precipitation and stated that the containment capacity requirements must be based on rainfall volume, such as a 25–year, 24–hour rainfall event. A few dealers recommended the example of the Illinois pesticide containment rule, which requires that stormwater be diverted from containment structures.

iv. *EPA response - storm protection*. A 25–year, 24–hour storm is commonly used as a benchmark for the capacity of secondary containment structures, and is recommended in the National Pollution Discharge Elimination System (NPDES) Best Management Practices Guidance Document.(Ref. 74) EPA believes that, just as a 25–year, 24–hour storm is a reasonable criterion for stormwater retention (prevention of run-off), it would also serve as sufficient freeboard and a reasonable standard for prevention of stormwater seepage and run-on from adjacent lands or structures. Such a standard allows flexibility for varying climatic conditions. It is also the standard required for certain tank systems storing or treating hazardous waste. See, for example, 40 CFR 265.1(e)(1)(ii) and (e)(2)(ii). However, the Agency has decided not to require a 25–year, 24–hour storm criterion here in order to be consistent with the final EPA rule on Oil Pollution Prevention and Response: Non-Transportation-Related Onshore and Offshore Facilities (67 FR 47042, Ref. 47). The Oil Prevention Rule states that while a 25–year, 24–hour storm event standard is appropriate for most facilities and protective of the environment, it may be difficult and expensive for some facilities to secure recent information concerning such storm events at this time. Recent data do not exist for all areas of the United States, or may be costly for small operators to secure. Should recent and inexpensive information concerning a 25–year, 24–hour storm event become easily accessible for every part of the United States, we will reconsider proposing such a standard. Instead, at this time, we are requiring, as a few commenters suggested, that the containment structure have sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures. Most States with containment regulations do not use a 25–year, 24–hour storm criterion, and have indicated that, in their experience, requiring a numerical capacity (110 percent) or sufficient freeboard to accommodate local precipitation conditions provides adequate protection.

3. *Capacity requirements for new stationary liquid pesticide containment units and new containment pads in pesticide dispensing areas (§ 165.85(c))*—i. *Capacity for new stationary liquid pesticide containment units—Final regulations*. These are the capacity requirements:

- New secondary containment units for stationary liquid containers, if protected from precipitation, must have a capacity of at least 100 percent of the volume of the largest stationary container plus the volume displaced by other containers and appurtenances within the unit.
- New secondary containment units for stationary liquid containers, if exposed to or unprotected from precipitation, must have a capacity of at least 110 percent of the volume of the largest stationary container plus the volume displaced by other containers and appurtenances within the unit.

a. *Changes*. The proposed rule required higher capacity of 110 percent for units protected from precipitation and 125 percent for units exposed to precipitation.

b. *Comments*. Several State regulatory agencies supported the proposed standards, stating that adjusting the standard to reflect variable rainfall would add confusion. Many commenters (dealers, dealer groups and a State regulatory agency) supported instead the standard that EPA had proposed for the interim period for existing structures, namely 100 percent/110 percent capacity (indoor/outdoor). Reasons cited included: (1) Many dikes that meet this standard have been in place for years with no overflows; (2) EPA provides little or no justification that capacity in excess of 100 percent of the volume of the largest container is necessary; (3) modifying a dike to add additional capacity would be expensive; and (4) many Midwestern States have adopted the 100 percent/110 percent standard from the AAPCO model rule.

c. *EPA response*. EPA agrees with comments based on practical field experience and has reduced the volumes needed to 100 percent and 110 percent, respectively for indoor and outdoor units. The 110 percent criterion for storage areas without roofing adds an extra margin of safety for retention of precipitation. An extra 10% is not needed indoors as long as the displaced volume or other containers is added. However, the Agency recognizes that, for enforcement purposes, it may be difficult to reconcile capacity with climatic conditions. For example, in the case of a 2–inch rain, capacity at a new outdoor liquid pesticide facility could be temporarily reduced to less than 110 percent of the largest tank if that tank were full, and the facility would no longer be in compliance. To avoid disputed calculations of capacity, the Agency recommends that facilities make allowances for additional capacity beyond the 110 percent required, such as 125 percent, to build in a margin of error.

ii. *Capacity for new containment pads in pesticide dispensing areas*—i. *Final regulations*. These are the capacity requirements:

- New containment pads in pesticide dispensing areas subject to the regulations in this subpart which have a pesticide container or pesticide-holding equipment with a volume of

750 gallons or greater must have a holding capacity of at least 750 gallons.

• New containment pads in pesticide dispensing areas subject to the regulations in this subpart which do NOT have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.

ii. *Changes.* The proposal required that pads have a minimum holding capacity of 1,000 gallons, or, if no equipment used on the pad exceeded 1,000 gallons, at least 100% of the capacity of the largest container or equipment used on the pad. Today's rule reduces the minimum pad holding capacity to 750 gallons in the most likely scenario where large (greater than 750 gallon) containers or pesticide-holding equipment will be on the pad. Additionally, the capacity requirement refers to gravity capacity, as defined in oral comments by Wisconsin state regulatory officials (Ref. 46) in 2003. The gravity capacity of a sump or containment structure is the capacity before any method of removing or transferring the contained liquid by pump or other means is employed. For example, a facility is prohibited from claiming a capacity of 750 gallons if the sump or containment structure has an actual capacity of less than 750 gallons but is serviced by a pump which transfers accumulated liquid into holding tanks such that the effective capacity would be 750 gallons. Since achieving 750–gallon storage capacity under those circumstances relies on the proper and dependable functioning of a pump as well as a continual supply of fuel or electrical current to run the pump, this is not an acceptable way of achieving the required capacity because if these conditions are not met, a spill is more likely.

iii. *Comments.* Indiana state regulators argued that the state had spent three difficult years and had invested considerable resources in implementing its regulations, which require a pad capacity of 750 gallons. They stated that to get the cooperation and voluntary compliance of the impacted industries, they had to suggest to those making the investment that there would be no significant changes in requirements. To reverse themselves now, they stated, would jeopardize their credibility. Illinois, a state with over 1,000 bulk facilities, suggested that the pad capacity requirement should take into account the additional volume of a 6–inch rainfall (the volume expected from a 24–year, 25–hour storm). A few State regulatory agencies did not object to EPA's proposed pad capacity requirements, although their State regulations are slightly more stringent. A State regulatory agency noted that the difference between 750 gallon and 1,000 gallon capacity would do little to accommodate a spill from a 3,000 gallon delivery truck.

iv. *EPA response.* The Agency did not have a technical basis for choosing the 1,000 gallon capacity in the proposed rule, but based it on a review of proposed and actual State containment regulations. Based on comments and subsequent research, we determined that the criteria of 750 gallons used in some States has proven adequate. We believe that in most actual situations of spillage on a pad, 750 gallons would be adequate, especially since product transfers must be attended under the requirements of this subpart. In a catastrophic event, neither 750 gallons nor 1,000 gallons would be sufficient to contain a large spill, and the added cost of increasing capacity to 1,000 from 750 would exceed any marginal environmental benefit. The Agency also agrees with Wisconsin State regulators that a 750–gallon pad may be as small as 12 feet square, and that a top-loaded tank may risk splashing during the refilling process. Consequently, while we are lowering the gallon capacity to 750 gallons of gravity capacity, we are recommending that the pad have a minimum size of 15 feet by 15 feet (or 225 square feet). Additionally, for new operational pads unprotected from precipitation, we recommend constructing a pad with a gravity capacity of 1,000 gallons.

4. *Specific requirements for new stationary liquid pesticide containment units (§ 165.85(d))*—i. *Final regulations.* In addition to meeting the requirements of § 165.85(a), (b) and (c), each new stationary liquid container protected by a secondary containment unit must either be anchored or elevated to prevent flotation in the event that the secondary containment unit fills with liquid.

ii. *Changes.* The proposed rule required that the containment unit had to allow for observation of leakage from the base of any enclosed stationary pesticide container. Thus, a flat-bottomed container would have had to be elevated so that leakage would be visible. In addition, the proposed rule required that flotation of the container, in the event the containment filled with liquid, be prevented by either elevating or anchoring the container. The final rule requires either elevation or anchoring in response to comments that argued that elevating containers is not necessary to detect leaks and may engender risks from inadequate support devices.

5. *Specific requirements for new containment pads in pesticide dispensing areas (§ 165.85(e))*—i. *Final regulations.* In addition to meeting the requirements for § 165.85(a), (b) and (c), each new containment pad in a pesticide dispensing area must:

• Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.

• Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.

• Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

• Have its surface sloped toward a liquid-tight sump where liquids can be collected for removal.

ii. *Changes.* These requirements are identical to those in § 165.152(b) of the proposed rule. The proposed rule noted that tanker trucks are considerably larger than containers or equipment normally used on the containment pad, but that such deliveries are not expected to be frequent, and did not propose that the pad had to be large enough to accommodate the entire vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides, since the primary function of such a vehicle would be pesticide storage rather than transport. EPA reasons that the full containment requirements imposed on fixed containers would also apply to non-fixed containers that remain at an applicable facility for at least 30 days.

6. *Specific Requirements for new stationary dry pesticide containment units (§ 165.85(f))*—i. *Final regulations.* In addition to the requirements in § 165.85(a) and (b), each new stationary dry pesticide containment must meet the following requirements:

• The stationary dry pesticide containers within the containment unit

must be protected from wind and precipitation.

- Stationary dry pesticide containers must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.
- The stationary dry pesticide container storage area must be enclosed by a curb that is a minimum of a 6 inches high and that extends at least 2 feet beyond the perimeter of the container.

ii. *Changes*. The proposal required that dry bulk secondary containment units have a capacity of 100 percent of the largest container plus the volume displaced by other containers and appurtenances within the containment. The Agency was concerned that dry pesticide could still mix with rainwater, fire suppression water, etc., to reach and contaminate groundwater and soil. The proposed rule did not have any provisions for protection from wind and precipitation, nor for elevated storage to prevent water accumulation under the pesticide, but did request comment on such options. The final rule does not have a numerical capacity requirement.

iii. *Comments*. Several commenters (State regulatory agencies and a dealer group) opposed the 100 percent proposed capacity as excessive, since dry materials do not spread and disperse like liquid materials. Several State regulatory agencies suggested that dry bulk secondary containment should be protected by roofing or similar cover from wind and precipitation, which would make 100 percent capacity unnecessary. One State noted that it already has dry bulk containment regulations which require that the containers be raised off the floor, and several States require at least a 6–inch curb around an area extending at least 2 feet beyond the perimeter of the bulk tank. A registrant stated that the typical practice is to store dry pesticides under a roof. Some commenters offered alternative strategies, generally based on existing State regulations, including a curb 6 inches high at least 2 to 3 feet beyond the perimeter.

iv. *EPA response*. EPA has reviewed State bulk storage regulations and best management practices for storing dry bulk pesticides and has noted that States require storage under a roof and, if outdoors, on pallets or raised concrete platforms, and that the most common requirement for dry bulk is a 6–inch berm at least 2 to 3 feet from the container. (Ref. 34) Given that the States with the most experience with dry bulk storage have the most practical experience with dry spill containment, EPA agrees with the common sense arguments of commenters regarding protection from precipitation, elevation, and the flow properties of dry material, and has changed the dry containment requirement accordingly. In regard to roofing, EPA believes that the advantages of keeping rainwater out of containment will outweigh the cost of installing a roof. However, in arid regions, a roof may not be cost-effective, and if EPA provided roofing specifications, it is possible that they would conflict with local construction requirements and building codes. Therefore, the final rule requires protection from wind and precipitation rather than specifically requiring a roof to allow some flexibility. The Agency agrees that 100 percent capacity, given that dry materials spread differently that liquids, would be excessive. We also recognize that significant quantities of dust may be generated during the refilling process, where the dry product is a dust, granules or flowable formulation. While today's rule makes no requirement for dust minimization or collection, we recommend that every effort be made to contain the dust generated, both for the respiratory protection of the persons attending the transfer and for the preservation of air and soil quality in the vicinity of the facility.

I. Design and Capacity Requirements for Existing Structures (§ 165.87)

1. *Construction Materials for all existing containment structures (§ 165.87(a))*—i. *Final regulations*. Existing containment structures must be made of steel, reinforced concrete or other rigid material which will withstand the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The construction material must not be natural earthen material, unfired clay, or asphalt, and must be compatible with the stored pesticide.

ii. *Changes*. The requirements in § 165.87(a) for existing structures are identical to the requirements for construction materials for new containment structures in § 165.85(a). The proposed rule stated that the construction material had to be resistant to pesticide, while the final rule requires the material to be compatible with the stored pesticides. In addition, the following proposed standard for existing structures is not being finalized:

During the interim period, each existing structure must have a hydraulic conductivity standard less than or equal to 1 x 10^{-6} centimeters per second. After the interim period, each new containment structure must meet the hydraulic conductivity standard for new structures of less than or equal to 1 x 10^{-7} centimeters per second.

iii. *Comments*. General comments and EPA's response on construction material are discussed in Unit VIII.H.1. EPA believes that existing structures should easily meet these requirements based on the information we have gathered. We are not aware of secondary containment units being constructed of any of the prohibited materials. We are aware of the existence of some asphalt containment pads, but we believe these are mostly used by aerial applicators that probably are not subject to these regulations because they do not have large stationary pesticide containers.

2. *General design requirements for all existing containment structures (§ 165.87(b))*—i. *Final regulations*. These are the general design requirements for existing containment structures:

(1) Protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

(2) Seal (permanently close) all appurtenances, discharge outlets and gravity drains through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart.

(3) Construct the containment structure with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.

(4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.

ii. *Changes*. Requirements are similar to those proposed in proposed § 165.146, except that (4) is added to clarify a statement in the proposed rule under § 165.152. The requirement in paragraph (2) was proposed for existing structures 10 years after the publication date of the rule (at the expiration of an interim period that was proposed for existing units. See discussion on compliance dates in Unit VIII.D. above.) In addition, at the end of the interim period, existing structures had to meet the requirements for new structures, including configuring appurtenances in such a way that leaks and spills could be readily observed. The final rule requires facilities with existing structures to seal appurtenances, discharge outlets and gravity drains at the base and walls. EPA believes it is

necessary for existing structures to comply with this requirement because some studies cited in the proposed rule estimated that 30 percent of the reported pesticide spill incidents resulted from appurtenance failure, and many releases were reported from discharge outlets and gravity drains. Requirements in paragraph (3) have also been changed. In the proposed rule, the requirement was to prevent storm water run-on from seeping into or flowing onto it from adjacent land or structures during a 25–year, 24–hour rainfall event. The requirement has been changed to ensuring sufficient freeboard to prevent run-on. The comments on general design requirements and EPA's responses are discussed in Unit VIII.H.2.

3. *Capacity requirements for existing stationary liquid pesticide containment units and existing containment pads in pesticide dispensing areas (§ 165.87(c))*—i. *Capacity for existing stationary liquid pesticide containment units*—a. *Final regulations.* Each existing stationary liquid pesticide containment unit must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

b. *Changes.* The proposed rule required a capacity of 100 percent for existing liquid bulk containment units protected from precipitation and 110 percent for units exposed to precipitation for the 8–year interim compliance period. At the expiration of the interim period, the capacity requirements would be the same as those proposed for new structures, that is, 110 percent for units protected from precipitation and 125 percent for outdoor, unprotected units. The approach of having an interim period is not being finalized. The final rule requires existing liquid pesticide containment units to have capacities of 100 percent whether protected from precipitation or not.

c. *Comments.* The comments on capacity requirements for new and existing stationary liquid pesticide containment units are discussed in the comment section under Unit VIII.H.3.a. In addition, many commenters noted that changes in capacity requirements for existing structures would require major modification, re-certification by an engineer and significant costs. A few State regulatory agencies noted that little if any additional benefit will be afforded by requiring extra capacity, and that they had never experienced a breach of containment structure based on existing laws.

d. *EPA response.* As discussed in Unit VIII.H.3., EPA agrees, based on field experience, that the proposed capacity requirements were excessive and has reduced the capacity requirements in the final rule. In addition, the Agency is not requiring a numerical standard of 110 percent for existing unprotected units (in contrast to the requirements for new unprotected units) in order to harmonize with existing State containment regulations which have chosen to require unprotected units to have 100 percent capacity plus either a 6–inch freeboard or capacity to withstand a 25–year/24–hour storm. The Agency understands that some existing units would need to retrofit to meet a 110 percent capacity requirement, and that the burden of adding the extra capacity appears to outweigh any benefit of the extra capacity. The Agency recognizes that States may have existing structures in low-precipitation areas, and is allowing them the flexibility to define capacity requirements above 100 percent according to local conditions.

ii. *Capacity for Existing containment pads in pesticide dispensing areas*— a. *Final regulations.* Existing containment pads with pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons. Pads which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.

b. *Changes.* The proposal required that existing pads have a minimum holding capacity of 1,000 gallons or 100 percent of the capacity of the largest container or equipment used on the pad. The final rule reduces the minimum pad holding capacity to 750 gallons in the most likely scenario where large (greater than 750 gallon) containers or pesticide-holding equipment will be on the pad. Comments and EPA responses apply as discussed in Unit VIII.H.3. for new containment pads.

4. *Specific design requirements for existing stationary liquid pesticide containment units (§ 165.87(d))*—i. *Final regulations.* In addition to the requirements in § 165.87(a), (b) and (c), each existing stationary liquid pesticide container protected by a secondary containment unit must be adequately elevated or anchored to prevent flotation in the event that the secondary containment unit fills with liquid.

ii. *Changes.* This requirement is identical to that proposed in § 165.148(b)(2). In the proposed rule, existing secondary containment units would have had to allow for the observation of leakage from the base of all stationary bulk containers after the interim period expired. As explained in Unit VIII.H.4., the standard for observing leakage from the base of stationary bulk containers is not being finalized.

5. *Specific design requirements for existing containment pads in pesticide dispensing areas (§ 165.87(e))*—i. *Final regulations.* In addition to meeting the requirements for § 165.87(a), (b) and (c), each existing containment pad in a pesticide dispensing area must:

- Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.
- Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.
- Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

ii. *Changes.* The requirements in the final rule are identical to those in the proposal. The proposed rule noted that tanker trucks are considerably larger than containers or equipment normally used on the containment pad, but that such deliveries are not expected to be frequent, and did not propose that the pad had to be large enough to accommodate the entire vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides, since the primary function of such a vehicle would be pesticide storage rather than transport. In addition, the proposed rule required that, at the expiration of the interim period, each existing containment pad would be sloped to a liquid-tight sump where liquids can be collected for removal. The interim period has been deleted, and the requirement for sloped pads is not being finalized for existing containment pads. The requirement for sloped pads applies only to new containment pads in the final rule.

6. *Specific design requirements for existing stationary dry pesticide*

containment units (§ 165.87(f))—i. *Final regulations*. In addition to the requirements in § 165.87(a) and (b), each existing dry stationary pesticide containment must meet the following requirements:

- The containment must protect stationary dry pesticide containers within it from wind and precipitation.
- Dry stationary pesticide containers must be stored on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.
- The container storage area must be enclosed by a minimum of a 6–inch high curb that extends at least 2 feet beyond the perimeter of the container.

ii. *Changes*. The proposal required that dry bulk secondary containment units have a capacity of 100 percent of the largest container plus the volume displaced by other containers and appurtenances within the containment. The proposed rule did not have any provisions for protection from wind and precipitation, nor for elevated storage to prevent water accumulation under the pesticide. The final rule does not have a numerical capacity requirement. All modifications must now be made within 3 years instead of the 10 years in the proposed rule, but the requirements are modified and simplified such that the Agency believes they are feasible within the 3–year period. See Unit VIII.H.6. for a summary of the significant comments and EPA's responses.

