Economic Analysis of the Bulk Pesticide Container Design and Residue Removal Standards

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Executive Summary of the Economic Analysis of the Final Pesticide Container Design and Residue Removal Standards

The Environmental Protection Agency (EPA) is finalizing the standards for pesticide container design and residue removal as required under Section 19 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The final standards include design and labeling requirements for non-refillable and refillable pesticide containers to ensure that

- 1. containers are strong and durable;
- 2. minimize human and environmental exposure during container handling;
- 3. facilitate container disposal and recycling;
- 4. minimize cross-contamination of pesticides distributed in refillable containers;
- 5. codify safe refilling management practices;
- 6. encourage the us e of refillable containers to reduce container disposal problems; and
- 7. provide instructions for proper cleaning of pesticide containers.

The improvements made in the design of pesticide containers and the removal of residues from containers prior to disposal as a result of the final pesticide container standards are expected to benefit pesticide users, non-users and the environment through a reduction in exposure to pesticides from unintended pesticide container spills and leaks.

The total annual cost of compliance with the final standards to the regulated industries (i.e., pesticide registrants, agricultural pesticide refillers, and swimming pool applicators) is estimated at \$8.4 million. This estimate is based on an examination of the current level of compliance of pesticide containers with the final standards, and the cost of moving from the current level of compliance to the final standards. The cost to pesticide registrants is estimated at \$5.6 million per year. None of the more than 1,800 pesticide registrant companies (including 1,658 small businesses as defined by SBA) subject to the final standards are estimated to be significantly impacted by compliance with the final standards (the ratio of the cost of compliance to current industry average revenues for all businesses is estimated to be less than 0.02 percent). Pesticide registrants are responsible for ensuring that pesticide containers are designed in accordance with the final container design and labeling standards, and for following the pesticide container refilling requirements for pesticide containers in the agricultural and industrial/commercial/government pesticide markets.

Agricultural pesticide refillers and swimming pool applicators are responsible for following the pesticide container refilling requirements for containers in the agricultural pesticide market and pool chemicals market, respectively. The estimated annual cost of compliance with the final pesticide container standards for pesticide refillers is \$2.6 million. For swimming pool applicators, the estimated annual cost of compliance is \$0.2 million. As is the case with pesticide registrants, none of the estimated 16,795 agricultural pesticide refilling businesses (of which16,642 are small businesses as defined by SBA) and 322 swimming pool supply companies (of which 305 are small businesses as defined by SBA) are estimated to be significantly impacted by compliance with the final standards (the ratio of the cost of compliance to current industry average revenues for all businesses in each industry is estimated to be less than 0.01 percent)

The human health-related benefits expected as a result of the final pesticide container standards include a reduction in the estimated number of unintentional container-related pesticide human exposures of an estimated 610 to 768 incidents per year. This amounts to an estimated \$264,051 to \$332,311 in avoided costs of illness per year. The non-human health-related benefits expected as a result of the final rule include a cost savings of \$4.5 million from the disposal of nonrefillable containers as nonhazardous rather than hazardous material, because of compliance with the container standards. We are unable to quantify other non-health related benefits of the final rule, but they include a reduction in the number of unintentional pesticide exposures to terrestrial and aquatic wildlife, and avoided costs of property damage/spill cleanup costs from pesticide container-related spills.

The pesticide container design and residue removal standards were proposed in 1994. In response to public comments submitted on the proposed standards, a number of changes were made to the proposed pesticide container design and residue removal standards, and these changes are reflected in the final rule. The changes result in a reduction in the total estimated cost of compliance with the pesticide container standards by as much as 80 percent from the proposed rule (which was originally estimated at \$40.1 million to \$55.5 million per year for compliance with the proposed standards (EPA preferred option), compared to \$8.4 million for the current final standards). The lower estimated costs are due in part to the exemption in the final rule of household pesticide product labels from containing language requiring triple rinsing of nonrefillable pesticide containers prior to disposal. As a result of this change, no end user impacts are estimated in the final rule, which were estimated at more than \$8 million in the proposed rule impact analysis. Other significant changes in the regulations for the final rule, which led to decreased costs for the industries impacted by the rule include reference to and the adoption of existing Department of Transportation (DOT) standards in the regulations, and the relaxation of the residue removal standard for nonrefillable containers from 99.9999 percent to 99.99 percent.

In general, the expected benefits of the pesticide container standards are similar between the proposed and final rule. Due to the availability of more detailed data on pesticide container-related human exposures, the estimated number of pesticide container-related human exposure incidents avoided as a result of the pesticide container standards declined from an estimated 1,650 to 2,250 incidents avoided per year as a result of the proposed standards, to an estimated 610 to 768 incidents avoided per year as a result of the final standards. And, due to the change in the scope of the pesticide container standards, which resulted in fewer nonrefillable containers affected by the final rule, the nonrefillable container disposal benefits (from reduced hazardous waste) declined by more than 30 percent from the proposed to the final rule.

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Economic Analysis of the Final Container Rule

1.0 Introduction

The U.S. Environmental Protection Agency (EPA) is imposing requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for pesticide container design. EPA is also establishing procedures, standards, and label language to facilitate removal of pesticides from containers prior to disposal. Additionally, EPA is imposing requirements for bulk pesticide containment and procedures for container refilling operations. These regulations are necessary to implement statutory authority requiring EPA to develop regulations for the safe storage and disposal of pesticides as a means of protecting human health and the environment.

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) also provides that EPA, in its discretion, may exempt products intended solely for household use.

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.

The following economic analysis (EA) is one of two economic analyses that estimate the costs and benefits of compliance with the regulations for the safe storage and disposal of pesticides. It estimates the costs and benefits of compliance with the pesticide container design and residue removal requirements of the final rule, including the container refilling requirements and the

label language requirements for pesticide container residue removal. The second EA provides estimates of the costs and benefits of compliance with the bulk pesticide containment requirements of the final rule.¹

The EA for pesticide container design and residue removal is organized into five chapters. The first two chapters present the regulatory background of the final rule, a description of the final pesticide container standards, and a summary of the results of the EA. Chapter 3 presents an analysis of pesticide container compliance with the final container standards. Chapter 4 presents the analysis of the estimated costs of compliance with the final container standards. And Chapter 5 presents the estimated benefits of compliance with the final container standards. A detailed description of the scope of the EA is presented in Section 1.2.

1.1 Need for Regulation

The container design and residue removal standards are largely pollution prevention regulations that will safeguard workers, such as loaders, mixers, and applicators, and the environment by reducing the risk of exposure to concentrated pesticides. The improvements in pesticide container designs will enhance the safe handling, dispensing, use, and residue removal efficiency of pesticide containers. The improvement in procedures and/or container designs will also help facilitate the "clean rinsing" of emptied containers either prior to disposal or recycling, or prior to reuse. There are numerous types of human health-related benefits and non-human health-related (environment-related) benefits that will stem from such improvements because of relatively fewer expected spills, leaks, and other risks associated with exposure (e.g., handling by workers during disposal, discharges to the environment, and potential public exposures).

Table 1.1 summarizes the various types of expected benefits (i.e., improved worker safety, improved public health, reduced environmental risk, and other effects) resulting from the proposed container design/residue removal regulations. It also characterizes the sources of the expected benefits. Other than human health-related and environment-related benefits, the regulation will have other effects such as property damage, personal liability effects, and insurance costs. In addition, there are likely to be cost savings from the disposal of rigid non-refillable containers as non-hazardous rather than hazardous waste as a result of the regulations, and a reduction in the number of environmental effects and property damage/spill cleanup costs as a result of the container regulations.

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¹ Two separate economic analyses are conducted for the rule primarily because the standards for pesticide containers and the standards for containment of bulk pesticides are different, and, as a result, require two distinct economic analyses. That is, because the standards regulate different structures (containers versus bulk containment), and different industries (registrants, agricultural refillers, and swimming pool supply companies for the container standards; agricultural refillers and commercial pesticide applicators for the bulk containment standards), different assumptions and inputs will be used in the EA for each set of standards. Rather than creating a single, lengthy document containing two different economic analyses, the Agency chose to write a separate document for each EA.

Table 1.1. The Types of Expected Benefits from the Container Design and Residue Removal Regulations and Their Sources

Expected Benefit	Source of Expected Benefit			
Human Health-Related Benefits				
Improved Worker Safety	 Reduced accidental spills Fewer leaks Less dripping Less frequent container stress failure (durability, formulation/container degradation) Reduced personal sickness and injury Improved worker productivity 			
Improved Public Health	 Less risk of exposure to spills and leaking/dripping Less contamination of surface water and groundwater sources Less personal injury from accidental spills and chronic contamination sources 			
N	Non-Human Health-Related Benefits			
Reduced Environmental Risk	 Reduced accidental spills Fewer chronic accumulations of chemicals in loading/mixing/cleaning areas Reduced risk of harm from pesticide residues to terrestrial and aquatic wildlife including sensitive and critical habitats Less disposal of hazardous containers in landfills 			
Other Effects	 Reduced property damage Reduced risk of personal injury and liability Lower costs for personal liability insurance Reduced disposal costs for cleaner containers Reduced loss of product from spills and leaks 			

1.2 Regulatory Background of the Final Rule

In a Notice of Proposed Rulemaking (NPRM) issued on February 11, 1994 (59 FR 6712), EPA proposed standards for pesticide containers and containment structures. The proposal included requirements for non-refillable and refillable containers that would ensure the safe use, refill, reuse, and disposal of the containers. The proposal also included standards for containment structures, which would promote safe storage of pesticides in bulk 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 many comments during the public comment period on a few issues. In particular, comments addressed the scope of the container standards and the relationship between the 1994 proposed rule and the 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 56917, EPA 1999). The notice also provided an alternative definition of small business for certain sectors of the pesticide industry. The purpose of the alternative definition was for use in analyzing the potential impacts to small businesses that were presented as part of the economic analysis.²

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, EPA reopened the comment period for 45 days to solicit public input on any policies, market practices, technology, or other issues relating to this rule's requirements that would not have been available, or could not have been addressed at the time of either the proposed rule in 1994 or the supplemental notice in 1999. While EPA has attempted to stay current on developments in pesticide container and containment structure policies, regulations, technology, and practices, the Agency believed that it was appropriate to solicit input from the regulated community, state regulators, and others to ensure that we are fully aware of the current state of the pesticide container and containment universe before finalizing the pesticide container and containment regulations. The comment period generated 50 comments mainly from pesticide manufacturers, state regulatory agencies, and agricultural pesticide dealers. (See the preamble to the proposed rule and Section 2.3 of this document for a more complete discussion of comments received by EPA.)

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. 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 final pesticide container and containment regulations promulgated are being inserted into a newly established Part 165.

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² As discussed by EPA in the 1999 Supplemental Notice on Standards for Pesticide Containers and Containment (EPA, 1999b), the alternative definition disaggregates small businesses as defined by the Small Business Administration (SBA) into three size categories: small-small, medium-small, and large-small businesses. EPA is concerned that using an overly broad definition of small business in the economic analysis of the regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector. (See Chapter 3 for industry-specific small business definitions.)

1.3 Scope of the Economic Analysis for the Final Pesticide Rule

The EA conducted for the final pesticide container standards estimates the costs and benefits of compliance with four sets of standards, including: (1) container design standards for non-refillable containers; (2) container design standards for refillable containers; (3) repackaging (refilling) standards for refillable containers; and (4) standards for container labeling for all containers. The components of the final pesticide container standards EA include:

- (1) A profile of the regulated community. This includes specific economic characteristics of each industry regulated under the container regulations—such as North American Industry Classification System (NAICS) codes, the average company size, revenues for the average company, total industry revenues, the distribution of firms between small and large—to be used to estimate the costs and impacts of the container standards. (See Chapter 3.)
- (2) A profile of the containers not in compliance with the final pesticide container design and residue removal requirements. The profile contains the estimates and analysis of the baseline estimated number of containers, the number of containers covered under the scope of the regulations, and the number of containers not in compliance with the regulations. (See Chapter 3.)
- (3) An analysis of the cost of compliance with the final pesticide container design and residue removal requirements. The analysis includes the methodology for calculating the costs of compliance and the estimates of the costs for standards related to:
 - (a) refillable and non-refillable containers—how containers must be constructed, permanently marked, and labeled to ensure safety;
 - (b) refilling—what activities (i.e., container inspection, rinsing, and recordkeeping) are required to ensure that the act of refilling containers does not pose safety or health problems. The estimated costs are presented at different levels of aggregation for all regulated industries, each industry, a representative facility in each industry, and for each standard. (See Chapter 4.)
- (4) An analysis of the small business impacts of compliance with the final pesticide container standards for each regulated industry. These impacts are presented using both the Small Business Administration (SBA) definition of a small business, and the alternative definition of a small business adopted specifically for this rule.³ Impacts are estimated as the proportion of increased facility costs to current facility revenues. (See Chapter 4.)
- (5) An analysis of the human and non-human health-related benefits of compliance with the final pesticide container standards. The quantified human health-related benefits are estimated as the cost savings from eliminating container-related human exposure incidents. The quantified non-human health-related benefits are estimated as the cost savings from disposing of non-refillable containers as non-hazardous rather than hazardous material. (See Chapter 5.)

1.4 Estimated Costs and Benefits of the Final Rule

The pesticide container regulations specify a number of standards that create costs to the regulated community of bringing containers into compliance with the container standards, as well as benefits to humans and the environment. Improvements in the design and removal of

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³ See footnote 2.

residues from containers will benefit humans and the environment by reducing exposures to pesticides from pesticide containers. Table 1.2 provides a summary of the final pesticide container design and residue removal standards, which will be described in more detail in Chapter 2.

As is evident from the table, there are a number of requirements common to both non-refillable and refillable containers (i.e., DOT standards and some labeling), and a number of requirements specific to non-refillable containers (i.e., container dispensing capability, standardized closures, residue removal, and some labeling) and refillable containers (i.e., serial number marking, one-way valves/tamper-evident devices, bulk container requirements, refilling requirements, and some labeling). The EA addresses each standard separately in regards to pesticide container compliance and the estimated cost of compliance.

Table 1.2. Overview of the Rule Requirements

Non-Refillable Containers	Refillable Containers	Refilling Pesticide Products	Labels
1. DOT container design, construction, and marking standards	1. DOT container design, construction, and marking standards	1. Pesticide registrants (see Section 3.1) develop information	1. Identify container as non-refillable or refillable (all labels)
2. Container dispensing capability3. Standardized closures4. Residue removal5. Recordkeeping	Serial number marking One-way valves or tamper-evident devices Bulk container requirements	2. Registrants and others comply with specified conditions 3. Refillers (registrants and others) obtain and follow registrant information, and clean, inspect, and label containers before refilling them	2. Statements to prohibit reuse and offer for recycling; batch code (all non-refillable containers) 3. Cleaning instructions (some non-refillable containers) 4. Cleaning instructions before final disposal (all refillable containers) 5. Leave blank spaces for net contents and establishment number (some refillable containers)

Source: Final Container Rule.

The following two subsections summarize the estimated costs (including small business impacts) and benefits, respectively, of compliance with the final pesticide container standards. Chapters 4 and 5 present the analysis of the estimated costs and benefits of compliance with the final pesticide container standards.

1.4.1 Costs Summary

The total annualized costs of the pesticide container design and residue removal requirements are estimated to be approximately \$8.4 million and \$8.5 million at 3 percent and 7 percent discount rate respectively, while the total estimated annualized benefits range from \$4.7 million to \$4.8

⁴ The total estimated costs are nearly the same at both 3 percent and 7 percent because the majority of the costs of compliance (as discussed in Chapter 4) are attributed to the container-related standards (i.e., standards for residue removal, recordkeeping, container markings, closures, bulk containers, certification, and labeling), which incur most

million (depending on the discount rate used)⁵ (see Table 1.3). The estimated non-human health-related benefits account for more than 90 percent of the quantified total benefits of compliance with the requirements of the rule.

Assuming 610–768 human health-related illness and injuries potentially avoided as a result of the container regulations (see Chapter 5), the total cost per avoided case ranges from \$10,896 to \$13,718 (Table 1.3).

Table 1.3. Quantified Costs and Benefits of the Rule Requirements (2005\$)

Cost/Benefit Category	Annualized Cost/Benefit at a 3% Discount Rate	Annualized Cost/Benefit at a 7% Discount Rate		
Total Cost	\$8,367,385	\$8,449,929		
Total Benefits	\$4,735,981–\$4,804,240	\$4,235,280–\$4,296,452		
Human Health-Related Benefits	\$264,051-\$332,311	\$236,635–\$297,807		
Non-Human Health-Related Benefits	\$4,471,929	\$3,998,645		
Total Cost Per Avoided Human Health-Related Case				
Number of Cases Avoided	610–768 Cases	610–768 Cases		
Total Cost Per Avoided Case	\$10,896–\$13,718	\$11,003-\$13,852		

Table 1.4 provides a summary of the estimated annualized cost of compliance with the final container design and residue removal standards (at a 3 percent discount rate) for the average entity and totaled for each of the regulated industries (i.e., pesticide registrants, agricultural pesticide refillers, and swimming pool supply companies), across all market sectors⁶ for each entity size category (i.e., large, large-small, medium-small, and small-small). The costs include the estimated cost of compliance with the standards for residue removal, recordkeeping, container markings, container openings, bulk containers, labeling, and repackaging. The other standards (i.e., DOT packaging, container closures, and container dispensing) do not have any costs associated with them due to the availability of containers compliant with these standards as discussed in Chapter 3.

The estimated costs are highest for pesticide registrants, accounting for more than 70 percent of the total cost of compliance. Pesticide registrants are primarily responsible for the pesticide container-related standards (i.e., residue removal, recordkeeping, container markings, container openings, bulk containers, and labeling), although they do have some repackaging responsibilities (i.e., inspection, cleaning, and recordkeeping) in both the agricultural and industrial/commercial/ government markets. The estimated costs for agricultural pesticide refillers and swimming pool supply companies, which are responsible for the pesticide container refilling requirements in their associated markets, are significantly less (Table 1.4).

of their costs in the first year of compliance. The refilling-related requirements (container inspection, cleaning, and recordkeeping before each refill), which represent a smaller proportion of total costs, are estimated to be nearly the same each year.

⁵ For ease of presentation, the estimates using only the 3 percent discount rate will be presented in the text of the document. Chapters 4 and 5 present in tabular format the estimated costs and benefits of compliance with the final container standards, respectively, at both the 3 percent and 7 percent rates.

⁶ The market sectors analyzed include the agricultural, industrial/commercial/government (I/C/G), and home and garden (H&G) market sectors. See Chapter 3 for a description of each market sector.

Table 1.5 provides a summary of the total estimated annual cost of compliance by final pesticide container standard. As a result of assumed pesticide container compliance, no costs of compliance are estimated for meeting the DOT packaging standards, closure standards, and standards for container dispensing capability for non-refillable containers, and the DOT packaging standards for refillable containers. Approximately 16 percent of the cost of compliance is attributed to compliance with the residue removal standards. The refilling-related standards and labeling standards account for 38 percent and 27 percent of the total cost of compliance, respectively.

Table 1.4. Estimated Annual Cost of Compliance a with the Final Container Design and Residue Removal Standards for the Average Regulated Entity (2005\$)

		Cost for the Ave Entit		Cost over All Regulated Entities ^{b, c}			
Regulated Entity	Number of Entities	Interest Rate = 3%	Interest Rate = 7%	Interest Rate = 3%	Interest Rate = 7%		
Pesticide Registrants	Pesticide Registrants						
Small		\$1,806	\$1,936	\$2,993,825	\$3,209,477		
Large-Small	166	\$5,434	\$5,975	\$903,024	\$992,891		
Medium-Small	495	\$2,613	\$2,854	\$1,293,158	\$1,412,186		
Small-Small	997	\$800	\$807	\$797,642	\$804,400		
Large	146	\$17,967	\$19,078	\$2,623,114	\$2,785,386		
Total ^d				\$5,616,939	\$5,994,863		
Agricultural Pesticide I	Refillers						
Small		\$88	\$80	\$1,464,350	\$1,330,876		
Large-Small	251	\$871	\$764	\$218,684	\$191,692		
Medium-Small	2395	\$267	\$237	\$640,191	\$566,418		
Small-Small	13996	\$43	\$41	\$605,474	\$572,767		
Large	153	\$7,255 \$6,336		\$1,110,296	\$969,709		
Total ^d				\$2,574,646	\$2,300,585		
Swimming Pool Supply	Companies						
Small		\$19	\$20	\$5,808	\$6,034		
Large-Small	14	\$34	\$33	\$474	\$458		
Medium-Small	117	\$23	\$24	\$2,732	\$2,755		
Small-Small	174	\$15	\$16	\$2,602	\$2,821		
Large	17	\$10,000	\$8,732	\$169,993	\$148,448		
Total ^d				\$175,800	\$154,481		
Total Cost Across All R	Regulated Indus	stries ^e		\$8,367,385	\$8,449,929		

^a See Chapter 4 for information on calculations and estimated costs.

^b For pesticide registrants, average entity costs and costs for all entities by entity size are averaged across all market sectors (see Chapter 4).

^c For each industry, costs across all entities are found by multiplying the average entity cost by the number of entities of that size. May not be equal to the multiplication of the numbers in the table due to rounding. ^d Total equals the sum of the cost over all regulated entities for each industry.

^e Total Cost Across All Regulated Industries equals the sum of Total for each industry.

Table 1.5. Estimated Annual Cost of Compliance with the Pesticide Container Design and Residue Removal Standards by Standard^a

	Annual National Cost (3% Interest Rate)		
Standard	Interest Rate = 3 percent	Interest Rate = 7 percent	
For Non-Refillable Containers			
DOT Packaging Standards - hazardous material	\$0	\$0	
DOT Packaging Standards - non-hazardous material	\$0	\$0	
Closure Standards	\$0	\$0	
Standards for Container Dispensing Capability	\$0	\$0	
Residue Removal Standards	\$1,465,967	\$1,343,068	
Other Administrative Requirements - recordkeeping	\$202,617	\$210,575	
For Refillable Containers			
DOT Packaging Standards - hazardous material	\$0	\$0	
DOT Packaging Standards - non-hazardous material	\$0	\$0	
Standards for Container Markings	\$241,402	\$227,685	
Standards for Openings (for liquid minibulks ⁷ only)	\$261,018	\$291,648	
Bulk Container Standards	\$574,504	\$641,923	
Other Administrative requirements - recordkeeping	\$138,849	\$136,753	
For Refilling	\$3,198,256	\$2,849,969	
For Labeling	\$2,252,148	\$2,715,685	
Cost of Waivers	\$32,624	\$32,624	
Total National Annual Cost	\$8,367,385	\$8,449,929	

^a See Chapter 4 for information on calculations and estimated costs.

As discussed later in Chapter 4, small businesses are not estimated to be significantly impacted by compliance with the final container design and residue removal requirements. The estimated costs of compliance for small businesses in each of the regulated industries, as a proportion of their current revenues, are estimated to be less than 1 percent. Using the Small Business Administration (SBA) definition of small businesses, the costs of compliance for small businesses are estimated to be less than 0.02 percent of the current average entity revenues. According to the alternative small business definition used in this analysis (which further divides small businesses into large-small, medium-small, and small-small business), no small business is estimated to incur costs that account for more than 0.04 percent of current average entity revenues.

⁷ Minibulks are bulk containers of liquid pesticide greater than 55 gallons but less than 500 gallons and dry pesticide containers greater than 100 pounds and less than 400 pounds in capacity.

⁸ See footnote 2.

1.4.2 Benefits Summary

Table 1.6 presents the human and non-human health-related benefits of the final pesticide container standards as discussed in Chapter 5. The estimated annual human health-related benefits of compliance with the final container standards are estimated to range from \$264,051 to \$332,311 due to the cost savings from avoiding 610–768 container-related incidents as a result of the final container standards. The estimated annual non-human health-related benefits of compliance with the final container standards are estimated to range from \$4.0 million to \$4.5 million. These benefits are estimated as the cost savings from disposal of non-refillable pesticide containers as non-hazardous material, rather than hazardous material, as a result of the final pesticide container regulations. Additional, non-quantified benefits include the reduction in the number of environment-related incidents of exposure, and avoided property damage/spill cleanup costs, which suggest that the social value of the benefits is higher than the quantified amount (see Chapter 5 for a more detailed discussion).

Table 1.6. Estimated Benefits Associated with the Final Pesticide Container Design and Residue Removal Regulations (2005\$)^a

Benefit Category	Type of Benefit		Estimated Benefits
Human Health- Related Benefits	Avoided cases	•	610–768 cases annually (= \$264,051–\$332,311 in annualized health benefits) Additional 1,945 to 2,449 cases annually with "possible" cases (= an additional \$841,644 million to \$1,059,240 in annualized health benefits)
	Improved worker safety	•	Possible health benefit; lost productivity valued as part of health benefits from avoided cases
	Improved public health	•	Possible health benefit; continued benefit of avoided cases throughout the compliance schedule
Non-Human Health-Related	Tipping fee cost savings for non-refillable containers	•	\$4,471,929 (3% discount rate)—\$3,998,645 (7% discount rate) in annualized cost savings
Benefits	Environment-related effects	 Damage reduction from fewer exposures of terrest aquatic wildlife, including those in sensitive and cr habitats, to pesticides and residues 	
	Avoided property damage/spill cleanup costs	•	Pesticide container rules will prevent property damage and/or reduce the costs associated with unintended, container-related pesticide releases

^a See Chapter 5 for the discussion of human health-related and non-human health-related benefits.

1.5 Limitations of the Final Rule Economic Analysis

Conducting the EA for the final pesticide container standards required extensive information. For example, in determining the baseline level of pesticide container compliance with the final standards, information had to be obtained on: (1) the number of existing refillable and non-refillable containers, by container type, size, and end-use market; (2) the number of existing refillable and non-refillable containers that fall under the scope of the container rule; and (3) the number of refillable and non-refillable containers that fall under the scope of the container rule and that are in compliance with each container design and residue removal standard. To obtain the information necessary to complete the analysis, EPA relied on the regulatory impact analysis (RIA) conducted for the proposed container design and residue removal standards (EPA, 1993).

Contacts with industry experts and various state and federal agency personnel (including EPA personnel), as well as a review of the literature, were used to estimate, verify, and update the data throughout the report to the extent possible. We make every attempt to clearly state the assumptions throughout the analysis, and we present a sensitivity analysis in Chapter 4. The sensitivity analysis presents the costs of compliance with the container standards using lower and upper bounds on the assumptions used in the EA.

In summary, Chapter 1 has presented the statutory basis for the promulgation of the pesticide container standards final rule, a summary of the regulatory history of the standards, and a summary of the results of the EA. The next chapter continues with the introduction to the final pesticide container standards; presenting the final pesticide container design and residue removal standards, the changes in the standards from the proposed to the final standards, the response to comments to the proposed standards, and the economic impacts (i.e., the change in the costs and benefits of compliance) of the changes from the proposed to the final standards. The final three chapters (Chapters 3, 4, and 5) present the analysis of the costs and benefits of compliance with the final pesticide container standards.

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⁹ The RIA for the proposed standards for pesticide container design and residue removal was a major source of the data used in the EA for the final standards. EPA verified and updated the majority of the data used. However, it was infeasible to reconstruct some of the data, and EPA therefore used the data as presented in the RIA for the proposed container standards.

2.0 Final Rule Standards and Comparison of the Costs and Benefits of the Final and the Proposed Rule Standards

Chapter 1 presented the regulatory history of the pesticide container and bulk containment rule, an analysis of the scope of the EA, and a summary of the results of the EA. In Chapter 2, the final pesticide container design and residue removal standards are presented. These are the standards for which pesticide container compliance is determined in Chapter 3, and for which we estimate the costs and benefits of compliance in Chapters 4 and 5, respectively. Chapter 2 also presents a description of the changes made in the pesticide container standards from proposed to final, and presents a comparison of the costs and benefits of compliance estimated for the final and proposed container standards.

2.1 Final Rule Standards

Until now, the design of containers holding pesticides has been guided only by an interrelated combination of nationwide recommendations, ¹⁰ federal regulations, ¹¹ and state regulations and standards. (See Appendix F for complete discussion of these standards.) These recommendations, regulations, and standards form the basis for the final rule for pesticide container design and residue removal. Given the large set of standards already in existence, this rule is primarily a harmonizing and consolidation exercise, and EPA estimates that most containers are in compliance with many aspects of the rule because containers are already meeting a variety of other standards, as discussed in more detail in the pesticide container compliance profile presented in Chapter 3.

The pesticide container standards as described below are the end result of revisions made to the 1994 proposed standards for pesticide containers, based on the public comments submitted and discussions with a number of interested parties, including other EPA offices, government agencies, and the regulated community (see Section 2.2 for a discussion of the changes in the standards from proposed to final and Appendix G for a comparison of the proposed and final pesticide container standards.) The first seven standards presented apply to certain non-refillable and refillable containers (as specified for each standard), while the eighth standard (the repackaging standard) applies only to refillable containers, and the final labeling standard applies to all containers. The final pesticide container design and residue removal standards are as follows:

(1) Pesticide Container Design Standards

The final container standards adopt a subset of the Department of Transportation Hazardous Materials Regulations (DOT HMR) packaging standards at the Packing Group III level for pesticides not classified as DOT hazardous materials. Pesticides that are classified as DOT hazardous materials must comply with all applicable DOT regulations. For the purpose of enforcing the pesticide container regulations, the final rule identifies the DOT requirements for all three packing groups that are "equivalent" to the Packing Group III requirements applicable to products that are not DOT hazardous materials. Under the regulations, sale or distribution of

¹⁰ United Nations (1999); Mid America Crop Protection Association (MACA, 1999 and 1986).

¹¹ Department of Transportation Hazardous Materials Regulations (DOT HMR) (49 CFR Parts 107-179).

pesticides in containers not meeting all of the standards (the specifically listed ones in the pesticide regulations and the adopted DOT packaging standards) is prohibited. Both non-refillable and refillable pesticide containers must meet these standards.

(2) Pesticide Container Permanent Markings

The regulations for non-refillable pesticide containers and refillable pesticide containers refer to and adopt the DOT standards, which include marking requirements. Additionally, the regulations require a serial number or other identifying code for each refillable container.

(3) Pesticide Container Dispensing Capability

The regulations stipulate that liquid pesticide non-refillable containers with a capacity greater than 20 liters (5.3 gallons) be designed to eliminate splash and leakage during normal pouring of the contents. No dispensing capability requirements are specified for refillable pesticide containers.

(4) Pesticide Container Closures

Four closures are specified for non-refillable rigid containers having a capacity greater than 3.0 liters for liquid agricultural pesticides, and the final standard should not overlap with the Child-Resistant Packaging requirements. Liquid minibulk refillable containers (refillables) require a one-way valve, tamper-evident device, or both on each opening. Liquid bulk refillables must be equipped with a pressure-relieving device and locking shutoff valve, and cannot have external sight gauges.

(5) Pesticide Container Residue Removal Design Standard and Procedures

With regard to non-refillable containers, the regulations specify that every registrant test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable of achieving a "four-9s" laboratory performance standard (a reduction of the original active ingredient concentrate to 0.01 percent in a fourth rinse, equivalent to 99.99 percent removal). Percent removal represents the percentage 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 according to a formula.

(6) Pesticide Container Standards Waiver

The regulations include procedures for allowing a compliance waiver from adopting the specified DOT requirements for both non-refillable and refillable containers. In addition, for non-refillable containers, the regulations provide for waivers from the standard closure, container dispensing, and residue removal standards.

(7) Pesticide Container Recordkeeping

The regulations require several types of recordkeeping. The first addresses the documentation that the container used meets each aspect of the non-refillable container design standards. For non-refillables, the period extends for as long as the container design type is used with the registered pesticide product, plus 3 years.

The second type of recordkeeping requirement involves records kept by the registrants regarding repackaging. The registrants are required to keep copies of the contracts or authorizations, residue removal procedures for refilling, and list of acceptable containers for the current operating year and for 3 years thereafter.

The third type of recordkeeping involves refillers keeping copies of the documents identified in the previous paragraph for the registrants for the current operating year and for 3 years thereafter (as with the registrant recordkeeping).

The fourth type of recordkeeping involves information the refillers have to record when they repackage and when they receive refillable containers. Refillers must record three pieces of information when a pesticide is repackaged. No recordkeeping is required when a refillable container is received. These records must be kept for 3 years.

(8) Pesticide Container Refilling

Registrants who directly sell or distribute pesticide products in refillables or sell or distribute pesticide products to refillers for repackaging are held responsible for providing instructions and documentation for refilling. Refillers who repackage pesticide products into refillable containers for distribution or sale must comply with the refilling residue removal procedure developed by registrants and can repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, refillers must inspect the exteriors and interiors of the containers to ensure that the containers meet the necessary criteria for container integrity, required markings, and openings. Refillers must also clean each refillable container according to the residue removal procedure for pesticide product refilling (supplied by the registrant) before repackaging the product, unless certain criteria are met.

(9) Pesticide Container Labeling

The scope of the labeling requirement includes all labels for all pesticide products, not just those that fall within the scope of the non-refillable container, refillable container, and repackaging (refilling) regulations. However, the final regulations exempt household products from the residue removal instructions. Labels may include blank areas to allow a refiller to put any amount of product into a refillable and designate on the label the amount and to add its EPA-designated number for the refilling establishment. Other information to be included on the label is a description of the container type giving its intended purpose (such as a refillable or non-refillable statement) and detailed residue removal instructions. The regulations state that household products are exempt from requiring residue removal instructions on their labels and that durable permanent marking (versus permanent marking) is acceptable.

The level of required compliance for a pesticide product to these standards is not the same for all products. While the labeling standards apply to all pesticide products, there is a subset of pesticide products that are not subject to the pesticide non-refillable and refillable container design standards and refilling standards. The level of compliance with these requirements depends on a number of factors, such as the type of product (e.g., end-use, manufacturing, antimicrobial), toxicity of the product, and use of the product. Chapter 3 provides a complete description of the scope of the pesticide container requirements.

2.2 Changes in Pesticide Container Design and Residue Removal Standards from the Proposed to the Final Rule

The final pesticide container design and residue removal standards differ significantly from the 1994 proposed standards. The final standards are narrower in scope than the proposed regulations, exempt certain antimicrobial pesticides, require less stringent container design and residue removal requirements, and adopt some of the Department of Transportation (DOT) hazardous materials regulations. As a result, the estimated economic impacts on the regulated community under the final standards are different from the estimated economic impacts under the proposed standards.

EPA received approximately 1,900 pages of comments from more than 200 commenters (e.g., trade associations, pesticide manufacturers, pesticide retailers, and many state regulatory agencies) on the proposed rule. In response, two significant issues were readdressed, and the comment period was reopened in 1999. The two issues were: (1) the scope of the container standards; and (2) the relationship between the 1994 proposed rule and the DOT standards for hazardous materials packaging. In the final rule (as discussed below), EPA has revised the scope of the container standards to be risk-based with exemptions, and has adopted many of the design and construction standards that would apply to DOT Packing Group III materials. These and other changes made to each standard are as follows. (See Appendix G for additional information on the changes from the proposed to the final rule.)

(1) Scope of the Pesticide Container Design and Residue Removal Standards

Regarding the scope of the pesticide container design and residue removal regulations, the proposed regulations generally affected all containers used to package pesticide products, without regard to industry, use, risk, or container type and size. Only manufacturing use products were exempt from the proposed regulations. The final rule exempts manufacturing use products, plant-incorporated protectants, and certain antimicrobial products from the non-refillable container, refillable container, and repackaging (refilling) regulations. All other products are subject to the container-related regulations, although the number of non-refillable container standards is greatly reduced for some products. As proposed, all pesticide products (except household products) are subject to the container labeling requirements in the final rule.

(2) Pesticide Container Design Standards

The proposed regulations included some very general design standards, but also included some specific tests, such as a drop test for minibulk containers. The final standards specify some DOT HMR packaging standards for pesticides classified as DOT hazardous materials. Pesticides that are not classified as DOT hazardous materials are required to be packaged in accordance with the specified design and construction standards that would apply to a DOT Packing Group III material.

(3) Pesticide Container Permanent Markings

The proposed standards required many more specific permanent markings for non-refillable and refillable containers. For example, non-refillables required the EPA registration number and name and a symbol or code of materials used to make the container, and refillables required the statement, "Meets EPA standards for refillable containers." The final regulations, as described

above, refer to and adopt the DOT standards for non-refillables and refillables (which specify certain markings), and require a serial number or other identifying code for each refillable container.

(4) Pesticide Container Dispensing Capability

The proposed regulations stipulated that liquid containers be designed to eliminate the splash and leakage during normal pouring of the contents, closing or resealing the container, and during storage and cleaning of the container. The final regulations regarding pouring are the same except that they apply only to non-refillables liquid containers with a capacity greater than 20 liters (5.3 gallons). The proposed requirement to reseal completely was not finalized because an equivalent requirement is included in the adopted DOT standards.

(5) Pesticide Container Closures

The proposed and final standards for container closures are the same.

(6) Pesticide Container Residue Removal Design Standard

With regard to non-refillable containers, the proposed regulations specified that registrants must demonstrate that each rigid/dilutable container/formulation combination achieved a "six-9s" laboratory performance standard (a reduction of the original active ingredient concentrate to 0.0001 percent in a fourth rinse, equivalent to 99.9999 percent removal). The final regulations require that every registrant test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable of attaining at least 99.99 percent removal of each active ingredient in the fourth rinsate after a triple rinse.

(7) Pesticide Container Design and Residue Removal Standard Waiver

The proposed regulations permitted a waiver for standard closures and the residue removal standard only (non-refillable containers), while the final regulations include provisions for both non-refillable and refillable containers to waive adoption of the subset of DOT standards, and, for non-refillables, the standard closure, container dispensing, and residue removal requirements.

(8) Pesticide Container Certification

The proposed rule required registrants to certify that the non-refillable and refillable containers used for the distribution or sale of pesticides meet the container design standards. The final rule does not require certification.

(9) Pesticide Container Recordkeeping

The proposed and final regulations require similar types of recordkeeping, although the final rule requires fewer records and decreases the length of time that many of the records must be kept.

(10) Pesticide Container Refilling

The proposed and final regulations contain nearly the same requirements for the refilling of pesticide containers, including specific guidelines for registrants and refillers. However, the final rule changes two of the conditions to: (1) require a contract between the parties (rather than

a contract or an authorization as proposed); and (2) allow repackaging at an end user location under certain circumstances (rather than requiring the repackaging to be conducted at a registered establishment as proposed).

(11) Pesticide Container Labeling

The proposed and final regulations for container labeling are similar, but the final regulations are generally more flexible because they provide a range of specific statements. While the proposed regulations required the residue removal instructions on all rigid non-refillable containers with dilutable products, the final regulations exempt household containers and allow for durable container markings (rather than only permanent as proposed).

2.3 Response to Comments to the Proposed Standards

As previously mentioned, EPA received approximately 1,900 pages of comments from more than 200 commenters in response to the proposed pesticide container standards. The majority of the comments received were directed toward the proposed container standards and their effect on the regulated industries, resulting, in part, in the changes to the proposed standards as described in the previous section. Only a relatively small portion of the comments submitted in response to the proposed container standards were directed toward the regulatory impact analysis (RIA) conducted for the proposed container standards. As a result, there were few changes made in the assumptions used to calculate the costs of compliance from the proposed to the final container standards based on the comments submitted. Rather, the differences between the proposed and final rule economic analyses (EAs) primarily reflect changes made in the scope and requirements of the container standards.

There are two exceptions. The first is the consideration of the swimming pool industry in the final EA. This industry was not considered separately in the RIA for the proposed container standards. As a result of comments submitted by the swimming pool industry, which provided a reasonable justification for being considered separately, the EA for the final standards considers swimming pool supply companies relative to the refilling standards. The other exception is the calculation of the indirect, non-health benefits in the RIA associated with the movement from non-refillable to refillable containers. In the proposed rule, these indirect benefits (see Section 2.4) were estimated, and, in response, a number of comments were submitted by the regulated industry questioning the magnitude of these benefits. Although EPA still maintains that there could be a shift from non-refillables to refillable containers as a result of the final pesticide container standards, EPA acknowledges that there is more uncertainty in the assumptions made in the analysis of indirect benefits and the magnitude of these benefits than is made evident in the proposed rule RIA. As a result, the EA for the final pesticide container standards does not attempt to quantify these indirect benefits.

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¹² The swimming pool industry, which includes pool, spas, hot tubs, and whirlpools, successfully argued that it is unique because it uses and refills a large number of small refillables (an estimated 1 million 1- or 2.5-gallon containers).

2.4 Comparison of the Estimated Costs and Benefits of the Final and Proposed Standards

As described in Section 2.2, EPA made a number of significant changes to the pesticide container standards from the proposed to the final standards. As a result, there are differences in the level of compliance with these standards for existing containers, leading to differences in the estimated costs and benefits of compliance with the pesticide container standards between the proposed and final rule. Tables 2.1 and 2.2 present the estimated costs and benefits of compliance for the final and proposed pesticide container standards.

Table 2.1. Annual Compliance Cost Comparison Between the Final and Proposed Pesticide Container Standards (2005\$)

Cost Item	Compliance Cost for Final Container Standards ^a	Compliance Cost for Proposed Container Standards b			
Total Cost of Compliance	\$8.4 million	\$40.1 to \$55.5 million			
Total Cost of Compliance by Regulated 1	Total Cost of Compliance by Regulated Industry				
Pesticide Registrants	\$5.6 million	\$27.3 to \$37.3 million			
Agricultural Pesticide Refillers	\$2.6 million	\$4.7 million			
End Users	No Analysis Completed	\$8.2 to \$13.6 million			
Swimming Pool Supply Companies	\$0.2 million	No Analysis Completed			
Total Cost of Compliance by Standard					
Container-Related Standards ^c	\$2.9 million	\$22.2 to \$32.2 million			
Refilling-Related Standards d	\$3.2 million	\$4.7 million			
Labeling Standards	\$2.3 million	\$13.3 to 18.7 million			

^a See Chapter 4 for the cost analysis of the pesticide container regulations. Figures presented here are calculated using a 3% discount rate. Figures for both 3% and 7% discount rates are presented in Chapter 4.

^b Based on the costs estimated for Regulatory Option 2 in the proposed rule RIA for pesticide containers, which was EPA's preferred option in the proposed rule. The range of cost estimates results from the consideration of two scenarios under each regulatory option (see Appendix E).

^c The container-related standards include DOT packaging standards and recordkeeping standards for refillable and non-refillable containers; closure standards, standards for container dispensing, and residue removal standards for non-refillables; and standards for container marking, openings, and bulk containers for refillable containers.

^d The refilling-related standards include the inspection, cleaning, and recordkeeping of refillable containers.

Table 2.2. Comparison of Human Health-Related and Non-Human Health-Related Benefits for the Proposed and Final Container Standards (2005\$)

Benefit Category	Final Container Standards ^a	Proposed Container Standards b			
Human Health-Related Benefits					
Avoided Cases	 610 to 768 cases annually (= \$264,051 to \$332,311 in annualized health benefits per year) Additional 1,945 to 2,449 cases annually with "possible" cases (= an additional \$841,644 to \$1,059,240 in annualized health benefits) 	1,650 to 2,250 acute illnesses annually			
Improved Worker Safety	Possible health benefit; lost productivity valued as part of health benefits from avoided cases	 Reduced personal sickness and injury Improved worker productivity 			
Improved Public Health	Possible health benefit; continued benefit of avoided cases throughout the compliance schedule	Less personal injury from accidental spills and chronic contamination sources			
Non-Human Health-Related Benefits					
Non-Refillable Container Disposal Benefit (2005\$)	• \$4.5 million per year	• \$5.6 to \$6.9 million per year			
Non-Refillable to Refillable Container Benefit	Not quantified	\$36 to \$109 million per year			

^a See Chapter 5 for the pesticide container regulations human health related and non-human health related benefits analysis. Figures presented here are calculated using a 3% discount rate. Figures for both 3% and 7% discount rates are presented in Chapter 5.

The total cost of compliance with the final standards is estimated to be significantly lower than the estimated total cost of compliance with the proposed standards (see Table 2.1). This is primarily the result of the changes in the container standards from the proposed to final rule. One of the significant changes between the proposed and final pesticide container rule is the elimination of the labeling standard requiring household users to triple rinse non-refillable containers prior to disposal. The estimated cost of this requirement accounts for a significant portion of the difference between the final and proposed container standards in terms of estimated total cost and estimated labeling standards cost, and all of the difference between the end user costs (which are not expected in the final rule without the labeling requirement for household users to triple rinse containers prior to disposal).

The difference in costs between the final and proposed rule for pesticide registrants (and the container-related standards, for which the pesticide registrants are responsible) is attributed primarily to the changes in the container standards from the proposed to final rule. Change in residue removal standards, which are now applicable to only flowable concentrate products, has significantly reduced the total cost of the rule. In addition, reduction in the estimated time to inspect, clean, and record information for refillable containers and the elimination of certification requirements also account for the difference between the total estimated costs for pesticide refillers (and the refilling-related standards) to comply with the final container standards versus the proposed container standards. Swimming pool supply companies face similar costs for refilling; however, this industry was not addressed in the proposed rule RIA. The proposed rule RIA for pesticide containers estimated costs to refill containers for agricultural refillers only, ignoring not only the swimming pool industry, but also some agricultural and

^b Proposed container rule RIA (EPA, 1993, pg. XIV-3). See Appendix E.

industrial/commercial/government product refilling responsibilities (and therefore increased costs of compliance) for pesticide registrants.

Table 2.2 presents the estimated human health-related and non-human health-related benefits of compliance with the final and proposed container standards. Both analyses estimate the number of potentially avoided illnesses. In addition, there were other human health-related benefits discussed qualitatively in the proposed regulations, such as improved worker safety and improved public health, which remain relevant to the final regulations. In the RIA for the proposed container standards, the avoided cases were estimated by extrapolating 1988–1989 California incident data to the national level. For that analysis, the number of cases per year found to be attributable to container-related problems in California was assumed to represent approximately 10 percent of the nation's total, resulting in a total annual estimate of 1,650 to 2,250 potentially avoided cases. In the EA for the final standards, it is similarly assumed that the percentage of illnesses related to pesticide products occurring in California in 1999 would not differ significantly from the United States as a whole. However, unlike the proposed regulations, this ratio is applied to national data on pesticide exposures, rather than extrapolating it to a national estimate. The EA for the final container standards also estimates dollar benefits for the potentially avoided cases as a result of the final container standards, which was not done in the RIA for the proposed container standards. The total human health-related benefits calculated in the final rule EA (\$264,051 to \$332,311 per year) are estimates of the costs avoided as a result of estimated avoided cases of pesticide illness. The analysis considers costs including outpatient costs, inpatient costs, the value of lost productivity, and the value of premature mortality.

The only quantified non-human health-related benefits calculated in the EA for the final pesticide container standards is the annual cost-saving benefit associated with the diversion of non-refillable containers from the hazardous waste management stream to the solid (non-hazardous) waste stream. This annual benefit was also calculated in the RIA for the proposed pesticide container standards. The differences between the results of the two analyses stems from the changes in the scope criteria in the final rule, leading to a smaller number of containers estimated to be diverted from the hazardous to non-hazardous waste stream in the final rule EA, and, as a result, lower estimated dollar benefits.

In addition to the non-refillable container disposal benefits, the RIA for the proposed container standards estimated indirect benefits associated with the switch from use of non-refillable containers to refillable containers, which was expected (not required) as a result of the container standards. The types of indirect cost savings estimated as a result of the switch to refillable containers include: (1) container cost savings, (2) container disposal cost savings, and (3) substantial labor savings associated with triple rinsing of used non-refillable pesticide containers. The sum of indirect benefits was estimated to range from \$36 million to \$109 million. These benefits are not quantified in the final container standards EA.

In summary, this chapter presented (1) the final standards for pesticide containers and the changes that have been made to the standards from the proposed to the final rule, and (2) a summary of the estimated costs and benefits of compliance with the final and with the proposed pesticide container standards. The remaining three chapters present the analysis of the costs and benefits of compliance with the final pesticide container standards. The first step in this analysis

(Chapter 3) involves determining the level of compliance of pesticide containers with the final container standards. This information feeds into the second step of the analysis (Chapter 4), which estimates the cost of compliance with the final standards. The final step (Chapter 5) estimates the benefits to humans and the environment expected to result from compliance with the final pesticide container standards.

3.0 Pesticide Container Compliance Profile

3.1 Introduction

This chapter presents a baseline regulatory compliance profile of pesticide containers that will be affected by the container regulations. In general, the container regulations address four categories, which include:

- Non-refillable container standards;
- Refillable container standards;
- · Repackaging of pesticide products; and
- Container labeling.

The container regulations compliance affects several types of entities across multiple pesticide market sectors. The three entities that are potentially affected by the container regulations are pesticide registrants, agricultural pesticide refillers, and swimming pool supply companies. The following is a description of each of these entities as well as a description of how these entities are affected by the container rule. For a more detailed description of each entity type see Appendix D.

• **Pesticide registrants** include all establishments engaged in the formulation and preparation of all types of pesticides (e.g., insecticides, fungicides, and herbicides). This regulated entity includes both pesticide manufacturers and independent formulators who hold one or more pesticide registrations. Registrants include those who distribute or sell pesticides in non-refillable containers or refillable containers directly, those who distribute or sell pesticides to independent formulators or refillers, and in some cases direct refiller establishments.

Pesticide registrants are basically required to ensure that all non-refillable and refillable containers meet the container rule construction and design standards, develop and provide information to refillers, and ensure that labels include the specified information. Pesticide registrants are responsible for procedural and handling activities for approximately 10 percent of the refillables in the agricultural market (Paulson, 2002) and all of the refillables in the industrial/commercial/government (I/C/G) market. The primary NAICS code designation for pesticide registrants is 325320 – Pesticide and Other Agricultural Chemical Manufacturing. The Dun & Bradstreet (D&B) database of company information and financial data provides NAICS codes with company information where available. Registrants may serve one or more of the pesticide use market sectors (i.e., agricultural,

¹³ Don Paulson recently retired from Ciba/Novartis and is currently a consultant to Syngenta and CropLife America, formerly the American Crop Protection Association (ACPA). Mr. Paulson was very active in the ACPA packaging task force in the 1990s and co-surveyed the number of agricultural pesticide containers for ACPA with Tom Gilding between 1989 and 1996.

Other NAICS codes associated with pesticide registrants include: (1) 422690 – 1997 NAICS - Otr Chem & Allyd Prdct Whlslrs, (2) 422910 1997 NAICS – Farm Supplies Wholesalers, (3) 325612 – Polish and Other Sanitation Good Manufacturing, (4) 325998 – All Other Miscellaneous Chemical Product and Preparation Manufacturing, (5) 325188 – All Other Basic Inorganic Chemical Manufacturing, (6) 453998 – All Other Miscellaneous Store Retailers (except Tobacco Stores), and (7) 325412 – Pharmaceutical Preparation Manufacturing. (See Appendix D.)

industrial/commercial/government, and/or home and garden). (See below for a discussion of each market sector.)

• Agricultural pesticide refillers include only independent agricultural market sector refillers. The agricultural pesticide refiller entity is generally an agricultural chemical dealer (or retailer) who supplies pesticide products to farmers or other end users in refillable containers for large-scale application, although it could also be a distributor. Agricultural pesticide refillers are subject to container refilling requirements each time a refillable container is repackaged. Generally, this regulated entity is responsible for inspecting, rinsing, relabeling containers prior to reuse, and maintaining appropriate records. It is estimated that 90 percent of agricultural pesticide product is distributed or sold by agricultural pesticide refillers, and the remaining 10 percent is distributed or sold directly by registrants (Paulson, 2002).

Agricultural pesticide refillers are generally represented under NAICS 422910 – Farm Supplies and Wholesale Sector, which consists of "establishments primarily engaged in wholesaling farm supplies, such as animal feeds, fertilizers, agricultural chemicals, pesticides, plant seeds and plant bulbs" (U.S. Department of Commerce, 1997).

• Swimming pool supply companies include registrants and other companies that repackage sodium hypochlorite, an antimicrobial used in pools and spas. Swimming pool supply companies are affected by certain requirements in the final rule for repackaging (refilling) sodium hypochlorite. These companies must meet certain refilling requirements, but not all. Refillables are required to be inspected, cleaned, and properly labeled. Swimming pool repackagers must maintain certain records, but not all. Copies of the residue removal procedures for refilling and description of acceptable containers must be on file, but a record of certain information recorded each time a container is refilled (e.g., product, amount) is not required. A primary NAICS code for swimming pool supply companies is 453998 – All Other Miscellaneous Store Retailers (except Tobacco Stores).

Other entities handle pesticide containers but are not regulated under the final rule. For example, agricultural commercial applicators and self-applicators (farmers) routinely use combinations of non-refillable and refillable containers. These entities typically do not redistribute or resell refillable containers or provide refilling services other than for self-application or self-use; therefore, these entities will not be subject to the final refilling requirements. As a result, these entities are not included in this industry profile.

It is difficult to estimate the impact of the container regulations on end users or consumers of pesticide containers. The container regulations do not include specific requirements for end users or consumers. However, the labeling requirements for pesticide registrants require that certain information, including proper residue removal procedures prior to disposal, be included on pesticide labels. The impact of these labeling requirements on end users and consumers is uncertain. Information on the current residue removal practices of end users and consumers is not readily available; thus, estimating the change in behavior associated with the container rule labeling requirements is also unavailable. We assume the labeling requirement impact on end users or consumers is indirect and negligible.

The container regulations are associated with three major market sectors of pesticide use: agricultural, I/C/G, and home and garden (H&G). The market sectors used in the compliance profile are consistent with EPA's *Pesticides Industry Sales and Usage: 2000-2001 Market Estimates* report (EPA, 2002b) and the *Economic Profile of the U.S. Pesticide Industry* (EPA, 2000a). The agricultural sector forms the largest market for conventional pesticides, with herbicides used most commonly, followed by insecticides and fungicides. The I/C/G sector includes use of pesticide products by professional applicators at I/C/G facilities, on military bases, in hospitals, for janitorial use, and in homes and gardens. The H&G sector represents pesticide products formulated for household use in and around the home.

The market sectors considered in this analysis differ slightly from the market sectors considered in the proposed container rule RIA (EPA, 1993). Table 3.1 illustrates how the market sectors considered in this analysis compare with the market sectors used previously.

Table 3.1. Market Sector Equivalent Between the Current Analysis and the 1993 EPA Proposed Container Rule RIA

Current Analysis	Proposed Container Rule RIA
Agricultural	Agricultural
Industrial/Commercial/Government	Industrial Institutional
Swimming Pool Supply Companies ^a	Not considered separately
Home & Garden	Household

^a Swimming pool supply companies are subject to a subset of the refilling requirements. Swimming pool supply companies must meet certain refilling requirements, but not all. Refillables are required to be inspected, cleaned (unless specified conditions in §165.170 are met), and properly labeled. Swimming pool supply companies must maintain certain records, but not all. Copies of the residue removal procedures for refilling and description of acceptable containers must be on file (§165.218(a)), but a record of certain information recorded each time a container is refilled (e.g., product, amount) is not required (§165.218(b)). Swimming pool supply companies could be considered part of both the I/C/G and H&G markets. For the purposes of this analysis, however, swimming pool supply companies were considered separately for the refillable container and repackaging requirements. For non-refillable containers, the containers holding sodium hypochlorite for swimming pool use are included with the estimates of containers in the I/C/G and H&G markets.

Table 3.2 illustrates which regulated entities are responsible for which container regulations. Table 3.2 is not intended to be comprehensive; rather, it is designed to provide a brief overview showing how each of the regulated entities identified and characterized in this chapter will be affected by the container rule.

Table 3.3 illustrates the SBA and EPA alternative small business definitions for entities affected by the container regulations. A small entity is defined as:

• A small business according to the Small Business Administration (SBA) regulations at 13 CFR 121.201. The SBA defines small businesses by category of business using NAICS codes. Not all companies within a given regulated entity have registered under the same NAICS code. The SBA definition is based on the primary NAICS code or codes that best represent(s) the regulated entity.

Table 3.2. Generalization of Impacts of Pesticide Container Regulations on Regulated Entities

Container Rule Activities	Pesticide Registrants	Agricultural Pesticide Refillers	Swimming Pool Supply Companies
Non-Refillable Containers			
Ensure that all containers meet a subset of DOT packaging standards	✓		
Ensure that liquid product containers dispense properly and have standard closures	✓		
Ensure that containers meet the residue removal standard for dilutable pesticides in rigid containers	✓		
Refillable Containers			
Ensure that containers meet a subset of DOT packaging standards	✓		
Mark containers with a serial number	✓		
Ensure that a one-way valve and/or tamper-evident device is in place for liquid minibulks	✓		
Ensure that a vent, gauge, and shutoff valve are in place for liquid bulk containers	✓		
Meet repackaging conditions	✓ a	✓	✓
Develop cleaning procedures for repackaging	✓ a		
Inspect, clean, and ensure proper labeling of containers	✓ a	✓	✓ b
Maintain records	✓ a	✓	✓ °
Labeling Standards			
Ensure that labels include specified information	✓		

^a Refilling requirements affect pesticide registrants for 10 percent of the total refillable containers in the agricultural market sector and all of the containers in the I/C/G market sector. Available data are insufficient to differentiate pesticide registrants that also repackage I/C/G market pesticide products from those that do not. Therefore, pesticide registrants are held accountable.

^b Swimming pool supply companies must meet certain refilling requirements, but not all. Refillables are required to be inspected, cleaned (unless specified conditions in §165.170 are met), and properly labeled.

^c Swimming pool supply companies must maintain certain records, but not all. Copies of the residue removal procedures for refilling and a description of acceptable containers must be on file (§165.218(a)), but a record of certain information recorded each time a container is refilled (e.g., product, amount) is not required (§165.218(b)).

Table 3.3. SBA and EPA Alternative Definitions of Small and Large Businesses Affected by the Pesticide Container Regulations

Regulated Entity	SBA	A Definitio	ns	EPA Alto	ernative Definitions
	Primary NAICS Code(s)	Size	Definition (13 CFR Part 121)	Size	Definition
Pesticide Registrants	325320 – Pesticide and Other	Small	500 or fewer employees	Small-Small	1 to 19 employees
	Agricultural Chemical			Medium-Small	20 to 99 employees
	Manufacturing			Large-Small	100 to 500 employees
		Large	501 or more employees	Large	501 or more employees
Agricultural	422910 – Farm Supply	Small	100 or fewer employees	Small-Small	1 to 9 employees
Pesticide Refillers	Wholesalers			Medium-Small	10 to 49 employees
				Large-Small	50 to 100 employees
		Large	101 or more employees	Large	101 or more employees
Swimming Pool	453998 – All Other	Small	Maximum revenues of \$6.0	Small-Small	1 to 9 employees
Supply Companies	Miscellaneous Store Retailers		million ^a	Medium-Small	10 to 49 employees
	(except Tobacco Stores)			Large-Small	50 or more employees
		Large	Revenues greater than \$6.0 million ^a	Large	Revenues greater than \$6.0 million ^a

^a The SBA small business size standard is no more than \$6 million in revenue for NAICS 453998. The analysis divided the SBA small businesses into the three EPA alternative small business size categories regardless of employee or revenue totals once the regulated entity passed the SBA-defined small business screening.

- 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.
- Any small, not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

This economic analysis (EA) evaluates an alternative definition of small entities or businesses potentially affected by the container regulations. As discussed by EPA in the 1999 Standards for Pesticide Containers and Containment Proposed Rule Supplemental Notice (EPA, 1999), the alternative definition disaggregates the SBA-defined small businesses into three size categories: small-small, medium-small, and large-small businesses. EPA is concerned that using an overly broad definition of small business in the EA of the container regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector. Table 3.3 represents each affected industry by the SBA definition of small business and the alternative definition used in this analysis.

Two industry sectors considered in the 1999 Supplemental Notice were pesticide formulators and agrichemical dealers. These regulated entities correspond with pesticide registrants and agricultural pesticide refillers, respectively, in this EA. We have also developed an alternative small business definition that disaggregates the SBA-define small businesses into small-small, medium-small and large-small businesses for the swimming pool supply companies.

The remainder of this chapter is divided into three sections. Section 3.2 describes how we estimated the total universe of pesticide containers in use for the three market sectors (agricultural, I/C/G, and H&G). Section 3.3 illustrates how we applied the scope criteria to the total universe of pesticide containers to estimate how many containers are ultimately affected by the container regulations. Section 3.4 examines the extent to which pesticide containers are already in compliance with various components of the container regulations.

3.2 Pesticide Container Universe

An estimate of the current number of non-refillable and refillable containers in the agricultural, I/C/G, and H&G markets is based on data from the following sources:

- 1996 agricultural pesticide container survey by the American Crop Protection Association (ACPA, 1997).
- Container number estimates derived from a 1989 pesticide container survey conducted by the
 pesticide industry. The groups that participated include the National Agricultural Chemicals
 Association (NACA), the Mid America CropLife Association (MACA), the International
 Sanitary Supply Association (ISSA), and the Chemical Specialties Manufacturers
 Association (CSMA).
- Non-refillable container numbers from 2001 and 1991 surveys conducted by the American Chemistry Council (formerly the Chemical Manufacturers Association).
- Information and best professional judgment from industry and association representatives (EPA, 2005, and Paulson, 2002).

Because of the pesticide use diversity among the major pesticide markets, the number of containers is estimated separately for each market. The general approach we took was to summarize the number of containers by type from the appropriate source(s) and adjust container numbers as appropriate to reflect current use levels based on 2001 information and best professional judgment (EPA, 2005). Tables 3.4 and 3.5 illustrate the estimated number of non-refillable and refillable containers, respectively, that are currently in use. Table 3.6 gives estimates of the number of swimming pool chemical containers affected by the container regulations. A more detailed discussion of how the estimates were derived for refillable containers can be found in Appendix B.

Table 3.4. Estimated Number of Non-Refillable Pesticide Containers in Use by Major Market Sectors

	iviajoi iviai	Industrial/		
		Commercial/	Home &	_
Container Size Category	Agricultural ^a	Government b	Garden ^c	Total
Liquid Pesticide Products				
30-55 Gallons				
Plastic	309,100	1,600,000	0	1,909,100
Steel	115,500	2,320,000	0	2,435,500
5 Gallons				
Plastic	58,100	14,048,000	0	14,106,100
Steel	28,800	960,000	0	988,800
1 To < 5 Gallons				
Plastic	27,877,500	21,072,000	28,000,000	76,949,500
Steel	0	1,440,000	8,000,000	9,440,000
< 1 Gallon				
Plastic	1,007,000	20,560,000	104,000,000	125,567,000
Steel	0	160,000	12,000,000	12,160,000
Glass	0	240,000	8,000,000	8,240,000
Water Soluble Packets				
PVA	544,600	0	0	544,600
Barrier	82,200	0	0	82,200
Bag-In-Box	500	260,000	0	260,500
Aerosol Cans	0	23,200,000	200,000,000	223,200,000
Other Sizes	0	0	0	0
Subtotal	30,023,300	85,860,000	360,000,000	475,883,300
Dry Pesticide Products		<u>.</u>		
> 100 lb Bulk	429,500	0	0	429,500
56-100 lb Bags	0	0	0	0
45-55 lb Bags				
Plastic	1,849,200	0	0	1,849,200
Paper	8,161,000	0	0	8,161,000
11-44 lb Bags	0	1,120,000	39,500,000	40,620,000
Plastic	3,764,900	0	0	44,384,900
Paper	2,216,600	0	0	2,216,600
1-10 lb Bags				
Plastic	328,900	0	0	328,900
Paper	5,730,200	0	0	5,730,200
Jugs				· · · · ·
2.5 gallons	26,400	0	0	26,400
1 quart to < 2.5 gallons	2,273,000	370,000	500,000	3,143,000

Table 3.4 (Continued). Estimated Number of Non-Refillable Pesticide Containers in Use by Major Market Sectors

Container Size Category	Agricultural ^a	Industrial/ Commercial/ Government ^b	Home & Garden ^c	Total
PVA	44,070,700	1,300,000	0	45,370,700
Barrier	11,879,100	430,000	0	12,309,100
Fiber Drums				
> 30 pounds	12,300	1,280,000	0	1,292,300
< 30 pounds	129,600	0	0	129,600
Other Sizes	3,442,200	0	0	3,442,200
Subtotal	84,313,600	4,500,000	40,000,000	128,813,600
Total - Non-Refillables	114,336,900	90,360,000	400,000,000	604,696,900
Percentage of Non-Refillables	18.91%	14.94%	66.15%	

^a Current estimates of the number of non-refillable containers in the agricultural market were taken from the most recent (1996) ACPA Container Survey (ACPA, 1997). Number of containers has been rounded to the nearest hundred for purposes of this table. Actual container estimates surveyed are used throughout the pesticide container compliance profile (Chapter 3) and cost analysis (Chapter 4). EPA (2005) determined that the 1996 ACPA Container Survey results were reasonable and should be used based on correspondence with Tom Gilding of CropLife America (formerly ACPA).

b Current estimates of the number of non-refillable containers in the I/C/G market were based on the combined total number of containers for the industrial and institutional market sectors used in the proposed container rule RIA (EPA, 1993). EPA solicited comments from the American Chemistry Council (ACC) and ISSA in May 2001 to aid in updating the I/C/G non-refillable container estimates. The ACC received information on the number of containers used by 11 out of 40 member companies. This information was used to modify the current estimated number of containers in the I/C/G market sector. As a result, EPA made the following changes in the estimated number of non-refillable container estimates for the I/C/G market sector (EPA, 2005):

- Bag-in-box: Two companies reported 133,162 bag-in-box containers. Since only a small number of companies reported using these containers, this estimate was doubled and rounded down to 260,000.
- One quart to < 2.5 gallon plastic: Two companies reported 184,617 containers in this category. This estimate was doubled and rounded to 370,000.
- Water soluble PVA packets and barrier packs: Three companies reported 653,305 water soluble PVA packets. This estimate was doubled and rounded to 1,300,000. The number of barrier packs was calculated based on a ratio of three PVA packets to one barrier pack, resulting in an estimated 430,000 barrier packs.
- ^c Current estimates of the number of non-refillable containers in the H&G market were based on the total number of containers in the household market sector used in the proposed container rule RIA (EPA, 1993). EPA received the following qualitative feedback from John DiFazio of Consumer Specialty Products Association (CSPA) with regard to the current number of H&G non-refillable containers in use versus the 1993 estimates:
- Liquid non-refillables: (1) 1 to <5 gallon plastic about the same; (2) <1 gallon plastic about the same; (3) <1 gallon steel much less; and (4) aerosol cans about the same.
- Dry non-refillables: (1) 11 to 44 pound plastic bags a bit less; (2) 1 to 10 pound paper bags a bit more; (3) 1 quart to <2.5 gallon plastic a bit less; and (4) subtotal for dry non-refillables more, possibly much more.

As a result, the following non-refillable container estimate modifications were made:

- <1 gallon steel: Assumed that "much less" reduced the estimate for this category from 24,000,000 to 12,000,000.
- Flexible bags (see note "d" below): Assumed that "a bit less" 11 to 44 pound plastic bags combined with "a bit more" 1 to 10 pound paper bags increased the estimate for this category from 28,000,000 to 40,000,000, with 500,000 of this total allocated to the "1 quart to <2.5 gallon plastic" size category specifically and the remaining 39,500,000 allocated to flexible bags with no size criteria specified.

^d As with the proposed container rule RIA (EPA, 1993), no size criteria are specified for flexible bags. For the purposes of this analysis, all of the flexible bags for the market sector were allocated to the "11 to 44 pound paper/plastic bags" category.

Table 3.5. Estimated Number of Refillable Pesticide Containers in Use by Major Market Sectors

	by Major Mai	THE SECTION S		
Container Size Category	Agricultural ^a	I/C/G b	Home & Garden ^c	Total
Liquid Pesticide Products				
Retail Bulk Tanks (>500 Gal)				
Plastic	12,060	7,200	0	19,260
Steel	1,340	800	0	2,140
Large Tanks (251-500 Gal)				
Plastic	1,170	8,400	0	9,570
Steel	130	2,800	0	2,930
126-250 Gallons				
Plastic	34,800	9,000	0	43,800
Steel	6,700	1,000	0	7,700
61-125 Gallons				
Plastic	172,600	9,000	0	181,600
Steel	57,600	1,000	0	58,600
26-60 Gallons				
Plastic	48,800	2,920	0	51,720
Steel	4,000	4,380	0	8,380
5-25 Gallons				
Plastic	127,900	0	0	127,900
Steel	99,800	0	0	99,800
Other Sizes	0	0	0	0
Subtotal	566,900	46,500	0	613,400
Dry Pesticide Products	·	·	·	
Retail Bulk Tanks (> 4,000 lbs)	175	0	0	175
Large Tanks (2,501-4,000 lbs)	5,425	0	0	5,425
101-2,500 lb Bags	13,300	0	0	13,300
< 100 lb Bags	677,800	0	0	677,800
Other Sizes	0	0	0	0
Subtotal	696,700	0	0	696,700
Total - Refillables	1,263,600	46,500	0	1,310,100
Percentage of Refillables	96.45%	3.55%	0.00%	

Note: See Table 3.6 for estimates of the number of swimming pool chemical containers in use.

^a Current estimates of the number of refillable containers in the agricultural market were based on converting the formulated volume (gal) and formulated weight (lbs) of pesticides reported in the 1996 ACPA Container Survey (ACPA, 1997) to the number of refillable containers in use. The non-bulk container estimates were rounded to the nearest hundred, and the bulk container estimates were rounded to nearest multiple of five. See Appendix B. ^b Current estimates of the number of refillable containers in the I/C/G market were based on the combined total number of containers for the industrial and institutional market sectors used in the proposed container rule RIA (EPA, 1993). EPA solicited comments from the ACC and ISSA in May 2001 to aid in updating the I/C/G refillable container estimates. No changes to the estimated number of refillable containers were warranted, based on responses from the ACC and ISSA.

^c The analysis assumes that there are no refillable containers in the H&G market.

Table 3.6. Estimated Number of Swimming Pool Chemical Refillable Containers Affected by the Pesticide Container Regulations

Container Size Category	Number of Containers ^a
Liquid Pesticide Products	
Retail Bulk Tanks (>500 Gal)	
Plastic	1,620
Steel	180
Bulk Tanks (251-500 Gal)	
Plastic	4,680
Steel	520
126-250 Gallons	
Plastic	0
Steel	0
61-125 Gallons	
Plastic	0
Steel	0
26-60 Gallons	
Plastic	140,000
Steel	0
5-25 Gallons	
Plastic	70,000
Steel	0
Other Sizes b	1,000,000
Total – Refillables	1,217,000

^a Estimates are based on comments to the 1999 Supplemental Notice submitted by relevant trade associations (i.e., the Chlorine Institute, National Spa and Pool Institute, and Swimming Pool Chemical Manufacturers Association) that provide the average number of refillings and volume. Based on the comments, the number of refillings was assumed to be 8. A smaller refilling rate of 4 was assumed for larger containers. This refilling rate was used with the data on volume from the comments (38 million gallons of sodium hypochlorite in use for pools in spas annually) to arrive at the total number of containers.

3.3 The Implications of the Scope of the Regulations on the Container Estimates

The regulations specify which pesticide products are and are not subject to the regulations (40 CFR Part 165 Subparts C, D, and E). The container scope criteria are relatively complex, but some of the key points are briefly summarized here and in Table 3.7:

^b Other sizes include relatively smaller, 1- or 2.5-gallon plastic containers known to be in use.

Table 3.7. Summary of Regulatory Scope

Pesticide Products NOT Subject to the Pesticide Container Regulations

Non-Refillable and Refillable Containers

The following three categories of pesticide products *are not subject* to the non-refillable container, refillable container, and repackaging regulations:

- (1) Manufacturing use products (MUPs);
- (2) Plant-incorporated protectants (PIPs); and
- (3) Antimicrobial pesticide products that satisfy *all four* of these criteria:
- It 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." ^a
- 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 the container provisions to prevent an unreasonable adverse effect on the environment.

Pesticide Products Subject to the Pesticide Container Regulations

Non-Refillable Containers

Other than MUPs, PIPs, and exempt antimicrobial products, a pesticide product sold or distributed in a non-refillable container is subject to all of the non-refillable container regulations if it satisfies at least one of the following criteria: ^b

- (1) It meets the criteria of Toxicity Category I;
- (2) It meets the criteria of Toxicity Category II; or
- (3) It is classified for restricted use (as set out in 40 CFR parts 152.160–152.175).

If a product (other than MUPs, PIPs, and exempt antimicrobials) does not meet any of these criteria, the product is subject to only the basic DOT requirements in 49 CFR 173.24.

Refillable Containers and Repackaging

Other than MUPs, PIPs, and exempt antimicrobial products, a pesticide product sold or distributed in a refillable container is subject to the refillable container and repackaging regulations.

Pesticide Products Subject to the Pesticide Container Labeling Standards

All pesticide products are subject to the new labeling standards.

- ^a The "household, industrial, or institutional" antimicrobial product use categories are: (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; and (10) swimming pools.

 ^b The residue removal standard affects a smaller subset of Toxicity Category I, II, and restricted use products
- The residue removal standard affects a smaller subset of Toxicity Category I, II, and restricted use products because it is applicable to only flowable concentrate products.
- (1) The *non-refillable container*, *refillable container*, and *repackaging* regulations do not apply to the same subset of pesticide products, although the structure of the non-refillable container regulations is different.
- (2) For the non-refillable container regulations, only "higher-risk" products are subject to all of the non-refillable container requirements. The "lower-risk" products are subject only to the basic DOT requirements. In particular:

- (a) A product is subject to all non-refillable 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. 15
- (b) 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.
- (3) For the *refillable container* and *repackaging* regulations, antimicrobial products that are used only in swimming pools (and closely related sites such as hot tubs, spas, or whirlpools) are exempt from some of the standards.
- (4) The new *labeling* standards apply to all pesticide products.

The remainder of this section discusses how the container regulations' scope affects the estimate of the number of containers affected by the regulation.

3.3.1 Manufacturing Use Products and Plant-Incorporated Protectants

Manufacturing use products (MUPs) and plant-incorporated protectants (PIPs) are explicitly exempt from the pesticide container regulations. MUPs are any products intended (labeled) for formulation or repackaging into other pesticide products and therefore assumed to be excluded from estimates of the pesticide container universe. PIPs are substances that plants produce for protection against pests. These substances and the genetic material necessary to produce them are pesticides under FIFRA if humans intend these substances to prevent, repel, or mitigate any pest. Bags of seed or other containers containing PIPs are assumed to be excluded from the estimates of the pesticide container universe based on the scope of the data sources used. In particular, the 1996 ACPA Container Survey (ACPA, 1997) used as the basis for the agricultural market container estimates did not assess containers containing PIPs. Therefore, it is assumed that none of the containers considered in this analysis will be affected by the MUP or PIP exemptions.

3.3.2 Antimicrobial Pesticide Products

The container rule's antimicrobial exemption applies only to containers in the I/C/G and H&G markets. EPA (2005) determined that 27.7 percent of the total number of containers in each of the two markets (and distributed by container type) would be antimicrobial product containers. Additionally, EPA (2005) identified the number of antimicrobial products subject to the container regulations (1,350 products or 29.8 percent of the total number of antimicrobial products [4,528]), and the number of antimicrobial products that are exempt from the regulations (3,178 products, or 70.2 percent of the total number of antimicrobial products). As a result, it is

¹⁵ The residue removal standard affects a smaller subset of Toxicity Category I, II, and restricted use products because it is applicable to only flowable concentrate products.

¹⁶ The estimate of the total number of antimicrobial product containers is based on the estimated usage of antimicrobial pesticides in the H&G and I/C/G markets. The estimate of 27.7 percent assumes that the total number of antimicrobial product containers is in the same proportion as the number of antimicrobial products subject to the regulations. The estimate is calculated by multiplying 29.8 percent, the percentage of antimicrobial products subject to container regulations (EPA, 2005), by the total amount of antimicrobial usage, and dividing this value by the total usage of pesticides: antimicrobial, conventional (e.g., herbicides, insecticides), and other (e.g., petroleum oil).

assumed that approximately 8.25 percent (.277 * .298) of all I/C/G and H&G non-refillable and refillable containers are antimicrobial products subject to all the container regulations.

EPA's attempt in the 1999 Supplemental Notice (EPA, 1999) to partially exempt antimicrobials used in swimming pools from some refillable container requirements was drafted to apply to products that were eligible for exemption. EPA acknowledges that some of the products that were intended to be partially exempted from the refillable container standards are hazardous wastes when they are disposed. They are therefore not eligible for the antimicrobial exemption from the container rule. In other words, the partial exemption from the refillable container standards as described in the Supplemental Notice would not have applied to the products for which it was intended to provide relief. Antimicrobial products that were not eligible for exemption would have had to comply with the full set of container regulations.

As stated in the Supplemental Notice, EPA acknowledges that applying some of the refillable container standards (specifically, the serial number marking, one-way valves or tamper-evident devices, and recordkeeping) to sodium hypochlorite used in swimming pools would disrupt the current refillable container system for these products and would probably cause the refillables to be replaced by millions of single-use, non-refillable containers. EPA believes that adding millions of pounds of these non-refillable containers to the waste stream is inconsistent with the goals of Section 19(e) of FIFRA, particularly the goal that the regulations facilitate the safe refill and reuse of containers. Therefore, in the Supplemental Notice, EPA attempted to create a partial exemption from the refillable container standards for these products.

Based on comments and an analysis of which antimicrobial pesticides may be hazardous waste when they are disposed, EPA is revising the partial exemption in the final rule so that it accomplishes EPA's intended goal. The partial exemption will apply to "antimicrobial" products that are:

- Distributed in refillable containers;
- Subject to the container regulations; and
- Used in swimming pools, spas, hot tubs, and whirlpools.

EPA is limiting the scope of the reduced set of refillable container standards to products used only in swimming pools, spas, hot tubs, and whirlpools because commenters on the proposed container rule and the Supplemental Notice made a convincing case that applying the full set of refillable container regulations to the refillable containers servicing these sites would be burdensome. A significant factor was the large amount of detail about the refillable containers used for distributing pool chemicals (generally 1- or 2.5-gallon plastic containers), the large amount of product distributed in these containers, and the system that the pesticide registrants had in place for managing these containers.

The estimated number of refillable containers in the swimming pool industry is not readily available. Comments to the 1999 Supplemental Notice submitted by relevant trade associations (i.e., the Chlorine Institute, National Spa and Pool Institute, and Swimming Pool Chemical Manufacturers Association) were considered in the process of determining a reasonable number of refillable containers of various sizes used by the estimated 305 small and 17 large swimming

pool supply companies (or companies that routinely refill containers for distributing sodium hypochlorite for pool disinfection). Table 3.6 illustrates the estimated number of swimming pool chemical refillable containers subject to the container regulations.