J. Operational, Inspection and Maintenance Requirements (§ 165.90)

1. *Operating procedures for all new and existing pesticide containment structures (§ 165.90(a))*—i. *Final regulations*. An owner or operator of a new or existing pesticide containment structure must:

- Manage the structure in a manner that prevents pesticides or materials containing pesticides from escaping from the containment structure (including, but not limited to, pesticide residues washed off the containment structure by rainfall or cleaning liquids used within the structure.)
- Ensure that pesticide spills and leaks on or in any containment structure 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.
- Ensure that all materials resulting from spills and leaks and any materials containing pesticide residue are managed according to label instructions and applicable Federal, State and local laws and regulations.
- Ensure that transfers of pesticides between containers, or between containers and transport vehicles are attended at all times.
- Ensure that each lockable valve on a stationary pesticide container, if it is required by § 165.45(f), is closed and locked whenever the facility is unattended.

ii. *Changes*. These requirements are substantially the same as those proposed in § 165.146(c). The order of the standards and several minor wording modifications were made to improve the clarity of the requirements.

2. *Inspection and maintenance of all new and existing pesticide containment structures (§ 165.90(b))*—i. *Final regulations*. The owner or operator of each pesticide containment structure must:

- Inspect each stationary pesticide container and its appurtenances at least monthly during periods when pesticides are being stored or dispensed on the containment structure. Your inspection must look for visible signs of wetting, discoloration, blistering, bulging, corrosion, cracks or other signs of damage or leakage.
- 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.
- Not store any pesticide on a containment structure if the structure fails to meet the requirements of this subpart until suitable repairs have been made. Prompt removal of pesticides, including emptying of stationary containers, in order to effect repairs or recovery of spilled material is acceptable.

ii. *Changes*. These inspection and maintenance requirements are substantially the same as those proposed in § 165.146(d). A few minor modifications were made to improve the clarity of the language. In addition, several changes were made to be consistent with other changes in the regulations. In particular, EPA decided not to finalize the hydraulic conductivity standard, so the corresponding inspection and maintenance requirement is also not being finalized. Also, the final rule specifies that the containment structure be compatible with the pesticides, rather than resistant as proposed. The corresponding inspection and maintenance standard was changed accordingly.

K. Combined Pads and Units (§ 165.92)

1. *Final Regulation*. Facility owners and operators may combine containment pads and secondary containment units as an integrated system provided the requirements set out in this subpart for pads and units in §§ 165.85(a) and (b), 165.87(a) and (b) and 165.190, and as applicable, §§ 165.85(c)-(f) and 165.87(c)-(f) are satisfied separately.

2. *Changes*. This provision for allowing integrated containment systems is substantially the same as that proposed in § 165.153.

L. Recordkeeping (§ 165.95)

1. *Final regulations*. Facility owners and operators subject to the requirements of this rule must maintain the following records, and must furnish these records for inspection and copying upon request by any employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

- Records of inspection and maintenance for each containment structure and for each stationary pesticide container and its appurtenances must be kept for 3 years and must include the following information:
- name of the person conducting the inspection or maintenance;
- date the inspection or maintenance was conducted;
- conditions noted;
- specific maintenance performed.
- Records for any non-stationary container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide that holds pesticide but is not protected by a secondary containment unit meeting today's regulations must be kept for 3 years. Records on these non-stationary pesticide containers must include the time period that the container remains at the same location.
- Records of the construction date of the containment structure must be kept for as long as the pesticide containment structure is in use, and for 3 years afterwards.

2. *Changes*. The proposed rule required additional recordkeeping of inventory reconciliation for existing bulk liquid containers that were not elevated during the interim period. The proposed rule also required owners and operators to maintain records of written confirmation of hydraulic conductivity and statements of resistance to pesticide for as long as the structure was in use,

and for 3 years thereafter. These requirements are not being finalized, so the corresponding recordkeeping requirements are also not being finalized. Since the standards differ depending on whether the facility was considered existing or new at the time of this final rule, a new recordkeeping requirement has been added: each facility must maintain records of the construction date of the containment structure for as long as the pesticide containment structure is in use, and for 3 years afterwards.

M. States With Existing Containment Programs (§ 165.97)

1. *Final regulations.* States that have promulgated containment regulations effective prior to August 16, 2006, and which also have primary enforcement responsibility and/or certification programs, have the option of continuing to implement their own programs in lieu of today's Federal regulations under certain conditions.

A State that wishes to continue implementing the State's containment regulations must request the authority to do so by August 16, 2007 in the following manner:

- The State must submit a letter and any supporting documentation to EPA. Supporting documentation must demonstrate that the State's program is providing environmental protection equivalent to that expected to be provided by the Federal regulations in 40 CFR subpart E.
- The State must identify any significant changes to State regulations which would be necessary in order to provide environmental protection equivalent to the EPA regulations, and develop an estimated timetable to effect these changes. The letter must be signed by the designated State Lead Agency (SLA).

EPA's Office of Pesticide Programs (OPP), in collaboration with the EPA Regions and other EPA offices, will review the State's correspondence and determine whether the State's program is adequate to provide environmental protection equivalent to or more protective than these Federal regulations for new and existing containment structures. OPP will inform the State of its determination through a letter authorizing or declining to authorize the State to continue implementing its containment regulations and will detail any reasons for declining authorization.

Any State that has received authorization to continue implementing its State containment regulations must inform EPA by letter signed by the designated State Lead Agency within 6 months of any revision to the State containment regulations. EPA will inform the State by letter if it determines that the State's containment regulations are no longer adequate based on the revisions. The State containment regulations will remain in effect, unless and until EPA sends the State a letter making this determination.

2. *Changes.* The proposed rule made no provision for States to implement their own containment regulations in lieu of EPA's rule.

3. *Comments.* Many commenters to the 1994 proposed rule (dealers, a dealer group, a State regulatory agency group and individual State regulatory agencies) opposed setting any Federal standards that are more stringent than existing State requirements. They requested that EPA accept current State rules and statutes where the discrepancies are not significant from Federal standards. The State regulatory agency group requested EPA to seriously consider accepting small discrepancies in some standards due to differences in existing State legislation, and said that while national uniformity in regulation is desirable, it should not be at the expense of States that have already enacted rules that vary slightly from the Federal rule. A dealer group suggested that EPA set the Federal standards as a baseline, which would allow the proactive work of some States to stand and would preclude dealers from incurring the same economic burdens twice (i.e., to build and then rebuild containment structures).

Several commenters (State regulatory agencies, a dealer, and a grower group) recommended that EPA grandfather existing containment facilities that are in compliance with State standards or that are comparable in function, design, and construction. Similarly, a grower group said that State rules for bulk containment should take precedence over this proposal. A State regulatory agency elaborated on these difficulties, stating that States with containment requirements would have to reinitiate their compliance efforts and would lose credibility and the trust of the regulated industry, with whom they worked closely to develop and implement the State rules.

A dealer commented that forcing States to enforce different rules from their own would cause difficulties for the enforcing agency, distributors, retailers and end users who will have to learn an extra set of requirements. A few State regulatory agencies commented that millions of dollars have been spent by industry on compliance with State regulations, some of which have been in place since 1985, and that containment structures have not had failures when built to State standards. They recommended that the final rule be crafted to harmonize with State or other environmental statutes, and that it should not penalize States which have spent years building effective relationships with the regulated community for safe pesticide handling.

Similarly, many commenters to the 2004 Notice reiterated these arguments and said States have taken a pro-active role and have enacted pesticide containment regulations which have proven to be protective of the environment and which EPA should accept by a grandfather clause. A few commenters in 2004 pointed out that in some States it is not the State lead pesticide regulatory agency (usually, department of agriculture) that has authority for regulating the storage of hazardous materials/pesticides, but instead the State environmental protection or pollution control agency. They argued that situations where one State agency does the comprehensive pesticide regulatory work but another is charged with the containment regulations begs questions about responsibilities for and resources necessary to accomplish expected compliance monitoring and enforcement response.

4. *EPA response.* The Agency agrees that Federal regulations should reinforce, rather than undermine or conflict with the efforts of proactive States. While the Agency believes in the need for national standards, EPA does not want to burden proactive States and facilities in those States with additional expenditures to revise their regulatory implementation system if the differences between their containment regulations and today's rule are minimal, and especially where State standards are more stringent than Federal standards. EPA has evaluated the pesticide containment regulations in those States that have promulgated them, and believes that the regulations in those States have generally brought facilities into compliance with today's regulations, with some potential deficiencies in certain States. EPA recognizes that simply reading regulations without awareness of the field reality, State enforcement discretion, and policy and guidance directives provided to inspectors may provide a less accurate reading of the equivalency of regulations. Consequently, EPA expects that States will be able to readily document their equivalency by providing existing information or pre-existing documents. EPA does not anticipate a significant paperwork burden for States, and is

offering this opportunity in response to States' requests in comments to be allowed to continue to implement their own regulations. EPA believes that in States where the lead pesticide agency is not responsible for enforcing containment regulations, collaboration between the State's agencies will be feasible. State regulators are encouraged to consult with EPA prior to preparing their submission.

IX. Labeling Requirements for Pesticides and Devices

A. Overview

1. *Final regulations.* Today's final rule changes the requirements for labeling pesticides in 40 CFR part 156 in several ways. First, these regulations add a new subpart H, entitled Container Labeling to part 156. The new container labeling regulations include the following requirements:

- A statement identifying the container as nonrefillable or refillable is required on all pesticide labels. In addition, nonrefillable container labels must include several statements providing basic instructions for managing the container and a batch code for the product. (See Units IX.B. - IX.D. for more details.)
- Cleaning instructions for some nonrefillable containers, specifically for dilutable products that are sold or distributed in rigid containers and that are not household/residential. (See Units IX.E. - IX.K. for more details.)
- Instructions for cleaning all refillable containers before disposal. (See Units IX.E. and IX.L. for more details.)

In addition, today's final rule modifies several existing requirements in 40 CFR 156.10 to allow for blank spaces on the labels of some refillable containers for the net contents and EPA establishment number. In addition, the paragraph in 40 CFR 156.10 that requires storage and disposal statements is being changed to be consistent with the label requirements added to 40 CFR part 156 in subpart H and the container regulations being added to 40 CFR part 165 in today's rule. (See Unit IX.M.)

Container-related labeling instructions for plant-incorporated protectants will be determined on a case-by-case basis until specific labeling guidance for plant-incorporated protectants are promulgated under 40 CFR part 174.

Existing EPA guidance on label statements for cleaning, recycling and disposing of pesticide containers, includes:

- The Label Review Manual (Ref. 44);
- PR Notice 83–3, Label Improvement Program — Storage and Disposal Label Statements (Ref. 73);
- PR Notice 84–1, Clarification of Label Improvement Program (Ref. 72);
- PR Notice 94–2, Recycling Empty Aerosol Pesticide Containers (Ref. 65);
- PR Notice 98–10, Notifications, Non-Notifications and Minor Formulation Amendments (Ref. 56); and
- PR Notice 2001–6, Disposal Instructions on Non-Antimicrobial Residential/Household Use Pesticide Product Labels (Ref. 49).

This guidance will be revised, if necessary, to be consistent with the requirements in today's final regulation.

2. *Changes.* The final labeling regulations in today's rule cover the same statements and topics that were included in the proposed rule. However, a number of changes have been made to the regulations, including but not limited to modifying specific statements, adding alternative statements, restructuring the regulations based on the plain language format, and exempting household/residential pesticide products from the requirements for cleaning instructions on nonrefillable container labels. The specific changes are described in the section-by-section discussion below.

B. Identification of Container Types (§ 156.140)

1. *Final regulations.* This section applies to all pesticide products and requires statements that, among other things, identify the container as nonrefillable or refillable. These statements must be placed on the label or container. The regulations in 40 CFR 156.10(a)(4)(i) require the label to ''appear on or be securely attached to the immediate container of the pesticide product.'' Therefore, the statements required by § 156.140 cannot be placed only on labeling that is not attached to the container, because it may become separated. The information may be located on any part of the container except the closure. If the statements are placed on the container, they must be durably marked on the container. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.

2. *Changes.* In the final rule, EPA has changed the word ''permanent'' to ''durable'' to describe the required container marking. In addition, the language from the preamble of the proposed rule that lists acceptable formats of the marking was added to the regulations to clearly establish our intent. Finally, the phrase ''as applicable'' was added to the first sentence to accommodate the fact that the statements in paragraph (a) apply only to labels on nonrefillable containers and the statements in paragraph (b) apply only to the labels on refillable containers.

C. Statements Required for Nonrefillable Containers (§ 156.140(a))

1. *Final regulations.* The final rule requires all nonrefillable containers to have the following four items on the label or the container:

- The phrase ''Nonrefillable container;''
- A statement regarding reuse;
- A statement about recycling or reconditioning; and
- A batch code.

If the first three items are placed on the label, they must be put under an appropriate heading under the heading ''Storage and Disposal.'' If any of the first three items are placed on the container, an appropriate referral statement, such as the statement in § 156.140(a), must be placed on the label under the heading ''Storage and Disposal.''

2. *Changes.* These statements were reorganized by separating each phrase or statement into a different regulatory paragraph to accommodate the addition of alternative statements. The proposed rule included all four items, but included the first three as one statement: ''Nonrefillable container. Do not reuse or refill this container. Offer for recycling if possible.'' Also, the final rule specifies that if the first three statements are placed on the label (rather than on the container), they must be placed under the ''Storage and Disposal'' heading on the label. EPA added this language to reinforce the requirement in § 156.10(i)(2)(ix) for the instructions in subpart H to appear under the ''Storage and Disposal'' heading. These three statements must be under an appropriate heading under the storage and disposal heading, although they may be in any order. EPA believes it is better to provide registrants flexibility in where to place these statements. Some registrants may choose to place them all together, while others may choose to place the recycling statement after the cleaning (residue removal) instructions.

The final rule was revised to require a referral statement on the label if any of the statements except the batch code are placed on the container. Examples of appropriate referral statements are ''See container for handling and recycling statements.''; ''Recycling information is located on the container.''; and ''See the container for refill limitations.'' The

referral statement will provide information to allow users who look for refill prohibitions or recycling statements in the storage and disposal section of the label to find the information.

i. *Statement identifying a nonrefillable container—Final regulations and changes.* The identifying phrase ''Nonrefillable container'' is identical to the identifying phrase in the proposed regulations.

ii. *Reuse Statement—Final regulations.* Registrants must choose to use one of the following reuse statements, as appropriate. Products with labels that allow household/residential use must use the statement in item (1) or (3). All other products must use one of the three statements.

(1) ''Do not reuse or refill this container.''

(2) ''Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsates). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.''

(3) The following statement may be used if a product is ''ready-to-use'' and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: ''Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container.''

iii. *Changes.* The proposed rule required the first statement, ''Do not reuse or refill this container.'' The second statement was added to address a common practice where pesticide applicators use plastic jugs to hold rinsate that contains the pesticide on the label, which could be interpreted as a violation of a ''Do not reuse'' statement. While EPA has some concerns about the widespread storage of rinsate or other pesticide-containing materials in pesticide containers (without proper management practices such as marking the contents and date on the container), we acknowledge the day-to-day reality of pesticide operations that sometimes there are materials such as rinsates or leftover tank mix that must be dealt with. While temporarily storing these materials in pesticide containers can create disposal problems if the material is not managed properly and promptly, temporary storage is better than most of the other low-cost, practical alternatives such as dumping the rinsate or leftover material. Therefore, the second statement was added to provide some flexibility while still prohibiting the reuse of nonrefillable containers for materials other than pesticides, including but not limited to water, food, feed and oil. However, EPA does not believe that household/residential pesticide users are likely to be able to properly manage rinsate and other pesticide-containing materials in this way, so this statement cannot be used on household/residential use products.

The third statement was added in response to comments describing ready-to-use products in containers that are intended to be sold or distributed only once, but that can be refilled by the end user with a concentrate (a different product) and then diluted. The third statement gives registrants the option to continue distributing products in this way, but still provides end users with the message that these containers should generally not be reused or refilled.

iv. *Comments - refill with concentrate.* Several commenters noted that a prohibition on reuse or refill would make a common practice illegal. Specifically, some ready-to-use products are distributed or sold in containers that are intended to be sold or distributed only once (and therefore meet the definition of nonrefillable containers). However, these containers can be refilled by the end user (generally a household user) with a concentrate and then diluted. A few respondents suggested not requiring the reuse statement on ready-to-use product containers and several others offered an alternative statement for these products.

v. *EPA response - refill with concentrate.* EPA agrees that the use of containers of ready-to-use products to be refilled with a different product (that is a similar, but concentrated formulation) and diluted by the end user should be allowed to continue. In a relatively quick search of product labels, EPA found a number of household/residential use herbicides with label directions that allowed this practice. This environmentally beneficial practice reduces the amount of packaging used and packaging waste produced, since a smaller container can be used to distribute the concentrate. Therefore, the final regulation includes an alternative statement that allows this practice to continue. Currently, we believe this situation is most commonly used for household products, although the final regulations were written to allow any products (not just household/residential use products) to be able to use the appropriate refill/reuse statement on their labels.

3. *Recycling or reconditioning statement*—i. *Final regulations.* Registrants must use at least one of the following statements:

(1) ''Offer for recycling if available.''

(2) ''Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]. For example, this statement could be ''Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1–877–952–2272 (toll-free) or *www.acrecycle.org*.''

(3) A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.

(4) An alternative recycling statement that has been reviewed and approved by EPA.

(5) ''Offer for reconditioning if appropriate.''

ii. *Changes.* The final rule includes options for container recycling statements to account for differences in the process for recycling different kinds of containers (e.g., aerosol cans or plastic jugs) and differences in recycling among markets (agricultural or household). In addition, the proposed rule specified the statement ''Offer for recycling if possible.'' In the final rule, EPA changed the word possible to available. Finally, EPA added a statement ''Offer for reconditioning if appropriate'' as an alternative.

iii. *Comments - recycling.* Several commenters addressed the issue of recycling. A user group supported the continued development of container collection and recycling programs. A registrant endorsed recycling but commented that the language must comply with Federal Trade Commission (FTC) guidance. A registrant group requested that the terms of PR Notice 94–2 ''Recycling Empty Aerosol Pesticide Containers'' as amended by letter on June 9, 1994, be codified into regulation. A State regulatory agency urged EPA to specifically direct users to agricultural pesticide container collection programs to prevent agricultural pesticide containers being offered for household recycling collection. Another State regulatory agency suggested a label statement requiring small rinsed containers to be delivered to State-authorized container collection programs. This commenter stated that use of the word ''possible''

would be problematic because while it is possible for farmers to travel more than 100 miles to a recycling center, it would be unreasonable to expect that. A group of people involved with pesticide container recycling in Washington State submitted suggestions for changing the storage and disposal statements on pesticide containers. These comments specifically supported the efforts of the Ag Container Recycling Council (ACRC) and recommended a statement that refers to the ACRC and provides the ACRC web site.

In response to the 2004 notice, four State regulatory agencies and a registrant group urged the Agency to do more to encourage recycling of pesticide containers and to remove label references to burning or burying containers. A few State agencies noted efforts by ACRC, Earth 911 and the National Pesticide Stewardship Alliance to promote recycling and reform label language. These respondents noted that the Agency needs to go further than what was proposed in the rule in order to improve labeling such that burning and burying of containers is no longer allowed.

iv. *EPA response - recycling*. EPA agrees with intent of the commenter who suggested codifying PR Notice 94–2. The third option included in the final rule, a recycling statement approved by EPA and published in an EPA document, is included to account for PR Notice 94–2, other PR Notices, the label review manual, and other documents.

EPA agrees with the State regulatory agencies and Washington container recycling group that it may be beneficial to provide more specific information about pesticide container collection and recycling programs in this statement, particularly for agricultural pesticide products. Therefore, the final regulations allow the use of a new recycling statement that provides details about how to obtain more information on agricultural pesticide container collection and recycling programs such as the ACRC. The ACRC is a non-profit organization that promotes and supports the collection and recycling of plastic pesticide containers in the U.S. The collection and recycling programs conducted by the ACRC grew significantly during the 1990's, so EPA is adding this statement to reflect currently available programs (that were in the developmental stage when the proposed regulations were being written). For example, in 1993 the ACRC collected about 2.5 million pounds of plastic containers. In 2001, ACRC collected over 7 million pounds of plastic containers, which represents about 25 percent of the plastic containers distributed by the ACRC member companies. (Ref. 1) EPA has been told by ACRC recyclers and member companies and by ACRC's State partners that participation could be increased if the label specifically referred to the ACRC program. EPA hopes to encourage the recycling of pesticide containers by including this recycling statement as an option. EPA also recognizes the need for flexibility in the label instructions, as other, equally effective organizations may come into existence in the future, and that the organization Earth 911 (*www.earth911.org*), a clearinghouse of information on household hazardous waste disposal and recycling, may eventually include information resources specifically for managing agricultural chemicals and containers.

EPA agrees that the word ''possible'' may not be clear, and has replaced it with the word ''available.'' ACRC programs are available that is, accessible for agricultural pesticide users across much of the U.S., but not all areas have local collection programs. EPA believes that a reasonable interpretation of ''available'' is that pesticide containers are collected at a location that is the same distance or closer than the distance the user traveled to purchase the pesticides. It is worth noting that the statement ''Offer for recycling if available'' and the other statements in § 156.140(a)(3) give pesticide users an option for managing the containers. These statements do not require the recycling or reconditioning of containers. EPA believes that recycling or reconditioning pesticide containers is a responsible, preferable way of managing pesticide containers. We encourage these practices to save resources and minimize the amount of material being disposed, although there are other legal ways of managing the containers.

The final rule also includes the option for a registrant to offer an alternative recycling statement. This is intended to allow for the possibility of changes in the extent to which and the manner in which pesticide containers are recycled over time. EPA must review and approve an alternative recycling statement before it can be placed on a pesticide label. One part of our review will involve considering whether the alternative statement is consistent with the FTC guidelines on environmental statements in 16 CFR part 260, ''Guides for the Use of Environmental Marketing Claims.'' (Ref. 5) (*http://www.ftc.gov/bcp/conline/edcams/eande/index.html*)

EPA agrees with commenters that label language regarding burning and burying containers needs to be improved and is engaged in discussions with stakeholders to address this issue. Container disposal instructions were not addressed in the proposed container and containment regulations and therefore are outside the scope of the final regulations. In addition, EPA staff are actively working on improving the label manual.

v. *Comments - reconditioning*. Many commenters on the proposed regulations, including container manufacturer and registrant groups, stated that the regulations do not account for the reconditioning of containers and opposed many proposed provisions because they would be problematic for reconditioning. These respondents also commented that some containers are commonly reconditioned, particularly plastic and steel drums holding non-agricultural pesticides.

vi. *EPA response - reconditioning*. EPA added a statement about reconditioning to the final rule as an alternative for containers that are commonly reconditioned. The statement says ''Offer for reconditioning if appropriate'' because reconditioning is a logical, reasonable option only for certain containers, specifically drums, and not others, such as plastic jugs and aerosol cans. EPA believes this flexibility should alleviate some of the commenters' concerns about the apparent disregard for reconditioning.

4. *Batch code*—i. *Final regulations*. A lot number, or other code used by the registrant or producer to identify the batch of the pesticide product, is required for each nonrefillable container either on the label or the container.

ii. *Changes*. The text specifying a lot number or other code in the final rule is identical to the text in the proposal. In the final rule, though, the introductory paragraph was modified to clarify that the lot number/batch code could be placed anywhere on the label or durably (not permanently) marked on the container.

D. Statements Required for Refillable Containers (§ 156.140(b))

1. *Final regulations*. For refillable containers, one of the following statements is required on the label or the container:

(1) ''Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose.''

(2) ''Refillable Container. Refill this container with *[common chemical name*] only. Do not reuse this container for any other purpose.''

If the statement is on the label, it must be placed under the ''Storage and Disposal'' heading. If the statement is

put on the container, the label must include an appropriate referral statement under the ''Storage and Disposal'' heading.

2. *Changes.* The proposed rule specified only the first statement. In response to comments, the second statement was added to the final rule as an option to accommodate containers that may be filled with a chemical that has both pesticidal and non-pesticidal uses. Also, the phrase ''Refillable container'' was added to both statements to allow pesticide users, registrants and government regulators to clearly identify whether a container is nonrefillable or refillable. The final rule specifies that if the statement is placed on the label (rather than on the container), it must be placed under the ''Storage and Disposal'' heading. EPA added this language to reinforce the requirement in § 156.10(i)(2)(ix) for the instructions in subpart H to appear under the ''Storage and Disposal'' heading. Lastly, the final rule was revised to require a referral statement on the label if the statement is placed on the container. An example of an appropriate referral statement is ''Refilling limitations are on the container.'' The referral statement will provide information to allow users who look for refill prohibitions in the storage and disposal section of the label to find the information.

E. Residue Removal Instructions - General (§ 156.144)

1. *Final regulations.* Unless exempt from these requirements, the label of each pesticide product must have instructions on the removal of pesticide residue prior to disposal, as specified in §§ 156.146 and 156.156. The regulations in § 156.144 include the following specifications:

- Residue removal statements are required for both nonrefillable and refillable containers.
- Residue removal statements must be placed under the heading ''Storage and Disposal.''
- Residential/household use pesticide products are exempt from the residue removal statement requirements.
- EPA may modify or waive the residue removal requirements or permit or require alternative labeling statements.

2. *Changes.* The most significant change to this section is that the final rule exempts residential/household use pesticide products from the residue removal statement requirements. The proposed rule would have applied to the labels of all products, regardless of the pesticide market in which they are sold, distributed and used. EPA also made a few minor changes in the final rule. The proposed rule specified a subheading entitled ''Container Cleaning'' under the heading ''Storage and Disposal.'' In the final rule, EPA deleted this subheading because it is unnecessary. Section 156.144(b) regarding placement of the residue removal statements was shortened by deleting the reference to Directions for Use, which isn't necessary. EPA believes requiring the statements to be placed under the heading ''Storage and Disposal'' is sufficient because § 156.10(i)(2)(ix) requires this heading to be included in the directions for use. Finally, a few editorial changes were made to shorten the phrase ''residue removal statements and instructions'' to ''residue removal instructions'' to be more precise and consistent. The rest of the requirements of § 156.144 are identical to those in the proposed rule.

FIFRA section 19(f) mandates ''regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal'' and says that EPA ''may, at the discretion of the Administrator, exempt products intended solely for household use'' from these requirements. In the proposed rule, EPA chose not to exercise this discretion and proposed to require cleaning instructions on the labels of household products because the preamble of the proposed rule stated that, in many instances, the same pesticide product in the same container is sold for agricultural or industrial use, as well as for use in the home, yard, or garden.

The 1999 Supplemental Notice (Ref. 53) stated that the changes in scope would only apply to the container standards and that:

> EPA believes that it is appropriate to have container cleaning and disposal instructions on the labels of all pesticides because of safety and environmental protection considerations for recycling operations. It is necessary for pesticide containers to be properly emptied and cleaned prior to being recycled to protect workers who handle the recyclable material and to prevent releases of pesticides to the environment. Because pesticide containers from all segments of the pesticide industry are currently being recycled, container cleaning and disposal instructions are needed on the labels of all pesticides. ...

During the development of the final PR Notice 2001–6, ''Disposal Instructions on Non-Antimicrobial, Residential/Household Use Pesticide Product Labels,'' however, EPA decided to change this position for non-antimicrobial, residential/household use pesticide products. (Ref. 49). As stated in PR Notice 2001–6:

> Specific instructions to consumers to rinse their empty containers have been left out of these revised instructions. Experience has shown that many consumers are confused by rinsing procedures and often incorrectly dispose of the rinse water down the drain or down sewers. States have reported some detections of pesticides in drinking water that appear, in some cases, to be linked to disposal or rinsing in residential waste water systems. In addition, storage of rinsate is highly discouraged because of the absence of adequate labeling or packaging. There is also the potential risk of adverse chemical reactions occurring when products are poured down drains, singly, or in combination with other products.

One potential solution that EPA considered but rejected when finalizing PR Notice 2001–6 was to require rinsing of non-antimicrobial, residential/household use pesticide containers and to include instructions on the label for how to manage the rinse water. For example, the label statement in PR Notice 2001–6 could have instructed the user to add the rinse water to the pesticide mixture that will be applied, or if that isn't feasible, the rinse water could be applied to a site on the label in accordance with the other label provisions. EPA rejected this option because it could confuse consumers, it could lead to the storage of rinse water in the absence of adequate labeling or packaging, and it would require several additional sentences on an already crowded label.

Therefore, EPA has decided to omit rinsing instructions from the label directions specified for non-antimicrobial, residential/household pesticide products in PR Notice 2001–6. In markets where empty containers of these pesticides are recyclable, it is assumed that the recycling programs will provide consumers with instructions to rinse the containers if the recycling program believes it is necessary. Additionally, if a manufacturer wants to include a rinsing statement on the labels of these pesticides, EPA would consider such a request. However, if a manufacturer chooses to include a rinsing statement, it should also include instructions about how to manage the rinse water.

In the final rule, EPA is continuing the policy to omit rinsing instructions from the label directions for non-antimicrobial, residential/household pesticide products. In addition, EPA decided to extend this policy to antimicrobial, residential/household pesticide products in the final rule. Antimicrobial products were not included in the scope of PR Notice 2001–6 because of differences of opinions on the disposal statements in the PR Notice, not because of problems

with applying the no-rinsing policy to household/residential antimicrobial products. EPA believes that some of the same concerns about household/residential pesticide users, including users being confused and trying to prevent the storage of rinsate, apply equally to antimicrobial and non-antimicrobial products used by these household/residential pesticide users.

F. Residue Removal Instructions for Nonrefillable Containers - General (§ 156.146)

1. *Final regulations.* Section 156.146 sets out the residue removal instructions for nonrefillable containers. The label of a product must comply with these instructions if all of the following criteria are met:

- The product must comply with the residue removal instructions based on § 156.144 (i.e., it is not a residential/household product, EPA has not waived the requirement, or EPA has not established an alternative requirement);
- The product is dilutable (it could be a liquid or a solid); and
- The product is distributed or sold in a nonrefillable container that is rigid.

The preamble to the proposed rule stated that EPA was holding sections in reserve for residue removal instructions for other formulation/container combinations, such as dilutable products in non-rigid containers. While EPA may address other kinds of nonrefillable containers in the future, the final rule establishes residue removal instructions only for dilutable products in rigid nonrefillable containers.

The labels of dilutable products that are subject to this requirement and that are sold or distributed in rigid, nonrefillable containers must comply with the following standards:

- A statement instructing the user to clean the container promptly after emptying is mandatory;
- Triple rinsing instructions are mandatory;
- Pressure rinsing instructions are optional; and
- A registrant must obtain EPA approval before including a rinsing procedure that specifies a diluent other than water.

These requirements are discussed in more detail in Units IX.G. through IX.K. below.

2. *Changes.* The final regulation includes several changes from the proposal. The most significant changes are that the final rule requires registrants to place the triple rinse instructions on all labels and provides registrants the option to also include the pressure-rinse instructions. The proposed rule gave registrants the option to include either triple rinsing or pressure rinsing or both. Based on comments, EPA changed the final rule because triple rinsing is always possible, whereas pressure rinsing requires specific equipment. Other substantial changes to the residue removal instructions include:

- Adding the phrase ''or equivalent'' as an option so labels allow equivalent means of rinsing containers. This was added to account for systems (such as closed system rinsing or home-made pressure rinsing systems) that are designed to clean containers thoroughly but do not technically triple rinse the containers. This change was made to the statement identifying when containers must be rinsed and is discussed in more detail in Unit IX.G.
- Both the triple rinse and pressure rinse procedures were modified so they would take less time. For example, the intervals of time for draining and shaking the containers were reduced. These changes are intended to make the procedures more practical and therefore more likely to be followed by end users. These changes are discussed in more detail in Unit IX.H.

Numerous other minor modifications, which are described in Units IX.G. - IX.K., were made to the residue removal instructions for nonrefillable containers.

3. *Comments - which procedure*? The proposed rule would have required the placement of either the triple rinse or the pressure rinse procedure on the label, with the option of including both. The preamble requested comments on this approach. The following comments addressed this question.

i. *Both procedures.* Several State regulatory agencies and a registrant group supported including both triple and pressure rinsing instructions on labels. A few of these commenters pointed out that pressure rinsing alone is not available to all applicators.

ii. *Alternative approach.* A few dealer groups recommended using the statement ''Pressure rinse or triple rinse'' so users and dealers will not have to worry about having both rinse systems available.

iii. *Either or both procedures.* A registrant group supported the approach of allowing the registrant to put either or both of the statements on the label, because pressure rinsing would not be appropriate for institutional products and including both would crowd the label.

iv. *Limit pressure rinsing.* Some commenters, including registrants, registrant groups, and a State regulatory agency, expressed concern about household users pressure rinsing small containers. Many of these respondents suggested excluding pressure rinsing from household product labels. A registrant group also added institutional and industrial products to this suggested exclusion. Similarly, another registrant group commented that pressure rinsing is not common in the institutional sector. Alternatively, a few registrant groups and a registrant recommended that pressure rinsing instructions be permitted only on containers with capacities larger than one gallon.

v. *Decision making process.* Some registrants and registrant groups commented that EPA implies that some sort of decision making process must be used to determine if triple rinsing, pressure rinsing, or both should be included and requested EPA to clarify this. For example, does a container have to meet a six 9's standard by a laboratory pressure rinsing test for pressure rinsing instructions to be included on the label? If so, EPA has to specify the pressure rinsing test procedure.

vi. *Effectiveness of procedures.* Several commenters addressed the efficacy of pressure rinsing vs. triple rinsing. A registrant group and two registrants commented that pressure rinsing should be recommended on labels only if it has been shown to be as effective as triple rinsing. Another registrant stated that their studies (in addition to the work of other companies) shows that pressure rinsing is not as effective as triple rinsing. A State regulatory agency commented that pressure rinsing is a more effective method of cleaning containers.

vii. *Advantages of pressure rinsing.* A State regulatory agency and a registrant commented that pressure rinsing is advantageous to the pesticide users because it is a faster procedure.

4. *EPA response - which procedure*? EPA agrees with several of the points made by commenters, in particular, that pressure rinsing alone is not available to all applicators, that pressure rinsing isn't appropriate for certain containers based on the pesticide market and/or container size, and that pressure rinsing is attractive to pesticide users because it is a faster procedure. Therefore, EPA changed the approach so the final regulation requires labels to include the triple rinse procedure and gives registrants the option to also include the pressure rinse procedure. This approach provides a rinse procedure (triple rinsing) that all pesticide users can follow. It also gives registrants the option to include pressure rinsing if they believe it is appropriate (with EPA concurrence during the review of

labels), which is preferable to establishing criteria for appropriate (or inappropriate) pressure rinsing situations in the regulations.

EPA believes that both triple rinsing and pressure rinsing are effective ways for users to clean most containers (with possible exceptions for size and other situations) in the field. This conclusion is based on the rinsing studies described in Reference 40 and on the field experience of people who have inspected containers over the past decade of pesticide container recycling programs. One registrant group provided comprehensive comments during the 2004 reopening of the comment period based on the ACRC's experience over the past 10 years. This commenter described ACRC's efforts to assess and control the risk from using the recycled plastic and noted that, since ACRC's inception in 1992, there have been no reports of incidents where public health or safety has been compromised as a result of exposure to the minimal residues found in recycled plastic pesticide containers. This registrant group also stated that ACRC's experience with recycling clean, rinsed one-way pesticide containers for more than a decade leads them to believe that residue removal is an issue of instructing applicators to triple or pressure rinse containers immediately after use.

EPA's goal is to establish a situation where all containers are adequately cleaned before they are recycled, disposed, or otherwise managed. As stated in Unit V.H.1., one regulatory contribution to achieving this goal is ensuring that pesticide users have access to clear, detailed instructions for how to clean the containers. In the final rule, pesticide labels must include triple rinse instructions and may also include pressure rinse instructions.

Another regulatory contribution is to ensure the use of container designs and formulations that facilitate effective residue removal, which is the intent of the residue removal standard for nonrefillable containers in § 165.25(f). The residue removal test procedure requires containers to be triple rinsed. In this case, triple rinsing is used as an indication of how easily the pesticide can be removed from the container. The residue removal test procedure does not require containers to be pressure rinsed nor is it intended to evaluate whether triple rinsing or pressure rinsing is more effective for a certain container and pesticide formulation. Therefore, the decision of whether or not to include pressure rinsing instructions on the pesticide label is not tied to the results of laboratory residue removal testing. Instead, registrants have the option to include pressure rinsing if they believe it is appropriate (with EPA concurrence during the review of labels).

There are other integral parts to achieving the goal of having clean containers before they are disposed or recycled, including educating pesticide users on the importance of rinsing and the proper procedures, potential spot checks/inspections to ensure that the labels and regulations are being complied with, and creating an incentive for pesticide users to comply (or a disincentive for non-compliance). EPA looks forward to working with all stakeholders, including State regulatory agencies, pesticide registrants, distributors and dealers, pesticide users, pesticide educators, and trade associations in accomplishing this goal.

G. Timing of the Residue Removal Procedure (§ 156.146(a))

1. *Final regulations*. For products that are subject to the requirements for residue removal instructions, the label of each nonrefillable container must include one of the following statements:

(1) ''Clean container promptly after emptying.''

(2) ''Triple rinse or pressure rinse container (or equivalent) promptly after emptying.''

(3) ''Triple rinse container (or equivalent) promptly after emptying.''

The statement about timing must immediately precede the rinsing instructions and must be consistent with the rinsing instructions (triple rinse or both triple and pressure rinse) that are include on the label.

2. *Changes*. This section of the final rule includes three changes from the proposed regulation. First, the proposed requirement to rinse ''immediately'' after emptying was replaced in the final rule by requiring the container to be rinsed ''promptly'' after emptying it. Second, the final rule adds the phrase ''(or equivalent)'' to the two statements that identify a specific cleaning procedure, e.g., triple rinsing. Third, the proposed rule included four options for statements to include on the label. EPA is not finalizing one of these statements in the final rule--''Pressure rinse container immediately after emptying'' --because it is no longer needed. The final rule does not allow pressure rinsing to be the only procedure listed on the label, so this statement is irrelevant.

3. *Comments - clean promptly*. Some State regulatory agencies supported the statement regarding the timing of rinsing, stating that it should improve the management of the containers. Two other State regulatory agencies stated that, based on results from their container collection and recycling programs in the early 1990's, it is obvious that not all containers are rinsed immediately. A registrant group suggested using the phrase ''reasonably promptly'' rather than ''immediately'' to account for industrial situations where its not practical to rinse immediately such as when multiple oil wells are treated from the same drum of an industrial biocide and rinsing equipment is not available. An agricultural pesticide registrant supported immediate rinsing in a farm context so that the rinsate could be added to the application mixture, but noted that clean water may not be available at every loading site.

4. *EPA response - clean promptly*. EPA considers the timing of the residue removal procedure to be a critical factor in effectiveness, and is maintaining the approach in the proposed rule that requires users to rinse containers within a certain (short) time period after emptying them. When rinsing is not performed soon after emptying the container, the residue can dry and adhere to the inside and outside of the container, and is then more difficult to remove. Containers with dried residue are likely to be rejected by pesticide container recycling and collection programs as well as at solid waste landfills.

EPA believes that requiring pesticide users to rinse containers promptly after emptying them is the best approach for the final rule. Specifying that the containers are cleaned promptly accomplishes the goal of rinsing them soon after they are emptied and before the residue dries in the containers. Also, prompt rinsing provides a little more flexibility than immediate rinsing. As an example, consider a pesticide applicator who pours product from one container, sets it down to pour out another container, and then rinses both containers. Technically, this could be considered a violation if the label specified immediate rinsing, because some time passed between the emptying and the rinsing of the first container. However, this example fits within EPA's understanding of prompt action.