3.3.3 Non-Exempt Products Sold or Distributed in Non-Refillable Containers: Toxicity Categories I and II

The scope criteria for the container standards limit the universe of non-refillable containers that are affected by all of the non-refillable container requirements. Pesticide products classified in Toxicity Category I or II are subject to all of the non-refillable container regulations.

Based on an analysis of pesticide registration data in an Office of Pesticide Programs database and literature searching, we estimated the percentage of pesticide active ingredients (PAIs) in Toxicity Categories I and II used in the agricultural, I/C/G, and H&G markets. The pounds of PAIs applied in each market sector was based on 1999 information compiled for the "Pesticide Industry Sales and Usage: 1998 and 1999 Market Estimates" report (EPA, 2002b). We cross-checked all PAIs comprising 0.05 percent or greater of the pounds applied in the agricultural market, and all I/C/G and H&G PAIs, to determine their toxicity category and whether the PAI was also classified for restricted use. In the agricultural market, it is estimated that Toxicity Category I and Toxicity Category II PAIs account for 28.7 percent and 22.9 percent of the total pounds applied, respectively. In the I/C/G market, Toxicity Category I and II PAIs account for an estimated 28.4 percent each of the pounds applied. In the H&G market, Toxicity Category I and II PAIs account for an estimated 18.5 percent and 45.7 percent of the total pounds applied, respectively. It is assumed that the relative percentage of the pounds applied for PAIs categorized as Toxicity Category I or II is applicable to the number of pesticide containers affected by the container regulations according to the toxicity scope criteria (see Table 3.8).

Table 3.8. Percentage of Pesticide Containers Affected by the Final Rule Scope Criteria

Pesticide Container Final Rule Scope Criteria	Agricultural (%)	Industrial/Commercial/ Government (%)	Home & Garden (%)					
Pesticide Products NOT Subject to the Pesticide Container Regulations								
Manufacturing Use Products	0	0	0					
Plant-Incorporated Protectants	0	0	0					
Antimicrobials ^a	0	8.25	8.25					
Pesticide Products Sold or Distributed in Non-Refillable Containers Subject to All of the Non-Refillable Container Regulations ^b								
Toxicity Category I	28.7	28.4	18.5					
Toxicity Category II	22.9	28.4	45.7					
Restricted Use Products	12.9	5.2	3.0					

^a The antimicrobial exemption only applies to containers in the I/C/G and H&G markets. EPA (2005) determined that 27.7 percent of the total number of containers in each of the two markets (and distributed by container type) would be antimicrobial product containers. Additionally, EPA (2005) identified the number of antimicrobial products subject to the container regulations (1,350 products or 29.8 percent of the total number of antimicrobial products [4,528]), and the number of antimicrobial products that are exempt from the regulations (3,178 products, or 70.2 percent of the total number of antimicrobial products). As a result, approximately 8.25 percent (.277 * .298) of all I/C/G and H&G non-refillable and refillable containers were assumed to be antimicrobial products subject to all the container regulations.

3.3.4 Non-Exempt Products Sold or Distributed in Non-Refillable Containers: Restricted Use Products

Pesticide products classified for restricted use are also subject to all of the non-refillable container regulations. The same data set and assumptions used to evaluate PAI toxicity were used to develop the percentage of pesticide containers affected by the restricted use nonrefillable container scope criteria. PAIs and/or pesticide products ranging in toxicity (i.e., Toxicity Categories I through IV) may be classified for restricted use. Those PAIs that did not meet the scope criteria based on toxicity (Toxicity Categories III and IV) were separated from those that were affected by the container regulations (Toxicity Categories I and II). Each of the PAIs in the Toxicity Categories III and IV were evaluated to determine if they were classified for restricted use. In the agricultural market, Toxicity Category III and Toxicity Category IV restricted use products account for an estimated 12.9 percent of the total pounds applied. In the I/C/G and H&G markets, Toxicity Category III and Toxicity Category IV restricted use products account for an estimated 5.2 percent and 3.0 percent of the pounds applied in each of these markets, respectively. 17 It is assumed that the relative percentage of PAIs categorized as Toxicity Category III or IV substances and classified for restricted use were applicable to the number of pesticide containers affected by the container regulations according to the restricted use scope criteria (see Table 3.8).

^b The container rule scope criteria limit compliance with all of the non-refillable container regulations to non-exempt products that meet the Toxicity Category I, Toxicity Category II, and/or restricted use criteria. Other non-exempt products sold in non-refillable containers (those in Toxicity Categories III and IV that are not restricted use products) must comply only with the basic DOT packaging standards in 49 CFR 173.24. These products are considered separately because they are not subject to the full set of non-refillable container requirements.

¹⁷ Pesticide usage in the H&G market includes some applications by lawn care professionals and pest control operators, who may be certified pesticide applicators and can, therefore, apply restricted use pesticides.

3.3.5 Non-Exempt Products Sold or Distributed in Non-Refillable Containers: Toxicity Categories III and IV That Are Not Restricted Use Products

Pesticide products classified in Toxicity Categories III and IV that are not restricted use products are not subject to the full set of non-refillable container requirements. Instead, these products are subject only to the basic DOT requirements in 49 CFR 173.24. These products are not subject to the other non-refillable container requirements, such as the container closure, container dispensing, and residue removal standards. Also, these products are not subject to the other DOT requirements that are adopted by the pesticide container regulations.

3.3.6 Summary of Pesticide Container Scope Criteria

Table 3.8 summarizes the percentage of non-refillable and refillable containers affected by the container scope criteria. As stated in Sections 3.3.1–3.3.4, the percentage of pesticide products subject to the container scope criteria was applied to the estimated number of containers for each size category.

We estimated the number of containers that are affected by the container regulations out of the total universe of pesticide containers based on the percentage of containers affected by the scope criteria listed in Table 3.8. For example, for "1 to <5 gallons" plastic non-refillables in the agricultural sector, we estimated the number of containers affected by the container rule as:

$$(0.287 + 0.229 + 0.129) * 27,877,500 = 17,980,988$$
 containers

where:

- "27,877,500" is the total number of containers in use in this size category (see Table 3.4.);
- "(0.287 + 0.229 + 0.129)" represents the percentage of containers subject to the container regulations based on the Toxicity Category I, Toxicity Category II, and restricted use product classifications, respectively.

For the I/C/G and H&G markets, the same considerations as for the agricultural market sector applied for determining the number of containers subject to the container regulations with one exception. In these market sectors, we considered antimicrobial pesticide containers separately from non-antimicrobial pesticide containers. Therefore, the number of containers containing antimicrobials subject to the container regulations was added to the number of non-antimicrobial pesticide containers that met the container rule scope criteria based on Toxicity Category I, Toxicity Category II, and restricted use product classifications. For example, for I/C/G "30 to 55 gallon" plastic non-refillables, we estimated the number of containers affected by container rule as:

$$(1,600,000 * 0.277 * 0.298) + \{(0.284 + 0.284 + 0.052) * [1,600,000 * (1 - 0.277)]\} = 848,711 \text{ containers}$$

where:

- "1,600,000" is the total number of 30 to 55 gallon plastic non-refillable containers in use in the I/C/G market (see Table 3.4);
- "0.277" is the percentage of containers that hold antimicrobials;
- "0.298" is the percentage of antimicrobials that are subject to the container regulations; and
- "(0.284 + 0.284 + 0.052)" represents the percentage of containers subject to the container regulations based on the Toxicity Category I, Toxicity Category II, and restricted use product classifications, respectively.

We calculated the number of pesticide containers affected by the scope criteria for each non-refillable and refillable container size category. Tables 3.9 and 3.10 detail the number of non-refillables and refillables, respectively, that are within the scope of the container regulations and are potentially affected by the regulations.

As mentioned earlier, all products are subject to the refillable container and repackaging regulations. As a result of this requirement, the number of refillable containers in the agricultural market sector affected by the container regulations as displayed in Table 3.10 is the same as in Table 3.5, which establishes the baseline number of refillable pesticide containers in use. However, certain antimicrobial products in the I/C/G market sector (in fact, 70.2 percent of antimicrobial products, as previously discussed) are exempt from the container regulations. As a result of this exemption, the number of refillable containers in the I/C/G market is less than the baseline for I/C/G refillable containers as described in Table 3.5. For example, in the baseline, there are an estimated 7,200 refillable liquid plastic retail bulk tanks in the I/C/G market sector. Due to the antimicrobial exemption, an estimated 5,800 containers of this type fall under the scope of the regulations. The calculation is as follows:

$$(7,200 * 0.277 * 0.298) + [7,200 * (1-0.277)] = 5,800.$$

Table 3.9. Estimated Number of Non-Refillable Pesticide Containers Affected by the Pesticide Container Regulations ^a

		Industrial/		
		Commercial/	Home &	
Size Category	Agricultural	Government	Garden	Total
Liquid Pesticide Products				
30-55 Gallons				
Plastic	199,434	848,711	0	1,048,145
Steel	74,518	1,230,631	0	1,305,149
5 Gallons				
Plastic	37,496	7,451,684	0	7,489,181
Steel	18,594	509,227	0	527,821
1 to < 5 GALLONS				
Plastic	17,986,536	11,177,527	15,909,183	45,073,245
Steel	0	763,840	4,545,481	5,309,321
< 1 Gallon				
Plastic	649,731	10,905,939	59,091,250	70,646,921
Steel	0	84,871	6,818,221	6,903,092
Glass	0	127,307	4,545,481	4,672,787
Water Soluble Packets				
PVA	351,374	0	0	351,374
Barrier	53,012	0	0	53,012
Bag-In-Box	303	137,916	0	138,219
Aerosol Cans	0	12,306,312	113,637,020	125,943,332
Other Sizes	0	0	0	0
Subtotal	19,370,998	45,543,965	204,546,636	269,461,599
Dry Pesticide Products				
> 100 lb Bulk	277,097	0	0	277,097
56-100 lb Bags	0	0	0	0
45-55 lb Bags				
Plastic	1,193,113	0	0	1,193,113
Paper	5,265,477	0	0	5,265,477
11-44 lb Bags	0	1,120,000	39,500,000	0
Plastic	2,429,134	594,098	22,443,311	25,466,543
Paper	1,430,124	0	0	1,430,124
1-10 lb Bags				
Plastic	212,196	0	0	212,196
Paper	3,697,147	0	0	3,697,147
Jugs				
2.5 gallons	17,020	0	0	17,020
1 quart to < 2.5 gallons	1,466,578	196,264	284,093	1,946,935

Table 3.9 (Continued). Estimated Number of Non-Refillable Pesticide Containers Affected by the Pesticide Container Regulations ^a

by the resticiae Container Regulations						
Size Category	Agricultural	Industrial/ Commercial/ Government	Home & Garden	Total		
Water Soluble Packets						
PVA	28,434,409	689,578	0	29,123,987		
Barrier	7,664,424	228,091	0	7,892,515		
Fiber Drums						
> 30 pounds	7,925	678,969	0	686,894		
< 30 pounds	83,628	0	0	83,628		
Other Sizes	2,220,893	0	0	2,220,893		
Subtotal	54,399,166	2,387,000	22,727,404	79,513,570		
Total - Non-Refillables	73,770,164	47,930,965	227,274,040	348,975,169		
Percentage of Non-Refillables	21.14%	13.73%	65.13%			

^a Estimates based on the container rule scope criteria (see Section 2.3) applied to the total universe of non-refillable containers (see Section 2.2).

Table 3.10. Estimated Number of Refillable Pesticide Containers Affected by the Pesticide Container Regulations ^a

Container Size Category	Agricultural	Industrial/ Commercial/ Government	Swimming Pool Industry ^b	Home & Garden	Total
Liquid Pesticide Products					
Retail Bulk Tanks (>500 Gal)					
Plastic	12,060	5,800	1,620	0	19,480
Steel	1,340	644	180	0	2,164
Large Tanks (251-500 Gal)					
Plastic	1,170	6,767	4,680	0	12,617
Steel	130	2,256	520	0	2,906
126-250 Gallons					
Plastic	34,800	7,250	0	0	42,050
Steel	6,700	806	0	0	7,506
61-125 Gallons					
Plastic	172,600	7,250	0	0	179,850
Steel	57,600	806	0	0	58,406
26-60 Gallons					
Plastic	48,800	2,352	140,000	0	191,152
Steel	4,000	3,528	0	0	7,528
5-25 Gallons					
Plastic	127,900	0	70,000	0	197,900
Steel	99,800	0	0	0	99,800
Other Sizes ^c	0	0	1,000,000	0	1,000,000
Subtotal	566,900	37,458	1,217,000	0	1,821,358
Dry Pesticide Products	•			<u>.</u>	
Retail Bulk Tanks (>4,000 lbs)	175	0	0	0	175
Large Tanks (2,501-4,000 lbs)	5,425	0	0	0	5,425
101-2,500 lb Bags	13,300	0	0	0	13,300
Fiber Drums	677,800	0	0	0	677,800
Other Sizes	0	0	0	0	0
Subtotal	696,700	0	0	0	696,700
Total – Refillables	1,263,600	37,458	1,217,000	0	2,518,058
Percentage of Refillables	50.18%	1.49%	48.33%	0.00%	

^a Estimates based on the container regulations scope criteria (see Section 2.3) applied to the total universe of refillable containers (see Section 2.2 and Table 3.5).

^b Assumed estimates based on comments to the 1999 Supplemental Notice submitted by relevant trade associations (i.e., the Chlorine Institute, National Spa and Pool Institute, and Swimming Pool Chemical Manufacturers Association).

^c Other sizes include relatively smaller, 1- or 2.5-gallon plastic containers.

3.4 Regulatory Compliance Baseline

Table 3.11 provides an overview of the pesticide container regulatory requirements broken down by various components of the rule.

Table 3.11. Overview of the Container Regulations

	Tuble 5:11: Overview of the Container Regulations						
Non-Refillable	D #11 11 G	Repackaging Pesticide					
Containers	Refillable Containers	Products	Labels				
All Non-Exempt	Non-Exempt Products	All Non-Exempt	All Products				
Products	(1) DOT container design,	Products	(1) Identify container as				
(1) Basic DOT packaging	construction, and marking	(1) Pesticide registrants	non-refillable or refillable				
standards (49 CFR 173.24)	standards	develop information					
	(2) Serial number	(2) Registrants and others	All Products in Non-				
All Non-Exempt	marking*	comply with specified	Refillable Containers				
Products Meeting Scope	(3) One-way valves or	conditions	(1) Statements to prohibit				
Criteria	tamper-evident devices*	(3) Refillers (registrants	reuse and offer for				
(1) DOT container design,	(4) Bulk container	and others) obtain and	recycling; batch code				
construction, and marking	requirements	follow registrant					
standards		information, and clean,	Some Products in Non-				
(2) Container dispensing	* Swimming pool	inspect, and label	Refillable Containers				
capability	antimicrobial products are	containers before refilling	(1) Cleaning instructions				
(3) Standardized closures	not subject to these	them*					
(4) Residue removal	requirements.		All Products in Refillable				
(5) Recordkeeping		*Swimming pool	Containers				
		antimicrobial products are	(1) Cleaning instructions				
		not subject to several of	before final disposal				
		these requirements.					
			Some Products in				
			Refillable Containers				
			(1) Leave blank spaces for				
			net contents and				
			establishment number				

3.4.1 Regulatory Compliance Rates for Non-Refillable Containers

The regulatory components and compliance rates affecting non-refillable containers are discussed below. The regulatory components affect three different sets of non-refillable containers; all non-exempt products (Section 3.4.1.1), all non-exempt products meeting the scope criteria (Section 3.4.1.2), and all products (Section 3.4.1.3). Table 3.12 summarizes the container rule regulation compliance rates for non-refillable containers.

3.4.1.1 All Non-Exempt Products

All non-exempt products sold or distributed in non-refillable containers must comply with the basic DOT packaging requirements in 49 CFR 173.24. It is assumed that all containers comply with these requirements, which establish minimum standards for container integrity, compatibility, and filling limits.

Table 3.12. Regulatory Compliance Rates for Non-Refillable Containers ^a

	DOT	DOT									
	Packaging	Packaging									
	Standards	Standards –									
	hazardous	non-									Other
	materials b	hazardous								Labeling	administrative
	(§165.60-	materials ^c	- do			Standards for container dispensing				requirements	requirements
	64)	(§165.60-64)	Closure Standards d, e (§165.66)			capability f, g, h (§165.68)				(Sec.156)	(recordkeeping)
Small-Small Establishments											
Agriculture	100.0%	100.0%	100.0%	95.0%	90.0%	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	N/A	N/A	N/A	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
Home & Garden	100.0%	100.0%	N/A	N/A	N/A		100.0%	80.5%	50.0%	0.0%	0.0%
Medium-Small Establishments											
Agriculture	100.0%	100.0%	100.0%	95.0%	90.0%	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	N/A	N/A	N/A	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
Home & Garden	100.0%	100.0%	N/A	N/A	N/A		100.0%	80.5%	50.0%	0.0%	0.0%
Large-Small Esta	Large-Small Establishments										
Agriculture	100.0%	100.0%	100.0%	95.0%	90.0%	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	N/A	N/A	N/A	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
Home & Garden	100.0%	100.0%	N/A	N/A	N/A		100.0%	80.5%	50.0%	0.0%	0.0%
Large Establishments											
Agriculture	100.0%	100.0%	100.0%	95.0%	90.0%	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	N/A	N/A	N/A	100.0%	81.5%	35.0%	50.0%	0.0%	0.0%
Home & Garden	100.0%	100.0%	N/A	N/A	N/A		100.0%	80.5%	50.0%	0.0%	0.0%

^a In many cases, a regulation is not applicable to particular types of containers in a particular market sector. For example, the closure standards for non-refillables are applicable only to containers that hold at least 1 gallon and that hold liquid products in the agricultural market sector.

^b Under the container rule, both containers for hazardous materials and non-hazardous materials must comply with the DOT standards for containers for hazardous materials. The costs of complying with the DOT standards for containers holding hazardous materials are therefore attributed to the DOT standards and not the container rule.

^c For non-hazardous materials, we assume that DOT-compliant containers can be purchased on the market at prices comparable to non-compliant containers. We also assume that within the compliance period, regulated entities will exhaust their inventory of non-compliant containers and replace them with compliant containers at no extra cost. This assumption was based on inputs from container manufactures that indicated that only DOT-compliant containers are sold. Accordingly, we assume that all non-compliant containers will be out of use by the time the rule goes into effect.

^d The closure standards are not applicable to I/C/G and H&G establishments. They are also not applicable to liquid containers less than 1 gallon in capacity, water-soluble packets, bag in boxes, and aerosol cans. They are also not applicable to dry product containers.

Table 3.12 (Continued). Regulatory Compliance Rates for Non-Refillable Containers ^a

^e The first percentage represents the compliance rate for liquid containers 30 to 55 gallons. The second percentage represents the compliance rate for liquid containers of 5 gallons, and liquid containers in the "other sizes" category. The third percentage represents the compliance rate for liquid containers 1 to <5 gallons.

The standards for container dispensing capability are not applicable to liquid containers 30 to 55 gallons, water soluble packets, bag in boxes, and aerosol cans. They are also not applicable to dry product containers.

^g For agricultural and I/C/G establishments: The first percentage represents the compliance rate for liquid containers of 5 gallons. The second percentage represents the compliance rate for liquid containers 1 to less than 5 gallons. The third percentage represents the compliance rate for liquid containers less than 1 gallon. The fourth percentage represents the compliance rate for liquid containers in the "other sizes" category.

^h For H&G establishments: The first percentage represents the compliance rate for liquid containers of 5 gallons. The second percentage represents the compliance rate for liquid containers less than 5 gallons. The third percentage represents the compliance rate for liquid containers in the "other sizes" category.

3.4.1.2 All Non-Exempt Products Meeting Scope Criteria

Non-exempt products are subject to all of the following non-refillable container regulations if the product is classified as Toxicity Category I, Toxicity Category II, or restricted use.

Department of Transportation (DOT) Standards

Products sold or distributed in non-refillable containers must meet a subset of the DOT Hazardous Materials Regulations (HMR), which establish standards for container design, construction, and marking. Pesticide products that are not DOT hazardous materials must comply with some of the general packaging requirements and the non-bulk and bulk packaging standards for Packing Group III (the least stringent requirements). Pesticide products that are DOT hazardous materials must comply with all of DOT's regulations. For purposes of the container regulations, EPA is specifically adopting the same kind of DOT requirements as for the non-DOT hazardous materials, but for the product's packing group.

EPA estimates that approximately 35 percent of pesticide products in use fall under the DOT definition of a hazardous material and therefore meet the DOT requirements (EPA, 1999). We assume that 35 percent of all pesticide containers in the three major markets and for each size category are DOT hazardous materials. Therefore, these containers are already in compliance with the container regulations.

It is assumed that the remaining 65 percent products sold or distributed in non-refillable containers contain DOT non-hazardous material. It is assumed that these containers are also already in compliance with the Packing Group III requirements. This assumption is consistent with the proposed EPA container rule RIA which assumed that most of the containers in use were DOT-compliant and that nearly all containers in production were also DOT-compliant. This assumption was also validated for the final EPA container rule EA through additional discussions with pesticide registrants, refillers and industry experts. Compliance with the DOT-related standards was high for the proposed rule, and, given the increasing availability and use of DOT-compliant containers, it is assumed in the final rule that those containers that were out of compliance have either been replaced or will be replaced with compliant containers within the compliance period.

Container Closures for Liquid Pesticide Products

To further allow for the safe use of pesticide containers, the container rule requires that rigid non-refillable containers that have a capacity of at least 3.0 liters (0.79 gallons) and are used to hold liquid agricultural pesticides have one of four standardized closures. Container closure requirements are not required for rigid non-refillables in the I/C/G or H&G markets. The container closure compliance rate for affected agricultural non-refillables is based upon an assumption that EPA made for the proposed container rule RIA (EPA, 1993):

- 100.0 percent compliance for "30 to 55 gallon" containers;
- 95.0 percent compliance for "5 gallon" and "other" size containers; and
- 90.0 percent compliance for "1 to <5 gallon" containers.

Container Dispensing Capability

The container regulations state that non-refillable containers of 20 liters (5.3 gallons) or smaller for liquid products must allow the contents to be poured without glugging and with minimal dripping. The major factors that reportedly affect pesticide dispensing are the design of the container opening, and the design and placement of the container handle. The container dispensing capability compliance rate for affected non-refillables is based upon assumptions that EPA made for the proposed container rule RIA. Since there are no new data with which to update these assumptions, the assumptions are left in place. Therefore, the following compliance rates are assumed for all of the affected liquid non-refillables:

Agricultural Market

- 100.0 percent compliance for "5 gallon" containers;
- 81.5 percent compliance for "1 to <5 gallons" containers;
- 35.0 percent compliance for "<1 gallon" containers; and
- 50.0 percent compliance for "other" size containers.

I/C/G Market

- 100.0 percent compliance for "5 gallon" containers;
- 81.5 percent compliance for "1 to <5 gallons" containers;
- 35.0 percent compliance for "<1 gallon" containers; and
- 50.0 percent compliance for "other" size containers.

H&G Market

- 100.0 percent compliance for "5 gallon" containers;
- 80.5 percent compliance for "1 to <5 gallons" and "< 1 gallon" size containers; and
- 50.0 percent compliance for "other" containers.

Residue Removal Standards

The container regulations specify a residue removal standard for rigid containers for flowable concentrate products that meets the Toxic Category I or II criteria and/or are classified for restricted use. The regulations specify a test protocol that requires every registrant to test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable of attaining at least 99.99 percent removal of each active ingredient in the fourth rinsate after a triple rinse.

It is assumed that the average establishment, regardless of size or market sector, uses three rigid container types per formulation, based on an assumption EPA made in its Container Rule RIA. The residue removal standards, however, are applicable to only flowable concentrate products. The representative number of existing and new formulations is assumed to vary by registrant size. It is assumed that there are 0.25 existing and new formulations for the large registrants, 0.20 existing and formulations for the large-small registrants, 0.10 existing and new formulations for

¹⁸ Refer to the Proposed Container Rule RIA (EPA, 1993), Table G-7, Non-refillable rigid containers: Compliance with container dispensing requirements for all three regulatory options, except as noted otherwise, "percent of plastic containers in market that meet requirement" and the table footnotes for information to substantiate the assumptions used in this analysis.

the medium-small registrants and 0.05 existing and new formulations for the small-small registrants that will be subject to the residue removal standards (see Appendix A).

Not all existing container/formulations will be tested because test data conforming to the residue removal protocol on a different non-refillable container/formulation may be used to demonstrate that a non-refillable container meets the residue removal standard ("me-too" scenario). In the proposed container rule RIA, EPA assumed that a lower range of 50 percent of all the container formulation combinations will be tested and an upper range of 100 percent of all such combinations will be tested. In the final economic analysis, the midpoint of this range, 75 percent, is used since the extent to which "me-toos" will apply is not known.

It is also assumed that a certain number of container/formulation combinations will fail the initial residue removal test, requiring a second test using a container carefully selected from the open market and expected to rinse more readily. Based on a study conducted for EPA, EPA assumed in the proposed container rule RIA that 13 percent of small, medium, and large agricultural containers and 3 percent of small and medium industrial/institutional/household containers would not pass a triple-rinse test where 99.999 percent ("five-9s") of a given formulation would be removed after rinsing (EPA, 1993 and 1992b). The 99.99 percent ("four-9s") standard in the final rule is expected to have a much lower initial failure rate. Testing data summarized in the final rule preamble show that one out of the 79 container/formulation combinations tested did not reach the four-9s level. However, since the residue removal standards apply to only flowable concentrate products, in the final economic analysis, a higher (30 percent) failure rate is assumed. This is based on the failure rate of flowable concentrate container/formulation combinations in the study of 79 container/formulation combinations tested (see Appendix A). For all other container/formulation combinations, the final economic analysis assumes a 2 percent failure rate for all containers (all markets and all sizes of facilities).

Recordkeeping

For each pesticide product that is distributed or sold in non-refillable containers that meet the scope criteria, pesticide registrants must maintain certain records to show compliance with the non-refillable container standards. It is assumed that none of the pesticide registrants are currently maintaining these records.

3.4.1.3 All Products

Labeling

The new labeling standards apply to *all* pesticide products. Therefore, the labeling compliance rates are applicable to all pesticide registrants selling or distributing pesticide products in non-refillable containers. The pesticide container regulations modify the label requirements in 40 CFR Part 156. The new standards require statements that:

- Identify a container as non-refillable;
- Prohibit the reuse or refilling of a non-refillable container;
- Provide a recycling statement for non-refillable containers;

- Provide a lot number or other identification code on non-refillable containers; and
- Provide residue removal instructions on some containers.¹⁹

All of these statements are to be grouped and appear under the heading, "Storage and Disposal." It is assumed that no non-refillable containers are labeled with all of the required statements at this time.

3.4.2 Regulatory Compliance Rates for Refillable Containers

Each of the regulatory components and compliance rates affecting refillable containers is discussed below. The regulatory components affect all non-exempt products sold or distributed in refillable containers, except for labeling requirements, which affect *all* refillable containers. Antimicrobial pesticides used in swimming pools are subject to a reduced set of these requirements. The H&G market does not include refillable containers and is not affected by the refillable container regulations.

DOT Standards

All non-exempt products sold or distributed in refillable containers must meet a subset of the DOT Hazardous Materials Regulations (HMR), which establish standards for container design, construction, and marking. Pesticide products that are not DOT hazardous materials must comply with some of the general packaging requirements and the non-bulk and bulk packaging standards for Packing Group III (the least stringent requirements). Pesticide products that are DOT hazardous materials must comply with all of DOT's regulations. For the purpose of the container regulations, EPA is specifically adopting the same kinds of DOT requirements as for the non-DOT hazard materials, but for the product's packing group.

EPA estimates that approximately 35 percent of non-exempt pesticide products in use meet the DOT definition of a hazardous material and are therefore in compliance with the DOT requirements (EPA, 1999b). It is assumed that 35 percent of all pesticide containers in the three major markets and for each size category are DOT hazardous materials.

The remaining 65 percent of non-exempt products sold or distributed in refillable containers are not DOT hazardous materials. However, it is assumed that containers used for the DOT non-hazardous materials are in compliance with the Packing Group III requirements. This assumption is consistent with the proposed EPA container rule RIA which assumed that most of the containers in use were DOT-compliant and that nearly all containers in production were also DOT-compliant. This assumption was also validated for the final EPA container rule EA through additional discussions with pesticide registrants, refillers and industry experts. Compliance with the DOT-related standards was high for the proposed rule, and, given the increasing availability and use of DOT-compliant containers, the final rule assumed that those containers that were out of compliance have either been replaced or will be replaced with compliant containers within the compliance period.

¹⁹ Residue removal instructions are required on the labels of all refillable containers and on the labels of rigid non-refillable containers holding dilutable products that are not for residential use.

Standards for Container Markings

The container regulations require that non-exempt pesticide products that are sold or distributed in refillable containers be durably marked with a serial number or other identifying code (using techniques including stamping, embossing, burning, or printing). The information must be visibly located on the outside part of the container. We assume that none of the pesticide registrants are durably marking refillable containers with a serial number at this time.

Standards for Openings

The container regulations limit access to the interior of liquid minibulk containers by requiring that each opening of a liquid minibulk container other than a vent have a one-way valve, a tamper-evident device, or both. EPA believes that one-way valves and tamper-evident devices will give repackagers reasonable assurance of the previous contents of the containers. Most agricultural minibulks and small volume returnable containers supplied by or purchased from registrants are equipped with either a one-way valve or a tamper-evident device (EPA, 1992b) and are therefore expected to be in compliance in the baseline. Agricultural minibulks obtained on the open market, rather than from registrants, usually lack tamper-evident devices or one-way valves, so refillers must add them (or something similar). The standards for openings are not applicable to bulk tanks.

The standards for the openings compliance rate for affected refillables is based on assumptions that EPA made for the proposed container rule RIA (EPA, 1993)²⁰:

- 65.0 percent compliance for minibulk containers in the agricultural market; and
- 10.0 percent compliance for minibulk containers in the I/C/G market (assumes that tote bins are minibulks, but small volume returnables in the I/C/G market are not minibulks).

Bulk Container Standards

The container regulations include a general integrity standard for all bulk containers and, for liquid bulk containers, require vents and lockable valves and prohibit external sight gauges. The bulk container standards compliance rate is based upon assumptions that EPA made for the proposed container rule RIA (EPA, 1993):

- 100.0 percent compliance for dry bulk containers;
- 75.0 percent compliance for liquid plastic bulk containers in the agricultural market;
- 20.0 percent compliance for liquid steel bulk containers in the agricultural market; and
- 5.0 percent compliance for I/C/G liquid bulk containers.

Labeling

The new labeling standards apply to *all* pesticide products. Therefore, the labeling compliance rates are applicable to registrants selling or distributing pesticide products in refillable containers. The pesticide container regulations modify the labeling requirements in 40 CFR Part 156. The new standards for refillables require statements that:

²⁰ Refer to the Proposed Container Rule RIA (EPA, 1993) Tables VII-8 and VII-9 and the table footnotes for information to substantiate the assumptions used in this analysis.

- Prohibit users of refillable containers from refilling such containers with substances other than pesticides; and
- Provide residue removal instructions.

All of these statements are to be grouped and appear under the heading, "Storage and Disposal." It is assumed that none of the refillable containers are labeled with all of the container rule's required statements at this time.

Other Administrative Requirements

For each non-exempt pesticide product that is distributed or sold in refillable containers, pesticide registrants must prepare and keep records of the repackaging-related documents. It is assumed that none of the pesticide registrants are currently keeping these records.

The regulatory compliance rates for refillable containers are summarized in Table 3.13.²¹ The compliance rates affect pesticide registrants selling or distributing refillable containers containing non-exempt pesticide products. It is assumed that the container standards for refillables in the swimming pool industry are unaffected by the container regulations because they are either partially exempt from or already in compliance with the applicable standards (EPA, 2002c). This assumption is based on comments received from pool supply companies, industry associations, and an antimicrobial manufacturer, who pointed out many positive aspects of the refillable containers they currently use, including: they are durable and appropriately sized; they meet applicable DOT standards; there is a deposit system that leads to nearly 100 percent return of the containers; the company inspects and, if necessary, reconditions the containers before refilling them; an applicator can tell if the container has been tampered with when removing the cap; and their one-gallon containers are of the "no-glug" design. It is assumed that swimming pool chemicals are not in compliance with the new labeling requirements in 40 CFR Part 156.

²¹ We used the compliance rates presented in this table to calculate the total number of containers not in compliance by regulation, which we then multiplied by the unit cost of regulation to develop total cost.

Table 3.13. Regulatory Compliance Rates for Refillable Containers

	DOT Packaging Standards hazardous materials ^a (§165.110-114)	DOT Packaging Standards – non-hazardous materials ^b (§165.110-114)	Standards for container marking ^c (§165.116)	Standards for openings (for liquid minibulks only) ^{d, e} (§165.118)	Bulk container standards ^{e, f} (§165.120)		Labeling requirements (§156)	Other administrative requirements – refilling documents	
Small-Small Estab	lishments								
Agricultural	100.0%	100.0%	0.0%	65.0%	100.0%	75.0%	20.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	0.0%	10.0%	100.0%	5.0	%	0.0%	0.0%
Swimming Pool Supply Companies	100.0%	100.0%	100.0%	100.0%	N/A	N/A	N/A	0.0%	0.0%
Home & Garden	N/A	N/A	N/A	N/A	100.0%	N/A		N/A	N/A
Medium-Small Est	tablishments								
Agricultural	100.0%	100.0%	0.0%	65.0%	100.0%	75.0%	20.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	0.0%	10.0%	100.0% 5.0%		0.0%	0.0%	
Swimming Pool Supply Companies	100.0%	100.0%	100.0%	100.0%	N/A	N/A	N/A	0.0%	0.0%
Home & Garden	N/A	N/A	N/A	N/A	100.0%	N/A	A	N/A	N/A
Large-Small Estab	lishments								
Agricultural	100.0%	100.0%	0.0%	65.0%	100.0%	75.0%	20.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	0.0%	10.0%	100.0%	5.0	%	0.0%	0.0%
Swimming Pool Supply Companies	100.0%	100.0%	100.0%	100.0%	N/A	N/A	N/A	0.0%	0.0%
Home & Garden	N/A	N/A	N/A	N/A	100.0%	N/A	A	N/A	N/A
Large Establishme	ents								
Agricultural	100.0%	100.0%	0.0%	65.0%	100.0%	75.0%	20.0%	0.0%	0.0%
I/C/G	100.0%	100.0%	0.0%	10.0%	100.0%	5.0	%	0.0%	0.0%
Swimming Pool Supply Companies	100.0%	100.0%	100.0%	100.0%	N/A	N/A	N/A	0.0%	0.0%
Home & Garden	N/A	N/A	N/A	N/A	100.0%	N/A		N/A	N/A

^a Under the container regulations, both containers for hazardous and non-hazardous materials must comply with the DOT standards for containers for hazardous materials. The costs of complying with the DOT standards for containers holding hazardous materials are therefore attributed to the DOT standards and not to the container regulations.

Table 3.13 (Continued). Regulatory Compliance Rates for Refillable Containers

^b For non-hazardous materials, we assume that DOT-compliant containers can be purchased on the market at prices comparable to non-compliant containers. We also assume that within the compliance period, regulated entities will exhaust their inventory of non-compliant containers and replace them with compliant containers at no extra cost.

^c The standards for container markings are not applicable to I/C/G plastic containers from 5 to 25 gallons and to I/C/G liquid containers under the "other sizes" category.

^d The standards for openings (for liquid minibulks only) are not applicable to retail bulk tanks, and to dry product containers. These standards are also not applicable to I/C/G liquid containers under the "other sizes" category.

^eThe bulk container standards are only applicable to retail bulk tanks.

For bulk containers in the all markets, the first percentage represents the compliance rate for dry bulk containers. For the agricultural market, the second percentage refers to liquid plastic bulk containers and the third percentage refers to liquid steel bulk containers. For the I/C/G market the percentage refers to all liquid bulk containers.

3.4.3 Regulatory Compliance Rates for Refilling Activities

The container regulations establish procedural and handling standards to ensure that containers are refilled legally and safely. Registrants have certain responsibilities to develop information, and, if a different company (such as a retailer) repackages their product into refillable containers, to ensure that certain conditions are met. The person who is actually doing the refilling—regardless of whether it is the registrant or another company—must obtain the registrant's information; comply with certain conditions; and clean, inspect, and ensure proper labeling of the refillable containers.

It is assumed that the refilling requirements for 90 percent of the total number of agricultural refillables under the scope of the container rule are attributed to agricultural pesticide refillers and the remaining 10 percent are attributed to pesticide registrants (Paulson, 2002). All refilling requirements in the I/C/G market are attributed to pesticide registrants because there is no readily available information to differentiate an industry sector that repackages pesticide products in the I/C/G market that is also not a registrant for products in that sector. All refilling requirements in the swimming pool industry are attributed to registrants and swimming pool supply companies.

The standards for establishments that repackage pesticide products into refillable containers (refillers) require that these entities inspect, clean, and keep certain records about the refillable containers that they refill (§165.198–§165.218). Using professional judgment based on consultations with pesticide registrants, refillers, and industry experts, we estimated that 60 percent of establishments inspect refillables before refilling, 92 percent properly clean the container before refilling, and none of the establishments currently implements recordkeeping that meets the standards.

Based on comments from pool supply companies, industry associations, and an antimicrobial manufacturer, EPA has determined that swimming pool supply companies in general inspect containers before refilling (EPA, 2002c). For this analysis, we assumed that 95 percent of refillable containers in the swimming pool industry are properly inspected prior to refill. EPA has also determined that refillables in the swimming pool industry will probably not have to be cleaned prior to refilling because specified conditions (§165.170) will be met and certain recordkeeping requirements do not apply (§165.178(b)) (EPA, 2002c). We assumed that all of the refillables in the swimming pool industry are already in compliance with the applicable cleaning and recordkeeping requirements.

Table 3.14 summarizes the container rule refilling requirements for entities handling pesticide products that are repackaged into refillable containers for sale or distribution.

²² We used these assumptions to allocate the total number of containers in each size and type category to the different markets (e.g., pesticide registrants, agricultural pesticide refillers). For example, out of the estimated 12,060 plastic bulk containers in the agricultural market, 10,854 (90 percent) are attributed to agricultural pesticide refillers. We then used these numbers to develop estimates of number of containers in not in compliance and finally to estimate the cost of compliance by registrants.

Table 3.14. Repackaging/Refilling Requirements and Responsibility

Requirement	Registrants Who Distribute or Sell in Refillable Containers	Registrants Who Distribute or Sell to Outside Refillers for Repackaging	Refillers Who Are Not the Registrants of the Product (Outside Refillers)
Ensure product integrity	Yes	Yes	Yes
Develop written documents describing: (1) how to clean containers and (2) acceptable containers	Yes	Yes	No
Comply with conditions to allow an outside refiller to repackage your product (e.g., provide contract or authorization) ^a	No	Yes	No
Comply with conditions to allow you to repackage a registrant's product (e.g., obtain contract or authorization) ^a	No	No	Yes
Have documents available at refilling establishment b	Yes	No	Yes
Be a registered producing establishment ^b	Yes	No	Yes
Repackage product only into acceptable container b	Yes	No	Yes
Repackage up to rated capacity of container b	Yes	No	Yes
No limits on size of container b	Yes	No	Yes
Identify product previously in container to determine the appropriate cleaning procedure b	Yes	No	Yes
Clean container b,c	Yes	No	Yes
Visually inspect container b,c	Yes	No	Yes
Label container b	Yes	No	Yes
Recordkeeping ^c	Yes	Yes	Yes
Compliance period	5 years	5 years	5 years

^a The conditions for a registrant to allow a refiller that is not part of the registrant's company to repackage a product include (a) the repackaging results in no change in the pesticide formulation; (b) the refiller is a registered producing establishment; (c) the registrant and refiller enter into a written contract for the refiller to repackage the pesticide product and to use the product's label; (d) the product is repackaged only into refillable containers that comply with the regulations; and (e) there are no changes to the pesticide label (other than adding the appropriate net contents and EPA establishment number).