Requiring that containers be rinsed promptly gives pesticide users, regulatory agencies and inspectors some discretion in determining appropriate time spans. It is beyond the scope of this preamble to describe every situation that is or is not appropriate, so EPA is relying on the good judgement of applicators, regulatory agencies and inspectors to assess the specific conditions of the situation. However, EPA believes that situations where the

time between emptying and rinsing is days or weeks and where the residue has completely dried inside the container are definitely beyond the boundaries of prompt rinsing. In addition, EPA strongly recommends that pesticide users rinse containers when the application mixture is being prepared so the rinsate can be added to the application mixture. This provides many benefits, including getting all of the value out of the product and avoiding the creation of a potential waste (which could happen if the rinsate was collected separately).

5. *Comments - equivalency*. In commenting on the proposed approach for residue removal instructions, a few commenters (a State regulatory agency and a registrant) supported maintaining the current cleaning statement of ''Triple rinse (or equivalent)'' because it is sufficient if followed and it offers flexibility.

6. *EPA response - equivalency*. EPA agrees with the commenters that including the phrase ''(or equivalent)'' that is on current labels is beneficial and the final rule adds this phrase as an option to the ''rinse promptly'' statement. This phrase was added to account for systems (such as closed system rinsing or home-made pressure rinsing systems) that are designed to clean containers thoroughly but do not technically triple rinse the containers. The alternative rinsing system should be thorough and it is the responsibility of the pesticide user to ensure that it is equivalent to triple rinsing.

H. Duration of Triple and Pressure Rinse Procedures (§ 156.146(b) and 156.146(c))

1. *Final regulations*. As discussed in Unit IX.I. for triple rinsing and Unit IX.J. for pressure rinsing, the rinsing procedures for containers that are small enough to shake that are defined in the final regulation take less time to conduct than the proposed procedures. The key time intervals identified in the procedures are:

- How long to drain liquid product from containers (both triple and pressure rinsing);
- How long to agitate/shake containers during triple rinsing;
- How long to drain rinsate from containers after each shaking interval during triple rinsing; and
- How long to pressure rinse the container during pressure rinsing.

2. *Changes*. The procedures in the final rule specify the following times for each of these intervals for containers that are small enough to shake:

- 10 seconds to drain liquid product from containers for both triple and pressure rinsing (changed from 30 seconds in the proposal);
- 10 seconds to agitate/shake containers during triple rinsing (changed from 30 seconds in the proposal);
- 10 seconds to drain rinsate from containers after each shaking interval during triple rinsing (changed from 30 seconds in the proposal); and
- At least 30 seconds to pressure rinse the container during pressure rinsing. (The proposed rule specified 30 seconds; the phrase ''at least'' was added to compensate for variations in pressure rinsing equipment and in pressure.)

3. *Comments*. A registrant group, a registrant and two State regulatory agencies commented that a shorter rinse time would be better and would encourage user compliance, although the two State regulatory agencies supported a shorter rinse time only if it was demonstrated that the containers are cleaned adequately. Another State regulatory agency stated that, in a 1991 survey, 43 percent of private applicators and 11 percent of commercial applicators responded that they did not rinse containers because it took too much time. A registrant group opposed the initial drain time of 30 seconds as too long and inappropriate for closed systems. This commenter also responded that some states have requirements different than a 30–second drain and urged EPA to consider these alternatives. A registrant commented that the times of the proposed rinsing procedures seemed reasonable and expressed doubts that the triple rinse procedure could be shortened much. This commenter added that a 40–second pressure rinse is inadequate to achieve 99.9999 percent removal.

4. *EPA response*. In the preamble of the proposed rule, EPA estimated that the proposed triple rinsing instructions would take approximately 5 minutes to perform and the pressure rinsing procedure would take approximately 2 minutes. EPA also requested comments on the time burden of the proposed rinsing procedures, and the voluntary submission of data on residue removal, including in particular the cleaning efficiency of any suggested shorter triple rinse and pressure rinse procedures.

EPA agrees with the commenters that a shorter rinse time would be better and would encourage user compliance with the requirement to rinse pesticide containers. In particular, we believe it is relatively unlikely that a pesticide user would spend about 5 minutes triple rinsing each container. The 30–second intervals for the initial container drain time, the shaking time and the rinsate-draining times were based on the rinsing instructions of many States, which were incorporated into the laboratory triple rinse test methodology for the proposed nonrefillable container residue removal standard.

EPA contracted for two studies on the effectiveness of shorter triple rinse procedures. In a study conducted by Formulogics (Refs. 7 and 38), a flowable concentrate product was tested in three containers: 1–gallon and 2.5–gallon plastic jugs and a 5–gallon steel flathead can. Nine different rinsing procedures were conducted for each container size by varying the initial drain, shake and rinsate drain times between 5, 10 and 30 seconds. The shake and rinsate drain times were always the same. For example, the three variations for the initial drain time of 5 seconds were: 5 second shake and 5 second rinsate drain; 10 second shake and 10 second rinsate drain; and 30 second shake and 30 second rinsate drain. These same three shake and rinsate drain times were conducted for the initial drain times of 10 second and of 30 seconds. The pesticide concentration in the second through fifth rinses was measured. EPA concludes that all nine rinsing procedures tested were effective in cleaning all three containers because the active ingredient concentration in the fourth rinse showed at least 99.99% removal in all rinse time iterations. Two of the rinse procedures for the 5–gallon container (5 sec. initial drain/5 sec. shake & rinsate drain and 30 sec. initial drain/5 sec. shake & rinsate drain) resulted in 99.99 percent removal; all other rinse procedures for all containers met at least five 9's percent removal and most resulted in six 9's percent removal.

In a study conducted by the University of Florida (Refs. 14 and 41), two formulations were tested in three containers, 1–gallon, 2.5–gallon and 5–gallon plastic jugs. The flowable concentrate was tested in all three containers and the emulsifiable concentrate was tested in the 2.5–gallon and 5–gallon containers. Four different rinsing procedures were conducted for each container size by varying the initial drain, shake and rinsate drain times between 10 and 30 seconds where the shake and rinsate drain times were always the same. Again, EPA concludes that all four rinsing procedures tested were effective in cleaning both formulations from all of the containers because the active ingredient concentration in the fourth rinse showed at least 99.99% removal in all rinse time iterations.

The triple rinse procedure for labels in the final rule includes 10 second initial drain, shake and rinsate drain

times. EPA believes the data described above shows that this shorter triple rinsing procedure, which should encourage end user compliance with the requirement to triple rinse, will adequately clean containers prior to recycling or disposal.

In addition, EPA has lowered the residue removal requirement in the final nonrefillable container regulations from six 9's (99.9999 percent) to four 9's (99.99 percent), as discussed in Unit V.H. The shorter rinse procedures reached at least 99.99 percent removal in all of the containers and formulations tested. As cited by one of the State regulatory agencies in its comments, the field reality is that many users who do not rinse claim the time factor as the reason. By reducing the time frames in the cleaning instructions, EPA hopes to increase compliance within the pesticide user community.

I. Triple Rinse Instructions (§ 156.146(b))

1. *Final regulations*. For products that are subject to the requirements for residue removal instructions, the label of each nonrefillable container must include triple rinse instructions. There are three different sets of triple rinsing instructions:

- For containers that are small enough for users to shake them, holding dilutable liquid pesticides;
- For containers that are small enough for users to shake them, holding dilutable solid pesticides; and
- For containers that are too large for users to shake.

In general, EPA believes that the largest containers that users can shake during a triple rinse are those with capacities of 5 gallons for liquids and 50 pounds for solids.

The triple rinse instructions for liquid dilutable pesticide products in containers small enough for users to shake are:

> Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank, and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

The final rule specifies slightly different instructions for solid dilutable pesticide products in ''shake-able'' containers, because solid materials do not ''drip'' as liquids do. The only difference for solid dilutable pesticide products is that the first line is ''Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full...'' The rest of the procedure is identical to the one for liquids.

For containers that are too large for users to shake (i.e., containers larger than 5 gallons for liquids or 50 pounds for solids), the triple rinse instructions are:

> Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

2. *Changes*. One significant change from the proposed rule is that the final regulation requires a triple rinse procedure to be on the label, where the proposal gave registrants the option to include triple rinsing or pressure rinsing or both. Another modification is that the final regulations provide a defined procedure for containers that are too large for users to shake. Also, the phrase ''or a mix tank'' was added as an option for where the product or the rinsate can be placed. In addition, the following clarifying changes were made to both sets of instructions for triple rinsing smaller containers that can be shaken:

- The introductory text specifies that the instructions apply to ''containers small enough to shake'';
- The instruction to ''agitate'' was changed to ''shake''; and
- As discussed in Unit IX.H., the time intervals were changed from 30 seconds to 10 seconds for the initial draining of the container (for liquid products only), the time the container needs to be shaken, and for the draining of the rinsate.

3. *Comments - general*. A State regulatory agency pointed out that the directions prohibit preparing the use dilution in a mix tank, which is a common practice. A registrant commented that the degree of agitation needs to be specified, e.g., shake vigorously for 30 seconds.

4. *EPA response - general*. EPA did not intend to prohibit users from pouring a product into a mix tank or diluting a product in a mix tank, and we have amended the triple rinse procedures to address this oversight. The phrase ''or a mix tank'' was added to the instructions for emptying containers and to the rinsate management instructions to allow the product and rinsate to be placed into application equipment or a mix tank.

EPA agrees with the registrant and believes that ''shake'' is a better description of the intended activity than ''agitate.'' We decided not to include the qualifier ''vigorously'' to keep the statement as succinct as possible. This kind of information could be passed along to users during training and outreach.

5. *Comments - large containers*. Several commenters described problems with cleaning drums according to the proposed triple rinse statement. A registrant group stated that it is impractical to fill a 55–gallon drum one quarter full because more than 40 gallons of rinsate would be produced. A different registrant group and a registrant recommended directing the user to place the drum on its side and roll it, because it is extremely difficult to shake a large container that is one-quarter full. Another registrant commented that an additional statement that describes rinsing by recirculation would be helpful, but pointed out that many drum users don't use pumps to empty them.

6. *EPA response - large containers*. EPA agrees with the suggestion by the commenters who recommended directing the user to place a drum on its side and roll it. EPA is hesitant to recommend a cleaning procedure for larger containers that requires equipment that a pesticide user may not have, such as a pump, or an appropriately sized, heavy-duty pressure rinse nozzle. Therefore, we decided to define a triple rinse procedure in the final regulation for containers that are too large to be shaken. This is consistent with the approach in the final rule to require triple rinsing because all pesticide users can comply with these instructions and to allow pressure rinsing as an optional, additional statement.

J. Pressure Rinse Instructions (§ 156.146(c))

1. *Final regulations*. For products that are subject to the requirements for residue removal instructions, the label of each nonrefillable container may include pressure rinse instructions. The decision regarding whether to include pressure rinsing instructions as an option is at the discretion of the registrant, based on the registrant's assessment of the procedure's effectiveness and appropriateness for the formulation/container combination. However, if the statement ''Triple rinse or pressure rinse container (or equivalent) promptly after emptying'' is used on the label as the statement about timing, pressure rinse instructions must be placed on the label. If a registrant

chooses to include pressure rinsing instructions on the label as an option for cleaning a liquid dilutable pesticide product, the statement must immediately follow the triple rinse instructions.

The pressure rinse instructions for liquid dilutable pesticide products are:

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Slightly different instructions are required for pressure rinsing dilutable liquid and dilutable solid pesticide formulations, because dry materials do not ''drip'' like liquids do. The pressure rinsing procedure specified in the final regulations for dilutable solid pesticides is identical to the one for liquids, except it does not include the initial 10–second draining prior to rinsing.

2. *Changes.* One significant change is that pressure rinsing instructions are optional in the final rule, which requires a triple rinse procedure to be included on the labels of products that must comply. The proposal gave registrants the option to include triple rinsing or pressure rinsing or both. In addition, the following changes were made to both sets of instructions for pressure rinsing:

- The phrase ''or a mix tank'' was added as an option for where the product or the rinsate can be placed.
- As discussed in Unit IX.H., several of the time intervals were changed from 30 seconds to 10 seconds for the initial draining of the container (for liquid products only) and for the draining of the rinsate after the pressure rinse. The length of the pressure rinse interval was changed from ''30 seconds'' to ''at least 30 seconds.''
- Several details about the orientation of the container were added, including that the user must hold the container upside down and insert the rinsing nozzle in the side of the container.
- The pressure requirement was changed from exactly 40 PSI to ''about 40 PSI'' to allow a range of pressures in response to several comments expressing concern about requiring a pressure of exactly 40 PSI in the field.

3. *Comments - container orientation.* A few commenters noted that the instructions are not clear in stating that the container must be inverted and that the rinse nozzle must be inserted on the side (or bottom) of the container. A registrant group suggested inserting the nozzle ''on the side of the container opposite the closure and in a direction towards the bottom of the container.'' A registrant recommended instructing the user to ''Force pressure rinsing nozzle through what was the bottom of the container or through the side of the container and...'' and also recommended that the instructions specify holding the container upside-down during the rinse process.

4. *EPA response - container orientation.* EPA agrees with these commenters that more details about how to hold the container and where the nozzle should be inserted should be included. Therefore, the procedure was modified to instruct the user to hold the container upside down and to insert the rinsing nozzle in the side of the container.

K. Non-Water Diluents (§ 156.146(d))

1. *Final regulations.* A registrant who wishes to require users to clean a container with a diluent other than water (e.g. solvents) must submit a written request to EPA to modify the residue removal instructions of this section. EPA may grant the request if certain conditions are met. The registrant must indicate why a non-water diluent is necessary and must propose appropriate residue removal instructions and disposal instructions that identify the diluent. If the non-water diluent is permitted by the label to be used in application, the instructions may allow the rinsate to be added to application equipment or mix tank. If use of the diluent in application is not permitted, the rinsate must be collected and stored for eventual disposal. EPA must approve, in writing, the modification of the residue removal instructions before the pesticide product can be distributed or sold.

2. *Changes.* The final regulations are almost identical to the proposed regulations regarding non-water diluents. The final rule adds the requirement for the registrant to propose disposal instructions to ensure that end users have information about how to appropriately dispose of rinsate from a diluent other than water. One minor modification was to add ''or mix tank'' as an option for where rinsate may be added if the label allows the non-water diluent to be part of the application mixture. This change was made to be consistent with the changes in the triple rinse and pressure rinse instructions. In addition, several minor editorial changes were made to make this section more clear.

L. Residue Removal Instructions for Refillable Containers (§ 156.156)

1. *General (Introductory Text for § 156.156*)—i. *Final regulations.* The label of each pesticide product packaged in a refillable container must include the residue removal instructions specified in § 156.156. The residue removal instructions must be given for all pesticide products that are distributed or sold in refillable containers, including those that do not require dilution prior to application.

ii. *Changes.* This requirement is substantively the same as it was in the proposed regulation. Some minor editorial and format changes were made to improve the clarity of the regulatory text. In addition, the second sentence, which reinforces that the instructions apply to all products that are distributed or sold in refillable containers, including those that do not require dilution prior to disposal, was moved from the subsection on instructions for residue removal to the introductory text. EPA made this change because the explanatory language applies to the whole section (including instructions on the timing of the procedures).

2. *Timing of residue removal procedures (§ 156.156(a))*—i. *Final regulations.* The label of a pesticide product packaged in a refillable container (and that is subject to this requirement) must have one of the following sets of instructions on the timing of container cleaning:

- ''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.''
- ''Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.''

The statement must immediately precede the residue removal instructions and must be consistent with those instructions.

ii. *Changes.* These statements were expanded in the final regulation to distinguish between cleaning before disposal and cleaning before refilling in response to comments. The proposed statements simply said ''Clean [or pressure rinse] container before disposal.'' The changes in the final rule include adding ''final'' to the description of disposal, adding that the person disposing of the container is responsible for cleaning it, and including the additional statement of ''Cleaning before refilling is the responsibility of the refiller.''

3. *Residue removal instructions prior to container disposal (§ 156.156(b))*—i.

Final regulations. For pesticide products sold or distributed in refillable containers, the label must include instructions for cleaning the container prior to disposal. The instructions must be appropriate for the characteristics of the product and adequate to protect human health and the environment. The instructions could include any one of the following, as long as the instructions meet the standards described in the previous sentence:

- The refilling residue removal procedure developed by the registrant for the pesticide product.
- Standard industry practices for cleaning refillable containers.
- For pesticides that require dilution prior to application, the following statement:

''To clean container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.''

- Any other statement the registrant considers appropriate.

ii. *Changes.* The final regulations are almost identical to those in the proposed rule, except for a few editorial and format changes. The phrase ''To clean container before final disposal'' was added to the specified procedure to emphasize that users should only clean the container before disposal and not before having the container refilled. The phrase ''into application equipment or a mix tank'' was added to be consistent with the emptying instructions for nonrefillable containers. One sentence that helps clarify the scope of the requirement for residue removal instructions on refillable containers was moved from this section to the introductory text since it applies to the whole section.

M. Amendments to Existing § 156.10

1. *Final regulations.* The final rule modifies the existing regulations in 40 CFR 156.10 in the following three ways:

- A new § 156.10(d)(7) is added that allows the labels for refillable containers to have a blank space to allow the net weight or contents to be marked in by a refiller according to 40 CFR 165.65(h) or 165.70(i);
- The existing § 156.10(f) was modified to allow labels for refillable containers to have a blank space to allow the EPA establishment number to be marked in by a refiller according to 40 CFR 165.65(h) or 165.70(i); and
- The existing § 156.10(i)(2)(ix) regarding storage and disposal instructions was modified to refer to the applicable requirements in the rest of today's final rule.

2. *Changes.* The most significant change to the approach taken in the proposed regulation is that ''shall'' was changed to ''may'' in the two paragraphs establishing blank spaces, thus changing them from requirements to options for pesticide registrants. This change was made to provide flexibility to registrants in response to comments. EPA decided to make several minor revisions to the paragraphs allowing blank spaces to link the 40 CFR part 156 regulations to the 40 CFR part 165 repackaging regulations and to clarify that the blank space does not change the requirement for having the net contents or EPA establishment number on the label. First, the regulatory text allowing blank spaces was modified to refer to the 40 CFR part 165 regulations that require refillers to ensure that the net contents and EPA establishment number appear on the label. Second, the new paragraph in § 156.10(d)(7) was amended to clarify that § 156.10(a)(1)(iii) requires the net contents to be shown clearly and prominently on the label.

The paragraph on storage and disposal instructions was modified to account for changes in the structure of the container-related labeling, so it refers to subpart H of part 156 rather than specific sections. Finally, a requirement about the type size of the storage and disposal heading was added to § 156.10(i)(2)(ix) after the container regulations were proposed in 1994. Today's final rule maintains this requirement and corrects the reference to the child hazard warnings, which are located in § 156.60(b).

N. Compliance Date (§ 156.159)

1. *Final regulations.* The final regulations provide a 3–year compliance period. Specifically, within 3 years from today's date, all pesticide products distributed or sold by a registrant must have labels that comply with the 40 CFR part 156 requirements established in the final rule. This gives registrants a phase in period of 3 years to comply with the labeling requirements in §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146, and 156.156.

2. *Changes.* The most significant change is that the phase-in period was extended from 2 years to 3 years from the publication of the final rule. In addition, the regulatory language was revised to make it more clear. EPA agrees with some of the commenters that a longer compliance period will make it easier and less burdensome to comply with the label standards. To facilitate compliance while trying to minimize the impact on companies, EPA lengthened the compliance period for the label standards to 3 years. EPA believes that a 3–year period is sufficient based on the results of the economic analysis. In addition, 3 years is consistent with the phase-in period for the nonrefillable container regulations.

X. Relationship to Other Programs and Agencies

Certain laws administered by EPA and other agencies may affect the design of pesticide containers or procedures and standards for removal of residue from pesticide containers. This section identifies the laws that EPA considers to have the most significant impact on pesticide containers and containment. The description of these laws is for informational purposes only; no changes are being made in the laws described below. Nothing in this final rule is intended to alter obligations under other statutes.

A. Resource Conservation and Recovery Act (RCRA)

Requirements under RCRA may affect the handling of pesticide containers under certain circumstances. RCRA Subtitles C and I are described briefly below.

FIFRA sections 19(f)(3) and 19(h) specify that FIFRA section 19 does not affect the requirements or authorities of RCRA. Accordingly, today's rule does not alter any existing RCRA requirements, and any applicable RCRA provisions will apply in addition to the provisions of any final rule issued under FIFRA section 19. In addition, FIFRA section 19(f)(1)(B)(iv) specifies that the residue removal regulations may be coordinated with requirements for container rinsing under RCRA. As outlined below, this rule provides for coordination in this area.

1. *Hazardous waste requirements.* Subtitle C of RCRA creates a cradle-to-grave system for managing hazardous wastes. RCRA Subtitle C regulations include requirements for generators, transporters, and others who handle hazardous wastes. The regulations cover any ''solid waste'' (defined at 42 U.S.C. 1004 and 40 CFR 261.2) that is listed as a hazardous waste or exhibits a characteristic of hazardous waste, as set out in part 261. Pesticides (including pesticide residues in containers that are not empty per the RCRA definition in § 261.7) that are discarded or intended to be discarded may qualify as hazardous wastes, if the pesticide is a hazardous waste as defined in § 261.33

(discarded commercial chemical products, off-specification products or manufacturing intermediates, container residues, and spill residues), or if they exhibit a characteristic of hazardous waste as described in part 261 subpart C, and are not otherwise exempt from regulation. A hazardous waste remaining in a container is not subject to Subtitle C regulation if, among other things, the container is ''empty'' as defined in § 261.7. A container is ''empty'' if the wastes are removed pursuant to § 261.7(b)(1) or (b)(2), or, in the case of an acute hazardous waste, the container has been triple rinsed or otherwise cleaned pursuant to § 261.7(b)(3). EPA believes that the triple rinsing procedure provided in today's final rule meets the requirements of § 261.7(b)(3), thus meeting the directive in FIFRA section 19(f)(1)(B)(iv).

2. *Underground storage tanks.* RCRA Subtitle I provides for the development and implementation of a comprehensive regulatory program for ''underground storage tanks'' (USTs), defined at 42 U.S.C. 6991 and 40 CFR 280.12 as tanks that are used to contain an accumulation of ''regulated substances'' and whose volume (including underground pipes connected thereto) is 10 percent or more below ground. Regulated substances include petroleum or substances defined as hazardous under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) (except hazardous wastes regulated under RCRA Subtitle C). CERCLA hazardous substances, enumerated at 40 CFR part 302, include a number of pesticides. UST requirements at 40 CFR part 280 include standards for new tanks as well as requirements for leak detection, closure, corrective action, and financial responsibility.

EPA is not aware of the extent of industry use of USTs to store agricultural pesticides, and solicited comment on the use of underground tanks to store agricultural pesticides and on the preferred means of coordinating UST and FIFRA requirements. No comments were received on the topic. Because today's final rule requires secondary containment of any bulk container holding pesticide, underground storage would be precluded unless the secondary containment structure was also underground. EPA considers that the expense of such a construction makes it unlikely that a facility would use underground storage, and assumes that since no comments were received, underground storage of agricultural pesticides is generally avoided in the industry. Furthermore, EPA has noted, in its review of State regulations, that underground storage of pesticides is forbidden by States with bulk containment regulations.

B. Clean Water Act

EPA has issued several regulations under the Clean Water Act (CWA) (33 U.S.C. 1251 *et seq.*) that are related to today's rule and that affect some sectors of the pesticide industry. The goal of the CWA is to achieve zero discharge of wastewater pollutants.

1. *Pesticide chemicals category, formulating, packaging and repackaging effluent limitations guidelines, pretreatment standards, and new source performance standards: Final rule.* On November 6, 1996, EPA promulgated regulations governing effluents from pesticide formulating, packaging and repackaging facilities (61 FR 57518, Ref. 57). Effluent guidelines establish limitations on the pollutants discharged into waters of the United States from industrial point sources. The Pesticide Formulating, Packaging and Repackaging (PFPR) effluent guidelines apply to facilities engaged in formulating, packaging or repackaging pesticides. The PFPR effluent guidelines regulation set limitations for facilities in two different regulatory subparts of 40 CFR part 455 (subparts C and E). Subpart C applies to facilities that discharge (or have the potential to discharge) wastewater from pesticide formulating, packaging, and/or repackaging operations. All pesticides with the exception of a few specific exemptions are included under subpart C. Subpart E applies only to refilling establishments that repackage agricultural pesticides into refillable containers. Subpart E does not apply to facilities that repackage non-agricultural pesticides. The same formulators, packagers, and repackagers (subpart E) and refilling establishments (subpart E) are affected by today's final pesticide container and containment rule. However, the PFPR effluent guidelines regulation does not include the other types of facilities covered by today's containment rule, namely commercial applicators and custom blenders.

Under the effluent guidelines rule, refilling establishments are required to achieve zero discharge of wastewater pollutants. For these facilities, the zero discharge regulation was based on reuse, recycle and water conservation practices, as well as contract hauling of any non-reusable wastewater for off-site disposal, if necessary. However, effluent guidelines do not require specific practices or control technologies. Many refilling establishments achieve the zero discharge requirement through water conservation and good housekeeping, which includes repairing leaking valves and fittings and collecting drips in pans under appurtenances. Facilities that also provide application services typically reuse rinsate as make-up water for application in accordance with the label. Compliance with today's pesticide container and containment rule regarding requirements for containment structures, and adherence to the recommendations regarding rinsate collection will assist refilling establishments in achieving the zero discharge of pollutants required by the effluent guidelines.

Under the PFPR effluent guidelines, subpart C facilities (formulators, packagers, and repackagers) are required to either achieve zero discharge of wastewater pollutants or to implement specific reuse, recycle, and water conservation practices (Pollution Prevention Alternative). For example, under the pollution prevention alternative, facilities must reuse their rinsates directly into the formulation or store rinsates for use in future formulation of the same or a compatible product.

When the PFPR effluent regulations were proposed in April 1994 (Ref. 64), the scope of subpart C included all pesticide active ingredients (PAIs) (with the exception of sodium hypochlorite and the partial exemption of specified sanitizers) and a wide variety of associated wastewater sources. EPA published a supplemental notice on June 8, 1995 (Ref. 61) which refined the scope of PAIs and wastewater sources. In the final rule, most sanitizer products were excluded, based on a number of factors, such as:

- Sanitizer products are formulated for the purposes of their labeled end use to ''go down the drain;''
- Sanitizer active ingredients are more likely to be sent to Publicly Owned Treatment Works (POTWs) in greater concentrations and volumes from their labeled end use than from rinsing formulating equipment at the PFPR facility;
- Biodegradation data received with comments on some of these sanitizer active ingredients support the hypothesis that they do not pass through POTWs;
- These sanitizer active ingredients represent a large portion of the low toxicity PAIs considered for regulation at the time of proposal; and
- Many sanitizer solutions containing these active ingredients are cleared by the Food and Drug Administration

(FDA) as indirect food additives under 21 CFR 178.1010.

The final PFPR effluent guidelines rule (subpart C) combined the pool chemicals exemption into the sanitizer exemption and exempted other pool chemicals in addition to the only pool chemical in the proposal, sodium hypochlorite. The additional chemicals that are included in the definition of pool chemicals in 40 CFR 455.10 include calcium hypochlorite, lithium hypochlorite, potassium hypochlorite, chlorinated isocyanurate compounds and halogenated hydantoins.

The bulk containment requirements in today's rule are consistent with the control technologies which are the basis for the PFPR effluent guidelines for refilling establishments (subpart E). In addition, the repackaging and refillable container requirements of today's rule, particularly the adherence to the recommendations regarding rinsate collection, will aid facilities in collecting and reusing rinsates to meet the zero discharge/pollutant prevention alternative requirements of subpart C of the PFPR effluent guidelines.

2. *National Pollutant Discharge Elimination System (NPDES) - Storm Water Phase II Final Rule*. EPA issued final regulations on December 8, 1999 (64 FR 68722, Ref. 52) addressing storm water discharges. The regulation established a ''no exposure'' exemption for storm water discharges from facilities where industrial materials and activities are not exposed to storm water. Upon review of earlier regulations that excluded storm water discharges from certain categories of light industry from NPDES permit requirements, a court invalidated the light industry exemption. In 1992, the Ninth Circuit court concluded that the exemption impermissibly relied on the unsubstantiated judgment of the facility operator to determine applicability of the exemption. The new rule established in 1999 now allows the exemption, but requires that the facility meet certain conditions and provide a certification for tracking and accountability. ''No exposure'' means that all industrial materials or activities are protected by storm-resistant sheltering so they are not exposed to rain, snow, snowmelt or runoff. (40 CFR 122.26(g))

Pesticide refilling operations and bulk storage operations required to apply for and obtain NPDES permits for storm water discharges associated with such operations may take advantage of this exemption if they provide a certification of ''no exposure'' and maintain the certified conditions at the facility. Even when an owner/operator certifies to no exposure, the NPDES permitting authority may still require a permit if it determines that there is a discharge interfering with water quality standards. This will provide an added incentive to place all tanks within secondary containment that is protected from the elements. Facilities that are not exempt will have to get a discharge permit.

3. *Effluent guidelines and standards for the transportation equipment cleaning (TEC) Industry*. On August 14, 2000, EPA published a final rule (65 CFR 49665, Ref. 51) establishing restrictions on the discharge of wastewater from cleaning the interiors of tank trucks, rail tank cars, inland tank barges, ocean/sea tankers, and other similar tanks used to transport materials, including agricultural chemicals and fertilizers. The TEC regulations do not apply to wastewaters generated from cleaning the interiors of pesticide drums or intermediate bulk containers (IBCs), defined as portable containers with 450 liters (119 gallons) to 3,000 liters (793 gallons) capacity. EPA subsequently studied the Industrial Container and Drum Cleaning Industry. The Preliminary Data Summary - Industrial Container and Drum Cleaning Industry (EPA–821–R–02–011 and Ref. 48) can be downloaded from the following link: *http://www.epa.gov/waterscience/pollcontrol/drum/index.html*.

4. *Spill prevention control and countermeasures (SPCC)*. On July 17, 2002, (67 FR 47042, Ref. 47), EPA promulgated regulations under section 311(j)(1)(C) of the Clean Water Act (known as the SPCC regulations) for the prevention of oil spills into navigable waters and adjoining shorelines. The regulations apply to facilities that, because of their location, could reasonably be expected to discharge oil into navigable waters or adjoining shorelines. Part 112 of 40 CFR outlines requirements for both the prevention and the response to oil spills. Facilities that are subject to the SPCC regulations include any non-transportation-related onshore or offshore facility engaged in drilling, producing, gathering, storing, processing, refining, transferring, distributing, using, or consuming oil and oil products, which due to its location, could reasonably be expected to discharge oil, in quantities that may be harmful, into navigable waters of the United States or adjoining shorelines. Because the definition of ''oil'' under CWA section 311 is very broad (including oil ''of any kind and in any form''), it could potentially include pesticides that contain oil or are oil-based. EPA expects that comparatively few, if any, of the facilities covered by today's pesticide container and containment rule are also subject to SPCC requirements, but if any are, both today's rule and SPCC requirements apply. On December 12, 2005, EPA proposed two separate amendments to the SPCC Rule. One of them (Ref. 24) streamlines the regulatory requirements for qualified facilities and equipment regulated under 40 CFR part 112 and proposes a separate extension of the compliance date for farms. The other amendment (Ref. 23) extends the SPCC compliance dates for all facilities.

C. Occupational Safety and Health Administration Requirements

The Occupational Safety and Health Act (U.S.C. 2601 *et seq.*) addresses occupational safety and health hazards by establishing requirements for employers and employees and authorizing the Occupational Safety and Health Administration (OSHA) to establish mandatory occupational safety and health standards.

Tanks and containers that are used to store flammable and combustible liquids in occupational settings are subject to OSHA requirements under 29 CFR 1910.106. For storage tanks, § 1910.106(b) contains design and construction requirements, including standards for materials, spacing, venting, drainage and diking, fire and flood resistance, and testing for strength and tightness. Section 1910.106(c) contains specifications for piping, valves, and fittings. Section 1910.106(d) sets out design and construction requirements for containers and portable tanks, and also contains specifications for storage areas. Today's regulations do not contradict or supercede any existing OSHA requirements, and any applicable OSHA provisions will apply in addition to the provisions of today's rule.

D. Department of Transportation Hazardous Materials Regulations

The Hazardous Materials Transportation Act of 1974, (49 U.S.C. 1801 et seq) authorizes DOT to designate as hazardous materials those materials that may pose unreasonable risk to health and safety or property, and regulate the handling and transportation of such materials. The DOT regulations and their relationship to today's final pesticide container and containment regulations are discussed in detail in Unit IV. and many other places throughout this preamble.

XI. FIFRA Mandated Reviews

In accordance with FIFRA sec. 25(a), the Agency submitted a draft of this final rule to the FIFRA Scientific

Advisory Panel (SAP), the Secretary of Agriculture, and the Committee on Agriculture in the House of Representatives, and the Committee on Agriculture, Nutrition, and Forestry in the United States Senate.

The FIFRA SAP waived its review of this final rule because the significant scientific issues involved have already been reviewed by the SAP and additional review isn't necessary. The USDA did not submit any official comments.

XII. References

The following is a listing of the documents that are specifically referenced in this final rule. These documents, and other supporting materials, are included in the docket established for this rulemaking under docket ID No.EPA-HQ-OPP–2005–0327 at *http://www.regulations.gov*.

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XIII. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this final rule is a ''significant regulatory action'' because these requirements may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted a draft final rule to OMB for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this rulemaking as required by sec. 6(a)(3)(E) of the Executive Order.

In addition, EPA has prepared two Economic Analyses (EAs) of the potential costs and benefits associated with this rule, one for the container requirements and another for the containment requirements. The reason for having two EAs is because the regulated community differs in each case. For example, the container requirements affect pesticide formulators and refillers of all pesticides while the containment requirements affect retailers, for-hire applicators and custom blenders of agricultural pesticides. The EAs, entitled *Economic Analysis of the Pesticide Container Design and Residue Removal Standards* (Ref. 22) and *Economic Analysis of the Bulk Pesticide Containment Structure Regulations* (Ref. 21), are available in

the docket for this rule and are briefly summarized here.

EPA estimates the total cost of the final rule to be $11.3 million ($8.37 million for containers + $2.93 million for containment) and the total benefits from the final rule to be $17 - 23.4 million. When the estimated cost of the final rule is compared to the estimated cost for the proposed rule, there is an annual cost reduction of approximately $27.4 - $38.6 million. This reduction in estimated cost is due to the choices made in the final rule that lead to a narrowing in the scope of regulated entities and products that are subject to the final rule. During the first year, regulated facilities will experience an increase in total paperwork cost burden of $1 million (containment) and $7.0 million (containers) due primarily to inspection and recordkeeping costs. For containers, in the second year and continuing thereafter, total paperwork cost burden per facility will decrease to 25 hours from 81 hours in the first year, reducing paperwork burden costs to $4.1 million annually.

Over 20 respondents submitted general comments on the Regulatory Impact Analyses (RIAs) or EAs for the proposed rule. Nearly all of the commenters wanted EPA to reevaluate the economic assessments. The most common comments were: 1) The costs far outweigh the benefits; 2) costs were underestimated; 3) benefits were overestimated; 4) this is a major rule, contrary to EPA's assessment; 5) the rule will have a significant impact on medium and large formulators as well as small formulators; 6) the rule will have a general impact on various industry segments; and 7) the rule does not comply with the standards of the Executive Order. Commenters who objected to the cost estimates mainly disagreed with EPA's estimate of the cost of complying with the six 9's residue removal standard. State regulatory agencies predicted that the rule would increase their workload and expressed the hope that EPA would increase State funding.

EPA reopened the comment period on the proposed rule on October 21, 1999 (64 FR 56918, Ref. 53) on three issues, proposing to reduce the scope of the container standards, add an exemption for certain antimicrobial pesticides, and adopt some of the Department of Transportation (DOT) hazardous materials regulations. These potential changes decreased the estimated economic impact by reducing the number of pesticide products subject to the container requirements compared to the original proposal.

Major changes resulted in cost reduction from the economic analysis for the proposed rule. Among these is the elimination of the requirement to demonstrate the hydraulic conductivity of containment structures, lowering of the residue removal standard from six 9's to four 9's, and limiting of rinse-testing requirement to those formulations expected to be problematic.

B. Paperwork Reduction Act (PRA)

The information collection requirements in this final rule have been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA for this final rule has been assigned EPA ICR No. 1631.02, and OMB control number 2070–0133. Consistent with the procedures at 5 CFR 1320.11, EPA sought comment on two Information Collection Request (ICR) documents that were submitted to OMB in conjunction with issuing the proposed rule (identified under EPA ICR No. 1631.01 and No. 1632.01). For the final rule, the two ICR documents were combined into one ICR document, which reflects the information collection provisions in this final rule. The ICR document for this final rule (identified under EPA ICR No. 1631.02) (Ref. 30) is included in the docket for the final rule.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. For the ICR activity contained in this final rule, in addition to displaying the applicable OMB control number in this Unit, the Agency is amending the table in 40 CFR 9.1 to list the OMB control number assigned to this ICR activity. Due to the technical nature of the table, EPA finds that further notice and comment about amending the table is unnecessary. As a result, EPA finds that there is good cause under section 553(b)(B) of the Administrative Procedures Act (APA), 5 U.S.C. 553(b)(B), to amend this table without further notice and comment.

Under the PRA, burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

In this final rule, the information collection requirement burden on the regulated community includes the administrative burden associated with keeping monthly inspection and maintenance records for bulk pesticide containment structures. The regulated community's administrative burden is defined as the time spent to record and file the inspection and maintenance of the bulk pesticide containment structures per month. There is not a requirement to submit the records or reports to the Agency, however, EPA or its representatives may, from time to time, request information under these regulations to ensure compliance with the regulation.

The two ICRs for the proposed rule were combined into a single ICR for the final rule. This ICR document provides detailed presentations of the estimated annual burden and costs for 3 years, which represents the maximum OMB approval period for any collection activity, after which the Agency must seek renewal of the ICR approval from OMB every 3 years for as long as the requirements exist.

1. *Container burden.* The public reporting burden for this collection of information is estimated to be 66 hours in the first year of compliance with this rule for approximately 1,804 pesticide registrant respondents, and 10 hours in subsequent years. For an estimated 16,795 agricultural pesticide refiller respondents, the reporting burden is 7.5 hours per year. For an estimated 322 swimming pool supply companies, the reporting burden is 7.5 hours per year. The total annual paperwork burden across all pesticide registrant respondents, assuming that 1,804 facilities will be affected by the requirements, is 112,209 hours in first year, and 11,185 hours in all other years. The total annual paperwork burden across all agricultural pesticide refiller respondents, assuming 16,795 facilities will be affected by the

requirements, is 125,963 hours. The total annual paperwork burden across all swimming pool supply companies, assuming 322 facilities will be affected by the requirements, is 2,415 hours.

2. *Containment burden*. The public recordkeeping burden for this collection of information is estimated to be 7.5 hours for approximately 4,665 respondents in the first year after promulgation of this rule, which includes initial rule familiarization. The average annual burden per respondent for subsequent years is estimated to be 7.5 hours. The total annual paperwork burden across all respondents, assuming that 4,665 facilities will be affected by the requirement, is 34,988 hours per year.