The repackaging regulations do not specifically apply these standards to registrants who distribute or sell to refillers that are not part of their company for repackaging. In this case, the registrant is not actually repackaging the product into refillable containers, which is the activity that these requirements are intended to address. The table therefore indicates "no" for these registrants. However, some of these requirements apply because of other regulations. For example, these registrants are required to be registered producing establishments by 40 CFR Part 167. In addition, a registrant may also repackage product directly into refillable containers as described in the previous column, and those requirements would thus apply.

^c Antimicrobial products that are used only in swimming pools (and closely related sites such as hot tubs, spas, or whirlpools) are exempt from the portions of the cleaning and inspecting requirements that relate to serial numbers and one-way valves/tamper-evident devices and from some of the recordkeeping.

In summary, this chapter presented the level of compliance of pesticide containers with the final container standards. We calculated the number of pesticide containers affected by the scope criteria for each non-refillable and refillable container size category for all the market sectors-Agriculture, I/CG and H&G. We also described the regulatory compliance baseline that presents the percentage of containers expected to be in compliance with the requirements of the container rule. This provides an estimate of the number of containers not in compliance, which we use in the cost analysis presented in the next chapter (Chapter 4).

4.0 Pesticide Container Standards Cost Analysis

4.1 Introduction

This chapter describes the methods and the results of the analysis of the costs of the container regulations. Section 4.2 defines the basic framework of the analysis: the categories of regulated entities considered, the market sectors examined, the container types included, the specific regulations covered, and the broad assumptions that underlie the analysis. Section 4.3 describes those characteristics of the regulated entities that are inputs to the cost analysis: the number of regulated entities and, for each category of regulated entity, the percentage of total annual revenue in each size class. Section 4.4 describes the method for estimating the costs incurred by pesticide registrants of complying with the container-related regulations. Section 4.5 describes the method for estimating the costs incurred by pesticide refillers (a broad category that includes several categories of regulated entities, described in Section 4.2 below) of complying with the refilling-related regulations.

The estimates of total annualized compliance cost, both by regulated entity and by regulation, are presented in Section 4.6. The total annualized costs of the pesticide container rule are calculated across all regulations contained within it, for:

- The average regulated entity in each combination of entity type, market sector, and company size class;
- All regulated entities in each combination of entity type, market sector, and company size class;
- The average pesticide registrant with a "representative share" in each market sector;²⁴
- All pesticide registrants (across all market sectors) in each company size class;
- All pesticide registrants across all market sectors and company size classes;
- All regulated entities within each category complying with refilling-related regulations; and
- All regulated entities.

These results are shown in Tables 4.17a and 4.17b in Section 4.6. Regulated entities in this analysis are companies rather than individual facilities. In addition to costs per regulated entity, costs are calculated by regulation, as shown in Tables 4.18a and 4.18b.

The impact of the container regulation on the average regulated entity in each regulated entity type is measured as the ratio of its annual compliance cost to its annual revenue. The results of the impact analysis, for each combination of market sector and size class, are presented in Section 4.7. The subcategories of the "small" size category are aggregated for the Small Business Regulatory Enforcement Fairness Act (SBREFA) analysis of impact. Finally, in

²³ Specific assumptions made at different points in the analysis are detailed in the appropriate sections.

²⁴ The cost analysis estimates the compliance costs of an average pesticide registrant in each market sector, as well as the compliance costs of an average pesticide registrant that works in all three market sectors. The average pesticide registrant that works in all three market sectors is assumed to have the same distribution of containers across market sectors as the distribution of pesticides (by volume) across market sectors. That is, if the distribution of pesticide usage by volume is 40 percent, 30 percent and 30 percent in the agricultural, I/C/G, and H&G markets, respectively, then the distribution of containers by an average pesticide registrant who for example has 100 containers will be 40, 30, and 30 for the three markets, respectively.

Section 4.8 the results of two sensitivity analyses are presented—one that uses a set of "low-end" input values (i.e., input values that will result in lower-cost estimates) and one that uses a set of "high-end" input values (i.e., input values that will result in higher-cost estimates).

4.2 The Basic Framework of the Cost Analysis

There are two broad sets of regulations under the pesticide container rule. One set of regulations pertains to pesticide containers themselves—how they must be constructed, marked, and labeled to ensure safety. The regulated entities that must comply with these regulations are the pesticide registrants. The other set of regulations concerns the refilling (or repackaging) of (refillable) pesticide containers, specifying what must be done to ensure that the act of refilling a pesticide container does not pose safety or health problems. The regulated entities (broadly termed "pesticide refillers") that must comply with this set of regulations are agricultural pesticide refillers, swimming pool supply companies, and some pesticide registrants (in particular, pesticide registrants in two of the three market sectors plus the swimming pool industry). Descriptions of each of these categories of regulated entities can be found in Section 3.1 and Appendix D.

To the extent possible, we estimated costs for regulated entities separately by the market sectors in which they operate. The categorization of regulated entities by market sector is shown in Table 4.1.

	Agricultural Sector	Industrial/ Commercial/ Government (I/C/G) Sector	Swimming Pool Industry	Home & Garden (H&G) Sector (Households)
Pesticide Registrants	✓	✓	✓	✓
Agricultural Pesticide Refillers	✓			
Swimming Pool Supply Companies			✓ a	

Table 4.1. Types of Regulated Entities by Market Sector

The types of containers covered under the container regulation are broadly categorized as non-refillable and refillable containers. Because the set of regulations pertaining to the activity of refilling obviously involves only refillable containers, only regulated entities that engage in refilling must comply with them. A broad overview of the regulated entities and the sets of regulations with which they must comply is provided in Table 4.2. A more detailed overview, identifying the pesticide container standards with which the different regulated entities must comply, is given in Table 4.3.²⁵

^a Swimming pool supply companies could be considered part of both the I/C/G and H&G markets. However, for the purposes of this analysis, we considered swimming pool supply companies separately.

 $^{^{25}}$ See Chapter 2, Chapter 3, and Appendix G for a more detailed description of the final pesticide container standards.

Table 4.2. Overview of Regulated Entities and Types of Regulations with Which They Must Comply

Regulated Entity	Regulation of Pesticide Containers (Non-Refillables and Refillables)	Regulation of Refilling (Refillables)
Pesticide Registrants:		
In the Agricultural Sector	✓	✓
In the I/C/G Sector	✓	✓
In the Home & Garden Sector	✓	
In the Swimming Pool Industry	✓	✓
Agricultural Pesticide Refillers		✓
Swimming Pool Supply Companies ^a		✓

^a Swimming pool supply companies are subject to a subset of the refilling requirements. Swimming pool supply companies must maintain certain records, but not all. Swimming pool supply companies must meet certain refilling requirements, but not all. Refillables are required to be inspected and cleaned (unless specified conditions in §165.170 are met) but not do not need to be relabeled. Copies of the residue removal procedures for refilling and description of acceptable containers must be on file (§165.218(a)), but a record of certain information recorded each time a container is refilled (e.g., product, amount) is not required (§165.218(b)). Swimming pool supply companies could be considered part of both the I/C/G and H&G markets. For the purposes of this analysis, however, we considered swimming pool supply companies separately.

Table 4.3. Intersection of the Pesticide Container Regulations and Regulated Entities

Pesticide Container Regulations	Pesticide Registrants	Agricultural Pesticide Refillers	Swimming Pool Supply Companies
Non-Refillable Containers			
Ensure that containers meet a subset of DOT packaging standards	✓		
Ensure that liquid product containers dispense properly and have standard closures	✓		
Develop residue removal procedures for dilutable pesticides in rigid containers	✓		
Refillable Containers	·		
Ensure that containers meet a subset of DOT packaging standards	✓		
Mark containers with a serial number	✓		
Ensure that a one-way valve and/or tamper-evident device is in place for liquid minibulks	√		
Ensure that a vent, gauge, and shutoff valve are in place for liquid bulk containers	✓		
Meet repackaging conditions	✓ a	✓	✓ b
Develop cleaning procedures for repackaging	✓ a		
Inspect, clean, and properly label containers	✓ a	✓	✓ b
Maintain records	✓ a	✓	✓ b
Labeling Standards			
Ensure that labels include specified information	✓		

^a Refilling requirements affect pesticide registrants for 10 percent of the total refillable containers in the agricultural market sector and all of the containers in the I/C/G market sector. Available data are insufficient to differentiate pesticide registrants that also repackage I/C/G market pesticide products from those that do not. Therefore, pesticide registrants are held accountable.

b Swimming pool supply companies must meet certain refilling requirements, but not all. Refillables are required to be inspected and cleaned (unless specified conditions in §165.170 are met) but not do not need to be relabeled. Swimming pool supply companies must maintain certain records, but not all. Copies of the residue removal procedures for refilling and description of acceptable containers must be on file (§165.218(a)), but a record of certain information recorded each time a container is refilled (e.g., product, amount) is not required (§165.218(b)).

Containers within the broad categories of non-refillable and refillable containers are further subdivided by size and material type, as shown in Table 4.4.

Table 4.4. Types of Containers Considered in the Analysis

Containers for Liquid Products	Containers for Dry Products
Non-Refillables	
30 - 55 gallons, plastic	56 - 100 lb. bags, paper/plastic
30 - 55 gallons, steel	45 - 55 lb. bags, plastic
5 gallons, plastic	45 - 55 lb. bags, paper
5 gallons, steel	11 - 44 lb. bags, plastic
1 - <5 gallons, plastic	11 - 44 lb. bags, paper
1 - <5 gallons, steel	1 - 10 lb. bags, plastic
< 1 gallon, plastic	1 - 10 lb. bags, paper
< 1 gallon, steel	2.5 gallon jugs
< 1 gallon, glass	1 qt < 2.5 gallon jugs
Water soluble packets – PVA packets	Water soluble packets – PVA packets
Water soluble packets – barrier packs	Water soluble packets – barrier packs
Bag in box	> 101 lb. bulk containers
Aerosol can	> 30 lb. fiber drums
	< 30 lb. fiber drums
	Other
Refillables	
Bulk Tanks (> 500 gallons), plastic	Bulk (> 4,000 lbs.), paper/plastic
Bulk Tanks (> 500 gallons), steel	Large (2,501 - 4,000 lbs.), paper/plastic
Large Tanks (251 - 500 gallons), plastic	101 - 2,500 lbs., paper/plastic
Large Tanks (251 - 500 gallons), steel	Fiber drums
126 - 250 gallons, plastic	Other sizes
126 - 250 gallons, steel	
61 - 125 gallons, plastic	
61 - 125 gallons, steel	
26 - 60 gallons, plastic	
26 - 60 gallons, steel	
5 - 25 gallons, plastic	
5 - 25 gallons, steel	
Other sizes	

4.3 Characteristics of the Regulated Entities That Are Inputs to the Cost Analysis

Regulated entities are divided into two size classes: small and large. As discussed in Chapter 3, for this analysis, the "small" category is further sub-divided into "small-small," "medium-small," and "large-small." We estimated costs for several of the cost categories listed above (e.g.,

²⁶ This analysis considers an alternative definition to the Small Business Administration's (SBA's) definition of small business for the industries potentially affected by the final pesticide container regulations. The analysis

costs for the average regulated entity in each combination of entity type, market sector, and size class) using the following two characteristics of regulated entities as inputs:

- The number of entities in each combination of market sector and size class; and
- The breakdown of total revenue by size class (i.e., the percentage of total revenue attributed to large establishments and to small-small, medium-small, and large-small establishments).

We used the number of entities in a combination of market sector and company size class to calculate the number of containers out of compliance with each regulation under the container rule per average regulated entity in that combination of market sector and size class. For example, there are estimated to be 26,703 1 to <5 gallon plastic non-refillable containers out of compliance with the standards for container dispensing capability among "large-small" pesticide registrants in the agricultural sector.²⁷ There are 66 such pesticide registrants, so the average number of containers out of compliance with that regulation per "large-small" registrant in the agricultural sector is 402 (=26,703/66).²⁸

We used the percentage of total revenue attributed to regulated entities in a given size class to allocate the number of containers that fall within the scope of the container rule within each market sector to the different size classes (see Section 4.4.3). For example, 0.8 percent of revenue among pesticide registrants is associated with "large-small" establishments. Using this as a proxy for the distribution of containers that fall under the scope of the rule, the analysis assumed that 0.8 percent of all such containers were registered by "large-small" establishments in each market sector.

Appendix D describes the data sources and procedures we used to characterize representative regulated entities for each market sector and size category. In general, Dun & Bradstreet financial data were matched to the representative list of companies for each regulated entity type, and the companies were profiled based on the SBA definition of small and large businesses and EPA's alternative definitions of small businesses (see Appendix D).

disaggregates the SBA-defined small businesses into three categories: small-small, medium-small, and large-small. EPA is concerned that using an overly broad definition of small business in the economic analysis of the container regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector.

We calculated the number of plastic non-refillable containers out of compliance for the container dispensing capability among "large-small" pesticide registrants in the agricultural sector by multiplying the total number of non-refillable containers affected by the container regulations (17,986,536, see Table 3.9) and multiplying it by the percentage of containers among the "large-small" containers (0.8%), which was obtained from the distribution of total revenues across the pesticide registrant company size categories. Out of the 144,339 (17,986,536*0.08) containers, 81.5% are expected to be in compliance with the container dispensing standards (see Table 3.12) which gives 26,703 containers not in compliance (144,339*0.185).

28 Discrepancy is due to rounding. The inputs to the calculation shown here (26,703 and 66) are rounded. The

output, 402, is based on the unrounded numbers.

Table 4.5 presents the estimated numbers of regulated entities by market sector and size category.²⁹ The percentages of total revenue in each size class within a regulated entity type are given in Table 4.6.³⁰

Table 4.5. Estimated Numbers of Regulated Entities by Market Sector and Size Class

			Size Classes						
Market Sector	Small-Small	Medium-Small	Large-Small	Large	All Size Classes				
Pesticide Registrants									
Agricultural	399	198	66	58	722				
I/C/G	299	148	50	44	541				
Home & Garden	299	148	50	44	541				
Total	997	495	166	146	1,804				
Agricultural Pesticid	le Refillers		<u> </u>						
Agricultural	13,996	2,395	251	153	16,795				
Total	13,996	2,395	251	153	16,795				
Swimming Pool Supply Companies									
Total	174	117	14	17	322				

Table 4.6. Percentages of Total Revenue in Each Size Class

	Size Classes					
Regulated Entity Type	Small-Small	Medium-Small	Large-Small	Large		
Pesticide registrants	0.2%	0.4%	0.8%	98.6%		
Agricultural pesticide refillers	18.0%	25.8%	9.1%	47.0%		
Swimming pool supply companies	0.2%	0.7%	0.2%	98.9%		

4.4 Estimating the Costs of Complying with the Final Regulations

This section describes the method of estimating the costs of complying with the set of container-related regulations incurred by the average pesticide registrant. For a given combination of market sector and size class, the analysis proceeds through the following series of steps to a final estimate of the cost to the average pesticide registrant in that market sector/size class per container-related regulation:

- Estimate the number of containers in the market sector:
- Estimate the number of those containers that fall within the scope of the container rule;
- Estimate the number of those containers that are associated with pesticide registrants in the size class;

²⁹ The number of regulated entities in each size category is distributed across the market sector based on the amount of pesticide product used in each market sector (see Appendix D for details). The 2001 pesticide use estimates that the agricultural, I/C/G, and H&G sectors used 40 percent, 30 percent, and 30 percent of pesticides, respectively. Based on these percentages, the number of registrants in the large size category (146) that are in the agricultural sector is calculated as 0.40*146 = 58.

³⁰ The revenue ratio for each pesticide registrant size category is based on the per size category total revenue compared to the revenue for the total universe of registrants based on the PPIS sample data set (see Appendix D for details).

- For each regulation under the container rule, estimate the number of those containers that are out of compliance with the regulation;
- Estimate the number of containers out of compliance with each regulation *per average* registrant in the market sector/size class;
- Estimate the cost, in each year of a 20-year period, of bringing those containers into compliance, and the present discounted value of that 20-year stream of costs, using a 3 percent discount rate and a 7 percent discount rate; and
- Annualize this present discounted value, using a 3 percent interest rate and a 7 percent interest rate.

The steps are described below in the order in which they were carried out in the analysis.

4.4.1 Estimate the Number of Pesticide Containers in Each Market Sector

The cost analysis begins by using the number of pesticide containers of each type within each market sector, separately for non-refillable and refillable containers, as described in Chapter 3.

4.4.2 Estimate the Number of Pesticide Containers in Each Market Sector That Fall Within the Scope of the Container Rule

As discussed in Chapter 3, not all containers fall within the scope of the full set of container regulations.³¹ For the next step in the cost analysis, we estimate the number of containers, within each combination of container type and market sector, that fall within the scope of the rule. The process of estimating the number of containers that fall within the scope of the container rule in each market sector is described in Chapter 3. The estimated numbers of containers (across all container types) in each market sector, and the estimated numbers and percentages that fall within the scope of the container rule, are presented, separately for non-refillables and refillables, in Table 4.7.

³¹ The scope criteria apply the full set of non-refillable container regulations to non-exempt products that meet the Toxicity Category I, Toxicity Category II, and/or restricted use criteria. The basic DOT packaging standards in 49 CFR 173.24 apply to all non-exempt products that are distributed/sold in non-refillable containers.

Table 4.7. Number of Containers by Market Sector, and Number and Percentages that Fall Within the Scope of the Container-Related Regulations Under the Container Rule

	Agricultural Sector	I/C/G Sector	Home & Garden Sector	Swimming Pool Industry ^a	Total
Non-Refillables					
Number of containers ^c	114,336,894	90,360,000	400,000,000	0	604,696,894
Number of containers within the scope of the container rule	73,770,164	47,930,965	227,274,040	0	348,975,169
Percentage of containers within the scope of the container rule	64.5%	53.0%	56.8%	0	57.7%
Refillables					
Total number of containers	1,263,600	46,500	0	1,217,000	2,527,100
Number of containers within the scope of the container rule b	1,263,600	37,458	0	1,217,000	2,518,058
Percentage of containers within the scope of the container rule	100.0%	80.6%		100.0%	99.6%

^a The swimming pool industry is part of the I/C/G and H&G sectors, but is analyzed separately for the refillable container analysis. Most refillables are in compliance with the regulations, except the labeling and other administrative requirements, because these containers store DOT hazardous materials.

4.4.3 Allocate Containers That Fall Within the Scope of the Rule in Each Market Sector to Each of the Size Classes

To allocate those containers that fall within the scope of the container rule to pesticide registrants within each of the different size classes, it is assumed that the percentage of total revenue (among all pesticide registrants) associated with establishments in a given size class is a reasonable proxy for the percentage of containers registered by registrants in that size class. This allocation of containers to size classes by percentage revenue was applied to each of the market sectors, and within each market sector, to each container type. For example, of the 73,770,164 non-refillable containers in the agricultural sector that fall within the scope of the container rule (see Table 4.7), 0.8 percent (see Table 4.6), or 591,993, are assumed to be registered by large-small pesticide registrants.³² Of the 73,770,164 non-refillable containers in the agricultural sector that fall with the scope of the container rule, 199,434 are 30–55 gallon plastic containers for holding liquid products. Of those, it is assumed that 0.8 percent, or 1,600 containers, are registered by large-small pesticide registrants (see Table K-1).³³ By the end of this step in the analysis, all containers that fall within the scope of the container rule are allocated to pesticide registrants in each combination of market sector and size class.

^b Swimming pool refillers are subject to a subset of the refilling requirements. Swimming pool refillers must meet certain refilling requirements, but not all. See Table 3.1 footnote for more detail.

^c See Tables 3.4 and 3.9 for non-refillables and Tables 3.5 and 3.10 for refillables.

³² Percentages given here are rounded. The numbers are based on the unrounded percentages, and are therefore slightly different from what would be obtained if the rounded percentages had been used.

³³ Table K-1 contains estimates of the number of containers by container type for each container and facility size category.

4.4.4 For Each Regulation Under the Pesticide Container Rule, Estimate the Number of Containers That Fall Within the Scope of the Rule That Are Out of Compliance with That Regulation

Many containers are already in compliance with one or more of the regulations under the pesticide container rule and therefore do not need to be brought into compliance. For this step of the cost analysis, the compliance rates estimated for each type of container in each combination of market sector and size class are used. The estimation of compliance rates is described in Chapter 3.

The number of containers of a given type within a given combination of market sector and size class that are out of compliance is just the number of containers of that type in that combination of market sector and size class that fall within the scope of the rule multiplied by one minus the corresponding compliance rate. For example, it is estimated that 35 percent of non-refillable plastic containers for holding liquid products smaller than one gallon registered by large-small establishments in the agricultural sector are in compliance with the dispensing capability requirement (§165.68 of the rule). It is estimated that 5,214 containers of that type in large-small establishments in the agricultural sector fall within the scope of the rule. The estimated number of containers of that type in that combination of market sector and size class that are out of compliance with the dispensing capability requirement is (1 - 0.35)*5,214 = 3,389.

The rates of compliance with the final pesticide container regulations by container type are described in Chapter 3. Tables 4.8a (for non-refillables) and 4.8b (for refillables) give the numbers of containers (over all types) estimated to be out of compliance with each of the container-related regulations under the pesticide container rule.

Table 4.8a. Estimated Numbers of Non-Refillable Containers Out of Compliance with the Container-Related Regulations ^a

	DOT Packaging Standards – hazardous materials ^b (§165.60-64)	DOT Packaging Standards — non- hazardous materials ^c (§165.60-64)	Closure Standards (§165.66)	Standards for container dispensing capability (§165.68)	Labeling requirements	Other administrative requirements – recordkeeping
Small-Small Establishments	Small-Small Establishments					
Agriculture	0	0	3,418	7,115	139,972	139,972
I/C/G	0	0	0	17,904	90,944	90,944
Home & Garden	0	0	0	33,636	431,230	431,230
Medium-Small Establishmer	ıts				,	
Agriculture	0	0	7,975	16,600	326,568	326,568
I/C/G	0	0	0	41,771	212,183	212,183
Home & Garden	0	0	0	78,476	1,006,105	1,006,105
Large-Small Establishments						
Agriculture	0	0	14,456	30,092	591,993	591,993
I/C/G	0	0	0	75,722	384,638	384,638
Home & Garden	0	0	0	142,259	1,823,837	1,823,837
Large Establishments						
Agriculture	0	0	1,775,609	3,696,028	72,711,631	72,711,631
I/C/G	0	0	0	9,300,532	47,243,200	47,243,200
Home & Garden	0	0	0	17,473,004	224,012,868	224,012,868
Total Number of Containers						
Agriculture	0	0	1,801,458	3,749,834	73,770,164	73,770,164
I/C/G	0	0	0	9,435,929	47,930,965	47,930,965
Home & Garden	0	0	0	17,727,375	227,274,040	227,274,040
Total Containers	0	0	1,801,458	30,913,138	348,975,169	348,975,169

^a In many cases, a regulation is not applicable to particular types of containers in a particular market sector. For example, the closure standards for non-refillables are applicable only to containers that hold at least 1 gallon and that hold liquid products in the agriculture sector. In all cases in which a regulation was not applicable, a compliance rate of 100% was used, so that there would be 0% "out of compliance."

^b Under the container rule, both containers for hazardous materials and non-hazardous materials must comply with the DOT standards for containers for hazardous materials. The costs of complying with the DOT standards for containers holding hazardous materials are therefore attributed to the DOT standards and not the container rule.

^c For non-hazardous materials, we assume that DOT-compliant containers can be purchased on the market at prices comparable to non-compliant containers. We also assume that within the compliance period, regulated entities will exhaust their inventory of non-compliant containers and replace them with compliant containers at no extra cost.

Table 4.8b. Estimated Numbers of Refillable Containers Out of Compliance with the Container-Related Regulations ^a

	DOT Packaging Standards – hazardous materials ^b (§165.110-114)	DOT Packaging Standards – non-hazardous materials ^c (§165.110-114)	Standards for container marking (§165.116)	Standards for openings (for liquid minibulks only) (§165.118)	Bulk container standards (§165.120)	Labeling requirements	Other administrative requirements – refilling documents ^d
Small-Small Establishments							
Agricultural	0	0	2,398	367	8	2,398	2,398
I/C/G	0	0	72	396	15	2,380	2,380
Home & Garden	0	0	0	0	0	0	0
Medium-Small Establishments							
Agricultural	0	0	5,594	856	18	5,594	5,594
I/C/G	0	0	168	924	35	5,553	5,553
Home & Garden	0	0	0	0	0	0	0
Large-Small Establishments							
Agricultural	0	0	10,140	1,551	33	10,140	10,140
I/C/G	0	0	304	1,676	63	10,067	10,067
Home & Garden	0	0	0	0	0	0	0
Large Establishments							
Agricultural	0	0	1,245,469	190,497	4,028	1,245,469	1,245,469
I/C/G	0	0	37,374	205,796	7,720	1,236,458	1,236,458
Home & Garden	0	0	0	0	0	0	0
Total Number of Containers							
Agriculture	0	0	1,263,600	193,270	4,087	1,263,600	1,263,600
I/C/G	0	0	37,919	208,792	7,832	1,254,458	1,254,458
Home & Garden	0	0	0	0	0	0	0
Total Containers	0	0	1,301,519	402,062	11,919	2,518,058	2,518,058

^a In many cases, a regulation is not applicable to particular types of containers in a particular market sector. In all cases in which a regulation was not applicable, a compliance rate of 100% was used, so that there would be 0% "out of compliance."

^b Under the container rule, both containers for hazardous materials and non-hazardous materials must comply with the DOT standards for containers for hazardous materials. The costs of complying with the DOT standards for containers holding hazardous materials are therefore attributed to the DOT standards and not the container rule.

^c For non-hazardous materials, we assume that DOT-compliant containers can be purchased on the market at prices comparable to non-compliant containers. We also assume that within the compliance period, regulated entities will exhaust their inventory of non-compliant containers and replace them with compliant containers at no extra cost.

^d Other administrative requirements relate to preparing and keeping records of the repackaging-related documents. The costs related to these requirements are included here (rather than the repackaging regulation) because these costs are solely the registrant's costs —not refillers' costs.

4.4.5 For Each Regulation Under the Container Rule, Estimate the Number of Containers That Fall Within the Scope of the Rule That Are Out of Compliance with That Regulation – for the Average Registrant in Each Combination of Market Sector and Size Class

For each combination of container type, market sector, and size class, the number of containers out of compliance with each container regulation is divided by the number of pesticide registrants in that combination of market sector and size class (see Table 4.5). This yields an estimate of the number of containers of each type that are out of compliance with each regulation for an "average registrant" in each market sector-size class combination.³⁴ For example, there are an estimated 836,533 plastic 30–55 gallon non-refillable containers for liquid products registered by large establishments in the I/C/G sector that are out of compliance with the labeling requirements (see Table K-2).³⁵ There are estimated to be 44 large establishments in the I/C/G sector. It is therefore estimated that the number of plastic 30–55 gallon non-refillable containers for liquid products that are out of compliance with the labeling requirements for the average large pesticide registrant in the I/C/G sector is 836,533/44 = 19,099.³⁶

4.4.6 Estimate the Cost, in Each Year of a 20-Year Period, of Bringing Containers into Compliance

There are two dimensions to the cost calculations. First, compliance costs may be fixed or variable.³⁷ (See Table A-1 of Appendix A for a description of the type of cost associated with each container standard.) Fixed costs do not depend on the number of containers that must be brought into compliance with the regulation, whereas variable costs do. Fixed costs include, for example, the cost of a filing cabinet or the cost of initial testing of each combination of container type and pesticide formulation. A fixed cost was estimated for each regulation, as described in detail in Appendix A.

Total variable cost increases with each container brought into compliance. The marginal variable cost curve was assumed to be horizontal; that is, there was assumed to be a constant unit variable cost, so that the variable cost incurred by bringing *N* containers into compliance is *N* times the variable cost of bringing one container into compliance. A unit variable cost was estimated for each regulation, as described in detail in Appendix A.

The second dimension of the cost calculations is the time dimension. Some costs are incurred only once (e.g., at the beginning of the period of time over which costs may be incurred), whereas other costs are incurred in each year of the period. The distinction between fixed costs and variable costs is not the same as the distinction between one-time costs and annual costs. Some fixed costs may occur year after year, whereas some variable costs may occur only once, at the beginning of the cost period. For example, the cost of testing combinations of non-refillable

³⁴ An "average registrant" in a market sector-size class combination is assumed to have the same combination of container types as the market sector-size class combination as a whole.

³⁵ Table K-2 presents estimates of the number of containers by container type for each container and facility size category.

³⁶ Discrepancy is due to rounding. The inputs to the calculation shown here (836,533 and 44) are rounded. The output, 19,099, is based on the unrounded numbers.

For some regulations there are only fixed costs (e.g., all container-related regulations for non-refillables have only fixed costs); for some, there are only variable costs; and for some there are both (see Appendix A).

containers and pesticide formulations is a fixed cost (it does not depend on the number of non-refillable containers subject to the regulations), but it is assumed to be incurred in each year, as new formulations are introduced. The cost of bringing liquid minibulk containers into compliance with the standards for openings is a variable cost (it increases as the number of liquid minibulk containers increases), but it occurs only once, at the beginning of the cost period.

Unless a pesticide registrant is able to obtain a waiver releasing it from the responsibility to comply with a given container regulation, the annual cost of complying with the regulation is found by:

- Calculating the cost in each year of the 20-year period;
- Calculating the presented discounted value of the resulting stream of costs; and
- Annualizing this present discounted value.

Pesticide registrants will have 3 years in which to bring their non-refillable containers into compliance with regulations under the rule. It is assumed that the compliance costs associated with non-refillables will be incurred beginning at the end of the third year. Pesticide registrants will have 5 years in which to bring their refillable containers into compliance with regulations under the rule. It is assumed that the compliance costs associated with refillables will be incurred beginning at the end of the fifth year. In calculating the present discounted value of the costs of a regulation, all costs are discounted back to the beginning of the first year of the 20-year period.

The costs incurred in a single year are the fixed costs (if any in that year) plus the variable costs (if any in that year). If:

- F_n denotes the fixed cost of complying with the regulation in the *n*th year (n=1, ..., 20);
- UVC_n denotes the unit variable cost of complying with the regulation in the nth year; and
- N denotes the number of containers out of compliance with the regulation annually, 38

then the cost of complying with the regulation in the *n*th year is:

$$F_n + UVC_n*N$$
.

Both fixed and unit variable costs, however, may differ for pesticide registrants in different market sectors and/or different size classes, and the cost analysis attempted to capture those differences whenever possible. For example, cost of testing to ensure compliance with the residue removal standard depends on the number of formulations, which tends to vary with the size of the establishment. The number of existing formulations for the average large establishment, for example, is estimated to be 0.25, whereas the number of existing formulations for the average small-small establishment is only 0.05 (see Appendix A, Table A.6). This results in greater testing costs for the average large pesticide registrant than the average small-small one.

³⁸ The number of containers to which the unit variable cost must be applied, if variable costs are annual, is assumed not to change over the 20-year period.

In addition, the type of container could affect the unit variable cost of compliance. The simple formula above is therefore made more specific as follows: The cost of complying with the *i*th regulation for the average pesticide registrant in the *j*th market sector and the *k*th size class in the *n*th year of the 20-year period is

$$CC_{ijkn} = F_{ijkn} + \sum_{m=1}^{M} (UVC_{ijkmn} * N_{ijkmn}),$$

where:

- CC_{ijkn} denotes the cost of complying with the *i*th regulation for the average pesticide registrant in the *j*th market sector and the *k*th size class in the *n*th year;
- F_{ijkn} denotes the fixed cost of complying with the *i*th regulation for the average pesticide registrant in the *j*th market sector and the *k*th size class in the *n*th year;
- *M* denotes the number of container types;
- UVC_{ijkmn} denotes the unit variable cost, specific to the mth container type, of complying with the ith regulation for the average pesticide registrant in the jth market sector and the kth size class in the nth year; and
- N_{ijkmn} denotes the number of containers of the *m*th type that are out of compliance with the *i*th regulation for the average pesticide registrant in the *j*th market sector and the *k*th size class in the *n*th year (assumed not to change over the *n* years).

For example, the unit (per-container) variable cost of meeting the bulk container standards for refillable containers is estimated to be \$856 (regardless of container type or market sector). There is no fixed cost. The average large establishment in the agricultural sector has 51 plastic "large" bulk tanks and 18 steel "large" bulk tanks out of compliance with the bulk container standards. The cost to the average large establishment in the agricultural sector of complying with this regulation in year 3 is, then,³⁹

$$$0 + (51)*($856) + (18)*($856) = $43,571 + $15,492 = $59,063$$

The 20-year schedules of costs associated with non-refillables and refillables, for the average pesticide registrant in each combination of market sector and size class, is shown in Tables 4.9a and 4.9b, respectively. Regulation-specific cost schedules for the average pesticide registrant in each combination of market sector and size class are shown in Appendix C. (Note: There are no costs for those regulations not shown in the tables in Appendix C due to assumed 100 percent compliance. In other words, for non-refillable containers no costs are associated with the DOT packaging standards, container closure standards, and standards for container dispensing capability. For refillable containers, no costs are associated with the DOT packaging standards.)

³⁹ Discrepancy is due to rounding. The inputs to the calculation shown here (51 and 18) are rounded. The output, \$59,063, is based on the unrounded numbers.

Table 4.9a. Total (Undiscounted) Costs ^a of Complying with All Regulations for Non-Refillables Under the Container Rule (2005\$)^b

	Y	ear ^c
Establishment	3	4 - 20
Large-Small Establishments	· ·	
Agricultural	\$58,808	\$2,274
I/C/G	\$58,808	\$2,274
Home & Garden	\$58,808	\$2,274
Medium-Small Establishments	· ·	
Agricultural	\$27,096	\$1,166
I/C/G	\$27,096	\$1,166
Home & Garden	\$27,096	\$1,166
Small-Small Establishments	· ·	
Agricultural	\$4,424	\$598
I/C/G	\$4,424	\$598
Home & Garden	\$4,424	\$598
Large Establishments		
Agricultural	\$92,638	\$2,814
I/C/G	\$92,638	\$2,814
Home & Garden	\$92,638	\$2,814

^a Costs are rounded to the nearest dollar.
^b Costs for the following regulations are included: residue removal standards, recordkeeping

requirements, and labeling requirements.

^c The compliance period for non-refillables is 3 years. The analysis assumes that costs are incurred beginning at the end of the third year.

Table 4.9b. Total (Undiscounted) Costs ^a of Complying with All Regulations for Refillables Under the Container Rule (2005\$)^b

	Y	ear ^c
Establishment	3	4 - 20
Large-Small Establishments		
Agricultural	\$2,153	\$126
I/C/G	\$2,194	\$102
Home & Garden	N/A	N/A
Medium-Small Establishments		
Agricultural	\$988	\$63
I/C/G	\$996	\$59
Home & Garden	N/A	N/A
Small-Small Establishments	•	
Agricultural	\$565	\$45
I/C/G	\$566	\$44
Home & Garden	N/A	N/A
Large Establishments	•	
Agricultural	\$155,894	\$3,819
I/C/G	\$161,637	\$455
Home & Garden	N/A	N/A

^a Costs are rounded to the nearest dollar.

4.4.7 Calculate the Present Discounted Value of the 20-Year Stream of Costs

In order to determine the total cost of complying with a regulation over the period of analysis, in this case 20 years, we could simply sum all the costs incurred regardless of the year in which they were incurred. However, when costs are incurred is very important. Economic theory holds that given a choice, people would rather consume goods and services now rather then in the future. All else being equal, regulatory options that create benefits now and incur costs later are preferred to options that incur costs now and create benefits later. Therefore, we must take this into account when comparing the costs and benefits of alternative regulatory options.

We accomplish this by discounting any costs that will be incurred in the future. The amount by which we discount future expenditures is known as the social discount rate. We conducted our analysis using both a 3 percent and 7 percent social discount rate.

^b Costs for the following regulations are included: container marking standards, standards for openings, bulk container standards, and recordkeeping requirements.

^c The compliance period for refillables is 5 years. The analysis assumes that costs are incurred beginning at the end of the fifth year.

The present discounted value (pdv) of the 20-year stream of compliance costs associated with the *i*th regulation for the average pesticide registrant in the *j*th market sector and the *k*th size class is

$$CC_{ijk}^{pdv} = \sum_{n=1}^{20} \frac{CC_{ijkn}}{(1+d)^n}$$

where *d* is the discount rate.

For example, costs to meet the residue removal standard begin in year 3 and go through year 20. In year 3, there are fixed costs associated with the existing containers; in subsequent years there are fixed costs associated with containers for new products. The compliance cost associated with existing containers for a small-small pesticide registrant in the agricultural sector, for example, in year 3 is \$494. The compliance cost associated with new containers in each subsequent year (years 4–20) is \$479. Using a 3 percent discount rate, and discounting back to the beginning of year 1, the present discounted value of the stream of costs associated with the residue removal standard for a small-small pesticide registrant in the agricultural sector is \$6,993. Since all costs are discounted back to year 1, this \$\$6,993 is the cost to society *as if* all costs were incurred in year 1.

4.4.8 Calculate the Annualized Cost of Complying with Each Regulation

As mentioned above, the present discounted value of the costs of a regulation tells us how much it would cost to comply with a regulation *if* all costs were incurred in the first year of implementation. In order to discuss the cost *per year* of complying with a regulation, we must annualize the present discounted value of costs over the period of analysis, in this case 20 years. If the present discounted value is like paying cash upfront for a house in year 1, then the annualized cost is the mortgage payment that would be required to pay off a mortgage equal to the present discounted value at a rate of interest equal to the discount rate. Annualization provides a "per year" cost for each regulatory option so that we can compare costs across regulatory options that require expenditures at different times. Also, later on we will be able to compare the annualized costs and benefits of each regulatory option.

The present discounted value of the costs of complying with a regulatory option is annualized over the 20-year period, using the same discount rate used to obtain present discounted values. The annualized (ann.) cost of complying with the ith regulation for the average pesticide registrant in the jth market sector and the kth size class is calculated using discount rate r, as:⁴¹

$$CC_{ijk}^{ann.} = \left(\frac{r}{[1+r]*[1-(1+r)^{-20}]}\right)*CC_{ijk}^{pdv}$$

The estimated annual cost of complying with each regulation for the average registrant in each combination of market sector and size class is shown in Tables 4.10a (for non-refillables) and

⁴⁰ See Table K-5 for presented discounted cost by market and by type of cost –fixed and variable.

⁴¹ The procedure for annualization is based on the guidelines for economic analyses that are published by EPA (EPA, 2000b).