In comments filed after reviewing the proposed ICRs in 1994, OMB commented that EPA should consider less burdensome testing requirements that meet the objective that disposal of containers poses no unreasonable risk to health of the environment. As discussed previously, EPA has modified the requirements to be less burdensome, decreasing the total industry burden for the final rule. The decrease in burden results mainly from the elimination of the hydraulic conductivity standard for containment structures, lowering of the residue removal standard to four 9's, and requiring residue removal testing only for problematic formulations.

The Agency is seeking additional comments on the paperwork burden estimates related to the provision in the final rule that allows States with existing regulations (§ 165.97) to request the authority to continue implementing its State containment regulations in lieu of EPA's regulations. As discussed previously, EPA added this provision in response to comments asking EPA to consider existing State regulations. Since this provision and related burden estimates were not part of the ICRs that were prepared and for which public comment was sought in conjunction with the proposed rule, EPA is providing this opportunity for public comment. Direct your comments on this to EPA using the public docket that has been established for this final rule (docket ID number EPA–HQ–OPP–2005–0327) at *http://www.regulations.gov*. In addition, send a copy of your comments to OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, Attention: Desk Office for EPA ICR No. 1361.02. Since OMB is required to complete its review of the ICR between 30 and 60 days after August 16, 2006, please submit your comments no later than September 15, 2006.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that this final rule will not have a significant adverse economic impact on a substantial number of small entities. This determination is based on the Agency's two economic analyses performed for this rulemaking, which are briefly summarized in Unit XIII.A., and copies of which are available in the docket for this rulemaking (Refs. 21 and 22). The following is a brief summary of the factual basis for this certification.

Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined in accordance with the RFA as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Based on the industry profiles for this rulemaking that EPA prepared as part of the Economic Analyses, EPA has determined that this final rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, small entity for purposes of this final rule is synonymous with small business.

In addition, for purposes of analyzing the potential impacts of this final rule on small businesses, the Agency disaggregated the universe of potentially impacted small business into subcategories of large-small businesses, medium-small businesses, and small-small businesses. The analysis disaggregated the impacts of small businesses into these sub-categories because the SBA size standard for small businesses, which are primarily intended to define whether a business entity is eligible for Federal government programs and preferences reserved for small businesses (13 CFR 121.101), may not be representative of all small businesses in the industry sectors impacted by this rulemaking. (See section 632(a)(1) of the Small Business Act.) The SBA size standard is generally based on the number of employees an entity in a particular industrial sector may have. For example, in the Pesticide and Other Agricultural Chemical Manufacturing sector (i.e., NAICS code 325320) approximately 92% of the industries would be classified as small businesses under the SBA definition (500 or fewer employees). However, 60% of the SBA defined small companies have 1 to 19 employees, which are considered small-small businesses in the Agency's analysis. By disaggregating the potential impacts of this final rule on small businesses, the Agency was able to consider the distribution of the estimated impacts among the universe of potentially impacted small businesses, particularly potential impacts on the small-small businesses.

Considering just the container requirements, the estimated costs of compliance for the universe of potentially impacted small businesses in each of the regulated industries as a proportion of their current revenues are estimated to be less than 1 percent. Specifically, using the SBA definition of small businesses, the costs of compliance for all small businesses are estimated to be less than 0.02 percent of the current average entity revenues. Looking at the estimated impacts using the disaggregated small business sub-categories used in the Agency's analysis (which further divides small businesses into large-small, medium-small and small-small business within each of the regulated industries), no small-small business is estimated to incur costs which account for more than 0.04 percent of current average entity revenues.

Considering just the containment requirements, the estimated costs of compliance for the universe of potentially impacted small businesses as a proportion of their current revenues are estimated to be less than 1 percent, except for small commercial applicators. When only looking at commercial applicators, and using the SBA definition of small business, the costs of compliance for potentially impacted small commercial applicators to install new secondary containment units are estimated to be as high as 2.7 percent of the current average entity revenues. Small-small commercial applicators, based on the disaggregated small business sub-categories used in the Agency's analysis, may face costs of compliance that are as much as 7.8 percent of the current average entity revenues. However, only 6 of the 3,000 small commercial applicators were identified as small-small commercial applicators that will need to install both a secondary containment unit and a containment pad and thus are estimated to be impacted in this way. The costs of compliance for potentially impacted

small commercial applicators to retrofit existing containment structures are estimated to be less than 1 percent of the current average entity revenues.

For agricultural pesticide refillers, the other industry estimated to be impacted by the containment regulations, the costs of compliance for small agricultural pesticide refillers are estimated to be less than 0.18 percent of current average entity revenues using the SBA definition of small businesses, and less than 0.34 percent of current average entity revenues based on the disaggregated small-small business subcategory used in the Agency's analysis.

Considering the overall impact of this final rule on the universe of potentially impacted small businesses using the SBA definition for small business, the Agency has determined that this final rule will not have a significant adverse economic impact on a substantial number of small entities.

In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and the Agency. In doing so for this particular rule, as discussed in more detail previously, the major changes that EPA made to the proposed requirements resulted in significant reductions in the potential costs of compliance for this rulemaking.

D. Unfunded Mandates Reform Act (UMRA)

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or for the private sector in any one year. As described in Unit XIII.A., the annual costs associated with this action are estimated to total $11.3 million ($8.37 millioin for containers + $2.93 million for containment). This cost represents the incremental cost to registrants, pesticide dealers, commercial applicators and custom blenders attributed to the requirements in this action. Accordingly, this action is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this final rule does not have federalism implications, because it would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. Under cooperative agreements with EPA, States will be involved in compliance monitoring and enforcement activities, but are not otherwise expected to engage in the activities regulated by this rule. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 22951, November 6, 2000), EPA has determined that this action does not have tribal implications because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. EPA is not aware of any tribal governments which are pesticide registrants, refillers or dealers storing large quantities of pesticides. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), does not apply to this action because it is not designated as an economically significant regulatory action as defined by Executive Order 12866 (see Unit XIII.A.). Further, this action does not establish an environmental standard that is intended to have a negatively disproportionate effect on children. To the contrary, this action will provide added protection for children from pesticide risk by ensuring the integrity of pesticide container design, as well as secure pesticide storage and disposal.

H. Executive Order 13211

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer Advancement Act (NTTAA)

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action requires performance standards for containment structures and residue removal testing for containers of certain pesticide formulations, but does not require specific methods or standards. Therefore, this action does not impose any technical standards that would require Agency consideration of voluntary consensus standards.

J. Executive Order 12898

This action does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has not considered environmental justice-related issues. Although not directly impacting environmental justice-related concerns, the Agency believes that the requirements in this rule will assist EPA and others in reducing potential exposures associated with the handling, storage, management and disposal of pesticide containers covered by the rule.

XIV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 156

Environmental protection, Labeling, Pesticides and pests.

List of Subjects in 40 CFR Part 165

Environmental protection, Packaging and containers, Containment structures, Pesticides and pests.

Dated: August 3, 2006.

Stephen L. Johnson,

Administrator.

■ Therefore, 40 CFR chapter I is amended as follows:

■ 1. Part 9 is amended as follows:

PART 9—[AMENDED]

■ a. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ b. In § 9.1 the table is amended by adding a new center heading entitled ''Pesticide Management and Disposal'' and an entry for new part 165 after the center heading and entries for ''State Registration of Pesticide Products,'' to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB Control No.
* * * * * * *	
Pesticide Management and Disposal	
Part 165	2070–0133
* * * * * * *	

PART 156—[AMENDED]

■ 2. Part 156 is amended as follows:

■ a. The authority citation for part 156 continues to read as follows:

Authority: 7 U.S.C. 136 through 136y.

■ b. In § 156.10 by adding paragraph (d)(7), and by revising paragraphs (f) and (i)(2)(ix) to read as follows:

§ 156.10 Labeling requirements.

* * * * *

(d)* * *

(7) For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank to allow the net weight or measure of content to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide. As required in paragraph (a)(1)(iii) of this section, the net contents must be shown clearly and prominently on the label.

* * * * *

(f) *Producing establishment's registration number.* The producing establishment registration number preceded by the phrase ''EPA Est.'', of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank after the phrase ''EPA Est.'' to allow the EPA establishment registration number to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide.

* * * * *

(i) * * *

(2)* * *

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part and part 165 of this chapter. These instructions must be grouped and appear under the heading, ''Storage and Disposal.'' This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in § 156.60(b))

* * * * *

■ c. By adding Subpart H entitled ''Container Labeling'' to read as follows:

Subpart H—Container Labeling

Sec.

156.140 Identification of container types.
156.144 Residue removal instructions - general.
156.146 Residue removal instructions for nonrefillable containers - rigid containers with dilutable pesticides.
156.156 Residue removal instructions for refillable containers.
156.159 Compliance date.

Subpart H—Container Labeling

§ 156.140 Identification of container types.

For products other than plant-incorporated protectants, the following statements, as applicable, must be placed on the label or container. The information may be located on any part of the container except the closure. If the statements are placed on the container, they must be durably marked on the container. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.

(a) *Nonrefillable container.* For nonrefillable containers, the statements in paragraphs (a)(1) through (a)(4) of this section are required. If placed on the label, the statements in paragraphs (a)(1) through (a)(3) of this section must be under an appropriate heading under the heading ''Storage and Disposal.'' If any of the statements in paragraphs (a)(1) through (a)(3) of this section are placed on the container, an appropriate referral statement such as ''See container for recycling [or other descriptive word] information.'' must be placed on the label under the heading ''Storage and Disposal.''

(1) *Statement identifying a nonrefillable container.* The following phrase is required: ''Nonrefillable container.''

(2) *Reuse statement.* One of the following statements is required. Products with labels that allow household/residential use must use the statement in paragraph (a)(2)(i) or (a)(2)(iii) of this section. All other products must use the statement in paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section.

(i) ''Do not reuse or refill this container.''

(ii) ''Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state.''

(iii) The following statement may be used if a product is ''ready-to-use'' and

its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: ''Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container.''

(3) *Recycling or reconditioning statement.* One of the following statements is required:

(i) ''Offer for recycling if available.''

(ii) ''Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone number] or [web site]. For example, this statement could be ''Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1–877–952–2272 (toll-free) or *www.acrecycle.org*.''

(iii) A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.

(iv) An alternative recycling statement that has been reviewed and approved by EPA.

(v) ''Offer for reconditioning if appropriate.''

(4) *Batch code.* A lot number, or other code used by the registrant or producer to identify the batch of the pesticide product which is distributed and sold is required.

(b) *Refillable container.* For refillable containers, one of the following statements is required. If placed on the label, it must be under the heading ''Storage and Disposal.'' If the statement is placed on the container, an appropriate referral statement, such as ''Refilling limitations are on the container.'' must be placed under the heading ''Storage and Disposal.''

(1) ''Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose.''

(2) ''Refillable Container. Refill this container with [*common chemical name*] only. Do not reuse this container for any other purpose.''

§ 156.144 Residue removal instructions - general.

(a) *General.* Except as provided by paragraphs (c) and (d) of this section, the label of each pesticide product must include the applicable instructions for removing pesticide residues from the container prior to container disposal that are specified in §§ 156.146 and 156.156. The residue removal instructions are required for both nonrefillable and refillable containers.

(b) *Placement of residue removal statements.* All residue removal instructions must be placed under the heading ''Storage and Disposal.''

(c) *Exemption for residential/household use products.* Residential/household use pesticide products are exempt from the residue removal instruction requirements in this section through § 156.156.

(d) *Modification.* EPA may, on its own initiative or based on data submitted by any person, modify or waive the requirements of this section through § 156.156, or permit or require alternative labeling statements.

§ 156.146 Residue removal instructions for nonrefillable containers - rigid containers with dilutable pesticides.

The label of each dilutable (liquid or solid) pesticide product packaged in a rigid nonrefillable container must include the following residue removal instructions as appropriate.

(a) *Timing of the residue removal procedure.* One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraphs (b) and (c) of this section:

(1) ''Clean container promptly after emptying.''

(2) ''Triple rinse or pressure rinse container (or equivalent) promptly after emptying.''

(3) ''Triple rinse container (or equivalent) promptly after emptying.''

(b) *Triple rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers must include one of the following sets of instructions.

(1) For liquid dilutable pesticide products in containers small enough to shake, use the following instructions: ''Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.''

(2) For solid dilutable pesticide products in containers small enough to shake, use the following instructions: ''Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.''

(3) For containers that are too large to shake, use the following instructions: ''Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.''

(c) *Pressure rinse instructions.* The label of each dilutable pesticide product packaged in rigid nonrefillable containers may include one of the following sets of instructions, and one of them must be used if the statement in paragraph (a)(2) of this section is used. If one of these statements is included on the label, it must immediately follow the triple rinse instructions specified in paragraph (b) of this section.

(1) For liquid dilutable pesticide products, use the following label instruction: ''Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.''

(2) For solid dilutable pesticide products, use the following label instruction: ''Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.''

(d) *Non-water diluent.* (1) A registrant who wishes to require users to clean a container with a diluent other than water (e.g., solvents) must submit to EPA a written request to modify the

residue removal instructions of this section. The registrant may not distribute or sell the pesticide with the modified residue removal instructions until EPA approves the request in writing.

(2) The registrant must indicate why a non-water diluent is necessary for efficient residue removal, and must propose residue removal instructions and disposal instructions that are appropriate for the characteristics and formulation of the pesticide product and non-water diluent. The proposed residue removal instructions must identify the diluent. If the Directions for Use permit the application of a mixture of the pesticide and the non-water diluent, the instructions may allow the rinsate to be added to the application equipment or mix tank. If the Directions for Use do not identify the non-water diluent as an allowable addition to the pesticide, the instructions must require collection and storage of the rinsate in a rinsate collection system.

(3) EPA may approve the request if EPA finds that the proposed instructions are necessary and appropriate.

§ 156.156 Residue removal instructions for refillable containers.

The label of each pesticide product packaged in a refillable container must include the residue removal instructions in this section. Instructions must be given for all pesticide products that are distributed or sold in refillable containers, including those that do not require dilution prior to application.

(a) *Timing of the residue removal procedure*. One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraph (b) of this section:

(1) ''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.''

(2) ''Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.''

(b) *Residue removal instructions prior to container disposal*. (1) Instructions for cleaning each refillable container prior to disposal are required. The residue removal instructions must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.

(2) Subject to meeting the standard in paragraph (b)(1) of this section, the statement on residue removal instructions could include any one of the following:

(i) The refilling residue removal procedure developed by the registrant for the pesticide product.

(ii) Standard industry practices for cleaning refillable containers.

(iii) For pesticides that require dilution prior to application, the following statement: ''To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.''

(iv) Any other statement the registrant considers appropriate.

§ 156.159 Compliance date.

As of August 17, 2009, all pesticide products distributed or sold by a registrant must have labels that comply with §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146, and 156.156.

■ 3. By adding a new part 165 to read as follows:

Part 165—Pesticide Management and Disposal

Sec.

Subpart A—General

165.1 Scope.
165.3 Definitions.
165.4–165.19 [Reserved]

Subpart B—Nonrefillable Container Standards: Container Design and Residue Removal

165.20 General provisions.
165.23 Scope of pesticide products included.
165.25 Nonrefillable container standards.
165.27 Reporting and recordkeeping.
165.28–165.39 [Reserved]

Subpart C—Refillable Container Standards: Container Design

165.40 General provisions.
165.43 Scope of pesticide products included.
165.45 Refillable container standards.
165.47 What information must I report about my refillable containers?
165.48–165.59 [Reserved]

Subpart D—Standards for Repackaging Pesticide Products into Refillable Containers

165.60 General provisions.
165.63 Scope of pesticide products included.
165.65 Registrants who distribute or sell pesticide products in refillable containers.
165.67 Registrants who distribute or sell pesticide products to refillers for repackaging.
165.70 Refillers who are not registrants.
165.71–165.79 [Reserved]

Subpart E—Standards for Pesticide Containment Structures

165.80 General provisions.
165.81 Scope of stationary pesticide containers included.
165.82 Scope of pesticide dispensing areas included.
165.83 Definition of new and existing structures.
165.85 Design and capacity requirements for new structures.
165.87 Design and capacity requirements for existing structures.
165.90 Operational, inspection and maintenance requirements for all new and existing containment structures.
165.92 What if I need both a containment pad and a secondary containment unit?
165.95 What recordkeeping do I have to do as a facility owner or operator?
165.97 States with existing containment programs.

Authority: 7 U.S.C. 136 through 136y.

Subpart A—General

§ 165.1 Scope.

The Part 165 regulations establish standards and requirements for pesticide containers, repackaging pesticides, and pesticide containment structures.

§ 165.3 Definitions.

Act means the Federal Insecticide, Fungicide, and Rodenticide Act.

Agricultural pesticide means any pesticide product labeled for use in a nursery or greenhouse or for use in the production of any agricultural commodity, including any plant, plant part, animal, or animal product produced by persons (including farmers, ranchers, vineyardists, plant propagators, Christmas tree growers, aquaculturalists, horticulturists, orchardists, foresters, or other comparable persons) primarily for sale, consumption, propagation or other use by man or animals.

Appurtenance means any equipment or device which is used for the purpose of transferring a pesticide from a stationary pesticide container or to any refillable container, including but not limited to, hoses, fittings, plumbing, valves, gauges, pumps and metering devices.

Container means any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding any application tanks) used to enclose a pesticide. Containers that are used to sell or distribute a pesticide product and that also function in applying the product (such as spray bottles, aerosol

cans and containers that become part of a direct injection system) are considered to be containers for the purposes of this part.

Containment pad means any structure that is designed and constructed to intercept and contain pesticides, rinsates, and equipment wash water at a pesticide dispensing area.

Containment structure means either a secondary containment unit or a containment pad.

Custom blending means the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when:

(1) The blend is prepared to the order of the customer and is not held in inventory by the blender;

(2) The blend is to be used on the customer's property (including leased or rented property);

(3) The pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend;

(4) The blend is prepared from registered pesticides; and

(5) The blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.

Dry pesticide means any pesticide that is in solid form and that has not been combined with liquids; this includes formulations such as dusts, wettable powders, dry flowable powders, granules, and dry baits.

Establishment means any site where a pesticidal product, active ingredient, or device is produced, regardless of whether such site is independently owned or operated, and regardless of whether such site is domestic and producing a pesticidal product for export only, or whether the site is foreign and producing any pesticidal product for import into the United States.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person who controls, who is controlled by, or who is under common control with such person).

Flowable concentrate means a stable suspension of active ingredients in a liquid intended for dilution with water before use.

Nonrefillable container means a container that is not a refillable container and that is designed and constructed for one time containment of a pesticide for sale or distribution. Reconditioned containers are considered to be nonrefillable containers.

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.

Operator means any person in control of, or having responsibility for, the daily operation of a facility at which a containment structure is located.

Owner means any person who owns a facility at which a containment structure is required.

Pesticide compatible means, as applied to containers, that the container construction materials will not chemically react with the formulation. A container is not compatible with the formulation if, for example, the formulation:

(1) Is corrosive to the container;

(2) Causes softening, premature aging, or embrittlement of the container;

(3) Otherwise causes the container to weaken or to create the risk of discharge;

(4) Reacts in a significant chemical, electrolytic, or galvanic manner with the container, or

(5) Interacts in a way, such as the active ingredient permeating the container wall, that would cause the formulation to differ from its composition as described in the statement required in connection with its registration under FIFRA section 3.

Pesticide compatible means, as applied to secondary containment, that the containment construction materials are able to withstand anticipated exposure to stored or transferred materials without losing the capacity to provide the required secondary containment of the same or other materials within the containment area.

Pesticide dispensing area means an area in which pesticide is transferred out of or into a container.

Portable pesticide container means a refillable container that is not a stationary pesticide container.

Pressure rinse means the flushing of the container to remove pesticide residue by using a pressure method with a pressure of at least 40 PSI.

Produce means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to section 5 of the Act, and any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

Producer means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

Refillable container means a container that is intended to be filled with pesticide more than once for sale or distribution.

Refiller means 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.

Refilling establishment means an establishment where the activity of repackaging pesticide product into refillable containers occurs.