4.10b (for refillables) assuming a discount rate of 3 percent, and Tables 4.10c and 4.10d assuming a discount rate of 7 percent. ⁴² As displayed in the tables, the highest cost of compliance is associated with the residue removal because of the testing procedure, and the labeling standards because all the containers are assumed to be not in compliance.

⁴² When compared to residue removal standards, much of the other administrative costs and labeling costs are incurred in the initial year. Therefore, the annualized costs for labeling and administrative requirements are higher at the 7 percent discount rate. The medium-small registrants and small-small registrants have low upfront year 1-5 costs (relative to ongoing year 6-20 costs) associated with residual removal requirements. Therefore, the annualized costs for these registrants are higher at the 3 percent discount rate than at the 7 percent discount rate.

Table 4.10a. Estimated Annual Cost of Complying with Each Container Regulation for Non-Refillable Containers for the Average Registrant by Market Sector and Size Class (Interest Rate = 3 percent) (2005\$)^a

	DOT Packaging Standards – hazardous materials (§165.60-64)	DOT Packaging Standards – non- hazardous materials (§165.60-64)	Closure Standards (§165.66)	Standards for container dispensing capability (§165.68)	Residue removal standards (§165.70)	Other administrative requirements – recordkeeping	Labeling requirements ^b	
Small-Small Establishments								
Agricultural	\$0	\$0	\$0	\$0	\$456	\$88	\$190	
I/C/G	\$0	\$0	\$0	\$0	\$456	\$88	\$190	
Home & Garden	\$0	\$0	\$0	\$0	\$456	\$88	\$190	
Medium-Small Establishment	s							
Agricultural	\$0	\$0	\$0	\$0	\$913	\$131	\$1,491	
I/C/G	\$0	\$0	\$0	\$0	\$913	\$131	\$1,491	
Home & Garden	\$0	\$0	\$0	\$0	\$913	\$131	\$1,491	
Large-Small Establishments								
Agricultural	\$0	\$0	\$0	\$0	\$1,825	\$161	\$3,314	
I/C/G	\$0	\$0	\$0	\$0	\$1,825	\$161	\$3,314	
Home & Garden	\$0	\$0	\$0	\$0	\$1,825	\$161	\$3,314	
Large Establishments	Large Establishments							
Agricultural	\$0	\$0	\$0	\$0	\$2,282	\$161	\$5,302	
I/C/G	\$0	\$0	\$0	\$0	\$2,282	\$161	\$5,302	
Home & Garden	\$0	\$0	\$0	\$0	\$2,282	\$161	\$5,302	

^a Rounded to the nearest dollar.

^bUnlike the other requirements, the labeling requirement is assumed to result in one fixed cost (and no variable costs) that covers labeling of both non-refillable and refillable containers. Therefore, although the costs given in this table are listed under "non-refillables," they actually include the (fixed) costs of labeling templates for all containers.

Table 4.10b. Estimated Annual Cost of Complying with Each Container Regulation for Refillable Containers for the Average Registrant by Market Sector and Size Class (Interest Rate = 3 percent) (2005\$) a

	DOT Packaging Standards – hazardous materials (§165.110-114)	DOT Packaging Standards – non- hazardous materials (§165.110-114)	Standards for container marking (§165.116)	Standards for openings (for liquid minibulks only) (§165.118)	Bulk container standards (§165.120)	Other administrative requirements – recordkeeping	Labeling require- ments ^b
Small-Small Estab	lishments						
Agricultural	\$0	\$0	\$1	\$1	\$1	\$59	
I/C/G	\$0	\$0	\$0	\$0	\$2	\$59	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	
Medium-Small Es	tablishments						
Agricultural	\$0	\$0	\$5	\$5	\$4	\$83	
I/C/G	\$0	\$0	\$0	\$1	\$11	\$83	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	
Large-Small Estab	olishments						
Agricultural	\$0	\$0	\$27	\$29	\$24	\$125	
I/C/G	\$0	\$0	\$3	\$3	\$61	\$125	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	
Large Establishme	ents						
Agricultural	\$0	\$0	\$3,807	\$4,084	\$3,325	\$125	
I/C/G	\$0	\$0	\$356	\$428	\$8,495	\$125	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	

^a Rounded to the nearest dollar.

^b The costs resulting from the labeling requirement are listed in Table 4.10a since, unlike the other requirements, these are assumed to result in one fixed cost (and no variable costs) that covers labeling of both non-refillable and refillable containers.

Table 4.10c. Estimated Annual Cost of Complying with Each Container Regulation for Non-Refillable Containers for the Average Registrant by Market Sector and Size Class (Interest Rate = 7 percent) (2005\$)^a

	DOT Packaging Standards – hazardous	DOT Packaging Standards – non-hazardous	Closure	Standards for container dispensing	Residue removal	Other administrative	
	materials (§165.60-64)	materials (§165.60-64)	Standards (§165.66)	capability (§165.68)	standards (§165.70)	requirements – recordkeeping	Labeling requirements ^b
Small-Small Establishments							-
Agricultural	\$0	\$0	\$0	\$0	\$418	\$91	\$229
I/C/G	\$0	\$0	\$0	\$0	\$418	\$91	\$229
Home & Garden	\$0	\$0	\$0	\$0	\$418	\$91	\$229
Medium-Small Establishmen	nts						
Agricultural	\$0	\$0	\$0	\$0	\$836	\$137	\$1,798
I/C/G	\$0	\$0	\$0	\$0	\$836	\$137	\$1,798
Home & Garden	\$0	\$0	\$0	\$0	\$836	\$137	\$1,798
Large-Small Establishments							
Agricultural	\$0	\$0	\$0	\$0	\$1,672	\$166	\$3,996
I/C/G	\$0	\$0	\$0	\$0	\$1,672	\$166	\$3,996
Home & Garden	\$0	\$0	\$0	\$0	\$1,672	\$166	\$3,996
Large Establishments							·
Agricultural	\$0	\$0	\$0	\$0	\$2,091	\$166	\$6,393
I/C/G	\$0	\$0	\$0	\$0	\$2,091	\$166	\$6,393
Home & Garden	\$0	\$0	\$0	\$0	\$2,091	\$166	\$6,393

^a Rounded to the nearest dollar.

^b Unlike the other requirements, the labeling requirement is assumed to result in one fixed cost (and no variable costs) that covers labeling of both non-refillable and refillable containers. Therefore, although the costs given in this table are listed under "non-refillables," they actually include the (fixed) costs of labeling templates for all containers.

Table 4.10d. Estimated Annual Cost of Complying with Each Container Regulation for Refillable Containers for the Average Registrant by Market Sector and Size Class (Interest Rate = 7 percent) (2005\$)^a

	DOT Packaging Standards – hazardous materials (§165.110-114)	DOT Packaging Standards – non-hazardous materials (§165.110-114)	Standards for container marking (§165.116)	Standards for openings (for liquid minibulks only) (§165.118)	Bulk container standards (§165.120)	Other administrative requirements – recordkeeping	Labeling requirements ^b
Small-Small Establishments							
Agricultural	\$0	\$0	\$1	\$1	\$1	\$58	
I/C/G	\$0	\$0	\$0	\$0	\$3	\$58	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	
Medium-Small Establishmer	Medium-Small Establishments						
Agricultural	\$0	\$0	\$5	\$6	\$5	\$83	
I/C/G	\$0	\$0	\$0	\$1	\$13	\$83	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	
Large-Small Establishments							
Agricultural	\$0	\$0	\$26	\$33	\$27	\$122	
I/C/G	\$0	\$0	\$2	\$3	\$68	\$122	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	
Large Establishments							
Agricultural	\$0	\$0	\$3,592	\$4,564	\$3,715	\$122	
I/C/G	\$0	\$0	\$334	\$478	\$9,492	\$122	
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	

^a Rounded to the nearest dollar.

^b The costs resulting from the labeling requirement are listed in Table 4.10a since, unlike the other requirements, they are assumed to result in one fixed cost (and no variable costs) that covers labeling of both non-refillable and refillable containers.

4.4.9 Estimate the Annualized Cost of Complying with All Regulations per Average Regulated Entity in Each Combination of Market Sector and Size Class – Assuming No Waivers

In the absence of any waivers, the total annualized cost of complying with all container-related regulations for the average pesticide registrant in the *j*th market sector and the *k*th size class is

$$CC_{jk}^{ann.}(w/o\ waiver) = \sum_{i=1}^{I} CC_{ijk}^{ann.}$$
,

where *i* is the number of such regulations. With one exception, regulations are directed at either refillable containers or non-refillables. Even for regulations that are essentially the same for non-refillables and refillables (e.g., administrative requirements – recordkeeping), the cost analysis assumes that any fixed costs incurred for non-refillables are separate from those incurred for refillables (e.g., it is assumed that a separate filing cabinet is purchased for each set of records). The exception is the labeling requirement, which results in only fixed costs that are not incurred separately for non-refillable and refillable containers.

The total annualized cost of complying with all regulations, in the absence of any waivers, for the average pesticide registrant in the *j*th market sector and the *k*th size class can then be rewritten as:

$$CC_{jk}^{ann.}(w/o\ waiver) = \sum_{i=1}^{N_{nr}} CC_{ijk}^{ann.}(nr) + \sum_{i=1}^{N_{r}} CC_{ijk}^{ann.}(r) + CC_{jk}^{ann.}(labeling)$$

where:

• N_{nr} denotes the number of container-related regulations for non-refillable containers;

- N_r denotes the number of container-related regulations for refillable containers;
- $CC_{ijk}^{ann.}(nr)$ denotes the annualized cost of complying with the *i*th regulation for non-refillables, for the average registrant in the *j*th market sector and the *k*th size class;
- $CC_{ijk}^{amn.}(r)$ denotes the annualized cost of complying with the *i*th regulation for refillables, for the average registrant in the *j*th market sector and the *k*th size class; and
- $CC_{ijk}^{ann.}(labeling)$ denotes the annualized cost of complying with the labeling requirements for the average registrant in the *j*th market sector and the *k*th size class.

The total annualized compliance cost without waivers, across all regulations, for the average registrant in the *j*th market sector and the *k*th size class is shown in Tables 4.11a and 4.11b. At 3 percent, costs of compliance without a waiver range from as high as \$19,807 (\$20,642 at 7 percent) for large registrants to \$796 (\$800 at 7 percent) for small-small registrants. As described in Tables 4.10a and 4.10b, the majority of the cost is associated with compliance with the residue removal and labeling requirements.⁴³

⁴³ When compared to large-small and large registrants, small-small and medium-small registrants have low upfront year 1-5 costs (relative to ongoing year 6-20 costs) associated with the residual removal requirements. Therefore, the annualized costs for the medium-small and small-small registrants are higher at the 3 percent discount rate than at the 7 percent discount rate, while the opposite is true for the large-small and large registrants.

Table 4.11a. Total Annualized Costs Over a 20-Year Period of the Pesticide Container Rule for the Average Registrant: Total Without a Waiver (Interest =3 percent)

Establishment	Annualized Cost
Large-Small Establishments	
Agricultural	\$5,506
I/C/G	\$5,492
Home & Garden	\$5,426
Medium-Small Establishments	
Agricultural	\$2,633
I/C/G	\$2,631
Home & Garden	\$2,618
Small-Small Establishments	
Agricultural	\$796
I/C/G	\$795
Home & Garden	\$793
Large Establishments	
Agricultural	\$19,087
I/C/G	\$17,149
Home & Garden	\$7,870

Table 4.11b. Total Annualized Costs Over a 20-Year Period of the Pesticide Container Rule for the Average Registrant: Total Without a Waiver (Interest =7 percent)

	` .		
Establishment	Annualized Cost		
Large-Small Establishments			
Agricultural	\$6,041		
I/C/G	\$6,030		
Home & Garden	\$5,956		
Medium-Small Establishments			
Agricultural	\$2,870		
I/C/G	\$2,867		
Home & Garden	\$2,854		
Small-Small Establishments			
Agricultural	\$800		
I/C/G	\$799		
Home & Garden	\$797		
Large Establishments			
Agricultural	\$20,642		
I/C/G	\$19,077		
Home & Garden	\$8,772		

4.4.10 Estimate the Annual Cost of Complying with All Regulations per Average Regulated Entity in Each Combination of Market Sector and Size Class – Allowing for Waivers

EPA may modify or waive the requirements for some but not all of the container-related Regulations. For non-refillables, EPA may:

- Modify or waive the requirements of the DOT packaging standards for non-hazardous materials (§165.60) and for hazardous materials (§165.62);
- Approve a non-standard closure (i.e., a closure not listed in §165.66);
- Modify or waive the container dispensing standards (§165.68); and
- Modify or waive the residue removal standard (§165.70).

For refillables, EPA may modify or waive the requirements of the DOT packaging standards for non-hazardous materials (§165.110) and for hazardous materials (§165.112).

The total annualized compliance cost, across all regulations, for the average registrant in the *j*th market sector and the *k*th size class when a waiver has been obtained is shown in Tables 4.11c and 4.11d. The standards, and their potential to be waived, are summarized in Table 4.12. As expected, given the range of standards that can be waived (in particular, the residue removal standard), costs are lower for the registrant that obtains a waiver compared to the registrant that does not obtain a waiver (see Tables 4.11a and 4.11b). With a waiver, costs of compliance range from \$17,167 at 3 percent (\$18,914at 7 percent) for large registrants, to \$698 at 3 percent (\$740 at 7 percent) for small-small registrants.

Table 4.11c. Total Annualized Costs Over a 20 Year Period of the Pesticide Container Rule for the Average Registrant: Total With a Waiver (Interest Rate = 3 percent)

Establishment	Annualized Cost
Large-Small Establishments	
Agricultural	\$4,042
I/C/G	\$4,028
Home & Garden	\$3,962
Medium-Small Establishments	
Agricultural	\$2,082
I/C/G	\$2,080
Home & Garden	\$2,067
Small-Small Establishments	
Agricultural	\$701
I/C/G	\$701
Home & Garden	\$698
Large Establishments	
Agricultural	\$17,167
I/C/G	\$15,229
Home & Garden	\$5,950

Table 4.11d. Total Annualized Costs Over a 20 Year Period of the Pesticide Container Rule for the Average Registrant: Total With a Waiver (Interest Rate = 7 percent)

Establishment	Annualized Cost				
Large-Small Establishments					
Agricultural	\$4,731				
I/C/G	\$4,719				
Home & Garden	\$4,646				
Medium-Small Establishments					
Agricultural	\$2,395				
I/C/G	\$2,393				
Home & Garden	\$2,379				
Small-Small Establishments					
Agricultural	\$744				
I/C/G	\$743				
Home & Garden	\$740				
Large Establishments					
Agricultural	\$18,914				
I/C/G	\$17,348				
Home & Garden	\$7,043				

Table 4.12. Container-Related Standards and Waivers

Standard	May It Be Modified or Waived?
Non-Refillables	
DOT packaging (design, construction, and marking) standards – for non-hazardous materials (§165.60)	Yes
DOT packaging (design, construction, and marking) standards – for hazardous materials (§165.62)	Yes
Closure standards (§165.66)	Yes
Standards for container dispensing capability (§165.68)	Yes
Residue removal standards (§165.70)	Yes
Recordkeeping (§165.86)	No
Labeling (§156.144(d)) ^a	Yes
Refillables	
DOT packaging (design, construction, and marking) standards – for non-hazardous materials (§165.110)	Yes
DOT packaging (design, construction, and marking) standards – for hazardous materials (§165.112)	Yes
Standards for marking (§165.116)	No
Standards for openings (§165.118)	No
Standards for bulk containers (§165.120)	No
Labeling (§156.144(d)) ^a	Yes

^a The regulations specify that the label requirements can be modified or waived. For the purposes of the cost analysis, we assume that the label requirements are more likely to be modified than completely waived, so it is assumed that registrants still incur the cost of changing the pesticide label. Therefore, label waivers are not included in the waiver cost analysis.

The cost analysis assumes that:

- Pesticide registrants will apply for a waiver only if they are reasonably certain of getting it;
- Five percent of registrants will apply for a waiver;
- All those who apply will get the waiver;
- If a requirement is waived, the cost of meeting the requirement is zero; and
- There is a cost to apply for a waiver.

The total annualized cost of complying with the container rule for the average pesticide registrant in the *j*th market sector and the *k*th size class who applies for and gets a waiver can be written as:

$$CC_{jk}^{ann.}(w/waiver) = \sum_{i \in S_{nr}} CC_{ijk}^{ann.}(nr) + \sum_{m \in S_r} CC_{ijk}^{ann.}(r) + C_{jk}(waiver) + CC_{jk}^{ann.}(labeling)$$

where:

• S_{nr} is the set of container-related regulations for non-refillable containers for which a waiver cannot be obtained;

- S_r is the set of container-related regulations for refillable containers for which a waiver cannot be obtained;
- $C_{jk}(waiver)$ is the cost of applying for a waiver for the average pesticide registrant in the *j*th market sector and the *k*th size class; and
- All other components on the right-hand side of the equation are as described above.

The expected annualized cost for the average pesticide registrant in the jth market sector and the kth size class, given that p_{jk} percent of all pesticide registrants in the jth market sector and the kth size class apply for and obtain waivers (which relieve them of the responsibility of complying with some but not all regulations), is:

$$E(CC_{jk}^{ann.}) = p_{jk} * CC_{jk}^{ann.}(w/waiver) + (1 - p_{jk}) * CC_{jk}^{ann.}(w/owaiver)$$

As noted above, it is assumed that $p_{jk} = 0.05$ for all j and k; that is, 5 percent of pesticide registrants apply for and receive a waiver.⁴⁴ The cost of the waiver is an estimated \$362 (see Appendix A). The expected cost to a large-small agricultural pesticide registrant, for example, using the estimates of total annualized costs with and without a waiver at 3 percent found in Tables 4.11a and 4.11c, respectively, would be:

$$(0.05)*(\$4.042) + (1-0.05)*(\$5.506) = \$5.433^{45}$$

Total expected annualized costs (across all container-related regulations), given that waivers are available for some regulations, are given in Tables 4.17a and 4.17b in Section 4.6, where total expected costs for both container-related and refilling-related regulations are summarized.

4.5 Estimating the Costs of Compliance with Refilling-Related Regulations

The method use to estimate the costs of complying with the set of refilling-related regulations incurred by the average pesticide refiller is basically the same as the method of estimating the costs of complying with the set of container-related regulations. For a given pesticide refiller category/size class (e.g., large agricultural pesticide refillers), the analysis proceeds through the following series of steps to a final estimate of the cost to the average pesticide refiller in that refiller category/size class per refilling-related regulation:

- Estimate the number of refillable containers in the relevant market sector;
- Estimate the number of those that fall within the scope of the rule;
- Estimate the number of those that are refilled by pesticide refillers in the refiller category (this is an issue only for the agricultural sector, in which there are two categories of pesticide refillers agricultural pesticide refillers and agricultural pesticide registrants);

⁴⁴ The assumption that the probability of applying for and getting a waiver is the same for all market sectors and size classes is made in the absence of sufficient information to the contrary.

⁴⁵ The difference between this estimated cost (\$5,433) and the estimate of cost provided in Table 4.17a (\$5,477) is the annual cost of complying with the refilling-related regulations for an average large-small agricultural pesticide registrant (\$44) (see Section 4.5).

- Using annual refilling rates estimated for each different type of refillable container refilled by each category of pesticide refiller, estimate the total number of refillings per year in each refiller category;
- Estimate the number of refillings per year in each refiller category/size class;
- For each refilling-related regulation under the rule, estimate the number of those refillings that are out of compliance with the regulation in each refiller category/size class;
- Estimate the number out of compliance with each regulation *per average refiller* in each refiller category/size class;
- Estimate the cost, in each year of a 20-year period, of bringing those refillings into compliance, and the present discounted value of that 20-year stream of costs, using a 3 percent discount rate and a 7 percent discount rate; and
- Annualize this present discounted value, using a 3 percent interest rate and a 7 percent interest rate.

This section describes the method of estimating the costs of complying with the refilling-related regulations under the pesticide container rule for the average refilling entity. The steps are described in the order in which they were carried out in the analysis. The first two steps in the process (estimating the number of refillable pesticide containers in each market sector and estimating the number of refillable pesticide containers in each market sector that fall within the scope of the rule) were already carried out for the analysis of the costs of the container-related regulations, and are described above in Sections 4.4.1 and 4.4.2. The description of methods presented here begins at the third step.

4.5.1 Allocate Refillable Containers That Fall Within the Scope of the Rule in Each of the Relevant Market Sectors to Each of the Regulated Refilling Entity Categories Within the Market Sector

The agricultural and I/C/G sectors have regulated entities that will have to comply with the set of refilling-related regulations under the pesticide container rule (see Tables 4.2 and 4.3). H&G containers, however, are not refilled, so this market sector does not enter into the refilling cost analysis. In the I/C/G sector, I/C/G pesticide registrants make up the only refiller category. Therefore, 100 percent of all refillable containers of each type in the I/C/G market sector that fall within the scope of the rule were allocated to I/C/G pesticide registrants for this part of the cost analysis.

Although swimming pool supply companies are considered to be in the I/C/G and H&G sectors, we treat them separately. As described in Chapter 3, refillable containers associated with swimming pool supply companies were not included in the data used to estimate the number of containers in the I/C/G market. Therefore, the refillables associated with swimming pool supply companies were estimated differently and are treated differently in the cost analysis because they are subject to a portion of the refilling requirements only. That is, the number of refillable containers of each type, and the number that fall within the scope of the rule, refilled by swimming pool supply companies were calculated separately. Therefore, the swimming pool industry is treated as its own market sector, and all of the refillable containers that fall within the scope of the rule in the swimming pool industry are allocated to swimming pool supply companies.

Within the agricultural sector there are two refiller categories:

- Agricultural pesticide refillers; and
- Agricultural pesticide registrants.

It is estimated that 90 percent of the refillable containers that fall within the scope of the rule in the agricultural sector are refilled by agricultural pesticide refillers, and 10 percent are refilled by agricultural pesticide registrants (see Table K-3). More details about this assumption are provided in Chapter 3.

4.5.2 Estimate the Number of Refillings per Year That Fall Within the Scope of the Rule for Each Category of Regulated Entity for Each Refillable Container Type

Table 4.13 lists the estimated annual refilling rates (number of refillings per container per year). Refilling rates for the agricultural sector are based on information provided by Paulson (2002). Refilling rates for the I/C/G sector are transferred from assumptions made in the proposed container rule RIA for small volume refillable containers (EPA, 1993, Appendix G). Refilling rates for the swimming pool industry (antimicrobial pesticide supply companies) are approximately twice the rate (eight times per year) used in the proposed container rule RIA. This is based on professional judgment and comments submitted to EPA. The relative amount of sodium hypochlorite used and the number of refillable containers needed to meet demand in the pool treatment industry are considered.

4.5.3 Estimate the Number of Refillings per Year That Fall Within the Scope of the Rule for Pesticide Refillers in Each Size Class Within Each Refiller Category

The same size classes that were applied to pesticide registrants were also applied to the different refiller categories, as shown in Table 4.5 above. Analogous to the method used to allocate containers within each market sector to the different size classes, the analysis assumed that the percentage of total revenue (among all pesticide refillers in a given category, such as agricultural pesticide refillers) associated with pesticide refillers in a given size class is a reasonable proxy for the percentage of refillings by pesticide refillers in that size class. This allocation of refillings to size classes by percentage revenue was applied to each category of pesticide refiller, and within each refiller category, to each container type. For example, there are assumed to be 54,810 refillings of 126-250 gallon plastic containers for holding liquid products per year by agricultural pesticide refillers. Of those, we assume 9.1 percent (see Table 4.6), or 5,009 refillings, to be refillings by large-small agricultural pesticide refillers. Across all sizes and types of container, there are assumed to be 2,083,500 refillings per year by agricultural pesticide refillers. By the end of this step in the analysis, all refillings that fall within the scope of the container rule are allocated to each combination of pesticide refiller category and size class.

⁴⁶ The number of refillings in each container type category is the product of the number of containers in that category and refilling rate per container. For the 126–50 gallon plastic container category for agricultural refillers, 31,320 containers * 1.75 refillings per year per container = 54,810 refillings per year.

⁴⁷ Percentages given in the text are rounded. The numbers here are based on the unrounded percentages, and are therefore slightly different from what would be obtained if the rounded percentages had been used.

⁴⁸ The total number of refillings for each refiller class is the sum of the number of refillings over all container type categories.

Table 4.13. Estimated Annual Pesticide Container Refilling Rates

	Estimated Annual Refilling Rate			
Refillable Container Type	Agricultural Pesticide Refillers ^a	Agricultural Pesticide Registrants ^a	I/C/G Pesticide Registrants b	Swimming Pool Industry – Antimicrobial Applicators ^c
Containers for Holding Liquid P	roducts			
5 - 25 gallon, plastic or steel	2.25	2.25	4	8
26 - 60 gallon, plastic or steel	1.75	1.75	4	8
61 - 125 gallon, plastic or steel	1.75	1.75	4	N/A
126 - 250 gallon, plastic or steel	1.75	1.75	4	N/A
Large (251 - 500 gallons)	1.25	1.25	4	4
Bulk (> 500 gallons)	1.25	1.25	4	4
Other	1.75	1.75	4	8
Containers for Holding Dry Proc	lucts		•	
< 100 lbs.	1.75	1.75	4	N/A
101 - 2500 lbs.	1.75	1.75	4	N/A
Large (2501 - 4409 lbs.)	1.25	1.25	4	N/A
Bulk (> 4409 lbs.)	1.25	1.25	4	N/A
Other	1.75	1.75	4	N/A

^a Agricultural sector refilling rates are based on Paulson (2002).

4.5.4 For Each Refilling-Related Regulation Under the Pesticide Container Rule, Estimate the Number of Refillings per Year That Fall Within the Scope of the Rule That Are Out of Compliance with That Regulation

As with the container-related regulations, it is estimated that for each refilling-related regulation, some percentage of refillings are already in compliance with the regulation and therefore do not need to be brought into compliance. This step of the cost analysis of refilling-related regulations relied on compliance rates estimated for refillings of each type of refillable container in each combination of refiller category and size class. The estimation of compliance rates is described in Chapter 3.

The number of refillings of a given type of refillable container within a given combination of pesticide refiller category and size class that are out of compliance with a given regulation is just the number of refillings of that type of container in that combination of refiller category and size class that fall within the scope of the rule multiplied by (1 - the corresponding compliance rate). For example, it is estimated that, among large agricultural pesticide refillers, 60 percent of refillings of 126–250 gallon plastic refillable containers for holding liquid products are in compliance with the requirement to inspect the container before refilling. There are estimated to

^b I/C/G refilling rates based are based on assumptions in the proposed container rule RIA (EPA, 1993, Appendix G).

^c Estimates are based on comments to the 1999 Supplemental Notice submitted by relevant trade associations (i.e., the Chlorine Institute, National Spa and Pool Institute, and Swimming Pool Chemical Manufacturers Association) that provide the average number of refillings. Based on the comments, the number of refillings was assumed to be 8. A smaller refilling rate of 4 was assumed for larger containers.

be 25,767 refillings per year of that type of container by large agricultural pesticide refillers that fall within the scope of the rule. It is estimated that the number of refillings of that type of container by large agricultural pesticide refillers that are out of compliance with the requirement to inspect the container before refilling is (1 - 0.6)*25,767 = 10,307.

The numbers of refillings (of all types of refillable containers) estimated to be out of compliance with each of the refilling-related regulations under the pesticide container rule is given in Table 4.14.

Table 4.14. Estimated Numbers of Refilling Steps (or Requirements) per Year Out of Compliance with Refilling-Related Requirements (2005\$)

	Requirement to Inspect Container	Requirement to Clean Container	Recordkeeping with
A - a' - I - a - I D - a' - ' I - D - C'II - a -	Before Refilling	Before Refilling	Each Refilling
Agricultural Pesticide Refillers	1.50.0==	20.015	2== 101
Small-Small	150,077	30,015	375,191
Medium-Small	215,367	43,073	538,418
Large-Small	76,159	15,232	190,397
Large	391,797	78,359	979,494
Agricultural Pesticide Registrants	•		
Small-Small	176	35	439
Medium-Small	410	82	1,025
Large-Small	743	149	1,858
Large	91,271	18,254	228,178
I/C/G Pesticide Registrants			
Small-Small	114	23	284
Medium-Small	265	53	663
Large-Small	481	96	1,202
Large	59,073	11,815	147,682
Swimming Pool Supply Companies			
Small-Small	996	0	0
Medium-Small	3,449	0	0
Large-Small	829	0	0
Large	480,126	0	0

4.5.5 For Each Refilling-Related Regulation Under the Pesticide Container Rule, Estimate the Number of Refillings That Fall Within the Scope of the Rule That Are Out of Compliance with That Regulation – for the Average Regulated Entity in Each Combination of Refiller and Size Class

For each combination of refillable container type, refiller category, and size class, we divide the number of refillings out of compliance with each refilling-related regulation (see Table 4.14) by the number of pesticide refillers in that combination of refiller category and size class (see Table 4.5). This yields an estimate of the number of refillings of each type of refillable container that is out of compliance with each regulation for an "average pesticide refiller" in each refiller type-

size class combination.⁴⁹ For example, there are an estimated 2,061 refillings of 126–250 gallon plastic containers for holding liquid products by large agricultural pesticide refillers that are out of compliance with the requirement to clean the container before refilling. There are estimated to be 153 large agricultural pesticide refillers. It is therefore estimated that the number of refillings of 126–250 gallon plastic containers for holding liquid products that are out of compliance with the requirement to clean the container before refilling for the average large agricultural pesticide refiller is 2,061/153 = 13.5 (see Table K-4b).⁵⁰

4.5.6 Estimate the Cost, in Each Year of a 20-Year Period, of Bringing Refillings into Compliance

The estimation of the costs of bringing refillings into compliance with refilling-related regulations follows the same pattern as the estimation of costs for container-related regulations. Compliance costs may be fixed or variable. Fixed costs do not depend on the number of refillings that must be brought into compliance with the regulation, whereas variable costs do. The only fixed cost associated with refilling requirements is the cost of a file cabinet, estimated at \$229.65. (See Appendix A for compliance cost figures.)

Total variable cost increases with each refilling brought into compliance. As with the container-related variable costs, the marginal variable cost curve was assumed to be horizontal; that is, there was assumed to be a constant unit variable cost, so that the variable cost incurred by bringing *N* refillings into compliance is *N* times the variable cost of bringing one refilling into compliance. The variable costs associated with refilling are the costs of inspecting, cleaning, and recording certain information about refillable containers when refilling. We estimate a unit variable cost for each regulation, as described in detail in Appendix A.

The second dimension of the cost calculations is the time dimension. Some costs are incurred only once (e.g., at the beginning of the period of time over which costs may be incurred), whereas other costs are incurred in each year of the 20-year period.

The cost of complying with a refilling-related regulation is calculated by:

- Calculating the cost in each year of the 20-year period;
- Calculating the presented discounted value of the resulting stream of costs; and
- Annualizing this present discounted value.

Waivers are not available for the refilling-related regulations. Pesticide refillers will have 5 years in which to bring their refillings into compliance with regulations under the rule. The analysis assumes that refilling-related compliance costs will be incurred beginning at the end of the fifth year. In calculating the present discounted value of the costs of a regulation, all costs are discounted back to the beginning of the first year of the 20-year period.

⁴⁹ An "average refiller" in a refiller category/size class combination is assumed to refill the same combination of refillable container types as the refiller category/size class combination as a whole.

⁵⁰ Table K-4 presents information for each combination of container type, container size, market type, and entity size.

The cost of compliance with the three refilling requirements—to inspect, clean, and record information about refillable containers when refilling—were combined together into a single cost estimate. The calculation of these costs is carried out in the same way as the cost of complying with a container-related regulation. The only difference is that the unit is now a refilling rather than a container. The costs incurred in a single year are the fixed costs (if any in that year) plus the variable costs (if any in that year). If

- F_n denotes the fixed cost of complying with the refilling regulations in the *n*th year (n=1, ..., 20):
- UVC_n denotes the unit variable cost of complying with the refilling regulations in the nth year; and
- N denotes the number of refillings out of compliance with the regulation annually;⁵¹

then the cost of complying with the refilling regulations in the *n*th year is:

$$F_n + UVC_n * N.$$

As with container-related compliance costs, it is possible that both fixed and unit variable costs differ for pesticide refillers in different refiller categories and/or size classes. There was insufficient information to capture any such differences in this cost analysis. (Total variable costs will vary, however, because the numbers of refillings varies across refiller categories and size classes.) It is also possible that unit variable or fixed costs could differ by refillable container type, but as with possible differences across refiller categories and/or size classes, there was insufficient information to capture any such possible differences.

Therefore, although in theory the calculation of the cost of complying with the *i*th regulation for the average pesticide refiller in the *j*th refiller category and the *k*th size class in the *n*th year of the 20-year period would follow the same basic pattern as for container-related compliance costs (shown in Section 4.4.6),

$$CC_{ijkn} = F_{ijk} + \sum_{m=1}^{M} (UVC_{ijkmn} * N_{ijkmn}) ,$$

in practice, a simpler formula is used, in which only the number of refillings varies by refiller category and/or size class and regulation, and the unit variable cost varies for the regulation.

The cost of complying with the three refilling requirements is just the fixed cost (it was assumed that a single file cabinet would suffice for all three refilling regulations) plus the three variable costs. Each unit variable cost was estimated by estimating the time required to meet the regulation (e.g., the time it takes to clean a refillable container before refilling) and multiplying by the hourly wage rate. For example, we estimate that it takes one minute, or 0.0167 hour, to inspect a container before refilling. We estimate the labor cost per hour to be \$29.13. The unit variable cost of inspection is, then, $0.0167 \times $29.13 = 0.4865 . There are estimated to be 90 refillings out of compliance with the inspection regulation for the average medium-small

⁵¹ The number of refillings to which the unit variable cost must be applied, if variable costs are annual, is assumed not to change over the 20-year period.

agricultural pesticide refiller each year. The annual (undiscounted) variable cost of meeting the inspection regulation for the average medium-small agricultural pesticide refiller is therefore $\$0.49 \times 90 = \43.78 .

The 20-year schedule of costs for the three refilling regulations combined for the average pesticide refiller in each market sector/refilling category/size class is shown in Table 4.15. Due to the significantly larger number of containers refilled by the large registrants compared to the small registrants, costs of compliance are estimated to be significantly higher in each year for the large registrants.

Table 4.15. Total Compliance Costs ^a Related to Refilling Requirements for Refillable Containers (2005\$)^b

	Year ^c	
Establishment	5	6-20
Large-Small Establishments	· · · · · · · · · · · · · · · · · · ·	
Agricultural Pesticide Refillers	\$1,408	\$1,178
Agricultural pesticide registrants	\$273	\$43
I/C/G – Pesticide registrants	\$267	\$37
Swimming Pool Supply Companies	\$258	\$29
Medium-Small Establishments		
Agricultural Pesticide Refillers	\$579	\$349
Agricultural pesticide registrants	\$238	\$8
I/C/G – Pesticide registrants	\$237	\$7
Swimming Pool Supply Companies	\$244	\$14
Small-Small Establishments	· · · · · · · · · · · · · · · · · · ·	
Agricultural Pesticide Refillers	\$271	\$42
Agricultural pesticide registrants	\$231	\$2
I/C/G – Pesticide registrants	\$231	\$1
Swimming Pool Supply Companies	\$232	\$3
Large Establishments	· · · · · · · · · · · · · · · · · · ·	
Agricultural Pesticide Refillers	\$10,174	\$9,944
Agricultural pesticide registrants	\$6,300	\$6,070
I/C/G – Pesticide registrants	\$5,468	\$5,238
Swimming Pool Supply Companies	\$13,942	\$13,712

^a Costs are rounded to the nearest dollar.

4.5.7 Calculate the Present Discounted Value of the 20-Year Stream of Costs

The present discounted value of the 20-year stream of compliance costs associated with the refilling regulations for the average pesticide refiller in the *j*th refiller category and the *k*th size class is:

$$CC_{jk}^{pdv} = \sum_{n=1}^{20} \frac{CC_{jkn}}{(1+d)^n}$$

^b Compliance with the refilling requirements involves both fixed and variable costs.

^c The compliance period for non-refillables is 5 years. The analysis assumes that costs are incurred beginning at the end of the fifth year.

where *d* is the discount rate. Two discount rates were considered: 3 percent and 7 percent. Table K-5 shows the present discounted value of each year's costs refilling requirement costs for each the average pesticide refiller in each market sector/refilling category and size class.

4.5.8 Calculate the Annualized Cost of Complying with the Refilling Regulations

The present discounted value of the cost of complying with the refilling regulations was annualized over the 20-year period, using two interest rates (r) that were assumed to be the same as the two discount rates used to obtain present discounted values (that is, when the discount rate was assumed to be 3 percent, the interest rate was also assumed to be 3 percent, and similarly for 7 percent). The annualized cost of complying for the average pesticide refiller in the jth refiller category and the kth size class is calculated using interest rate r as

$$CC_{jk}^{ann.} = \left(\frac{r}{[1+r]*[1-(1+r)^{-20}]}\right)*CC_{jk}^{pdv}$$

The estimated annualized cost of complying with the three refilling-related regulations (combined) for the average refiller in each combination of refiller category and size class is shown in Tables 4.16a (at 3 percent interest) and 4.16b (at 7 percent interest). As discussed earlier, due to the significantly larger number of containers refilled by the large registrants compared to the small registrants, the estimated annual cost of compliance is estimated to be significantly higher for large registrants.

Table 4.16a. Estimated Annual Cost of Complying with the Refilling-Related Container Regulations for the Average Refiller by Refiller Category and Size Class (Interest = 3 percent) (2005\$)^a

Refiller Category / Size Class	Cost of Requirements to Inspect, Clean, and Track Container Before Refilling
Agricultural Pesticide Refillers	
Small-Small	\$43
Medium-Small	\$267
Large-Small	\$871
Large	\$7,255
Agricultural Pesticide Registrants	
Small-Small	\$14
Medium-Small	\$19
Large-Small	\$45
Large	\$4,434
I/C/G Pesticide Registrants	
Small-Small	\$14
Medium-Small	\$18
Large-Small	\$40
Large	\$3,828
Swimming Pool Supply Companies	
Small-Small	\$15

Medium-Small	\$23
Large-Small	\$34
Large	\$10,000

^aCosts for all three refilling-related requirements are aggregated. Some costs are higher at the 7 percent discount rate while the others are higher at the 3 percent discount rate depending on whether the costs incurred in the initial year is high. If the initial year costs are high then the typically the cost estimate is higher for the 7 percent discount rate and vice versa. For example, the large swimming pool supply companies face a high cost in the initial year while the small-small agricultural pesticide refiller faces low initial year costs. Accordingly, the cost at the 7 percent discount rate is higher for the large former, while the opposite is true for the latter.

Table 4.16b. Estimated Annual Cost of Complying with the Refilling-Related Container Regulations for the Average Refiller by Refiller Category and Size Class (Interest = 7 percent) (2005\$)^a

Refiller Category / Size Class	Cost of Requirements to Inspect, Clean, and Track Container Before Refilling
Agricultural Pesticide Refillers	
Small-Small	\$41
Medium-Small	\$237
Large-Small	\$764
Large	\$6,336
Agricultural Pesticide Registrants	
Small-Small	\$16
Medium-Small	\$20
Large-Small	\$42
Large	\$3,874
I/C/G Pesticide Registrants	
Small-Small	\$15
Medium-Small	\$19
Large-Small	\$38
Large	\$3,345
Swimming Pool Supply Companies	
Small-Small	\$16
Medium-Small	\$24
Large-Small	\$33
Large	\$8,732

^a Costs for all three refilling-related requirements are aggregated.

4.6 The Total Annual Costs of the Rule

We calculated the total annual costs of the pesticide container rule, across all regulations contained within it, for:

- The average regulated entity in each combination of entity type, market sector, and size class;
- All regulated entities in each combination of entity type, market sector, and size class;
- The average pesticide registrant with a "representative share" in each market sector;
- All pesticide registrants (across all market sectors) in each size class;
- All pesticide registrants across all market sectors and size classes;

- All regulated entities within each category complying with refilling-related regulations; and
- All regulated entities.

The cost of complying with each of the container-related and refilling-related regulations under the rule, for the average regulated entity in each combination of regulated entity category, market sector, and size class are given above in Tables 4.10a–4.10d and 4.16a and 4.16b, respectively. The estimation of costs across all regulations for the average regulated entity is described in Sections 4.4 and 4.5. The sets of regulations to which each regulated entity category is subject are summarized in Table 4.2. The numbers of regulated entities in each category of regulated entity for each combination of market sector and size class are given in Table 4.5. The information in all these tables is synthesized in Tables 4.17a and 4.17b, which summarize the annualized costs across all regulations for each type of regulated entity and across all regulated entities, at 3 percent interest and 7 percent interest, respectively. In general, as displayed in Tables 4.17a and 4.17b (and as discussed earlier), costs are also higher for the average large entity than for the average small entity, and the costs are higher for large entities when considered over all entities. The exceptions include the large-small registrants, which have a similar number of regulated entities to large registrants, making their costs smaller over all regulated entities; and large agricultural pesticide refillers, which have higher costs over all entities, despite a relatively small number of entities in this market sector and size. At 3 percent and 7 percent, the total cost of compliance over all regulated entities is estimated to be \$8.4 million and \$8.5 million, respectively. With a 3 percent discount rate, pesticide registrants account for nearly \$5.6 million (or almost 70 percent) of the total cost of compliance, while agricultural pesticide refillers and swimming pool supply companies account for less than \$2.6 million and \$180,000 of the total cost of compliance, respectively.

Table 4.17a. Total Annual Costs of the Pesticide Container Rule for Regulated Entities (Interest Rate = 3 percent) (2005\$)

Regul	lated Entities	For the Average Regulated Entity	Number of Regulated Entities	Over All Regulated Entities
Pesticide Registrants				
Large-Small				
Agricultural		\$5,477	66	\$364,061
I/C/G		\$5,459	50	\$272,139
Home & Garden		\$5,352	50	\$266,825
	Average Across Market Sectors ^a	\$5,434		
	Na	ational Total Across	Market Sectors	\$903,024
Medium-Small				
Agricultural		\$2,625	198	\$519,462
I/C/G		\$2,621	148	\$389,096
Home & Garden		\$2,591	148	\$384,601
	Average Across Market Sectors ^a	\$2,613		
	Na	ational Total Across	Market Sectors	\$1,293,158
Small-Small				
Agricultural		\$805	399	\$321,217
I/C/G		\$805	299	\$240,698
Home & Garden		\$788	299	\$235,727
	Average Across Market Sectors ^a	\$800		
	Na	ational Total Across	Market Sectors	\$797,642
Large				
Agricultural		\$23,425	58	\$1,367,998
I/C/G		\$20,881	44	\$914,608
Home & Garden		\$7,774	44	\$340,508
	Average Across Market Sectors ^a	\$17,967		
	Na	ational Total Across	Market Sectors	\$2,623,114
	National Total Across	Market Sectors and	Size Categories	\$5,616,939
Agricultural Pesticide	Refillers			
Large-Small		\$871	251	\$218,684
Medium-Small		\$267	2,395	\$640,191
Small-Small		\$43	13,996	\$605,474
Large		\$7,255	153	\$1,110,296
	Na	ational Total Across	Size Categories	\$2,574,646

Table 4.17a (Continued). Total Annual Costs of the Pesticide Container Rule for Regulated Entities (Interest Rate = 3 percent) (2005\$)

Swimming Pool Supply Companies – Ant	imicrobial Applicators		
Large-Small	\$34	14	\$474
Medium-Small	\$23	117	\$2,732
Small-Small	\$15	174	\$2,602
Large	\$10,000	17	\$169,993
	National Total Across Siz	e Categories	\$175,800
	National Total Across All Regul	ated Entities	\$8,367,385

^a The average pesticide registrant across market sectors is assumed to have the same distribution across market sectors as the distribution of pesticides across market sectors (by volume of pesticide) in the pesticide industry as a whole:

Agricultural sector: 40 percent Industrial/commercial/govt. sector: 30 percent Home & Garden sector: 30 percent

Table 4.17b. Total Annual Costs of the Pesticide Container Rule for Regulated Entities (Interest Rate = 7 percent) (2005\$)

Regulated F	Entities	For the Average Regulated Entity	Number of Regulated Entities	Over All Regulated Entities
Pesticide Registrants		0 √		
Large-Small				
Agricultural		\$6,018	66	\$399,987
I/C/G		\$6,003	50	\$299,243
Home & Garden		\$5,891	50	\$293,661
	Average Across Market Sectors ^a	\$5,975		ŕ
		National Total Across N	Aarket Sectors	\$992,891
Medium-Small				
Agricultural		\$2,865	198	\$567,135
I/C/G		\$2,863	148	\$424,939
Home & Garden		\$2,830	148	\$420,112
	Average Across Market Sectors ^a	\$2,854		
		National Total Across N	Aarket Sectors	\$1,412,186
Small-Small				
Agricultural		\$813	399	\$324,089
I/C/G		\$812	299	\$242,890
Home & Garden		\$794	299	\$237,420
	Average Across Market Sectors ^a	\$807		
		National Total Across N	Aarket Sectors	\$804,400
Large				
Agricultural		\$24,430	58	\$1,426,696
I/C/G		\$22,335	44	\$978,272
Home & Garden		\$8,685	44	\$380,418
	Average Across	\$19,078		
	Market Sectors a	T . 1 . 2		00 - 05 00
		Total Across Market Se		\$2,785,386
A maisulturus Dogtisido D. Cli		ss Market Sectors and S	oize Categories	\$5,994,863
Agricultural Pesticide Refiller	S	Φ 7 < 4	251	0101.603
Large-Small		\$764	251	\$191,692
Medium-Small Small-Small		\$237	2,395	\$566,418
		\$41	13,996	\$572,767
Large		\$6,336	153	\$969,709
	National '	Total Across Size Categ	ories	\$2,300,585

Table 4.17b (Continued). Total Annual Costs of the Pesticide Container Rule for Regulated Entities (Interest Rate = 7 percent) (2005\$)

Swimming Pool Supply Companies – Antimicrobial Applicato	rs	,	
Large-Small	\$33	14	\$458
Medium-Small	\$24	117	\$2,755
Small-Small	\$16	174	\$2,821
Large	\$8,732	17	\$148,448
National	Total Across Size C	Categories	\$154,481
National Total A	Across All Regulate	d Entities	\$8,449,929

^a The average pesticide registrant across market sectors is assumed to have the same distribution across market sectors as the distribution of pesticides across market sectors (by volume of pesticide) in the pesticide industry as a whole:

Agricultural sector: 40 percent Industrial/commercial/govt. sector: 30 percent Home & Garden sector: 30 percent

Costs are presented by regulation in Tables 4.18a and 4.18b. Approximately 16 percent of the cost of compliance is attributed to compliance with the residue removal standards. The refilling-related standards and labeling standards account for 38 percent and 27 percent of the total cost of compliance, respectively.

Table 4.18a. Total Annual National Cost of Each Regulation Under the Pesticide Container Rule (Interest Rate = 3 percent) (2005\$)

Regulation	Annual National Cost
For Non-Refillable Containers	
DOT Packaging Standards - hazardous material ^a	\$0
DOT Packaging Standards - non-hazardous material ^a	\$0
Closure Standards ^a	\$0
Standards for container dispensing capability ^a	\$0
Residue Removal standards ^a	\$1,465,967
Other administrative requirements – recordkeeping	\$202,617
For Refillable Containers	
DOT Packaging Standards - hazardous material ^a	\$0
DOT Packaging Standards - non-hazardous material ^a	\$0
Standards for container markings	\$241,402
Standards for openings (for liquid minibulks only)	\$261,018
Bulk container standards	\$574,504
Other administrative requirements – recordkeeping	\$138,849
For Refilling	\$3,198,256
For Labeling	\$2,252,148
Cost of Waivers	\$32,624
Total National Cost Annually	\$8,367,385

^a Incorporates waivers for 5 percent of pesticide registrants.

Table 4.18b. Total Annual National Cost of Each Regulation Under the Pesticide Container Rule (Interest Rate = 7 percent) (2005\$)

Regulation	Annual National Cost
For Non-Refillable Containers	
DOT Packaging Standards - hazardous material ^a	\$0
DOT Packaging Standards - non-hazardous material ^a	\$0
Closure Standards ^a	\$0
Standards for container dispensing capability ^a	\$0
Residue Removal standards ^a	\$1,343,068
Other administrative requirements – recordkeeping	\$210,575
For Refillable Containers	
DOT Packaging Standards - hazardous material ^a	\$0
DOT Packaging Standards - non-hazardous material ^a	\$0
Standards for container markings	\$227,685
Standards for openings (for liquid minibulks only)	\$291,648
Bulk container standards	\$641,923
Other administrative requirements – recordkeeping	\$136,753
For Refilling	\$2,849,969
For Labeling	\$2,715,685
Cost of Waivers	\$32,624
Total National Cost Annually	\$8,449,929

^a Incorporates waivers for 5 percent of pesticide registrants.

4.7 Impact Analysis

The impact of the pesticide container rule on a regulated entity is measured as the ratio of that entity's annual cost of complying with the rule to its annual revenue. The impacts of the rule are estimated using both a 3 percent interest rate and a 7 percent interest rate. Estimated impacts are given for the average regulated entity in each combination of market sector and size class in Tables 4.19a and 4.19b. For all regulated entities (at both 3 percent and 7 percent) the annual cost to revenue ratio is less than 0.02 percent. The highest ratios are associated with the small pesticide registrants. Agricultural pesticide refillers and swimming pool supply companies have annual cost to revenue ratios very close to zero.

Table 4.19a. Ratio of Annual Compliance Cost to Annual Revenue for the Average Regulated Entity (Interest Rate = 3 percent) (2005\$)

	Annual Cost For		Annual Cost-
	the Average	Annual Revenue	Revenue Ratio For
	Regulated	For the Average	the Average
Regulated Entities ^a	Entity b	Regulated Entity ^c	Regulated Entity
Small Pesticide Registrants			
Agricultural	\$1,817	\$9,439,902	0.02%
I/C/G	\$1,813	\$9,439,902	0.02%
Home & Garden	\$1,784	\$9,439,902	0.02%
Large-Small Pesticide Registrants			
Agricultural	\$5,477	\$52,676,100	0.01%
I/C/G	\$5,459	\$52,676,100	0.01%
Home & Garden	\$5,352	\$52,676,100	0.01%
Medium-Small Pesticide Registrants			
Agricultural	\$2,625	\$9,758,400	0.03%
I/C/G	\$2,621	\$9,758,400	0.03%
Home & Garden	\$2,591	\$9,758,400	0.03%
Small-Small Pesticide Registrants			
Agricultural	\$805	\$2,075,800	0.04%
I/C/G	\$805	\$2,075,800	0.04%
Home & Garden	\$788	\$2,075,800	0.04%
Large Pesticide Registrants			
Agricultural	\$23,425	\$7,363,740,000	0.00%
I/C/G	\$20,881	\$7,363,740,000	0.00%
Home & Garden	\$7,774	\$7,363,740,000	0.00%
Agricultural Pesticide Refillers			
Small	\$88	\$1,985,935	0.00%
Large-Small	\$871	\$22,705,400	0.00%
Medium-Small	\$267	\$6,730,300	0.00%
Small-Small	\$43	\$802,500	0.01%
Large	\$7,255	\$191,604,900	0.00%
Swimming Pool (Antimicrobial) Supply			
Companies			
Small	\$19	\$1,537,432	0.00%
Large-Small	\$34	\$5,266,697	0.00%
Medium-Small	\$23	\$2,620,614	0.00%
Small-Small	\$15	\$509,031	0.00%
Large	\$10,000	\$2,511,092,910	0.00%

^a Average cost for the small size category is calculated by adding the cost for the small-small, medium-small, and large-small categories and dividing the sum by the total number of companies in the small size category. Similarly, the average revenue for the small size category was calculated by adding the total revenue for each of its component size categories and dividing the sum by the total number of companies in the small size category.

^b Annual cost of the average regulated entity is calculated by dividing the total cost for the regulated entities by the total number of entities under the scope of the rule.

^c Annual average revenue for the average regulated entity is calculated by dividing the total revenue by the total number of entities.

Table 4.19b. Ratio of Annual Compliance Cost to Annual Revenue for the Average Regulated Entity (Interest Rate = 7 percent) (2005\$)

	Annual Cost For	Annual Revenue For	Annual Cost-
	the Average	the Average	Revenue Ratio For
D	Regulated	Regulated	the Average
Regulated Entities ^a Small Pesticide Registrants	Entity ^b	Entity ^c	Regulated Entity
Agricultural	¢1.047	¢0.420.002	0.020/
I/C/G	\$1,947	\$9,439,902	0.02%
Home & Garden	\$1,944	\$9,439,902	0.02%
Large-Small Pesticide Registrants	\$1,912	\$9,439,902	0.02%
Agricultural	¢ (010	¢52 (7(100	0.010/
I/C/G	\$6,018	\$52,676,100	0.01%
Home & Garden	\$6,003	\$52,676,100	0.01%
	\$5,891	\$52,676,100	0.01%
Medium-Small Pesticide Registrants	Φ2.065	ФО 750 400	0.020/
Agricultural I/C/G	\$2,865	\$9,758,400	0.03%
	\$2,863	\$9,758,400	0.03%
Home & Garden	\$2,830	\$9,758,400	0.03%
Small-Small Pesticide Registrants	***	** • ** • • • • • • • • • • • • • • • • • •	0.0404
Agricultural	\$813	\$2,075,800	0.04%
I/C/G	\$812	\$2,075,800	0.04%
Home & Garden	\$794	\$2,075,800	0.04%
Large Pesticide Registrants			
Agricultural	\$24,430	\$7,363,740,000	0.00%
I/C/G	\$22,335	\$7,363,740,000	0.00%
Home & Garden	\$8,685	\$7,363,740,000	0.00%
Agricultural Pesticide Refillers			
Small ag. pesticide refillers	\$80	\$1,985,935	0.00%
Large-Small ag. pesticide refillers	\$764	\$22,705,400	0.00%
Medium-Small ag. pesticide refillers	\$237	\$6,730,300	0.00%
Small-Small ag. pesticide refillers	\$41	\$802,500	0.01%
Large ag. pesticide refillers	\$6,336	\$191,604,900	0.00%
Swimming Pool (Antimicrobial) Supply			
Companies			
Small swimming pool supply companies	\$20	\$1,537,432	0.00%
Large-Small swimming pool supply companies	\$33	\$5,266,697	0.00%
Medium-Small swimming pool supply companies	\$24	\$2,620,614	0.00%
Small-Small swimming pool supply companies	\$16	\$509,031	0.00%
Large swimming pool supply companies	\$8,732	\$2,511,092,910	0.00%

^a Average cost for the small size category is calculated by adding the cost for the small-small, medium-small, and large-small categories and dividing it by the total number of companies in the small size category. Similarly, the average revenue for the small size category was calculated by dividing the total revenue for each of its component size category and dividing it by the total companies in this size category.

^b Annual cost of the average regulated entity is calculated by dividing the total cost for the regulated entities by the total number of entities under the scope of the rule.

^c Annual average revenue for the average regulated entity is calculated by dividing the total revenue by the total number of entities.

For purposes of the analysis under the Small Business Regulatory Enforcement and Fairness Act (SBREFA), we combined the three sub-categories of small businesses within the "small" size class (i.e., large-small, medium-small, and small-small) into a single "small" size class for each regulated entity type in Tables 4.19a and 4.19b. A threshold for regulations potentially causing significant impacts to small businesses is an annual cost to revenue ratio of greater than 1 percent. As is evident from these tables, in no case are annual compliance costs for the average small regulated entity expected to exceed 0.02 percent of annual average revenue. As a result, significant impacts on small businesses are not expected as a result of the container regulations. The ratio is highest among small entities for small pesticide registrants, at 0.02 percent. Small agricultural pesticide refillers and small swimming pool supply companies are estimated to have annual revenue to cost ratios very close to zero.

We found similar results using the alternative definition of small businesses used in the EA. The impacts to small businesses using the alternative definition, in terms of the annual revenue to cost ratio, are estimated to be no more than 0.04 percent. As with the SBA-defined small entities, the highest ratio is measured for small pesticide registrants—ranging from a ratio of 0.01 percent for large-small registrants to 0.04 percent for small-small registrants. The annual cost to revenue ratio does not change using the alternative definition of small business (versus the SBA definition) for small agricultural pesticide refillers and small swimming pool supply companies. Redefining the small pesticide registrant has provided more information in regards to the impacts expected across the spectrum of small businesses impacted by the container regulations, but the impacts still remain below the threshold of causing a significant impact to small businesses.

4.8 Sensitivity Analysis

Many of the assumptions present in the preceding cost analysis discussion (and presented in detail in Appendix A) are inherently uncertain, though every effort has been made to use the best available data to inform our assumptions. Despite efforts to minimize the uncertainty, uncertainty remains. It is important, therefore, to attempt to characterize the impact that this uncertainty has on the magnitude of the total regulatory compliance costs we have estimated for the container regulations.

To test the sensitivity of total cost estimates to the assumptions in the analysis, compliance costs have been recalculated based on a suite of lower- and upper-bound assumptions that bound the central cost estimate presented in the primary analysis. The lower-bound suite of assumptions is composed of adjustments to the primary assumptions that lower the overall container regulations compliance cost. The upper-bound suite of assumptions is composed of adjustments to the primary assumptions that increase the overall compliance cost for the container regulations. We calculated the resulting upper- and lower-bound costs in the same manner as described in the preceding sections. We used a 3 percent discount rate to calculate the present discounted value of costs and in the annualization of those costs.

Parameters were selected for sensitivity analysis based on the following two criteria:

- (1) Total costs appear particularly sensitive to a given assumption; and
- (2) We have a reasonable idea regarding what the lower and upper bounds of a given assumption should be.

The sensitivity analysis is summarized in Table 4.20. As compared to the total cost estimate of \$8.4 million (3 percent discount rate) and \$8.5 million (7 percent discount rate), the "low-end" total cost is \$4.9 million, while the "high-end" estimate is \$11.0 million. ⁵² The low-end total cost estimate is 42 percent lower than the total cost under primary assumptions, while the high-end estimate is 32 percent higher.

Table 4.20. Annual National Cost of Regulation Under the Pesticide Container Rule (2005\$)

Sensitivity Scenario	Annual Cost Nationally
3% discount rate	\$8,367,385
7% discount rate	\$8,449,929
Low (3% discount rate)	\$4,852,818
High (3% discount rate)	\$11,043,774

The underlying suites of "low-end" and "high-end" assumptions are given in Table 4.21. The detailed breakdown of resulting costs are shown in Tables 4.22 and 4.23, based on the "low-end" suite of assumptions, and in Tables 4.24 and 4.25 based on the "high-end" suite of assumptions. These tables show the same set of total cost results that were shown for the primary analysis in Tables 4.17a, 4.17b, 4.18a, and 4.18b.

In order to assess the sensitivity of the cost estimates to the different assumptions, we calculated the percentage reduction in total costs associated with a change in each assumption for the "lowend" assumption. We find that the largest percentage reduction in cost is because of changes in the labeling requirements (22 percent). Under the primary cost assumption we assume that 50 percent of the label changes are "routine" and incur only one-third of the label change cost and 50 percent of the label changes are "necessary" and incur all the label change cost, while in the "low-end" cost assumptions we assume that all label changes are "routine." Since the labeling change cost is high, ranging from \$205 for a "routine" change small-small establishments to \$5,069 for a "necessary" change for all establishments except the small-small, changes in the assumptions about the number of entities for which this is a "routine" or a "necessary" change have a fairly significant implication on the cost.

The assumption about the percentage of container/formulations combinations that will be exempt from residue removal testing because of similarities to other container/formulations combinations ("me-toos") led to a 4 percent reduction in cost. Changing the percentage of containers that pass the initial residue removal test from 30 percent to 0 percent reduced the cost by 5 percent. Reducing the labor time assumptions by 25 percent for the refilling compliance criteria reduces the cost by 9 percent, while for standards for container markings and

⁵² Both cost estimates are based on a 3 percent discount rate.

administrative requirements for both non-refillables and refillables, the reduction in labor time assumptions by 25 percent reduces the cost by less than 2 percent.

In addition to the above assumption, we also considered the sensitivity of the cost analysis to changes in the assumption about the time it takes to inspect containers. The analysis assumes that on average it takes about 1 minute to inspect containers. Given that a relatively larger number of containers are small, this seems reasonable. When we change the inspection time to 5 minutes, the total cost estimate increases to \$10.5 million, which is a significant increase. It is not clear, however, that 5 minutes is a more reasonable assumption for the amount of time it takes to inspect containers. Although it is conceivable that in reality large containers take about 5 minutes and smaller containers take less, we did not have data to support different inspection times for different container sizes.

Table 4.21. "Low-End" and "High-End" Assumptions for Sensitivity Analysis

Regulation	"Low-End" Cost Assumptions	Primary Cost Assumptions	"High-End" Cost Assumptions
Non-Refillable Sensitivity	Tests		
Residue Removal Standard - Percent of Containers Retested ^a	All containers pass the initial residue removal test.	30% of the containers pass the initial residue removal test.	50% of the containers pass the residue removal test.
Residue Removal Standard - "Me-Toos" ^b	50% of all container/formulations combinations exempt from residue removal testing.	25% of all container/formulation combinations exempt from residue removal testing.	No container/formulation combinations exempt from residue removal testing.
Administrative Requirements - Recordkeeping ^c	Reduce labor time assumptions by 25%.	Large and Large-Small Establishments: 40 hours for existing container/formulation combinations and 4 hours for new container/formulation combinations. Medium-Small Establishments: 36 hours for existing container/formulation combinations and 3 hours for new container/formulation combinations Small-Small Establishments: 24 hours for existing container/formulation combinations and 2 hours for new container/formulation combinations and 2 hours for new container/formulation combinations	Increase labor time assumptions by 25%.
Refillable Sensitivity Tests	<u> </u>	Comomacions	
Administrative Requirements - Recordkeeping ^c	Reduce labor time assumptions by 25%.	Large and Large-Small Establishments: 31 hours for existing container/formulation combinations and 4.4 hours for new container/formulation combinations. Medium-Small Establishments: 21 hours for existing container/formulation combinations and 2.5 hours for new container/formulation combinations Small-Small Establishments: 11 hours for existing container/formulation combinations and 2 hours for new container/formulation combinations and 2 hours for new container/formulation combinations	Increase labor time assumptions by 25%.

Table 4.21. "Low-End" and "High-End" Assumptions for Sensitivity Analysis

Regulation	"Low-End" Cost Assumptions	Primary Cost Assumptions	"High-End" Cost Assumptions
Standards for Container Marking ^c	Reduce labor time assumptions by 25%.	It takes 5 minutes to mark each container.	Increase labor time assumptions by 25%.
Refiller Sensitivity Tests			
Refilling Compliance Criteria ^d	Reduce labor time assumptions by 25%.	For each refill, it takes 1 minute to inspect, 10 minutes to rinse, and 2 minutes to record information about a container.	Increase labor time assumptions by 25%.
Facility-Level Sensitivity	Γests		
Labeling Requirements ^e	Assume that all label changes during the compliance period are "routine" changes and incur only one-third of the label change cost.	Assume that 50% of label changes are "routine" and incur only one-third of the label change cost, and 50% of label changes are "necessary" and incur all of the label change cost.	Assume that all label changes during the compliance period are "necessary" and incur all of the label change cost.

^a Primary cost assumption based on final container regulations that require containers to achieve only a four-9s standard. It is assumed that all containers will pass the four-9s standard as a lower bound. The high-end assumption is based on a container's ability to achieve a six-9s standard. See EPA (1993, p. IX-13).

^b In the proposed container rule RIA, EPA made a lower cost assumption that 50 percent of container/formulation combinations would be exempt from residue removal testing because of similarities to other container/formulation combinations ("me-toos"). EPA's upper cost assumption stated that all container/formulations would be tested. These high- and low-end cost assumptions are retained here and use the mid-point between the two as the primary cost assumption. See EPA (1993, p. IX-13).

^c Labor times used in the primary analysis are based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, p. IX-13). It is assumed that plus or minus 25 percent of the labor time used in the primary analysis is a reasonable uncertainty bound.

^d Using professional judgment, based on estimates made by EPA in the proposed container rule RIA as a baseline (EPA, 1993, p. IX-13), the labor times associated with the primary cost assumptions are estimated.

^e The primary cost assumption is based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pp. X-1 through X-7). We believe a reasonable lower cost assumption is that all label changes during the compliance period are considered "routine" (therefore incurring only one-third the cost of changing a label). A reasonable high-end cost assumption is that all label changes during the compliance period are considered "necessary" (therefore incurring the total cost of changing a label). The primary analysis assumes that during the compliance period 50 percent of label changes are routine and the rest are necessary.

Table 4.22. Total Annual Costs of the Pesticide Container Rule for Regulated Entities: Using "Low End" Assumptions (Interest Rate = 3 percent) (2005\$)

Regulated Entities		For the Average Regulated Entity	Number of Regulated Entities	Over All Regulated Entities
Pesticide Registrants		•		
Large-Small	•	_	-	
Agricultural		\$1,745	66	\$115,978
I/C/G		\$1,734	50	\$86,438
Home & Garden		\$1,635	50	\$81,496
	Average	\$1,709	20	Ψ01,170
	Across Market	42,. 02		
	Sectors a			
	National To	tal Across Mark	et Sectors	\$283,912
Medium-Small	•			
Agricultural		\$884	198	\$174,928
I/C/G		\$882	148	\$130,895
Home & Garden		\$850	148	\$126,118
	Average	\$873	1.0	ψ1 = 0,110
	Across Market	40.0		
	Sectors a			
	National To	tal Across Mark	et Sectors	\$431,941
Small-Small				
Agricultural		\$384	399	\$153,067
I/C/G		\$383	299	\$114,671
Home & Garden		\$367	299	\$109,788
	Average	\$379	2,,,	Ψ105,700
	Across Market Sectors ^a	φ υ , γ		
	National To	tal Across Mark	et Sectors	\$377,527
Large	-		<u>.</u>	
Agricultural		\$15,778	58	\$921,459
I/C/G		\$14,249	44	\$624,126
Home & Garden		\$2,185	44	\$95,699
	Average	\$11,242	••	Ψ, Σ, Ο, ,
	Across Market			
	Sectors a	tal Aanass Mank	ot Contown	¢1 (41 3 03
		tal Across Marko Across Market Se		\$1,641,283 \$2,734,662
	National Total P	icross Market Se	Categories	\$2,734,002
Agricultural Pesticide Refillers			Categories	
Large-Small ag. pesticide refillers		\$657	251	\$164,824
Medium-Small ag. pesticide refillers		\$037 \$267	\$204	2,395
Small-Small ag. pesticide		φ207	\$204	2,393
refillers		\$36	13,996	\$499,340
Large ag. pesticide refillers		\$5,445	15,750	\$833,217
	National Total	Across Size Cates	ories	\$1,985,265

Table 4.22 (Continued). Total Annual Costs of the Pesticide Container Rule for Regulated Entities: Using "Low End" Assumptions (Interest Rate = 3 percent) (2005\$)

Regulated Entities	For the Average Regulated Entity	Number of Regulated Entities	Over All Regulated Entities
Swimming Pool Applicators – Antimicrobial			
Applicators			
Large-Small swimming pool applicators	\$29	14	\$401
Medium-Small swimming pool applicators	\$21	117	\$2,427
Small-Small swimming pool applicators	\$14	174	\$2,514
Large swimming pool applicators	\$7,503	17	\$127,549
National Total	Across Size Cate	gories	\$132,891
National Total Across All Regulated Entities \$4,852,5			\$4,852,818

^a The average pesticide registrant across market sectors is assumed to have the same distribution across market sectors as the distribution of pesticides across market sectors (by volume of pesticide) in the pesticide industry as a whole:

Agriculture sector: 40 percent Industrial/Commercial/Govt.: 30 percent Home and Garden: 30 percent

Table 4.23. Total Annual National Cost of Each Regulation Under the Pesticide Container Rule: Using "Low End" Assumptions (Interest Rate = 3 percent) (2005\$)

Regulation	Annual National Cost
For Non-Refillable Containers	
DOT Packaging Standards - hazardous material ^a	v
DOT Packaging Standards - non-hazardous material ^a	\$0
Closure Standards ^a	\$0
Standards for container dispensing capability ^a	\$0
Residue Removal standards ^a	\$708,913
Other administrative requirements – recordkeeping	\$151,963
For Refillable Containers	
DOT Packaging Standards - hazardous material ^a	\$0
DOT Packaging Standards - non-hazardous material ^a	\$0
Standards for container markings	\$181,065
Standards for openings (for liquid minibulks only)	\$261,018
Bulk container standards	\$574,504
Other administrative requirements – recordkeeping	\$109,480
For Refilling:	\$2,458,094
For Labeling:	\$393,188
Cost of Waivers:	\$14,594
Total National Cost Annually	\$4,852,818

^a Incorporates waivers for 5 percent of pesticide registrants.

Table 4.24. Total Annual Costs of the Pesticide Container Rule for Regulated Entities: Using "High End" Assumptions (Interest Rate = 3 percent) (2005\$)

Regulated Entities	For the A Regulated		Number of Regulated Entities	Over All Regulated Entities
Pesticide Registrants:				
Large-Small				
Agricultural		\$8,227	66	\$546,825
I/C/G		\$8,201	50	\$408,850
Home & Garden		\$8,087	50	\$403,165
Avei Mar	rage Across ·ket Sectors ^a	\$8,177		
	National Total Across I	Market Sect	tors:	\$1,358,840
Medium-Small				
Agricultural		\$3,874	198	\$766,744
I/C/G		\$3,869	148	\$574,358
Home & Garden		\$3,838	148	\$569,658
Avei	rage Across Market Sectors ^a	\$3,862		
	National Total Across I	Market Sect	tors:	\$1,910,760
Small-Small				
Agricultural		\$974	399	\$388,510
I/C/G		\$973	299	\$291,083
Home & Garden		\$956	299	\$286,024
Avei	rage Across Market Sectors a	\$969		ŕ
	National Total Across I	Market Sect	tors:	\$965,617
Large				,
Agricultural		\$29,842	58	\$1,742,799
I/C/G		\$26,285	44	\$1,151,286
Home & Garden		\$12,135	44	\$531,518
Avei	rage Across Market Sectors ^a	\$23,463		
	National Total Across I	Market Sect	tors:	\$3,425,603
Nat	tional Total Across Market Se	ctors and Si	ize Categories:	\$7,660,820
Agricultural Pesticide Refillers			•	, ,
Large-Small ag. pesticide				
refillers		\$1,086	251	\$272,544
Medium-Small ag. pesticide refillers		\$331	\$331	2,395
Small-Small ag. pesticide refillers		\$51	\$51	13,996
Large ag. pesticide refillers		\$9,066	153	\$1,387,376
	National Total Across S	Size Catego	ries:	\$3,164,027

Table 4.24 (Continued). Total Annual Costs of the Pesticide Container Rule for Regulated Entities: Using "High End" Assumptions (Interest Rate = 3 percent) (2005\$)

Swimming Pool Applicators – Antimicrobial A	applicators	• / / /	,
Large-Small swimming pool applicators	\$39	14	\$548
Medium-Small swimming pool applicators	\$26	117	\$3,037
Small-Small swimming pool applicators	\$15	174	\$2,690
Large swimming pool applicators	\$12,496	17	\$212,436
	National Total Across S	Size Categories	\$218,710
	National Total Across All Reg	ulated Entities	\$11,043,557

^a The average pesticide registrant across market sectors is assumed to have the same distribution across market sectors as the distribution of pesticides across market sectors (by volume of pesticide) in the pesticide industry as a whole:

Agriculture sector: 40 percent Industrial/Commercial/Govt.: 30 percent Home and Garden: 30 percent

Table 4.25. Total Annual National Cost of Each Regulation Under the Pesticide Container Rule: Using "High End" Assumptions (Interest Rate = 3 percent) (2005\$)

D 1.0		Annual National
Regulation		Cost
For Non-Refillable Containers		
DOT Packaging Standards - hazardous material ^a		\$0
DOT Packaging Standards - non-hazardous material ^a		\$0
Closure Standards ^a		\$0
Standards for container dispensing capability ^a		\$0
Residue Removal standards ^a		\$1,403,140
Other administrative requirements – recordkeeping		\$253,271
For Refillable Containers		
DOT Packaging Standards - hazardous material ^a		\$0
DOT Packaging Standards - non-hazardous material ^a		\$0
Standards for container markings		\$301,743
Standards for openings (for liquid minibulks only)		\$261,018
Bulk container standards		\$574,504
Other administrative requirements – recordkeeping		\$167,730
For Refilling		\$3,938,418
For Labeling		\$4,111,108
Cost of Waivers		\$32,624
	Total National Cost Annually	\$11,043,557

^a Incorporates waivers for 5 percent of pesticide registrants.

5.0 The Human and Non-Human Health Benefits of the Final Standards

5.1 Introduction

The container design and residue removal standards are largely pollution prevention regulations that will safeguard workers, such as loaders, mixers, and applicators, and the environment by reducing the risk of exposure to concentrated pesticides. First, the proposed improvements in pesticide container designs will enhance the safe handling, dispensing, use, and residue removal efficiency of pesticide containers. Second, the improvement in procedures and/or container designs will help facilitate the "clean rinsing" of emptied containers either prior to disposal or recycling, or prior to reuse. There are numerous types of human health-related benefits and non-human health-related (environment-related) benefits that will stem from such improvements because of relatively fewer expected spills, leaks, and other risks associated with exposure (e.g., handling by workers during disposal, discharges to the environment, and potential public exposures).

Table 5.1 summarizes the various types of expected benefits (i.e., improved worker safety, improved public health, reduced environmental risk, and other effects) resulting from the proposed container design/residue removal regulations. It also characterizes the sources of the expected benefits. Besides human health-related and environment-related benefits, there are other effects such as property damage, personal liability effects, and insurance costs that contribute to the overall benefits assessment. Due to limitations in the data available on these benefits, there is a high degree of uncertainty concerning both the number and average cost (including unquantifiable components of loss such as pain and suffering) of both container design and residue removal problems. As a result, the costs of all of the expected benefits cannot be quantified. However, data do exist to quantify some of the expected benefits of the regulations. Section 5.2 discusses the method and estimates of the number of pesticide-related illnesses and injuries potentially avoided as a result of the pesticide container regulations and presents the estimated value of these avoided illnesses and injuries. Section 5.3 discusses and estimates the cost savings from the disposal of rigid non-refillable containers as non-hazardous rather than hazardous waste as a result of the regulations, and discusses the potential for a reduction in the number of environmental effects and property damage/spill cleanup costs as a result of the container regulations.

Table 5.1. The Types of Expected Benefits from the Container Design and Residue Removal Regulations and Their Sources

Expected Benefit	Source of Expected Benefit		
	Human Health-Related Benefits		
Improved Worker Safety	 Reduced accidental spills Fewer leaks Less dripping Less frequent container stress failure (durability, formulation/container degradation) Reduced personal sickness and injury Improved worker productivity 		
Improved Public Health	 Less risk of exposure to spills and leaking/dripping Less contamination of surface water and groundwater sources Less personal injury from accidental spills and chronic contamination sources 		
N	Non-Human Health-Related Benefits		
Reduced Environmental Risk	 Reduced accidental spills Fewer chronic accumulations of chemicals in loading/mixing/cleaning areas Reduced risk of harm from pesticide residues to terrestrial and aquatic wildlife including sensitive and critical habitats Less disposal of hazardous containers in landfills 		
Other Effects	 Reduced property damage Reduced risk of personal injury and liability Lower costs for personal liability insurance Reduced disposal costs for cleaner containers Reduced loss of product from spills and leaks 		

5.2 Human Health-Related Benefits: Estimated Annual National Cases and Valuation of Pesticide Product-Related Illnesses and Injuries Potentially Avoided by the Standards

In this section, the annual nationwide number and value of pesticide-related illnesses and injuries potentially avoided as a result of the pesticide container design and residue removal regulations is estimated. The calculations involved in the results and the underlying methodology used in the derivation of the national estimate is described. Section 5.2.1 describes the overall methodological approach used. This is followed in Section 5.2.2 by a discussion of the state data used to derive the percentage of pesticide illnesses potentially related to the container design and residue removal standards. Section 5.2.3 describes the annual national number of pesticide exposures and resulting illnesses to which the state data were applied. Section 5.2.4 discusses the extrapolation of the state data to estimated pesticide illnesses nationwide and provides a discussion of these findings. Finally, Section 5.2.5 describes the approach to valuing the avoided illnesses by estimating the direct and indirect costs for several severity levels of illness. More detailed information on the general and health-related characteristics of the Toxic Exposure Surveillance System (TESS) exposure data subset underlying our discussion in Section 5.2.3 can be found in Appendix H, and additional data on direct costs for physician visits, relevant to Section 5.2.5, is listed in Appendix I. The detailed case summaries from California in 1999 that we used in the analysis (Section 5.2.2) to determine the percentage of pesticide illness potentially related to the container regulations are located in Appendix J.

5.2.1 Summary of Approach

The first step in estimating the number of illnesses expected to be avoided as a result of the container design and residue removal regulations required identifying the available surveillance data on the number of toxic substance related illnesses. After reviewing the available toxic substance surveillance systems, we selected TESS for estimating the number of injuries and illnesses associated with pesticide exposure per year. TESS is a comprehensive surveillance system developed in 1983 by the American Association of Poison Control Centers (AAPCC) to track acute illness and injury related to toxic substances. The system contains detailed toxicological information on poison exposures reported to more than 60 poison centers around the country, capturing an estimated 98.8 percent of all poison exposures reported to poison centers in the United States. We requested a detailed report from AAPCC (2002) describing "unintentional" exposures to fungicides, herbicides, insecticides, rodenticides, non-pine oil disinfectants, and anti-algae paints to estimate the annual number of unintentional pesticide illness cases expected per year. For the purposes of this analysis, we will refer to these conventional and antimicrobial pesticide substance categories as "pesticide products."

Given the estimated annual national illnesses associated with pesticide products in the TESS data, we estimated the percentage of those cases that may have resulted from incidents related to containers and residue removal. The percentage to be applied to the annual number of unintentionally caused pesticide product illnesses from TESS was based on EPA's examination of state-level case history data from California. EPA examined case summaries from the Pesticide Illness Surveillance Program (PISP) database maintained by the California Department of Pesticide Regulation (CDPR) for 1999 and estimated the number of cases that are "very likely," "possibly," and "unlikely" to be avoided as a result of the regulations (CDPR, 2001a,b). The estimates of cases that were "very likely" to be avoided as a result of the regulations were used to calculate the ratio of pesticide container design/residue-related cases to total pesticide product incidents in California. We applied this state-level proportion to the United States as a whole to estimate the annual national number of avoided pesticide product illnesses that are expected as a result of the container design and residue removal regulations.