Repackage means, for the purposes of this part, to transfer a pesticide formulation from one container to another without a change in the composition of the formulation, the labeling content, or the product's EPA registration number, for sale or distribution.

Rinsate means the liquid produced from the rinsing of the interior of any equipment or container that has come in direct contact with any pesticide.

Runoff means surface water leaving the target site.

Secondary containment unit means any structure, including rigid diking, that is designed and constructed to intercept and contain pesticide spills and leaks and to prevent runoff and leaching from stationary pesticide containers.

Stationary pesticide container means a refillable container that is fixed at a single facility or establishment or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

Tamper-evident device means a device which can be visually inspected to determine if a container has been opened.

Transport vehicle means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

Triple rinse means the flushing of the container three times to remove pesticide residue by using a non-pressurized method.

Washwater means the liquid produced from the rinsing of the exterior of any equipment or containers that have or may have come in direct contact with any pesticide or system maintenance compound.

§§ 165.4–165.19 [Reserved]

Subpart B—Nonrefillable Container Standards: Container Design and Residue Removal

§ 165.20 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The regulations in this subpart establish design and construction requirements for nonrefillable containers used for the distribution or sale of some pesticide products.

(b) *Do I have to comply with the regulations in this subpart*? You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in nonrefillable containers. If your pesticide product is subject to the regulations in this subpart as set out in § 165.23, your pesticide product must be distributed or sold in a nonrefillable container that meets the standards of these regulations.

(c) *When do I have to comply*? As of August 17, 2009, all pesticide products distributed or sold by you in nonrefillable containers must be distributed or sold in compliance with these regulations.

§ 165.23 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to manufacturing use products, as defined in § 158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.

(c) *Which antimicrobial pesticide products are not subject to the regulations in this subpart*? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (d) of this section.

(d) *How will EPA determine if an ''antimicrobial'' pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment*? (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the nonrefillable container regulations within the time frames established by EPA in the rule or in its notification.

(e) *What other pesticide products are subject to the regulations in this subpart*? (1) Except for manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt under paragraph (c) of this section, all of the regulations in this subpart apply to a pesticide product if it satisfies at least one of the following criteria:

(i) The pesticide product meets the criteria of Toxicity Category I as set out in § 156.62 of this chapter.

(ii) The pesticide product meets the criteria of Toxicity Category II as set out in § 156.62 of this chapter.

(iii) The pesticide product is classified for restricted use as set out in §§ 152.160 - 152.175 of this chapter.

(2) Except for manufacturing use products, plant-incorporated protectants, antimicrobial products that are exempt under (c) of this section, and other pesticide products that are regulated under paragraph (e)(1) of this section, a pesticide product must be packaged in compliance with 49 CFR 173.24. If the pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the Department of Transportation requires it to be packaged according to 49 CFR parts 171–180.

(f) *What does ''pesticide product'' or ''pesticide'' mean in the rest of this subpart*? In §§ 165.25 through 165.27, the term ''pesticide product'' or ''pesticide'' refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (e) of this section.

§ 165.25 Nonrefillable container standards.

(a) *What Department of Transportation (DOT) standards do my nonrefillable containers have to meet under this part if my pesticide product is not a DOT hazardous material*? A pesticide product that does not meet the definition of a hazardous material in 49

CFR 171.8 must be packaged in a nonrefillable container that is designed, constructed, and marked to comply with the requirements of 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material.

(b) *What DOT standards do my nonrefillable containers have to meet under this part if my pesticide product is a DOT hazardous material*? (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171–180.

(2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171–180.

(c) *What will EPA do if DOT proposes to change any of the cross-referenced regulations*? If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the **Federal Register**. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.

(d) *What standards for closures do my nonrefillable containers have to meet*? If your nonrefillable container is a rigid container with a capacity equal to or greater than 3.0 liters (0.79 gallons), if the container is not an aerosol container or a pressurized container, and if the container is used to distribute or sell a liquid agricultural pesticide, each nonrefillable container must have at least one of the following standard closures:

(1) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5 threads per inch, National Pipe Straight (NPS) standard.

(2) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.

(3) Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch.

(4) Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch. The cap may fit on a separate rigid spout or on a flexible pull-out plastic spout.

(e) *What standards for dispensing do my nonrefillable containers have to meet*? If your nonrefillable container has a capacity of 5 gallons (18.9 liters) or less, if the container is not an aerosol container, a pressurized container, or a spray bottle, and if the container holds a liquid pesticide, your nonrefillable container must do both of the following:

(1) Allow the contents of the nonrefillable container to pour in a continuous, coherent stream.

(2) Allow the contents of the nonrefillable container to be poured with a minimum amount of dripping down the outside of the container.

(f) *What standards for residue removal do my nonrefillable containers have to meet*? Each nonrefillable container and pesticide formulation combination must meet the applicable residue removal standard of this section.

(1) If the nonrefillable container is rigid and has a capacity less than or equal to 5 gallons (18.9 liters) for liquid formulations or 50 pounds (22.7 kilograms) for solid formulations and if the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application (that is, if the pesticide is dilutable), each container/formulation combination must be capable of attaining at least 99.99 percent removal of each active ingredient when tested using the EPA test procedure ''Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers.''

(2) The test must be conducted only if the pesticide product is a flowable concentrate or if EPA specifically requests the records on a case by case basis.

(3) For the rigid container/dilutable product standard in paragraph (f)(1) of this section, percent removal represents the percent of the original concentration of the active ingredient in the pesticide product when compared to the concentration of that active ingredient in the fourth rinse. Percent removal is calculated by the formula:

percent removal = [1.0 - RR] x 100.0, where

RR = rinsate ratio = Active ingredient concentration in fourth rinsate/Original concentration of active ingredient in the product

(g) *Can I obtain a waiver from or a modification to any of the nonrefillable container standards*? Yes, it is possible for you to obtain a waiver from or a modification to the nonrefillable container standards, as follows:

(1) EPA may waive or modify the requirements of paragraph (a) of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (a) of this section.

(2) EPA may waive or modify the requirements of paragraph (b) of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (b) of this section. EPA will modify or waive the requirements of paragraph (b) of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

(3) EPA may approve a non-standard closure (that is, a closure not listed in paragraph (d) of this section) if EPA determines that both of the following conditions are satisfied:

(i) The non-standard closure is necessary for the proper mixing, loading, or application of the pesticide product.

(ii) The non-standard closure offers exposure protection to handlers during mixing and loading that is the same or greater than that provided by the standard closures.

(4) EPA may waive or modify the container dispensing capability standards in paragraph (e) of this section if EPA determines that at least one of the following conditions is satisfied:

(i) The product is typically removed from the container by a method other than pouring.

(ii) Compliance with the container dispensing capability standards would increase exposure to the pesticide container handler.

(5) EPA may waive or modify the requirements of paragraph (f) of this section regarding the residue removal standard if EPA determines that both of the following conditions are satisfied:

(i) The residue remaining in the container would not cause an unreasonable adverse effect on the environment; and

(ii) The product offers significant benefits and cannot be economically reformulated or repackaged.

(h) *How do I obtain a waiver from or a modification to any of the nonrefillable container standards*? To obtain a waiver from or a modification to any of the nonrefillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania

Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a nonrefillable container that does not comply with all of the nonrefillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:

(1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

(2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.

(3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.

(4) A description of the nonrefillable container or containers for which the waiver or modification is requested.

(5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

§ 165.27 Reporting and recordkeeping.

(a) *What information must I report about my nonrefillable containers*? You are not required to report to EPA with information about your nonrefillable containers under the regulations in this subpart. You should refer to the reporting standards in part 159 of this chapter to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).

(b) *What recordkeeping do I have to do for my nonrefillable containers*? For each pesticide product that is subject to § 165.25 - 165.27 and is distributed or sold in nonrefillable containers, you must maintain the records listed in this section for as long as a nonrefillable container is used to distribute or sell the pesticide product and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe. You must keep the following records:

(1) The name and EPA registration number of the pesticide product.

(2) A description of the nonrefillable container(s) in which the pesticide product is distributed or sold.

(3) At least one of the following records to document compliance with the requirement for closures in § 165.25(d) for each nonrefillable container used to distribute or sell the pesticide product that must comply with § 165.25(d):

(i) A letter or document from the container supplier that describes the closure.

(ii) A specification about the closure in the contract between the registrant or applicant and the container supplier.

(iii) A copy of EPA's approval of any non-standard closure.

(4) At least one of the following records pertaining to the container dispensing capability requirements in § 165.25(e) for each nonrefillable container used to distribute or sell the pesticide product that must comply with § 165.25(e):

(i) Test data or documentation demonstrating that the nonrefillable container meets the standards in § 165.25(e) when it contains the pesticide product.

(ii) Test data or documentation demonstrating that a different nonrefillable container meets the standards in § 165.25(e) when it contains the pesticide product or even a different pesticide product and a written explanation of why such data or documentation demonstrates that the container meets the standards in § 165.25(e) for the pesticide product.

(5) At least one of the following records pertaining to the nonrefillable container residue removal requirement in § 165.25(f) if the pesticide product is a flowable concentrate or if EPA specifically requests the records on a case by case basis:

(i) Test data showing that the nonrefillable container and pesticide formulation meet the standard in § 165.25(f) .

(ii) Test data showing that a different nonrefillable container with the same or a different pesticide formulation meets the standard in § 165.25(f), together with a written explanation of why such data demonstrate that the nonrefillable container and pesticide formulation meet the standard in § 165.25(f).

§§ 165.28–165.39 [Reserved]

Subpart C—Refillable Container Standards: Container Design

§ 165.40 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The regulations in this subpart establish design and construction requirements for refillable containers used for the distribution or sale of some pesticide products.

(b) *Do I have to comply with the regulations in this subpart*? (1) You must comply with all of the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers. If your pesticide product is subject to the regulations in this subpart as set out in § 165.43, your pesticide product must be distributed or sold in a refillable container that meets the standards of these regulations. This includes your pesticide products that are repackaged according to subpart D of this part.

(2) You must comply with the regulations in § 165.45(f) for stationary pesticide containers if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. If the pesticide product is subject to the regulations in this subpart as set out in § 165.43, the stationary pesticide containers used to distribute or sell the product must meet the standards of § 165.45(f).

(c) *When do I have to comply?* As of August 16, 2011, all pesticide products distributed or sold by you in refillable containers must be distributed or sold in compliance with these regulations.

§ 165.43 Scope of pesticide products included.

(a*) Are manufacturing use products subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to manufacturing use products, as defined in § 158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.

(c) *Which ''antimicrobial'' pesticide products are not subject to the regulations in this subpart*? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (e) of this section.

(d) *Which requirements must an ''antimicrobial'' swimming pool product comply with if it is not exempt from these regulations?* An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except § 165.45(d) regarding marking and § 165.45(e) regarding openings. For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

(1) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

(2) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.

(e) *How will EPA determine if an ''antimicrobial'' pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment*? (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the refillable container regulations within the time frames established by EPA in the rule or in its notification.

(f) *What other pesticide products are subject to the regulations in this subpart*? The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt by paragraph (c) of this section. Antimicrobial products covered under by paragraph (d) of this section are subject to the regulations indicated in that section.

(g) *What does ''pesticide product'' or ''pesticide'' mean in the rest of this subpart*? In §§ 165.43(h) through 165.47, the term ''pesticide product'' or ''pesticide'' refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through(f) of this section.

(h) *Are there any other exceptions*? (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.

(2) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

§ 165.45 Refillable container standards.

(a) *What Department of Transportation (DOT) standards do my refillable containers have to meet under this part if my pesticide product is not a DOT hazardous material*? (1) 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 is designed, constructed, and marked to comply with the requirements of 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material.

(2) A refiller is not required to comply with 49 CFR 173.28(b)(2) for pesticide products that are not DOT hazardous materials if the refillable container to be reused complies with the refillable container regulations in this subpart and the refilling is done in compliance with the repackaging regulations in subpart D of this part.

(b) *What DOT standards do my refillable containers have to meet under this part if my pesticide product is a DOT hazardous material*? (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171–180.

(2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171–180.

(c) *What will EPA do if DOT proposes to change any of the cross-referenced regulations*? If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the **Federal Register**. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.

(d) *What standards for marking do my refillable containers have to meet*? Each refillable container 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. Durable marking includes, but is not limited to, etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, and marking with durable ink. The serial number or other identifying code must be located on the outside part of the container except on a closure. Placement on the label or labeling is not sufficient unless the label is an integral, permanent part of or permanently stamped on the container.

(e) *What standards for openings do my refillable containers have to meet*? If your refillable container is a portable pesticide container that is designed to hold liquid pesticide formulations and is not a cylinder that complies with the DOT Hazardous Materials Regulations, each opening of the container other than a vent must have a one-way valve, a tamper-evident device or both. A one-way valve may be located in a device or system separate from the container if the device or system is the only reasonably foreseeable way to withdraw pesticide from the container. A vent must be designed to minimize the amount of material that could be introduced into the container through it.

(f) *What standards do my stationary pesticide containers have to meet*? If a stationary pesticide container designed to hold undivided quantities of pesticides equal to greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide is located at the refilling establishment of a refiller operating under written contract to you, the stationary pesticide container must meet the following standards:

(1) Except during a civil emergency or any unanticipated grave natural disaster or other natural phenomenon of an exceptional, inevitable and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight, each stationary pesticide container (for liquid and dry pesticides) and its appurtenances must meet both of the following standards:

(i) Each stationary pesticide container and its appurtenances must be resistant to extreme changes in temperature and constructed of materials that are adequately thick to not fail and that are resistant to corrosion, puncture, or cracking.

(ii) Each stationary pesticide container must be capable of withstanding all operating stresses, taking into account static heat, pressure buildup from pumps and compressors, and any other foreseeable mechanical stresses to which the container may be subjected in the course of operations.

(2) Each stationary liquid pesticide container must meet all of the following standards:

(i) Each stationary liquid pesticide container must be equipped with a vent or other device designed to relieve excess pressure, prevent losses by evaporation, and exclude precipitation.

(ii) External sight gauges, which are pesticide-containing hoses or tubes that run vertically along the exterior of the container from the top to the bottom, are prohibited on stationary liquid pesticide containers.

(iii) Each stationary liquid pesticide container connection below the normal liquid level must be equipped with a shutoff valve which is capable of being locked closed. A shutoff valve must be located within a secondary containment unit if one is required by subpart E of this part.

(g) *Can I obtain a waiver from or a modification to any of the refillable container standards*? Yes, it is possible for you to obtain a waiver from or a modification to some of the refillable container standards, as follows:

(1) EPA may waive or modify the requirements of paragraph (a) of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (a) of this section.

(2) EPA may waive or modify the requirements of paragraph (b) of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (b) of this section. EPA will modify or waive the requirements of paragraph (b) of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.

(h) *How do I obtain a waiver from or a modification to any of the refillable container standards?* To obtain a waiver from or a modification to any of the refillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a refillable container that does not comply with all of the refillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:

(1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

(2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.

(3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.

(4) A description of the refillable container or containers for which the waiver or modification is requested.

(5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

§ 165.47 What information must I report about my refillable containers?

You are not required to report to EPA with information about your refillable containers under the regulations in this subpart. You should refer to the reporting standards in part 159 of this chapter to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).

§§ 165.48–165.59 [Reserved]

Subpart D—Standards for Repackaging Pesticide Products into Refillable Containers

§ 165.60 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The regulations in this subpart establish requirements for repackaging some pesticide products into refillable containers for distribution or sale.

(b) *Do I have to comply with the regulations in this subpart*? You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers, if you are a registrant who distributes or sells pesticide products to a refiller (that is not part of your company) for repackaging into refillable containers, or if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. Each pesticide product that is subject to the regulations

in this subpart as set out in § 165.63 and that is distributed or sold in a refillable container must be distributed or sold in compliance with the standards of these regulations.

(c) *When do I have to comply*? As of August 16, 2011, all pesticide products distributed or sold by you in refillable containers must be distributed or sold in compliance with these regulations.

§ 165.63 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to manufacturing use products, as defined in § 158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart*? No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.

(c) *Which antimicrobial pesticide products are not subject to the regulations in this subpart*? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (e) of this section.

(d) Which requirements must an antimicrobial swimming pool product comply with if it is not exempt from these regulations? (1) An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except for the following requirements:

Requirement	Requirement for registrants who distribute or sell directly in refillable containers	Requirement for refillers who are not registrants
Recordkeeping specific to each instance of repackaging	§ 165.65(i)(2)	§ 165.70(j)(2)
Container inspection: criteria regarding a serial number or other identifying code	§ 165.65(e)(3)	§ 165.70(f)(3)
Container inspection: criteria regarding one-way valve or tamper-evident device	§ 165.65(e)(4)	§ 165.70(f)(4)
Cleaning requirement: criteria regarding one-way valve or tamper-evident device	§ 165.65(f)(1)	§ 165.70(g)(1)
Cleaning if the one-way valve or tamper-evident device is not intact	§ 165.65(g)	§ 165.70(h)

(2) For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

(i) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

(ii) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.

(e) *How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?* (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be repackaged in compliance with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be repackaged in compliance with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to

comply with the repackaging regulations within the time frames established by EPA in the rule or in its notification.

(f) *What other pesticide products are subject to the regulations in this subpart*? The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt paragraph (c) of this section. Antimicrobial products covered under paragraph (d) of this section are subject to the regulations indicated in that section.

(g) *What does ''pesticide product'' or ''pesticide'' mean in the rest of this subpart*? In §§ 165.63(h) through 165.70, the term ''pesticide product'' or ''pesticide'' refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (f) of this section.

(h) *Are there any other exceptions*? (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.

(2) Custom blending is not subject to the regulations in this subpart.

(3) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

§ 165.65 Registrants who distribute or sell pesticide products in refillable containers.

(a) *Must I comply with the standards in this section*? You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products in refillable containers. This means that you conduct all of the repackaging for a pesticide product and that you do not distribute or sell the pesticide product to a refiller that is not part of your company for repackaging into refillable containers. If you are a registrant that repackages a product directly into refillable containers for sale or distribution and you also sell or distribute other quantities of that product to an independent refiller for repackaging, then you must meet the requirements in this section for those quantities you distribute or sell directly and the requirements in § 165.67 for those quantities that you distribute or sell to an independent refiller.

(b) *Am I responsible for product integrity*? Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(c) *What information must I develop*? For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.

(1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.

(i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under ''Directions for Use,'' or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.

(2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.

(i) An acceptable container is one that you have determined meets the standards in subpart C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.

(ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in subpart C of this part.

(d) *What requirements must my individual establishments follow regarding repackaging a pesticide product into refillable containers*? A refiller at your individual establishment that repackages a pesticide product into refillable containers for distribution or sale must comply with all of the following provisions.

(1) The establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.

(2) The refiller must not change the pesticide formulation unless the refiller has a registration for the new formulation.

(3) The refiller must repackage a pesticide product only into a refillable container that is identified on your description of acceptable containers for that pesticide product.

(4) The refiller may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that the refiller can use.

(5) The refiller must have all of the following items at the establishment before repackaging a pesticide product into any refillable container for distribution or sale:

(i) The pesticide product's label and labeling.

(ii) The written refilling residue removal procedure for the pesticide product.

(iii) The written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, the refiller must identify the pesticide product previously contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with paragraph (f) of this section. The refiller may identify the previous pesticide product by referring to the label or labeling.

(7) The refiller must inspect each refillable container according to paragraph (e) of this section.

(8) The refiller must clean each refillable container according to paragraph (f) or (g) of this section, if required by either paragraph.

(9) The refiller must ensure that each refillable container is properly labeled according to paragraph (h) of this section.

(10) The establishment must maintain records in accordance with paragraph (i) of this section.

(11) The establishment must maintain records as required by part 169 of this chapter.

(12) The establishment must report as required by part 167 of this chapter.