We purchased a single report from TESS itemizing the exposures involving the TESS pesticide product categories described above. We selected the product categories to most closely resemble the pesticide products covered in the California database. In particular, the active ingredients considered by CDPR as antimicrobials were determined to be covered by the TESS categories queried. Therefore, the percentage of pesticide-related illnesses avoided as a result of the regulations, estimated for California, could be applied to the national number of pesticide-related illnesses queried from TESS. The potential illnesses avoided from the container design and residue removal regulations described are therefore attributable to both antimicrobial and conventional pesticide products.

5.2.2 Derivation of the Annual Percentage of Pesticide Illnesses Potentially Avoided as a Result of the Container Design and Residue Removal Regulations

CDPR conducts ongoing surveillance of people and the environment to detect the potential for pesticide exposure as part of its pesticide safety program. CDPR's PISP has required mandatory reporting of pesticide illnesses since 1971, making it the most comprehensive monitoring

program in the country. Under a California state statute, physicians are required to report any suspected case of pesticide-related illness or injury to the local health officer within 24 hours of examining the patient.

In addition, CDPR reviews doctor's reports for workers' compensation claims under the pesticide illness surveillance program. Staff members investigate any claim that mentions (1) pesticides as a possible cause of illness or injury or (2) unspecified chemicals if the setting is one in which pesticide use is likely. CDPR also works with the California Poison Control System to facilitate reporting of pesticide-related illnesses by health care workers.

To estimate the percentage of unintentional pesticide product illnesses potentially avoided as a result of the container regulations, it is first necessary to determine the number of unintentional pesticide product-related illnesses in California. In 1999, CDPR reported 1,201 episodes in which the pesticide exposure was at least a possible contributing factor to illness or injury.⁵³ The number of intentional cases occurring in California, however, is not readily available in a summary report.

We examined the case summaries for a subset of the 1,201 CDPR cases in 1999, corresponding to a query on particular activity patterns.⁵⁴ Sixteen potential cases of intentional ingestion were identified among this subset, 15 of which were conventional pesticides and one antimicrobial. The 1999 CDPR summary table of pesticide-related illnesses summarized by activity and type of exposure reports that 35 of the 1,201 total incidents occurred as a result of ingestion (CDPR, 2001b). Of the 35 cases, only 10 would have been excluded in the subset examined, corresponding to "routine indoor" and "routine outdoor" activities.⁵⁵ Assuming that (1) pesticide ingestion would be the only means of intentional exposure and (2) none of the ingestion exposures occurring during "routine indoor" and "routine outdoor" activities were intentional, the 16 intentional incidents identified from case reports should reflect the total number of intentional pesticide-related illnesses in the CDPR database. Using these assumptions, it was estimated that for 1999, 1,185 of the pesticide cases in California were due to unintentional exposures.

⁵³ 1999 incident data is representative of the other years for which data have been analyzed relative to the container regulations. In 1999 there were 16 container related cases while from 1995-1999 there were on an average 15 container related cases.

⁵⁴ A total of 489 case summaries resulted from EPA's query of the 1999 CDPR incident database. The query was for incidents from the following field "activities," during which EPA believes container-related illnesses are likely to occur:

⁽¹⁾ Occupational: Mixer/loader, aerial (code 111); Mixer/loader, ground (112); Mixer/loader, hand (113); Applicator, hand (123); Applicator, other (124); Repair/maintenance (160); Exposed to concentrate (182); Emergency response (183); Other (199)

⁽²⁾ Non-Occupational: Application (220); Other (299).

⁵⁵ The CDPR incident database defines routine indoor and outdoor activity in the following way:

⁽¹⁾ Routine indoor activity: Conducts activities in an indoor environment with minimal expectation for exposure to pesticides. This includes people in offices and businesses, residential structures, etc., who are not handling pesticides.

⁽²⁾ Routine outdoor activity: Conducts activities in an outdoor environment with minimal expectation for exposure to pesticides. This excludes field workers in agricultural fields. This includes gardeners who are not handling pesticides.

Furthermore, since pine oil will not be subject to the regulations, and since it was not included in the revised TESS query, the cases in 1999 that involved pine oil must also be excluded. In the 1999 CDPR summary table of pesticide-related illnesses summarized by pesticide, it is reported that seven cases involved pine oil (CDPR, 2001a). However, the single antimicrobial intentional case identified above also involved pine oil; therefore, an additional six cases were ultimately excluded from the total number of unintentional pesticide product-related illnesses in California. The breakdown of pesticide product cases is summarized in Table 5.2.

Table 5.2. Number of Reported Total, Intentional, and Pine Oil-Related Illnesses ^a in California's Pesticide Illness Surveillance Program in 1999

Description	Number of Cases
Total Cases ^a	1,201
Intentional, antimicrobial pesticide case	1
Intentional, conventional pesticide cases	15
Pine oil cases	6
Total Unintentional Pesticide Product Cases	1,179

^a Only those cases in which the relationship between pesticide exposure and illness is designated as "possible," "probable," or "definite" are included.

To estimate the number of potentially avoided cases as a result of the rule, EPA examined the full set of 1999 CDPR cases summaries with regards to the container design and residue removal standards and whether or not an antimicrobial chemical would be subject to the regulations. The likelihood that an incident would have been prevented by the regulations was categorized into three groups:

- V = very likely the incident would have been prevented by the container regulations;
- P = possible the incident would have been prevented by the container regulations; and
- U = unlikely the incident would have been prevented by the container regulations.⁵⁶

EPA estimated that seven conventional pesticide illnesses and nine antimicrobial pesticide illnesses would be subject to and were "very likely" to be prevented by the regulations. These cases represent 1.36 percent of the 1,179 incidents in California that were due to unintentional, non-pine oil exposures. A flow chart showing the distribution of CDPR cases is presented in Figure 5.1.

In addition to the 16 incidents designated as "very likely" avoided by the rule, 51 incidents were are designated by EPA as "possibly" avoided: 15 conventional pesticide illnesses "possibly"

⁵⁶ An example of each category of likelihood (very likely, possibly, and unlikely, respectively) that an incident would have been prevented by the container regulations:

Case 1999-511 (glyphosate): While preparing to spray weeds, a homeowner pulled up on the plunger of a ready-to-use glyphosate container. The plunger handle broke off, allowing glyphosate to spray up into his face. He felt irritant symptoms, so he showered and sought medical attention.

Case 1999-56 (cypermethrin): A courtesy clerk dropped a can of insecticide as she returned it to the shelf. When she picked it up, it exploded in her face. She washed but developed symptoms 30 minutes later.

Case 1999-932 (methyl bromide): Two workers tried to remove the custom locking caps from a methyl bromide cylinder and replace it with a standard cap before returning the cylinder to the dealer. The valve was opened and released methyl bromide.

avoided as a result of the regulations; 30 non-exempt antimicrobial illnesses "possibly" avoided as a result of the regulations; and six antimicrobial illnesses that would "very likely" be avoided if subject to the regulations, but for which it is unclear from the information provided if they are subject to the regulations.

1201 total CDPR illness "possibly" , "probably" or "definitely" related to pesticide exposure. 385antimicrobial 815 nonantimicrobial related illnesses related illnesses 1 (pine oil) case 379 cases from 15 cases from 800 cases from from intentional unintentional unintentional intentional exposure + exposure exposure exposure 9 cases "very 331 cases 39 cases 7 cases 15 cases 778 cases "unlikely" "possibly" likely" related "unlikely" "unlikely" "unlikely" related to related to to container related to related to related to container container design and container container container design and design and residue design and design and design and residue residue removal residue residue residue removal standards removal removal removal removal 30/1179 = 2.54% cases 6/1179 = 0.51% cases 16/1179 = 1.36%15/1179 = 1.27%involving non-exempt involving antimicrobials pesticide and pesticide related antimicrobials possibly but whether subject to antimicrobials-related illnesses potentially prevented by the container regulations illnesses occurring in avoided by the container regulations and/or insufficient CA potentially avoided container design and by the container design information residue removal

Figure 5.1. Flow Chart of 1999 California Department of Pesticide Regulation (CDPR) Pesticide-Related Incidents

These 51 incidents are potentially avoided as a result of the regulations and if included in the analysis, would increase the percentage of unintentional pesticide product cases by 4.33 percent (51 of 1,179 cases). For the purposes of extrapolating California data to the national analysis and valuing the avoided cases, only those cases identified as "very likely" avoided by the regulations are included (16 of 1,179 cases). It is important to note, however, that additional benefits would be realized if a portion of these "possible" cases are also avoided as a result of the regulations.

In estimating the percentage of pesticide product-related illnesses potentially avoided, no adjustment was made for the proportion of pesticide users (e.g., end users, pesticide formulators, pesticide registrants) already in compliance with the new regulations. Although some percentage of pesticide users will already be in compliance, it was assumed that any pesticide user already in compliance should not experience illnesses related to container design and residue removal. Consequently, any container-related illnesses captured by CDPR's database should reflect entities that are not in compliance and, therefore, potentially avoided as a result of the regulations.

In addition, no adjustment was made based on the percentage of containers covered by the regulations due to toxicity category. We assumed that those container-related exposures resulting in illnesses and physician visits would have high enough toxicity levels to be covered by the regulations. To the extent to which some of the illnesses observed in the CDPR database were due to pesticide containers excluded by the regulations, the potential benefits could be overstated.

5.2.3 Profile of Annual National Pesticide Exposure Cases

In the previous section, it was estimated from the California PISP database for 1999 that approximately 1.36 percent (16 of 1,179 unintentional conventional or antimicrobial pesticide cases) of illnesses related to pesticide products occurring in California were likely to have been avoided as a result of the container design and residue removal standards. To estimate the number of illnesses to which this proportion may translate nationwide, this ratio is applied to the annual number of unintentional conventional and antimicrobial pesticide-related illnesses occurring across the country.⁵⁷ To determine the number of injuries and illnesses related to pesticide products throughout the United States on an annual basis, an annual detailed report of 2001 TESS data was acquired from the American Association of Poison Control Centers (AAPCC, 2002). Since TESS is a national surveillance system database in which reports of human *exposures* are recorded, the number of exposure cases that resulted in *illness* was determined before applying the ratio. This overall methodology is described below in more detail, including the query of TESS exposure data submitted (Section 5.2.3.1) and the estimated number of illnesses resulting from pesticide-related unintentional exposures (Section 5.2.3.2).

5.2.3.1 TESS Database Query

After reviewing the format of the findings published in the annual summary, a detailed 2001 TESS report was requested from AAPCC of "unintentional" exposures to the following

⁵⁷ In using this methodology, it is assumed that the ratio for California would not differ significantly for the United States as a whole.

conventional and antimicrobial pesticide substance categories. As described earlier, for the purposes of this analysis these substances are referred to as "pesticide products":

- Fungicides;
- Herbicides;
- Insecticides:
- Rodenticides:
- Non-pine oil disinfectants; and
- Anti-algae paints.

These categories are determined by AAPCC, and more detailed examples of included substances are identified in the annual summary published in the *American Journal of Emergency Medicine* (Litovitz et al., 2002). The illnesses resulting from exposures in which these substances are implicated were made compatible with those evaluated in CDPR's PISP by excluding cases involving pine oil. Similarly, because intentional cases were excluded from the California dataset in order to estimate the number of *potentially* avoided cases, the underlying reason for the exposure was required to be "unintentional." Therefore, it was requested that these data be limited only to those resulting from "unintentional" exposures among all other reasons for poison.⁵⁸

In 2001, unintentional exposures accounted for 85.2 percent of all reported human poison exposures (1,931,841 cases out of 2,267,979 reported). Exposures labeled as "intentional" were involved in 11.6 percent, "other" for 0.7 percent, "adverse reaction" for 2.2 percent, and "unknown" for 0.4 percent of total overall exposures. The specific definitions associated with unintentional reasons of exposure are described in Table 5.3.

From the entire TESS database in 2001, of the substances most frequently involved in human exposures, pesticides⁵⁹ accounted for 4 percent of the total number of overall toxic exposures. Among the substances most frequently involved in exposures of children under 6 years of age, pesticides also represented 4 percent of the total. This was slightly higher, at 4.5 percent of the total number of exposures, in adults over 19 years old. By limiting the search criteria for the TESS query, the detailed frequency and distributional information was evaluated just among accidental pesticide poisonings for the specific categories of pesticide products expected to be regulated under the rule. The results of the TESS query showed that in 2001, pesticide products were implicated in 80,978 unintentional exposures. These cases will be referred to as "unintentional exposures to pesticide products." The breakdown of these unintentional pesticide exposure cases by reason is provided in Table 5.3.

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⁵⁸ Other reasons for exposure in TESS were: (1) intentional (e.g., suicidal, abuse, misuse); (2) other (e.g., malicious, contaminant/tampering); (3) adverse reaction (e.g., drug, food); and (4) unknown.

⁵⁹ The pesticide group includes fungicides, herbicides, insecticides, repellents, and rodenticides as itemized in Litovitz, et al. (2002). Repellents were excluded from the query made by EPA.

Table 5.3. Profile of Unintentional Pesticide Exposures by Reason of Exposure

Exposure		With Concomitants ^a		Without Concomitants ^b	
Reason	Description	Number	Percent	Number	Percent
General	Any exposure not specifically defined below	65,766	81.21%	63,809	82.15%
Environmental	Any passive, non-occupational exposure that results from contamination of air, water, or soil (usually but not always caused by man-made contaminations)	6,571	8.11%	6,005	7.73%
Occupational	Any exposure that occurs as a direct result of the person being on the job or in the workplace	2,625	3.24%	2,271	2.92%
Therapeutic Error	An unintentional deviation from a proper therapeutic regimen that results in the wrong dose, incorrect route of administration, administration to the wrong person, or administration of the wrong substance (only exposures to medications or products substituted for medications are included)	603	0.74%	573	0.74%
Misuse	Improper or incorrect use of a non- pharmaceutical substance (exposure unplanned or not foreseen by the patient)	5,018	6.20%	4,694	6.04%
Bite/Sting	All animal bites and stings, with or without envenomation	56	0.07%	21	0.03%
Food Poisoning	Suspected or confirmed food poisoning and ingestion of food contaminated with microorganisms	42	0.05%	18	0.02%
Unknown	Exposure determined to be unintentional but exact reason is unknown	297	0.37%	281	0.36%
Total	·	80,978	100.00%	77,672	100.00%

Source: AAPCC (2002, Report 7 "Reason" and p. 8 "Field Definitions").

The majority (77,672 of 80,978 cases or 95.92 percent) of unintentional pesticide exposures in 2001 involved only a single pesticide product substance. These cases of exposure are detailed in the "Without Concomitants" column in Table 5.3. The remaining fraction (4.08 percent) of unintentional pesticide exposures in 2001 involved more than a single substance, but at least one pesticide product. These cases are reflected in the column "With Concomitants" along with the majority of cases without concomitants, to equal the total number of unintentional exposures to pesticide products for 2001 (80,978). Therefore, the column "With Concomitants" indicates exposures in which a pesticide substance was implicated, but another substance, which may or may not have been another pesticide product, may also have been involved. Since the exposure cases without concomitants only involve a single pesticide product, we considered restricting the analysis to those incidents. However, we did not believe that this would be appropriate since a pesticide product is still implicated in the exposure incident despite the possible co-occurrence of another substance. Therefore, subsequent estimates are based on the data that *included* concomitants.

^a "With Concomitants" indicates that a pesticide substance was implicated in the exposure case but could have involved another substance which may or may not have been another pesticide.

^b "Without Concomitants" indicates that only one pesticide substance was implicated in the exposure.

The unintentional reason categories were also reviewed to determine if the corresponding cases were suitable for this analysis. When we compared the definitions of reason categories, the "therapeutic error" and "bite/sting" categories initially appeared to be inappropriate for the objective of this analysis; however, when the data for unintentional exposures were reviewed without concomitants, the implication of pesticide products in the exposures was not dramatically altered (e.g., therapeutic error comprises 0.74 percent of all unintentional exposures to pesticide substances under both scenarios). Therefore, these categories are included in this analysis. In the discussion below regarding the estimation of annual illnesses related to conventional and antimicrobial pesticides from reported exposure cases, the overall figure of 80,978 cases of exposure with concomitants is used.

5.2.3.2 Annual National Illnesses Resulting from Unintentional Human Pesticide Product Exposure Cases

This section describes the number of illnesses used as the national estimate to which the California-derived proportion of container-related illnesses was applied to total illnesses. As described above, TESS is a national surveillance database for exposures to toxic substances. In this section, the evaluation of the proportion of these exposures that resulted in illness is described. Although the query was limited to pesticide products, not all the observed illnesses were a result of the pesticide. Three categories are used to describe the relationship between the clinical effect observed and the exposure in TESS: "related," "not related," and "unknown if related." For the purposes of this analysis, since we are interested in the number of illnesses that result from these exposures, we evaluated the cases in which the clinical effects were labeled "related" to the pesticide exposure as a "low-end" scenario estimate, and the cases in which the clinical effects were labeled "related" plus those labeled "unknown if related" as a "high-end" scenario estimate. The guidelines used to assess the relationship between observed clinical effects and unintentional exposures to pesticide products are summarized in Table 5.4.

Table 5.4. Guidelines for Field Definition of Clinical Effect Relationships to Exposure

Exposure-Clinical Effect Relationship	Selection Criteria
Related	 Timing of clinical effect is reasonable for reported exposure; Severity of effect is consistent with reported exposure; Effect is consistent with anticipated substance toxicity; Clinical assessment of relationship was made by a physician.
Not related	 Effect was pre-existing or began prior to the exposure, and was not augmented or worsened as a result of the exposure, or Effect can be ascribed to a documentable alternative etiology.
Unknown if Related	 Relationship between exposure and effect cannot be reasonably ascertained; Effect has never been ascribed to the particular substance, but an alternative etiology cannot be conclusively established; Effect is not expected based on reported exposure; Knowledge of patient's history (e.g., concomitant illnesses, other medications) is not adequate to allow a determination of the relationship between the exposure and the effect.

Source: AAPCC (2002, "Field Definitions," p. 8).

Of all the cases presented, 75.93 percent exhibited no clinical effects related to the pesticide exposure, 14.34 percent of patients exhibited one clinical effect, 6.40 percent showed two clinical effects, and 3.33 percent sustained three or more clinical effects (Table 5.5). Therefore, of the 80,978 exposure cases reported, 19,492 victims exhibited clinical effects related to the pesticide exposure. This estimate represents the "low-end" scenario estimate of the total annual national cases of pesticide illnesses. To verify the initial assumption to use the number of unintentional exposures to pesticide products with concomitants as the basis of this analysis, the frequency distribution for the clinical effects among exposures without concomitants was also examined. When the frequency of clinical effects is evaluated among exposures without concomitants, a similar pattern of distribution of clinical effects is present.

Table 5.5. Frequency of Clinical Effects "Related" to Unintentional Pesticide Product Exposures

Number of	With Concomitants			Without Concomitants	
Clinical Effects Observed	Number of Patients		Percentage of Patients	Number of Patients	Percentage of Patients
0		61,486	75.93%	59,543	76.66%
1	19,492	11,614	14.34%	11,024	14.19%
2]	5,181	6.40%	4,790	6.17%
3]	1,820	2.25%	1,586	2.04%
4		567	0.70%	488	0.63%
5 or more		310	0.38%	241	0.29%
Total		80,978	100.00%	77,672	100.00%

Source: AAPCC (2002, Report 12 "Frequency of Clinical Effects - Related").

There were 31,504 clinical effects observed among patients who were determined to have an illness "related" to the unintentional exposure. In total, these 31,504 clinical effects were observed for the 19,492 exposure cases that resulted in a related illness. This pattern is a result of the information highlighted in Table 5.5 and detailed in Table 5.6, where 11,614 patients sustained a single clinical effect, 5,181 patients had two effects, 1,820 exhibited three effects, 567 suffered four effects, and 310 cases resulted in five or more clinical effects.

Table 5.6. Detailed Distribution of Clinical Effects "Related" to Unintentional Pesticide Product Exposures Among Patients Experiencing With Concomitant" Pesticide Exposures

Name have a Collect and	With Cone	Number of Observed		
Number of Clinical Effects Observed	Number of Patients ^a	Percentage of Patients	Clinical Effects "Related" to Exposures ^b	
1	11,614	59.58%	11,614	
2	5,181	26.58%	10,362	
3	1,820	9.34%	5,460	
4	567	2.91%	2,268	
5 or more	310	1.59%	1,800	
Total	19,492	100.00%	31,504	

^a Number of patients with observed clinical effect from Table 5.5.

^b Number of "related" clinical effects corresponding to the number of patients from note (a) above.

Table 5.7 shows the distribution of the 31,504 clinical effects observed among patients who were determined to have an illness related to the unintentional pesticide product exposure. Of the cases in which some clinical effect related to a pesticide exposure was observed (approximately 24 percent of the total exposures overall from Table 5.5 above: $19,492 \div 80,978 = 0.24$), the majority of patients suffered ocular (26.95 percent), gastrointestinal (24.06 percent), and dermal (17.28 percent) health effects.

Table 5.7. Percent Distribution of Clinical Effects Among Patients Experiencing Effects "Related" to Unintentional Pesticide Product Exposures

Clinical Effect	Number of Observed Clinical Effects "Related" to Exposures ^a	Percent	Number of Observed Clinical Effects "Unknown if Related" to Exposures a	Percent
Cardiovascular	410	1.30%	185	2.27%
Dermal	5,445	17.28%	995	12.22%
Gastrointestinal	7,581	24.06%	2,700	33.15%
Hematologic/Hepatic	42	0.13%	24	0.29%
Neurological	3,122	9.91%	1,788	21.95%
Ocular	8,491	26.95%	323	3.97%
Renal/Genitourinary	32	0.10%	21	0.26%
Respiratory	3,735	11.86%	624	7.66%
Miscellaneous	2,646	8.40%	1,484	18.22%
Total	31,504	100.00%	8,144	100.00%

Source: AAPCC (2002, Report 13 "Distribution of Clinical Effects").

Table 5.7 also shows the number of observed clinical effects among patients in which the effect was "related" or "unknown if related" to the pesticide exposure. It is believed that these "unknown if related" cases should be considered in the analysis since it is known that a pesticide product was involved, but it is unclear from the report whether the exposure was responsible for the illness. However, while the available TESS data showed that 31,504 "related" clinical effects corresponded to 19,492 exposures cases, similar data are not available for the "unknown if related" effects. For these clinical effects, only 8,144 effects were "unknown if related" to the exposure. Below an approach is described for estimating the number of "unknown if related" illnesses, using the ratio of illnesses to effects from the "related" cases. Including "unknown if related" cases with the "related" cases could serve as a "high-end" estimate for the annual number of avoided unintentional pesticide illnesses expected nationwide as a result of the container design and residue removal regulations, since it is unclear what proportion of these cases are truly a result of the pesticide exposure.

5.2.4 Extrapolation to Estimate of Nationwide Cases Potentially Avoided from the Container Design and Residue Removal Standards

This section describes the method for deriving the frequency of cases and number of clinical effects avoided as a result of the container regulations. The number of cases avoided is estimated by applying the percentage of pesticide illnesses determined to be container-related

^a Number reflects clinical effects and not the number of exposure cases, since a single patient can sustain multiple clinical effects (frequency distribution for multiple clinical effects is shown in Table 5.5 and detailed in Table 5.6).

(1.36 percent as calculated in Section 5.2.2) to the number of cases resulting in illness in TESS that are (1) known to be "related" to pesticide exposure ("low-end" estimate) and (2) known to be "related" plus "unknown if related" to the exposure ("high-end" scenario). From Section 5.2.3.2 above, we determined that the number of nationwide illnesses resulting from unintentional pesticide-related exposures was estimated to be 19,492. Assuming that 1.36 percent of these illnesses are related to container design or residue problems, the number of potentially avoided cases with clinical effects is 265. In 2001, 64 poison centers participated in TESS, reporting more than 2 million human exposure cases, which represent an estimated 98.8 percent of all poison exposures reported to poison centers in the United States. If it is assumed that these cases represent 98.8 percent of the number of illnesses potentially avoided from the container design and residue removal regulations, then the "low-end" scenario number would be 268 (265 * 1.012 = 268, where the scaling factor of 1.012 is the inverse of 98.8 percent). The estimated frequency of associated clinical effects for these 268 illnesses (based on the frequency distribution in TESS for all unintentional, pesticide product-related illnesses) is provided in Table 5.8.

As a "high-end" estimate of cases avoided, we included those cases in TESS where some pesticide exposure was reported but it is unclear if the pesticide was responsible for the illness. As discussed earlier, the available TESS data for this subset of "unknown if related" cases were limited to the number of clinical effects, rather than the number of cases. Since one case may result in more than one clinical effect, the use of this data would overestimate the number of cases avoided. In order to extrapolate the number of cases from the number of clinical effects for this subset, we applied the ratio of cases to clinical effects for those illnesses known to be "related" to pesticide exposure (0.62, calculated as 19,492 related exposures cases to 31,504 clinical effects = 0.62) to the "unknown if related" cases (8,144) "unknown if related" clinical effects * 0.62 = 5,039 "unknown if related" cases). This was added to the number of "related" cases to determine an upper bound of 24,531 as the total number of pesticide-related cases in TESS for the "high-end" scenario:

19,492 "related" cases + 5,039 "unknown if related" cases = 24,531 "high-end" cases

The same percentage (1.36 percent) and scaling factor (1.012) were applied to generate the "high-end" estimate of 337 (24,531 "high-end" pesticide-related cases * 1.36 percent of these illnesses are related to container design or residue problems * 1.012 scaling factor = 337 cases) of the number of cases potentially avoided by the regulations, as shown in Table 5.8.

Table 5.8 also presents the distribution of the estimated number of clinical effects per avoided case. This estimate was generated by applying the frequency distribution observed in TESS for illnesses known to be "related" to pesticide exposures (see Table 5.6) to the estimated number of avoided cases. By doing so, it is assumed that the frequency of clinical effects for pesticide illnesses resulting from container design/residue issues is the same as for all pesticide-related illnesses. The assumption is also made that for those cases in which it is unclear that pesticides are the implicated agent, the same number of clinical effects would be observed per case.

⁶⁰ If possible container-related cases are included the "low-end" and "high-end" estimate of associated clinical effects is 853 and 1074 respectively. See Appendix J.

Table 5.8. Estimated Frequency of Clinical Effects for Avoidable Cases as a Result of the Container Regulations

Number of Clinical	Percent of Cases with	Number of (Cases Avoided b
Effects per Case	Clinical Effect ^a	"Low-End" Scenario ^c	"High-End" Scenario ^d
1	59.58%	160	201
2	26.58%	71	90
3	9.34%	25	31
4	2.91%	8	10
5 or more	1.59%	4	5
Total	100%	268	337

Notes: Numbers are scaled by a factor of 1.012 to reach 100 percent coverage of the national population. Frequency-specific estimates may not sum to totals due to rounding.

Table 5.9 shows the estimated number and type of avoided clinical effects as a result of the regulations. In order to estimate the number of clinical effects potentially avoided, the number of cases avoided was scaled by a factor of 1.616. This represents the ratio of clinical effects "related" to exposures in TESS to the total number of cases resulting in those effects (31,504 "related" clinical effects to 19,492 "related" exposure cases = 1.616). Therefore, on average, a pesticide product-related illness results in 1.616 clinical effects as defined in TESS. By applying this ratio to the number of cases avoided as a result of the regulation, it is assumed that the container-related illnesses, on average, result in the same number of clinical effects per case as all pesticide-related illnesses. It is also assumed that the relative distribution of types of clinical effects are the same for container-related cases. The clinical breakdown of the potentially avoided clinical effects shown in Table 5.9 was derived using the distributions in Table 5.7 for "related" and "unknown if related" cases, respectively. The number of clinical effects avoided per year is estimated to be in the range of 433 to 545. These correspond to the estimated range of 268 to 337 potentially avoidable pesticide product illness cases as a result of the rule. 61

The approach to scaling estimates of potentially avoided cases based on the reported population coverage of TESS is discussed above. In addition, although CDPR takes many steps to ensure that the data collected are as comprehensive as possible, it is inevitable that some illnesses related to pesticide products go unreported or undiagnosed. For the purposes of this analysis, if some cases are overlooked by CDPR, the percentage estimated and applied to the TESS data is not necessarily biased. As long as the proportion of those unreported or undiagnosed cases that are related to container design or residue problems is no different from the proportion reported by CDPR, then an unbiased percentage estimate will be obtained.

^a Derived from Table 5.5 and as shown in Table 5.6.

^b Distribution of number of cases avoided (e.g., with 1, 2, 3, 4, 5 or more clinical effects per case) are calculated from the total number (268 and 337 in "low-end" and "high-end" scenarios, respectively), using the percentage of cases with different numbers of clinical effects.

^c From cases "related" to exposure.

^d From cases "related" and "unknown if related" to exposure.

⁶¹ If possible cases are included the number of clinical effects avoided for "low-end", "unknown if related" and "high-end" scenario are 1379, 357 and 1736 respectively. See appendix J.

Table 5.9. Estimated National Number of Avoidable Clinical Effects as a Result of the Container Regulations

Clinical Effect	Number of Clinical Effects Avoided "Low-End" Scenario ^{a, b}	Number of Clinical Effects Avoided "Unknown if Related" to Exposures ^{a, b}	Number of Clinical Effects Avoided "High-End" Scenario ^b
Cardiovascular	6	3	8
Dermal	75	14	88
Gastrointestinal	104	37	141
Hematologic/Hepatic	1	<1	1
Neurological	43	25	67
Ocular	117	4	121
Renal/Genitourinary	<1	<1	<1
Respiratory	51	9	60
Miscellaneous	36	20	57
Total	433 °	112 °	545

Note: Clinical effect-specific estimates may not sum to totals due to rounding.

Another point to consider is the mechanism by which the data are collected for the TESS database. Since case reports are collected through reporting to poison control centers across the country, it is possible that acute illnesses and injuries are more likely to be reported than chronic effects resulting from the exposure. Similarly, clinical effects were generally recorded at the time of the poison report and may have been lost in follow-up and therefore gone unreported if the victim developed symptoms subsequent to the initial report. Since the estimate of avoidable cases and related clinical effects was based on these reports, the actual number of related illnesses may have been higher (see Appendix J for a description of these exposures potentially lost to follow-up).

5.2.5 Valuing Avoided Pesticide Product-Related Illnesses as a Result of the Container Regulations

This section describes the approach to the quantitative valuation of the cases of pesticide product illness that may be potentially avoided as a result of the container design and residue removal regulations. In order to estimate the potential cost savings from these avoided cases of pesticide product-related illness, these cases are first characterized into general illness severity categories for which the average costs for outpatient physician visits, inpatient hospitalizations, lost productivity, and premature mortality is derived. In using this methodology, we made use of the additional data available in the TESS report that provide insight into the type or degree of

^a Distributions of clinical effects shown here were derived from the total number of clinical effects calculated (see note (b) below), using the percentages shown in Table 5.7. (e.g., for the "low-end" scenario, 433 cases * 1.30 percent of total "related" effects are cardiovascular = 6 cardiovascular effects; for the "high-end" scenario, 112 cases * 2.27 percent of total "unknown if related" effects are cardiovascular = 3 cardiovascular effects added). ^b "Low-end" scenario clinical effects are represented by those effects "related" to the pesticide exposure, while the "high-end" scenario includes those "related" and those "unknown if related" to the pesticide exposure. If possible cases are included the number of clinical effects avoided for "low-end", "unknown if related" and "high-end" scenario are 1379, 357 and 1736 respectively.

^c Number of cases avoided from Table 5.8 are scaled by a factor of 1.616 to estimate the number of clinical effects resulting from those reported cases (e.g., for the "low-end" scenario, 268 cases * 1.616 = 433 clinical effects).

outcome/clinical effects observed for exposure cases. A profile of medical outcome severity as reported in TESS is presented in Appendix H.

5.2.5.1 Avoided Pesticide Product-Related Illnesses by Severity Level

The potentially avoided cases calculated above are classified into the following TESS outcome categories (see Table 5.10 and Appendix H):

- **Minor effect:** patient developed some signs or symptoms as a result of the exposure but they were minimally bothersome and generally resolved with no residual disability or disfigurement;
- **Moderate effect:** patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms (usually some form of treatment is indicated);
- **Major effect:** patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement; and
- **Death:** patient died as a result of the exposure or as a direct complication of the exposure.

Table 5.10. Expected Number of Avoidable Illnesses as a Result of Container Regulation by Severity of Clinical Effect

	TESS With Concomitants			Potential Cases Avoided from R		Regulations	
Medical Outcome/Severity	Number of Cases	Perce	ntage ^{a, b}	"Low-] Scena			h-End" nario ^a
No Effect	18,385		56.14%		343		431
Minor Effect	12,084	43.86%	36.90%	268	225	337	284
Moderate Effect	2,164		6.61%		40		51
Major Effect	111		0.34%		2		3
Death	2		0.01%		<1°		<1°
Total	32,746		100.00%		610 ^d		768 ^d

^a Numbers have been rounded for presentation purposes.

In addition, a "no effect" category is included ("no effect" represents a patient who reported an exposure but developed no signs or symptoms as a result of exposure). In theory, cases that did not result in any observed clinical effect should not be associated with any potential medical cost savings. However, TESS data show that, in reality, some proportion of those exhibiting "no effect" did visit a health care facility and therefore incurred medical costs (shown below). In addition, there are likely to be costs associated with lost productivity for the time and anxiety associated with a call to a poison control center.

^b Percentages were calculated to equal 100 percent for the five medical outcome categories using their associated number of cases from Table H-3 (Appendix H), since complete data were known for these five categories.

^c 0.04 deaths were estimated for the "Low-End" scenario and 0.05 deaths for the "High-End".

^d Totals were calculated assuming that the potential illnesses avoided as a result of the container regulations in Section 5.2.4 (268 for the "low-end" scenario and 337 for the "high-end" scenario) constitute the minor effect, moderate effect, major effect, and death severity categories: e.g., $268 \div 43.86\% = 610$. The breakdown by severity category was then calculated using this derived total.

Table 5.10 presents the expected number of overall avoided cases as a result of the container design and residue removal regulations, when cases both with and without any clinical effect are considered. Note that the "low-end" and "high-end" scenario estimates from Section 5.2.4 of 268 and 337 cases, respectively, correspond to the following four medical outcome categories: minor effect, moderate effect, major effect, and death.

The "no effect" cases, in which no clinical effect was observed, are not a component of the 268 to 337 cases calculated in Section 5.2.4 above, since the California incident data from CDPR cover only pesticide exposures that resulted in symptoms. In order to estimate the number of avoided exposure cases that did not result in clinical effects, the expected number of these cases is calculated based on the percentage distribution of medical outcome/severity observed across the entire TESS database of pesticide-related exposures (see Appendix H). This calculation is based on the information provided in Table H-3, which presents the cases according to the severity of the medical outcome, evaluating only the categories "No Effect," "Minor Effect," "Moderate Effect," "Major Effect," and "Death." Using the actual number of cases reported to TESS for these categories, the proportion of cases that each medical outcome category contributes to the total is recalculated, as presented in Table 5.10.⁶² As a result of this recalculated distribution, it is estimated that 43.86 percent of exposures resulted in clinical effects (including minor, moderate, and major effects, and death), and 56.14 percent of exposures resulted in "no effect," as shown in Table 5.10.63 For the "low-end" scenario, we estimated that 268 illnesses would be avoided by the rule. Assuming that the ratio between exposures with clinical effects and exposures with "no effect" from TESS holds true in this subset, the number of cases with "no effect" avoided by the rule can be estimated as follows:

$$\frac{268}{43.86\%} = \frac{x}{56.14\%} \Rightarrow x = 343$$

Using this methodology, it is assumed that the distribution of severity of effect (ranging from "no effect" to "death") for exposures related to container design and residue removal is no different than for all exposures to pesticide products resulting in calls to poison control centers nationwide. Data are not available to suggest that the subset of container-related pesticide

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⁶² After examining the medical outcome descriptions shown in Table H-3, we recalculated the distribution among only the first 5 categories (no effect, minor effect, moderate effect, major effect, and death) to use in this calculation of illness severity. We decided not to use the percentage distribution for all the categories shown in Table H-3 because sufficient information on the outcome of the exposure was not available for the remaining categories. For example, for the category "no follow-up, potentially toxic," we were not able to assign a reasonable medical outcome category to value based on the uncertainties presented in its description: "Patient was lost to follow-up, refused to follow-up or was not followed but the exposure was significant and may have resulted in a moderate, major, or fatal outcome." Similarly, for the "unrelated effect" category, we are not concerned with cases for which the exposure was not responsible for the medical outcome. Since we want to categorize the medical outcome of exposure in order to value the benefits, we decided that including such cases would not be representative of the exposure cases. Instead, we assumed that the distribution for those cases in which the medical outcome was known is representative of the outcomes from all exposures.

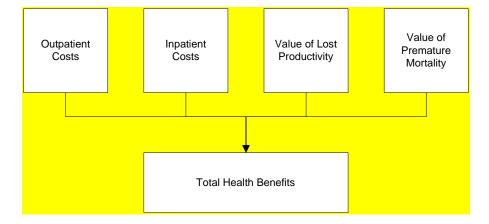
⁶³ The "no effect" category shown in Table H-3 differs from the 75.93 percent with zero clinical effects shown in Table 5.5 because the latter shows the number of clinical effects known at the time of the poisoning incident report. Alternatively, the medical outcome information presented in Table H-3 describes the known effect resulting from the incident. However, it is possible that the "no follow-up" categories in Table H-3 may or may not have had clinical effects, or could have had clinical effects later. This information is not known.

illnesses typically result in more or less severe illnesses than any other pesticide exposure. If this assumption is not true, the benefits calculated here could be over- or understated due to an over- or underestimate of the severity of health effects avoided.

5.2.5.2 Unit Costs for Morbidity and Mortality by Severity Level

The valuation of health benefits associated with reduced pesticide-related morbidity and mortality focuses on direct costs for outpatient visits and inpatient hospitalization stays, indirect costs of lost productivity, and premature mortality based on the "value of a statistical life" (VSL) approach (see Figure 5.2). The value of reduced morbidity is estimated below using TESS data on the likelihood of pesticide product-related cases of varying severity levels seeking medical care. These data are then used to generate unit costs associated with physician visits, hospital stays, and lost productivity for each level of clinical severity. Subsequently, the total value of reduced morbidity associated with the container rule is estimated by applying these costs to the number of avoided cases by level of severity and summing across severity levels. The premature mortality valuation is performed by first generating a VSL estimate in year 2005 dollars and then applying the number of premature deaths (or the probability of premature mortality), estimated in the previous section, to this VSL.

Figure 5.2. Components of the Health Benefits Valuation for the Container Design and Residue Removal Regulations



Medical Care Utilization

In order to estimate direct costs for medical care utilization, the unit costs per outpatient physician visit and inpatient hospitalization stay were derived. The unit costs per visit were then converted to unit costs per pesticide case for each severity level other than death (no effect, mild, moderate, and major) to reflect the probability of visiting a health care facility. The following equation presents the method used to generate unit costs by severity level:

$$UnitCost_{severity} = UnitCost_{pervisit} \times P(HCFvisit)$$

where:

 $UnitCost_{severity}$ = the unit cost per case for a particular severity level; $UnitCost_{per\ visit}$ = the unit cost per health care visit; and

P(HCFvisit) = the probability of visiting a health care facility for a particular severity level.