(e) *How must my individual establishments inspect refillable containers*? Before repackaging a pesticide product into any refillable container, a refiller at your establishment must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and

openings. If the condition in paragraph (e)(1) of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in paragraph (e)(2) or (e)(3) of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in subpart C of this part. The conditions are:

(1) The integrity of the container is compromised in at least one of the following ways:

(i) The container shows signs of rupture or other damage which reduces its structural integrity.

(ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.

(iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.

(iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.

(2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.

(3) 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.

(f) *How must my individual establishments clean refillable containers*? A refiller at your establishment must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in paragraph (f)(1) of this section and either paragraph (f)(2) or (f)(3) of this section are satisfied:

(1) If required, each tamper-evident device and one-way valve is intact.

(2) The refillable container is being refilled with the same pesticide product.

(3) Both of the following conditions are satisfied:

(i) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.

(ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.

(g) *How must my individual establishments clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve*? As required in paragraph (f) of this section, a refiller at your establishment must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.

(h) *How must my individual establishments label refillable containers*? Before distributing or selling a pesticide product in a refillable container, a refiller at your establishment must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of part 156 of this chapter. In particular, the refiller at your establishment must ensure that the net contents statement and EPA establishment number appear on the label.

(i) *What recordkeeping must my individual establishments do*? Each of your individual establishments that repackages a pesticide product into refillable containers for distribution or sale must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. The establishment must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

(1) For each pesticide product distributed or sold in refillable containers, both of the following records must be maintained for the current operating year and for 3 years after that:

(i) The written refilling residue removal procedure for the pesticide product.

(ii) The written description of acceptable containers for the pesticide product.

(2) Each time a refiller at your establishment repackages a pesticide product into a refillable container and distributes or sells the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:

(i) The EPA registration number of the pesticide product distributed or sold in the refillable container.

(ii) The date of the repackaging.

(iii) The serial number of the refillable container.

§ 165.67 Registrants who distribute or sell pesticide products to refillers for repackaging.

(a) *Must I comply with the standards in this section*? You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products to a refiller that is not part of your company for repackaging into refillable containers.

(b) *Under what conditions can I allow a refiller to repackage my pesticide product into refillable containers*? You may allow a refiller to repackage your pesticide product into refillable containers and to distribute or sell such repackaged product under your existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(ii) 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 as required by § 167.20 of this chapter.

(3) You have entered into a written contract with the refiller to repackage the pesticide product and to use the label of your pesticide product.

(4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refiller's EPA establishment number.

(c) *What violations are applicable to illegal repackaging*? Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the refiller that is repackaging your pesticide product under written contract with you may be liable for

violations pertaining to the repackaged product.

(d) *When must I provide the written contract to the refiller*? If you allow a refiller to repackage your product as specified in paragraph (b) of this section you must provide the written contract to the refiller before you distribute or sell the pesticide product to the refiller.

(e) *Am I responsible for product integrity*? Yes, for a product that you distribute or sell to a refiller that is not part of your company for repackaging into refillable containers, you are responsible for the pesticide product not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(f) *What information must I develop*? For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.

(1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.

(i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under ''Directions for Use,'' or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.

(2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.

(i) An acceptable container is one that you have determined meets the standards in subpart C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.

(ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in subpart C of this part.

(g) *When must I provide the information to the refiller*? You must provide the refiller with all of the following information and documentation before or at the time of distribution or sale of your pesticide product to the refiller:

(1) Your written refilling residue removal procedure for the pesticide product.

(2) Your written description of acceptable containers for the pesticide product.

(3) The pesticide product's label and labeling.

(h) *What recordkeeping must I do*? You must maintain all of the records listed in this section for the current operating year and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

(1) Each written contract entered into with a refiller for repackaging your pesticide product into refillable containers.

(2) Your written refilling residue removal procedure for the pesticide product.

(3) Your written description of acceptable containers for the pesticide product.

§ 165.70 Refillers who are not registrants.

(a) *Must I comply with the standards in this section*? You must comply with the standards in this section if you are a refiller of a pesticide product and you are not the registrant of the pesticide product.

(b) *Under what conditions can I repackage a registrant's pesticide product into refillable containers*? A registrant may allow you to repackage the registrant's pesticide product into refillable containers and to distribute or sell such repackaged product under the registrant's existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(ii) 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 as required by § 167.20 of this chapter.

(3) The registrant has entered into a written contract with you to repackage the pesticide product and to use the label of the registrant's pesticide product.

(4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refillers EPA establishment number.

(c) *What violations are applicable to illegal repackaging*? Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the pesticide product's registrant may be liable for violations pertaining to the repackaged product.

(d) *Am I responsible for product integrity*? Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(e) *What requirements must I follow regarding repackaging a pesticide product into refillable containers*? You must comply with all of the following provisions.

(1) Your establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.

(2) You must not change the pesticide formulation unless you have a registration for the new formulation.

(3) You must repackage a pesticide product only into a refillable container that is identified on the description of acceptable containers for that pesticide product provided by the registrant.

(4) You may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that you can use.

(5) You must have all of the following items at your establishment before repackaging a pesticide product into any refillable container for distribution or sale:

(i) The written contract from the pesticide product's registrant.

(ii) The pesticide product's label and labeling.

(iii) The registrant's written refilling residue removal procedure for the pesticide product.

(iv) The registrant's written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, you must identify the pesticide product previously

contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with paragraph (g) of this section. You may identify the previous pesticide product by referring to the label or labeling.

(7) You must inspect each refillable container according to paragraph (f) of this section.

(8) You must clean each refillable container according to paragraph (g) or (h) of this section, if required by either paragraph.

(9) You must ensure that each refillable container is properly labeled according to paragraph (i) of this section.

(10) You must maintain records in accordance with paragraph (j) of this section.

(11) You must maintain records as required by part 169 of this chapter.

(12) You must report as required by part 167 of this chapter.

(13) The stationary pesticide containers at your establishment must meet the standards in § 165.45(f).

(14) You may be required to comply with the containment standards in subpart E of this part.

(f) *How must I inspect refillable containers*? Before repackaging a pesticide product into any refillable container, you must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and openings. If the condition in paragraph (f)(1) of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in paragraph (f)(2) or (f)(3) of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in subpart C of this part. The conditions are:

(1) The integrity of the container is compromised in at least one of the following ways:

(i) The container shows signs of rupture or other damage which reduces its structural integrity.

(ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.

(iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.

(iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.

(2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.

(3) 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.

(g) *How must I clean refillable containers*? You must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in paragraph (g)(1) of this section and either paragraph (g)(2) or (g)(3) of this section are satisfied:

(1) If required, each tamper-evident device and one-way valve is intact.

(2) The refillable container is being refilled with the same pesticide product.

(3) Both of the following conditions are satisfied.

(i) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.

(ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.

(h) *How must I clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve*? As required in paragraph (g) of this section, you must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.

(i) *How must I label refillable containers*? Before distributing or selling a pesticide product in a refillable container, you must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of part 156 of this chapter. In particular, you must ensure that the net contents statement and EPA establishment number appear on the label.

(j) *What recordkeeping must I do*? You must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

(1) For each pesticide product distributed or sold in refillable containers, all of the following records must be maintained for the current operating year and for 3 years after that:

(i) The written contract from the pesticide product's registrant for the pesticide product.

(ii) The written refilling residue removal procedure for the pesticide product.

(iii) The written description of acceptable containers for the pesticide product.

(2) Each time you repackage a pesticide product into a refillable container and distribute or sell the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:

(i) The EPA registration number of the pesticide product distributed or sold in the refillable container.

(ii) The date of the repackaging.

(iii) The serial number of the refillable container.

§§ 165.71–165.79 [Reserved]

Subpart E—Standards for Pesticide Containment Structures

§ 165.80 General provisions.

(a) *What is the purpose of the regulations in this subpart*? The purpose of the containment regulations in this subpart is to protect human health and the environment from exposure to agricultural pesticides which may spill or leak from stationary pesticide containers. This protection is achieved by the construction of secondary containment units or pads at certain facilities handling agricultural pesticides. These regulations will also reduce waste generation associated with:

(1) Storage and handling of large quantities of pesticide products.

(2) Pesticide dispensing and container-refilling operations.

(b) *Do I have to comply with the regulations in this subpart*? You must comply with the regulations in this subpart if you are an owner or operator of one of the following businesses and if you also have a stationary pesticide container or a pesticide dispensing (including container refilling) area:

(1) Refilling establishments who repackage agricultural pesticides and whose principal business is retail sale (i.e., more that 50% of total annual revenue comes from retail operations).

(2) Custom blenders of agricultural pesticides.

(3) Businesses which apply an agricultural pesticide for compensation (other than trading of personal services between agricultural producers).

(c) *When do I have to comply*? You must comply with all applicable containment regulations for new and existing structures as of August 17, 2009.

§ 165.81 Scope of stationary pesticide containers included.

(a) *What is a stationary pesticide container*? A stationary pesticide container is a refillable container that is fixed at a single facility or establishment, or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

(b) *What stationary pesticide containers are subject to the regulations in this subpart*? Stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide are subject to the regulations in this subpart and must have a secondary containment unit that complies with the provisions of this subpart unless any of the following conditions exists:

(1) The container is empty, that is, all pesticide that can be removed by methods such as draining, pumping or aspirating has been removed (whether or not the container has been rinsed or washed).

(2) The container holds only pesticide rinsates or wash waters, and is labeled accordingly.

(3) The container holds only pesticides which would be gaseous when released at atmospheric temperature and pressure.

(4) The container is dedicated to non-pesticide use, and is labeled accordingly.

§ 165.82 Scope of pesticide dispensing areas included.

(a) *What pesticide dispensing areas are subject to the regulations in this subpart*? A pesticide dispensing area is subject to the containment regulations in this subpart and must have a containment pad that complies with the requirements of this subpart if any of the following activities occur:

(1) Refillable containers of agricultural pesticide are emptied, cleaned or rinsed.

(2) Agricultural pesticides are dispensed from a stationary pesticide container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide for any purpose, including refilling or emptying for cleaning. This applies when pesticide is dispensed from the container into any vessel, including, but not limited to:

(i) Refillable containers;

(ii) Service containers;

(iii) Transport vehicles;

(iv) Application equipment.

(3) Agricultural pesticides are dispensed from a transport vehicle for purposes of filling a refillable container.

(4) Agricultural pesticides are dispensed from any other container for the purpose of refilling a refillable container for sale or distribution. Containment requirements do not apply if the agricultural pesticide is dispensed from such a container for use, application or purposes other than refilling for sale or distribution.

(b) *What pesticide dispensing areas are exempt from the regulations in this subpart*? A pesticide dispensing area is exempt from the regulations in this subpart if any of the following conditions exist:

(1) The only pesticides in the dispensing area would be gaseous when released at atmospheric temperature and pressure.

(2) The only pesticide containers refilled or emptied within the dispensing area are stationary pesticide containers which are already protected by a secondary containment unit that complies with the provisions of this subpart.

(3) The pesticide dispensing area is used solely for dispensing pesticide from a rail car which does not remain at a facility long enough to meet the definition of a stationary pesticide container; that is, 30 days.

§ 165.83 Definition of new and existing structures.

(a) *What is a new containment structure*? A new containment structure is one whose installation began after November 16, 2006. Installation is considered to have begun if:

(1) You, as the owner or operator, have obtained all Federal, State, and local approvals or permits necessary to begin physical construction of the containment structure; AND

(2) You have either begun a continuous on-site physical construction or installation program OR you have entered into contractual obligations. The contract must be such that it cannot be canceled or modified without substantial loss, and must be for the physical construction or installation of the containment structure within a specific and reasonable time frame.

(b) *What is an existing containment structure*? An existing containment structure is defined as one whose installation began on or before November 16, 2006.

§ 165.85 Design and capacity requirements for new structures.

(a) *For all new containment structures, what construction materials must I use*? These are the material specifications for a new containment structure:

(1) The containment structure must be constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The structure must be liquid-tight with cracks, seams and joints appropriately sealed.

(2) The structure must not be constructed of natural earthen material, unfired clay, or asphalt.

(3) The containment structure must be made of materials compatible with the pesticides stored. In this case, compatible means able to withstand anticipated exposure to stored or transferred materials and still provide secondary containment of those same or other materials within the containment area.

(b) *For all new containment structures, what are the general design requirements*? These are the general design requirements for new containment structures:

(1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

(2) Appurtenances, discharge outlets or gravity drains must not be configured through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the

requirements of this subpart. Appurtenances must be configured in such a way that spills or leaks are easy to see.

(3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.

(4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.

(c) *For new stationary liquid pesticide containment and new containment pads in pesticide dispensing areas, what are the capacity requirements*? These are the capacity requirements:

(1) New secondary containment units for stationary liquid pesticide containers, if protected from precipitation, must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

(2) New secondary containment units for stationary liquid pesticide containers, if exposed to or unprotected from precipitation, must have a capacity of at least 110 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

(3) New containment pads in pesticide dispensing areas which have a pesticide container or pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons.

(4) New containment pads in pesticide dispensing areas which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.

(d) *For new stationary liquid pesticide containment, what are the specific design requirements?* You must either anchor or elevate each new stationary liquid pesticide container protected by a secondary containment unit to prevent flotation in the event that the secondary containment unit fills with liquid.

(e) *For new containment pads in pesticide dispensing areas, what are the specific design requirements*? Each new containment pad in a pesticide dispensing area must:

(1) Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.

(2) Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary pesticide container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.

(3) Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

(4) Have its surface sloped toward an area where liquids can be collected for removal, such as a liquid-tight sump or a depression, in the case of a single-pour concrete pad.

(f) *For new stationary dry pesticide containment, what are the specific design requirements*? These are the specific design requirements for new stationary dry pesticide containment:

(1) The stationary dry pesticide containers within the containment unit must be protected from wind and precipitation.

(2) Stationary dry pesticide containers must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.

(3) The stationary dry pesticide container storage area must be enclosed by a minimum of a 6–inch high curb that extends at least 2 feet beyond the perimeter of the container.

§ 165.87 Design and capacity requirements for existing structures.

(a) *For all existing containment structures, what construction materials must I use*? These are the material specifications for an existing containment structure:

(1) The containment structure must be constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The structure must be liquid-tight with cracks, seams and joints appropriately sealed.

(2) The structure must not be constructed of natural earthen material, unfired clay, or asphalt.

(3) The containment structure must be made of materials compatible with the pesticides stored. In this case, compatible means able to withstand anticipated exposure to stored or transferred materials and still provide secondary containment of those same or other materials within the containment area.

(b) *For all existing containment structures, what are the general design requirements*? These are the general design requirements for existing containment structures:

(1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

(2) You must seal all appurtenances, discharge outlets and gravity drains through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart.

(3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.

(4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.

(c) *For existing stationary liquid pesticide containment and existing containment pads in pesticide dispensing areas, what are the capacity requirements*? These are the capacity requirements:

(1) Existing secondary containment units for stationary liquid pesticide containers must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.

(2) Existing containment pads in pesticide dispensing areas which have a pesticide container or pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons.

(3) Existing containment pads in pesticide dispensing areas which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.

(d) *For existing stationary liquid pesticide containment, what are the specific design requirements*? You must either anchor or elevate each 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.

(e) *For existing containment pads in pesticide dispensing areas, what are the specific design requirements*? Each existing containment pad in a pesticide dispensing area must:

(1) Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.

(2) Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary pesticide container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.

(3) Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

(f) *For existing stationary dry pesticide containment, what are the specific design requirements?* These are the specific design requirements for existing stationary dry pesticide containment:

(1) The stationary dry pesticide containers within the containment unit must be protected from wind and precipitation.

(2) Stationary dry pesticide containers must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.

(3) The stationary dry pesticide container storage area must be enclosed by a minimum of a 6–inch high curb that extends at least 2 feet beyond the perimeter of the container.

§ 165.90 Operational, inspection and maintenance requirements for all new and existing containment structures.

(a) *What are the operating procedures required for all new and existing containment structures?* As the owner or operator of a new or existing pesticide containment structure, you must:

(1) Manage the structure in a manner that prevents pesticides or materials containing pesticides from escaping from the containment structure (including, but not limited to, pesticide residues washed off the containment structure by rainfall or cleaning liquids used within the structure.)

(2) Ensure that pesticide spills and leaks on or in any containment structure 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.

(3) Ensure that all materials resulting from spills and leaks and any materials containing pesticide residue are managed according to label instructions and applicable Federal, State and local laws and regulations.

(4) Ensure that transfers of pesticides between containers, or between containers and transport vehicles are attended at all times.

(5) Ensure that each lockable valve on a stationary pesticide container, if it is required by § 165.45(f), is closed and locked whenever the facility is unattended.

(b) *What are the inspection and maintenance requirements for all new and existing containment structures*? As owner or operator of a new or existing pesticide containment structure, you must:

(1) Inspect each stationary pesticide container and its appurtenances at least monthly during periods when pesticides are being stored or dispensed on the containment structure. Your inspection must look for visible signs of wetting, discoloration, blistering, bulging, corrosion, cracks or other signs of damage or leakage.

(2) 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.

(3) Not store any pesticide on a containment structure if the structure fails to meet the requirements of this subpart until suitable repairs have been made. Prompt removal of pesticides, including emptying of stationary pesticide containers, in order to effect repairs or recovery of spilled material is acceptable.

§ 165.92 What if I need both a containment pad and a secondary containment unit?

You may combine containment pads and secondary containment units as an integrated system provided the requirements set out in this subpart for containment pads and secondary containment units in §§ 165.85(a) and (b), 165.87(a) and (b) and § 165.90, and as applicable, §§ 165.85(c)-(f) and 165.87(c)-(f) are satisfied separately.

§ 165.95 What recordkeeping do I have to do as a facility owner or operator?

As a facility owner or operator subject to the requirements of this subpart, you must maintain the following records, and you must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

(a) Records of inspection and maintenance for each containment structure and for each stationary pesticide container and its appurtenances must be kept for 3 years and must include the following information:

(1) Name of the person conducting the inspection or maintenance;

(2) Date the inspection or maintenance was conducted;

(3) Conditions noted;

(4) Specific maintenance performed.

(b) Records for any non-stationary pesticide container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide that holds pesticide but is not protected by a secondary containment unit meeting these regulations must be kept for 3 years. Records on these non-stationary pesticide containers must include the time period that the container remains at the same location.

(c) Records of the construction date of the containment structure must be kept for as long as the pesticide containment structure is in use, and for 3 years afterwards.

§ 165.97 States with existing containment programs.

(a) *What options are available to States that already have containment regulations*? States that have promulgated containment regulations effective prior to August 16, 2006, and which also have primary enforcement responsibility and/or certification programs, have the option of continuing to implement their own programs in lieu of these Federal regulations.

(b) *How may a State request authority to continue implementing its State containment regulations*? A State with pesticide containment regulations may request the authority to continue implementing State containment regulations by August 16, 2007 in the following manner:

(1) The State must submit a letter and any supporting documentation to EPA.

Supporting documentation must demonstrate that the States program is providing environmental protection equivalent to or more protective than that expected to be provided by the Federal regulations in this subpart.

(2) The State must identify any significant changes to State regulations which would be necessary in order to provide environmental protection equivalent to the EPA regulations, and develop an estimated timetable to effect these changes. The letter must be signed by the designated State Lead Agency.

(c) *How will EPA notify the State if its request is granted*? EPA's Office of Pesticide Programs will review the State's correspondence and determine whether the State program is adequate to provide environmental protection equivalent to or more protective than these Federal regulations for new and existing containment structures. EPA's Office of Pesticide Programs will inform the State of its determination through a letter authorizing or declining to authorize the State to continue implementing its containment regulations and will detail any reasons for declining authorization.

(d) *How must a State inform EPA of revisions to its containment regulations*? Any state that has received authorization to continue implementing its state containment regulations must inform EPA by letter signed by the designated State Lead Agency within 6 months of any revision to the State's containment regulations. EPA will inform the state by letter if it determines that the State's containment regulations are no longer adequate based on the revisions. The State's containment regulations will remain in effect, unless and until EPA sends the state a letter making this determination.

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