TESS provides data on health care facility visits for clinical effects associated with pesticide-related exposure. Table 5.11 presents the distribution of health care visitation by medical outcome/severity. In TESS, a health care facility is defined as "any hospital-based ward or emergency department, free-standing emergency medical clinic (emergicenter), first aid station, physician's office, or clinic." Therefore, it is not possible to distinguish between outpatient physician visits, emergency room visits, and inpatient hospitalization stays. As would be expected, as the clinical effect severity level increases, the proportion of cases requiring health care facility visits increases as well.

Table 5.11. Medical Outcome by Management Site for Pesticide Product-Related Unintentional Exposures, TESS, 2001 ^a

	Management Site b		
Medical Outcome/Severity	Non-Health Care Facility	Health Care Facility	Refused Referral c
No Effect	76.86%	22.58%	0.56%
Minor Effect	67.30%	30.32%	2.38%
Moderate Effect	24.45%	70.65%	4.91%
Major Effect	9.52%	86.67%	3.81%
Death	0%	100%	0%

Source: Adapted from AAPCC (2002, Report 39 "Medical Outcome by Management Site").

The proportion of cases visiting health care facilities in Table 5.11 were used to adjust outpatient physician visit unit costs for each level of clinical effect severity. For hospitalization stays, it is assumed that only cases with major clinical effects require inpatient treatment. Table 5.12 presents TESS data on the duration of clinical effects by medical outcome/severity. For cases with minor effects, 74 percent lasted less than eight hours and 88 percent less than one day. Similarly, 43 percent of cases with moderate effects lasted less than eight hours and 63 percent less than one day. On the contrary, 59 percent of cases with major clinical effects lasted one or more days and 30 percent lasted three or more days. As a result, it is assumed that only cases with major effects would incur hospitalization inpatient costs and the unit cost per hospitalization stay is converted to a unit cost per major effect case in the same way as described for outpatient visits. Table 5.12 is also used to estimate the indirect cost of lost productivity, described in the section titled "Lost Productivity" below.

^a Excludes those cases with management site designated as "other" and "unknown."

^b Represents row percent.

^c Although refused referral cases are those that should have received health care facility treatment, they did not and therefore did not incur medical care costs. It is not clear whether some of these cases ultimately received treatment at a later time.

Table 5.12. Duration of Clinical Effect by Medical Outcome for Pesticide Product-Related Unintentional Exposures, TESS, 2001 ^a

Duration of		Medical Outcome/Severity b	
Clinical Effects	Minor Effect	Moderate Effect	Major Effect
≤2 Hours	53.84%	18.34%	6.82%
2-8 Hours	20.60%	24.19%	9.09%
8-24 Hours	13.70%	20.33%	25.00%
1-3 Days	6.99%	17.94%	29.55%
3-7 Days	3.30%	12.49%	11.36%
1 Week - 1 Month	1.24%	4.66%	6.82%
>1 Month	0.30%	1.70%	5.68%
Anticipated Permanent	0.03%	0.34%	5.68%

Source: Adapted from AAPCC (2002, Report 23 "Duration of Clinical Effects by Medical Outcome").

Outpatient Costs

To estimate outpatient unit costs, we obtained physician visit benchmark fees from the online division of Intellimed, a private corporation that provides analytical software with inpatient and outpatient databases to health care-related organizations. Evaluation and management costs are provided by Current Procedural Terminology, Fourth Edition (CPT-4) code, an American Medical Association classification used for defining outpatient treatment. Costs are available for new and established patients, based on the type of evaluation and management received. For this analysis, it is assumed that patients visit their current physician for evaluation and management based on a focused problem. Appendix I provides a list of benchmark costs for varying levels of complexity of care for both new and established patients.

Table 5.13 provides the current cost estimate for a physician visit of an established patient for an expanded, problem-focused evaluation, updated to 2005 dollars. The cost, \$39.35, represents only the evaluation and management costs. Diagnostic and medicinal costs are not included in this estimate and would be more likely to vary by level of severity. These costs would add to the estimates of direct medical costs avoided due to the container regulations.

^a Excludes those cases with "unknown" duration of clinical effect.

^b Represents column percent.

⁶⁴ Formerly the Medical Cost and Quality Assistance (MECQA) Web site, the Web site can now be accessed at www.myhealthscore.com.

Table 5.13. Benchmark Evaluation and Management Costs for Physician Office Visit for an Established Patient Requiring an Expanded, Problem-Focused Evaluation,

Adjusted to 2005 Dollars ^a

CPT-4 Code	Brief Description	Cost b
99213	Established patient requiring: 1. Expanded, problem-focused history	\$39.35
	2. Expanded, problem-focused examination	
	3. Medical decision-making of low complexity	

^a Cost data obtained from online division of Intellimed (Intellimed, 2002)

See Appendix I for benchmark costs for other CPT-4 codes.

Using the health care facility utilization data from TESS, reported in Table 5.11, the outpatient physician unit costs per case by level of clinical severity are estimated. Table 5.14 presents the adjusted unit costs for cases with no clinical effect, minor effect, moderate effect, and major effect. The adjusted unit costs range from \$8.89 for "no effect" to \$34.11 for "major effect."

Table 5.14. Outpatient Physician Unit Costs by Medical Outcome

Medical Outcome/Severity	Unit Cost ^a
No Effect	\$8.89
Minor Effect	\$11.93
Moderate Effect	\$27.80
Major Effect	\$34.11

^a Unit costs represent the cost per case and are calculated by multiplying the benchmark cost in Table 5.13 by the percentage of cases visiting health care facilities in Table 5.11.

Inpatient Costs

Hospital utilization data were obtained from the Healthcare Cost and Utilization Project (HCUP), a series of databases compiled by the Agency for Healthcare Research and Quality (AHRQ). 65 HCUP contains patient-level health care data on costs and quality of health services, treatment outcome, and access to health care collected through state data organizations, hospital associations, private data organizations, and the federal government. Unit cost estimates for hospital stays were obtained from the HCUP-3 Nationwide Inpatient Sample (NIS) Release 3 (AHRQ, 1994), which contains all 1994 discharge records from a 20-percent sample of U.S. community hospitals from 17 states.

Table 5.15 presents mean length of stay and mean charges for diagnosis-related group (DRG) 455, "other injury, poisoning, toxic effect diagnosis w/o CC," updated to 2005 dollars using an

^b Cost is updated to year 2005 from year 2000 by scaling based on Medicare Physician Fee Schedule conversion factors. See AAMC (1999) for the year 2000 conversion factor and AAPMR (2004) for the year 2005 conversion factor.

⁶⁵ Formerly called the Agency for Health Care Policy and Research (AHCPR), part of the U.S. Department of Health and Human Services.

⁶⁶ CC as defined AHCPR (1994) "(Complications, Comorbidities). Patients who are more seriously ill tend to require more hospital resources than patients who are less seriously ill, even though they are admitted to the hospital

adjustment based on the Consumer Price Index (CPI-U) for "medical care services". ⁶⁷ DRGs are a classification of hospital case types into groups expected to have similar hospital resource use. Therefore, DRG 455 should provide a reasonable approximation of the charges associated with treatment of pesticide-related illness.

Table 5.15. Mean Hospitalization Charges and Length of Stay for Injuries/Poisonings from HCUP 1994, Adjusted to 2005 Dollars ^a

Diagnosis-Related Group (DRG)	DRG Description	Mean Length of Stay	Mean Charges
455	Other injury, poisoning & toxic effect diagnosis w/o complications or comorbidities	1.64	\$6,856

^a Data obtained from HCUP-3 Nationwide Inpatient Sample (NIS) Release 3 AAPMR (2002) Updated to 2005 dollars using CPI-U for "medical care services" (Bureau of Labor Statistics, 2005).

Using the health care facility utilization data from TESS, reported in Table 5.11, and assuming that only cases with major effects will have inpatient hospital stays, the inpatient unit costs per severity level case by severity level are estimated (see Table 5.16). The unit cost for "major effect" is \$5,942, representing the average charge for a hospital stay across all "major effect" cases, based on the percentage of "major effect" cases that visit a health care facility (86.67 percent from Table 5.11).

Table 5.16. Inpatient Hospitalization Unit Costs

Medical Outcome/Severity	Unit Cost ^a
No Effect	\$0
Mild Effect	\$0
Moderate Effect	\$0
Major Effect	\$5,942

^a Unit cost for "major effect" is the average cost across all "major effect" cases. Unit costs represent the cost per case and are calculated by multiplying the benchmark cost in Table 5.15 by the percentage of cases visiting health care facilities in Table 5.11.

Lost Productivity

For the purposes of this analysis, a "lower-productivity day" is defined as a day when activity is restricted and the person may be less productive in the performance of normal activities (i.e., work, housekeeping, leisure). In order to calculate the value lost due to a lower-productivity day, it is first necessary to estimate the value of a day of full productivity and then estimate the magnitude of reduced productivity associated with each severity level. The socioeconomic data were collected from the U.S. Bureau of Labor Statistics and U.S. Bureau of the Census to calculate average number of hours spent on work, housekeeping, leisure, and sleep, as presented in Table 5.17. Using these data, the value of a day of full productivity can be calculated as

for the same reason. Recognizing this, the DRG grouper splits certain DRGs based on the presence of secondary diagnoses for specific complications or comorbidities (CC)."

⁶⁷ CPI-U for Medical Care Services http://data.bls.gov/cgi-bin/surveymost?cu

presented in Table 5.18. From a review of the pesticide exposure cases in California that were potentially avoidable as a result of the container standards, the majority of instances occurred during occupational activities. Therefore, the indirect cost of illness reflects estimated activity patterns for a typical working adult on any particular day.

Table 5.17. Socioeconomic Data Used to Calculate Indirect Cost of Illness

Data	Value
Average hours an employed person works per week	33.8 ^a
Average hours housekeeping per week (male)	13.4 ^b
Average hours housekeeping per week (female)	28.3 ^b
Number of males aged 16 years and over in the U.S.	111,256,354 °
Number of females aged 16 years and over in the U.S.	117,365,320 °
Average hours people aged 16 years and over spend housekeeping per week	21.0
Median hourly earnings (all workers)	\$16.41 ^d
Median hourly earnings (service, private household female)	\$9.62 ^d
2002 Effective Tax Rate (includes federal, state, and FICA)	29.1% ^e

^a Bureau of Labor Statistics (2005).

Economic theory dictates that the gross wage rate is the best indicator of the value of production associated with an hour of work. As show in Table 5.18, the average gross wage rate in the United States is \$16.41 per hour. Therefore, each hour of lost work due to illness will be valued at \$16.41. Since housekeeping is a non-market activity, no market value exists with which to value the loss to society when housekeeping activity is lost due to illness; an implicit value must be determined. Most cost of illness studies use the average after-tax wage for private household workers as a proxy (see Tolley et al., 1994; Research Triangle Institute, 1994). This value is calculated as \$6.82 per hour, as shown in Table 5.18. Finally, an hour of leisure is valued at the average after-tax wage rate of \$11.64 per hour.

In order to estimate the reduction in productivity resulting from a pesticide exposure potentially avoidable from the regulations, the TESS data on the duration of illness by medical outcome/severity were used (see Table 5.12). For each severity level, an average duration of clinical illness was generated and the proportion of a day spent with the illness was calculated. This proportion was applied to the value of a day of full productivity to estimate the indirect cost of illness. Therefore, the loss in productivity is directly proportional to the time spent with the illness.

^b Research Triangle Institute (1994).

^c U.S. Census Bureau (2004).

d Bureau of Labor Statistics (2004) (adjusted to 2005 using inflation rate): Median hourly earnings (all workers) calculated as \$657 in 2005 median weekly earnings for all workers 16 years and over (inflated from \$638 in 2004 median weekly earnings using an inflation rate of 1.029), divided by 40 hours of work per week. Median hourly earnings (service, private household female) calculated as \$385 in 2005 median weekly earnings (inflated from \$374 in 2004 median weekly earnings using an inflation rate of 1.029), divided by 40 hours of work per week.

Tax Foundation (2005).

Table 5.18. Value of a Day of Full Productivity

Activity	Hours/Day	Hourly Value	Total Value
Work	4.8 a	\$16.41	\$79.26
Housekeeping	3.0 a	\$6.82°	\$20.50
Leisure	8.2 b	\$11.64 ^d	\$95.03
Sleep	8.0	\$0.00	\$0.00
Total Value of a Day of Fu	\$194.80		

^a For work, based on the weekly estimate in Table 5.17 divided by 7 days per week; for housekeeping, based on the number of hours people aged 16 years and over spend on housekeeping per week (21.0 hrs/wk), divided by 7 days per week.

To determine the average duration of clinical illness for each severity level in TESS, a weighted average of the exposure durations was calculated based on the frequency distribution of clinical effect duration. Two scenarios were calculated: a "low-end" scenario based on the midpoint of the duration category and a "high-end" scenario based on the upper bound of the duration category. Two clinical effect duration categories (">1 month" and "anticipated permanent") were unbounded, and we assumed that the ">1 month" category stretched from 1 to 3 months and the "anticipated permanent" category was assumed to last 1 year for the "upper-bound" estimate and one-half of a year for the "lower bound."

In addition, data on duration of clinical effects were not available for "no effect" group. However, since approximately 25 percent of these cases visited health care facilities (see Table 5.11) it was assumed that these 25 percent experienced reduced productivity for the shortest clinical effect duration group (<2 hours) and the remaining 75 percent experienced no reduced productivity. Table 5.19 provides the average clinical effect durations and indirect unit costs associated with the "low-end" and "high-end" scenarios.

^b Leisure time is the time left per day after work, housekeeping, and assuming 8 hours of sleep (24 hours per day - 4.8 hours work - 3.0 hours housekeeping - 8.0 hours sleeping = 8.2 hours leisure).

^c Housekeeping rate is based on the median hourly earnings for service, private household female (shown in Table 5.17) less income tax (average of 29.1 percent for 2005).

d Leisure rate is based on the median hourly earnings for all workers (shown in Table 5.17) less income tax (average of 29.1 percent for 2005).

⁶⁸ Although the "anticipated permanent" category may reflect conditions that last indefinitely, since we do not know the nature of the permanent clinical effect, it is unclear that this will result in permanent lost productivity.

Table 5.19. Average Clinical Effect Duration and Indirect Cost of Illness by Medical Outcome

Medical Outcome/Severity	Scenario ^b	Average Duration of Clinical Effect (Days) ^c	Unit Cost for Lost Productivity Day ^d
No Effect ^a	Low-End	0.01	\$1.83
	High-End	0.02	\$3.67
Minor Effect	Low-End	0.9	\$179.82
	High-End	1.4	\$279.88
Moderate Effect	Low-End	3.7	\$717.35
	High-End	5.9	\$1,146.56
Major Effect	Low-End	16.4	\$3,192.25
	High-End	29.9	\$5,817.81

^a Data on duration of clinical effect were not available for "no effect" group. However, since approximately 25 percent of these cases visited health care facilities it was assumed that these 25 percent experienced reduced productivity for the shortest clinical effect duration group (<2 hours) and the remaining 75 percent experienced no reduced productivity.

Premature Mortality

A "value of a statistical life" (VSL) was used to estimate a value of the potential reduction in fatalities from pesticide-related illnesses. EPA's Office of Air and Radiation's (OAR) work on the value of a statistical life has been widely cited throughout the Agency. Recently, OAR responded to a recent SAB opinion about the previous VSL estimate used (\$4.8 million in 1990 dollars) and changed the estimates (EPA,2004):

"The mean value of avoiding one statistical death is assumed to be \$5.5 million in 1999 dollars. This represents a central value consistent with the range of values suggested by recent meta-analyses of the wage-risk VSL literature. The distribution of VSL is characterized by a confidence interval from \$1 to \$10 million, based on two meta-analyses of the wage-risk VSL literature. The \$1 million lower confidence limit represents the lower end of the interquartile range from the Mrozek and Taylor (2002) meta-analysis. The \$10 million upper confidence limit represents the upper end of the interquartile range from the Viscusi and Aldy (2003) meta-analysis (EPA,2004)."

^b The "low-end" scenario uses the midpoint of the range of clinical effect duration to calculate the average duration, and the "high-end" scenario uses the upper end of the range.

^c Average duration of clinical effect for all except the "No Effect" case is based on a weighted average of the durations presented in Table 5.12. The category ">1 month" was assumed to be 1-3 months (where the midpoint = 60 days) and the category "anticipated permanent" was assumed to be 1 year (where the midpoint = 182.5 days) for the low-end estimate and one half year for the high-end estimate. For example, the low-end estimate of average duration of clinical effect is calculated by multiplying the mid-point of average duration in the first column in Table 5.12 with the corresponding percentage of Minor Effect cases (calculating the sum of products of column 1 and column 2 in Table 5.12).

column 2 in Table 5.12). description Table 5.12). The unit cost is the indirect cost in terms of lost productivity associated with the average duration of clinical illness for a particular severity level. For example, the unit cost for lost productivity day was calculated by multiplying the value of a productive day (\$194.80) with the average duration of clinical effect (0.01). The average duration of clinical effect is rounded off therefore the value for unit cost is less than the simple multiplication of average duration and value of a productive day.

For this benefits analysis, EPA used the VSL estimate of \$5.5 million (in 1999 dollars), updated to the base year of the analysis (2005). Using CPI data for all items from the Bureau of Labor Statistics, this estimated VSL was calculated to be \$6.42 million in 2005 dollars.⁶⁹

In this analysis, it is estimated that less than one pesticide-related death (0.04 to 0.05 deaths) will be avoided as a result of the container regulations each year (see Table 5.10). A reduction in 0.04 deaths can be seen as four deaths avoided over a 100-year period. This can also be viewed as a reduction in mortality risk for every person in the United States of 1.27 x 10⁻¹⁰, based on the 2004 U.S. Census estimate of 294 million people in the United States. This estimate of avoided mortality is applied to the year 2005 value of a statistical death to estimate a range of \$240,000 to \$301,000 for annual avoided premature mortality as a result of the regulations (see Table 5.20).

Table 5.20. Value of Annual Avoided Pesticide-Related Cases as a Result of the Container Regulations (2005 dollars)^a

Medical Outcome/ Severity	Scenario	Avoided Cases ^c	Outpatient Costs d	Inpatient Costs ^e	Lost Productivity ^{f, g}	Premature Mortality	Total ^h
No effect	Low-end	343	\$3,045		\$628		\$3,674
	High-end	431	\$3,833		\$791		\$4,623
Minor effect	Low-end	225	\$2,688		\$40,512		\$43,200
	High-end	284	\$3,383		\$50,984		\$54,367
Moderate	Low-end	40	\$1,122		\$28,941		\$30,062
effect	High-end	51	\$1,412		\$36,422		\$37,834
Major effect	Low-end	2	\$71	\$12,297	\$6,606		\$18,973
	High-end	3	\$89	\$15,479	\$8,314		\$23,878
Death ^b	Low-end	<1				\$239,542	\$239,542
	High-end	<1				\$301,465	\$301,465
Total	Low-end	610	\$6,926	\$12,297	\$76,686	\$239,542	\$335,451
	High-end	768	\$8,716	\$15,476	\$96,510	\$301,465	\$422,167

^a All cost estimates are rounded to the nearest dollar.

^b Estimated deaths avoided as a result of the container rule are 0.04 for the lower-bound estimate and 0.05 for the upper-bound estimate. The value of avoided mortality is the same as the value of a reduction in four deaths or five deaths over a hundred-year period, respectively.

^c See Table 5.10 for derivations.

^dOutpatient costs are equal to the number of avoided cases times the per case outpatient cost (see Table 5.14). Costs may not add due to rounding.

^e Inpatient costs are equal to the number of avoided cases times the per case inpatient cost (see Table 5.16). Costs may not add due to rounding.

^f Lost productivity costs are equal to the number of avoided cases times the per unit cost of lost productivity (see Table 5.19). Costs may not add due to rounding.

g Lost productivity estimates are based on the "low-end" estimate of indirect cost of illness, as described in the "Lost Productivity" subsection of Section 5.2.5.2. The value of the "high-end" estimates for lost productivity are not shown here, but can be calculated using the unit costs from Table 5.19.

⁶⁹ \$5.5 million in 1999 dollars was adjusted using the Consumer Price Index-All Urban Consumers (CPI-U), U.S. All items, base period 1982-84=100, series ID CUUR0000SA0 from the Bureau of Labor Statistics (2005), as follows: 194.6 (April 2005 index) ÷ 166.6 (1999 index) * \$5.5 million = \$6.42 million.

5.2.5.3 Total Value of Avoided Pesticide Product-Related Illnesses

In Section 5.2.5.1 above, the annual number of cases of pesticide-related illnesses avoided as a result of the container regulations by level of severity was estimated. The value of these avoided cases are calculated by applying the unit costs by severity level estimated for outpatient physician visits, inpatient hospitalization stays, and lost productivity to the avoided cases of morbidity and the value of a statistical life to the avoided premature mortality estimate. Table 5.20 presents the annual health benefits valuation estimates for each of the endpoints and severity levels described above. The value of avoided pesticide-related illnesses is provided for the "low-end" and "high-end" estimates of cases avoided, described in Section 5.2.4 above.

It is estimated that 610 to 768 cases could have been avoided as a result of the container design and residue removal regulations each year, corresponding to approximately \$335,451 to \$422,167 in annual health benefits. If the 51 "possible" cases in California are included, which increases the percentage of total pesticide product-related cases potentially avoided by 4.33 percent, the annual health benefits would be an additional \$1.07 million to \$1.35 million annually (corresponding to an additional 1,946 to 2,449 cases).

Since the compliance period for the rulemaking is either 3 or 5 years depending on the type of container involved, we assume that 50 percent of average annual benefits will begin to accrue in year 3 and the remaining 50 percent of average annual benefits will begin to accrue in year 5. Given the compliance schedule, the annualized benefit over a 20-year period of analysis at a 3 percent discount rate is \$264,051 for the low-end scenario and \$332,311 for the high-end scenario. Similarly, the annualized benefit over a 20-year period of analysis at a 7 percent discount rate ranges from \$236,635 (low-end scenario) to \$297,807 (high-end scenario). If possible cases are included the annualized benefit for the low-end and high-end scenario are \$841,664 and \$1,059,240 respectively at the 3 percent discount rate, and \$754,274 and \$949,259 respectively at the 7 percent discount rate.

5.3 Non-Human Health-Related Benefits of the Pesticide Container Regulations

This section describes the inputs and assumptions used to calculate the non-human health-related benefits associated with the pesticide container regulations. For this analysis, three direct benefit categories are considered: benefits associated with the disposal of non-refillable containers (Section 5.3.1), benefits associated with reduced environmental and ecological incidents (Section 5.3.2), and the benefits associated with avoided cleanup costs and property damage (Section 5.2.3).

5.3.1 Non-Refillable Container Disposal Benefits

The pesticide container regulations will directly affect the use and disposal practices of rigid non-refillable containers for two reasons. First, rigid non-refillable pesticide containers that fall

^h If possible container-related cases are included the "low-end" and "high-end" benefit estimates are \$1,069,249 and \$1,345,657 respectively.

 $^{^{70}}$ See Appendix J for detailed information of the "possible" cases, defined by EPA as cases that may have possibly been prevented by the container regulations.

within the scope of the container regulations will be required to meet residue removal standards. Second, all rigid non-refillable pesticide containers that are not exempt under the new labeling requirements must have labels that include the applicable instructions for removing pesticide residues from the container prior to container disposal (§156.146). Benefits therefore should be related to containers that will meet the residue removal and/or the labeling requirements that did not do so previously. However, the residue removal standards are applicable to only certain flowable concentrate formulations and it is not clear how many containers should be tied to these formulations. Since we cannot accurately estimate the number of containers associated with reside removal standards we are conservatively not including the containers diverted from the waste stream as a result of this standard in the benefits estimate. This implies that the benefits estimate will understate the true estimate of benefits from the rule.

In the regulatory impact analysis (RIA) that EPA conducted for the proposed version of the pesticide container rule (EPA, 1993), EPA made a number of assumptions regarding non-refillable containers and their use that we retain in this analysis. It assumed that the number of non-refillable containers appropriately managed and disposed of will increase after promulgation of the final rule because of (1) the presence on container labels of specific rinsing information regarding how and when a triple rinse must be conducted due to the labeling requirements, and (2) an increased likelihood that landfills once hesitant to accept appropriately managed pesticide containers as solid waste would now do so instead of treating them as hazardous.

Though appropriate container management and disposal would result in fewer environmental damages, such as fewer pesticide residues in soil, surface and ground water, and fewer health-related damages over time (See Section 5.3.2), due to limitations in the data available, estimates of all of these potential benefits cannot be made. Instead, the difference in cost between the disposal of non-refillable pesticide containers that, before the rule, were disposed of as hazardous waste, and the disposal of non-refillable pesticide containers that, after the rule, would be disposed of as non-hazardous waste is calculated as a quantified measure of the environmental benefits of the container regulations. Because hazardous waste treatment is more costly than non-hazardous, the resulting cost savings is a direct benefit related to the regulations.

The benefits associated with the diversion of non-refillable pesticide containers from the hazardous waste stream (where waste treatment is more expensive) into the solid waste stream are calculated in a number of steps. Each step is discussed in the order in which it was carried out in the analysis.

5.3.1.1 Step 1: Determine Which Container Types Are Subject to the Labeling Requirements

There are a number of non-refillable container types that are considered in the estimation of costs associated with the pesticide container regulations. These include containers that hold dry and

⁷¹ The residue removal requirements apply to only flowable concentrate products that are non-antimicrobial and non-exempt antimicrobial that are included under the Toxic Category I or II criteria and/or are classified for restricted use and that are dilutable and packaged in rigid containers. The final regulations require that every registrant test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable for attaining at least 99.99 percent removal of each active ingredient in the fourth rinsate after the triple rinse (see Chapter 3).

liquid pesticides, plastic and steel containers of varying sizes, water-soluble packets, bag-in-box containers, aerosol cans, paper and plastic bags, glass jugs, fiber drums, and "other" containers. Not all of these containers are subject to the labeling requirements, however, since only rigid containers can be triple rinsed. Table 5.21 displays the container types and sizes that are subject to the labeling requirements.

Table 5.21 also displays the weights associated with the containers. Weights are needed to calculate the volume of containers that are no longer treated as hazardous waste. Weights for plastic containers are based on information gathered by the 2001 High-Density Polyethylene (HDPE) Container Survey, conducted by the Agricultural Container Recycling Council (ACRC, 2001). All other container weights are transferred from the proposed container rule RIA (EPA, 1993).

Table 5.21. Non-Refillable Containers Subject to the Labeling Requirements and Their Associated Weights

Container Size	Weight - Plastic (lbs.) ^a	Weight - Steel/Other (lbs.) b					
Container Type: Liquid Products							
< 1 Gallon	0.15	0.5					
1 to < 5 Gallons	0.54	1.38					
5 Gallons	3	6					
30 - 55 Gallons	23	42.5					
Container Type: Dry Products - Jug	şs						
Quart to < 2.5 Gallons	N/A	0.6					
2.5 Gallons	N/A	1.5					

^a Source: ACRC (2001).

5.3.1.2 Step 2: Determine the Number of Containers Included in the Scope of the Non-Health Benefits Analysis

The residue removal requirements apply to only flowable concentrate products that are non-antimicrobial and non-exempt antimicrobial that are included under the Toxic Category I or II criteria and/or are classified for restricted use and that are dilutable and packaged in rigid containers (see Chapter 3 for a complete discussion). As mentioned above, since we are unable to accurately determine the number of containers associated with the flowable concentrate products/formulations, we are not including the containers diverted from the waste stream as a result of this standard in the estimate.

The container labeling requirements apply to all pesticide products except those that are considered residential/household use pesticide products.⁷² Non-refillable containers subject to the labeling requirements must meet the following criteria:

^b Source: proposed container rule RIA (EPA, 1993, Table XIV-5).

⁷² The total universe of containers is based on the total number of containers in use from Chapter 3.

- Container does not hold a dilutable product that meets the Toxic Category I or II criteria and/or is classified for restricted use (this includes antimicrobial containers exempt from the residue removal requirements); and
- Container does not hold a residential/household use product.

It is assumed that all containers used in the home and garden (H&G) market sector are for residential and household purposes only and are therefore exempt from the labeling requirements. The containers in the H&G market sector are therefore excluded from consideration under this category. The total number of non-refillables included in the universe of containers subject to the labeling requirements is presented in Table 5.22.

Table 5.22. Non-Refillable Containers Included in the Scope of the Non-Health Benefits Analysis

	Container Type: Liquid Products										er Type: oducts
	30-55 Gallons 5 Gallons			1 To < 5 Gallons			< 1 Gallon		Jugs		
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Glass	2.5 Gallons	1qt-2.5 Gal
Number of Co	Number of Containers Subject to the Labeling Requirements ^a										
Agriculture	309,104	115,496	58,116	28,819	27,877,458	0	1,007,023	0	0	26,379	2,273,060
I/C/G	1,600,000	2,320,000	14,048,000	960,000	21,072,000	1,440,000	20,560,000	160,000	240,000	0	370,000
H&G	0	0	0	0	0	0	0	0	0	0	0
Total	1,909,104	2,435,496	14,106,116	988,819	48,949,458	1,440,000	21,567,023	160,000	240,000	26,379	2,643,060

^a The container labeling requirements apply to all pesticide products except those that are considered residential/household use (H&G market) pesticide products. See Table 3.4.

5.3.1.3 Step 3: Estimate the Number of Non-Refillable Containers Diverted from the Hazardous Waste Stream to the Non-Hazardous Waste Stream After Promulgation of the Labeling Requirements

To calculate this benefit category, the percentage of containers that will be appropriately rinsed and disposed of under the container rule needs to be estimated, as does the percentage of total containers that will continue to be inappropriately disposed of (without having been properly rinsed or with a container design that does not rinse clean). For lack of better data, these percentage estimates are based on educated extrapolations taken from the proposed container rule RIA (EPA, 1993). The proposed container rule RIA estimated its pre-regulation rinse rates based on information from the following sources:

- (1) The rinsing behavior observed in a late 1970s study (as reported by Taylor, undated) and two other surveys (Ozkan, 1991, and EPA, 1992a) related to agricultural pesticide use. The Taylor study suggested that 35 percent of farmer applicators triple rinse pesticide containers and only 18 percent of custom applicators triple rinse. The Ozkan study found that more than 90 percent of farmer-pesticide users in Wayandot County, Ohio, rinsed their empty pesticide containers at least once, though only 45 percent regularly rinsed three times. EPA reported that a 1988 South Dakota farmer survey of pesticide applicators in seven counties indicated that 55 percent of the farmers rinsed their empty containers, although many of them only once or twice. Across studies, it was therefore observed that between 45 percent and 82 percent of farmer applicators do not triple rinse. Though the rinsing behaviors were based on observations taken from the agricultural sector, we applied these rinsing rates to the other markets as well.
- (2) The percentage of agricultural and industrial/institutional containers not meeting the proposed standard (at that time a six-9s standard) after a triple rinse, as observed in a 1992 study (EPA, 1992c). The study tested the percentage of containers not meeting a five-9s standard. The study finds that 13 percent of the containers tested at small, medium, and large agricultural facilities and 3 percent of the containers tested at small and medium industrial/institutional facilities did not meet a five-9s requirement for residue removal. The final rule requires containers pass only four-9s standard. Based on the residue removal data in the preamble to the final rule that shows that only 1 of the 79 container/formulation combinations failed to meet the four-9s standard, a 2 percent failure rate is applied in this analysis.

The proposed container rule RIA acknowledged that it was likely that the proportion of farmers not triple rinsing was less than the upper bound of the observed range of rinsing behaviors (between 45 percent and 82 percent). The RIA therefore estimated that in the baseline, 50 percent of all containers were rinsed inadequately or not rinsed at all and should be considered hazardous prior to the labeling and residue removal requirements. The other 50 percent of containers were therefore rinsed adequately and considered non-hazardous waste. After promulgation of these requirements, however, the proposed container rule RIA estimated that 20 percent of all containers would remain hazardous (due to improper rinsing or no rinsing at all).

Transferring these assumptions to the current analysis, it is therefore assumed that 30 percent of those containers listed in Table 5.22 that are subject to the labeling requirements will be rinsed

properly after promulgation of the rule. However, non-refillable containers that comply with the labeling requirements may still be designed in such a way that inappropriate levels of pesticide residues remain in the containers even after a triple rinse. Based on the EPA container/formulation residue removal testing study (EPA, 1992c), a two percent failure was found across all container formulations to achieve the four-9s level. Therefore, an estimated 28 percent of containers listed in Table 4.22 that are subject to the labeling requirements will no longer be hazardous waste when disposed of [# of containers * 0.28]. The property of the labeling requirements will no longer be hazardous waste when disposed of [# of containers * 0.28].

For example, applying this 28 percent factor to the number of eligible 5-gallon plastic containers used in the agricultural market (58,116) yields 16,272 containers that will no longer be hazardous waste (see Table 5.23). Table 5.23 presents, by container size and market sector, the number of non-refillable containers that will be converted from hazardous to non-hazardous waste after the promulgation of the pesticide container labeling requirements.

⁷³ Based on assumptions made in the proposed container rule RIA (EPA, 1993), we assume that 50 percent of all containers are considered hazardous prior to the labeling requirements. After promulgation of these requirements, however, only 20 percent of all containers will remain hazardous (due to improper rinsing, no rinsing, etc.). Because these containers only have to comply with the labeling requirements, a number of rigid containers holding dilutable pesticides may be designed in such a way that inappropriate levels of pesticide residues remain in the containers even after a triple rinse. The cost analysis assumed that 2 percent of container/formulation combinations for all sizes and all market categories would not pass the residue removal test. That assumption is applied here, subtracting 2 percent from the 30 percent of containers no longer considered hazardous due to the labeling requirements. In other words, 28 percent of containers listed in Table 5.22 that are subject to only the labeling requirements will no longer be hazardous waste when disposed of [# of containers * 0.28].

Table 5.23. Number of Non-Refillable Containers Diverted from the Hazardous Waste Stream to the Non-Hazardous Waste Stream After the Promulgation of the Labeling Requirements

	Container Type: Liquid Products								Container Type: Dry Products		
	30-55 Gallons 5 Gallons 1 To < 5 Gallons < 1 Gallon			< 1 Gallon	1 Gallon		gs				
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Glass	2.5 Gallons	1qt-2.5 Gal
Number of C	Number of Containers Diverted from the Hazardous Waste Stream After Compliance with Labeling Requirements ^a										
Agriculture	86,549	32,339	16,272	8,069	7,805,688	0	281,966	0	0	7,386	636,457
I/C/G	448,000	649,600	3,933,440	268,800	5,900,160	403,200	5,756,800	44,800	67,200	0	103,600
H&G	0	0	0	0	0	0	0	0	0	0	0
Total	534,549	681,939	3,949,712	276,869	13,705,848	403,200	6,038,766	44,800	67,200	7,386	740,057

^a Based on assumptions made in the proposed container rule RIA (EPA, 1993), we assume that 50 percent of all containers are considered hazardous prior to the labeling requirements. After promulgation of these requirements, however, only 20 percent of all containers will remain hazardous (due to improper rinsing, no rinsing, etc.). Because these containers only have to comply with the labeling requirements, a number of rigid containers holding dilutable pesticides may be designed in such a way that inappropriate levels of pesticide residues remain in the containers even after a triple rinse. The cost analysis assumed that 2 percent of container/formulation combinations for all sizes and all market categories would not pass the residue removal test. That assumption is applied here, subtracting 2 percent from the 30 percent of containers no longer considered hazardous due to the labeling requirements. In other words, 28 percent of containers listed in Table 5.22 that are subject to only the labeling requirements will no longer be hazardous waste when disposed of [# of containers * 0.28].

5.3.1.4 Step 4: Calculate the Benefits Associated with the Diversion of Non-Refillable Containers from the Hazardous Waste Stream to the Non-Hazardous Waste Stream

Recall that this benefit category is based on the difference in cost between the disposal of non-refillable pesticide containers that, before the rules, were disposed of as hazardous waste, and the disposal of non-refillable pesticide containers that, after the rules, would be disposed of as non-hazardous waste. Because hazardous waste disposal is more costly than non-hazardous waste disposal, the benefit is the resulting cost savings per ton of container waste.

Now that the number of non-refillable containers converted from hazardous to non-hazardous waste after the promulgation of the labeling requirements has been estimated (Table 5.23), the number of containers must be converted to a total weight (in pounds) per container category. By multiplying the total number of containers that are no longer hazardous by each container size's listed weight in Table 5.21, the total weight of containers no longer considered hazardous can be estimated. For example, multiplying the total number of non-hazardous 5-gallon plastic containers subject to the labeling requirements (3,949,754) by the assumed weight of a representative 5-gallon plastic container (3 pounds) equals 11,849,137 pounds, or 5,925 tons, of 5-gallon plastic containers that can now be disposed of as non-hazardous waste in sanitary landfills (see Table 5.24).

The dollar benefits associated with the diversion of waste from hazardous facilities to non-hazardous landfills are based on the difference in per ton tipping fees associated with each type of waste treatment. We estimated non-hazardous (solid) waste tipping fees based on average tipping fees in 13 states.⁷⁴ The average across states was \$58/ton (2005\$). Hazardous waste tipping fees of \$233/ton (2005\$) were taken from the proposed container rule RIA (EPA, 1993) and adjusted for inflation to 2005 dollars. The cost savings achieved by diverting containers from the hazardous waste stream to the solid waste stream is therefore \$175/ton.

Total non-discounted benefits across all container sizes equal \$5,687,420 annually (2005\$). Benefits begin in the fourth year after promulgation, allowing for a 3-year compliance period for both the labeling and residue removal requirements. Table 5.24 presents the benefits in terms of tipping fee cost savings for each container type and size as well as the total benefits for this direct benefit category.

For the 20-year regulatory period we consider in this analysis, direct non-health benefits occur in each year from years 4 to 20. Discounting this stream of annual benefits, summing across years, and annualizing over a 20-year period yields a discounted annualized benefit of \$4,471,929 using a 3 percent discount rate and \$3,998,645 using a 7 percent discount rate.

⁷⁴ States included: CA, CT, IA, IL, MA, ME, MN, NH, NY, PA, RI, VT, WI. Sources: IA, IL, MI, MN, WI (Lovell, 2001); CA (CA IWMB, 2002); CT, MA, ME, NH, NY, RI, VT (Watson, 2002); PA (PA DEP, 1997).

Table 5.24. Non-Discounted Benefits Associated with the Diversion of Non-Refillable Containers from the Hazardous Waste Stream to the Non-Hazardous Waste Stream (2005\$)

Container Type: Liquid Products									Container Type: Dry Products		
	30-55 (Gallons	5 Gallons 1 To <		1 To < 5	To < 5 Gallons		< 1 Gallon		Jugs	
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Glass	2.5 Gal	1qt-2.5 Gal
Total Weight of Containers Diverted from the Hazardous Waste Stream											
Total (lbs)	12,294,630	28,982,402	11,849,137	1,661,216	7,401,158	556,416	905,815	22,400	33,600	4,432	1,110,085
Total (tons)	6,147	14,491	5,925	831	3,701	278	453	11	17	2	555
Tipping Fee C	Cost Savings (H	azardous Was	te Disposal v	s. Solid Was	te Disposal) o	of \$175/ton (2005\$) ^a				
Total ^b	\$1,078,731	\$2,542,916	\$1,039,643	\$145,755	\$649,378	\$48,820	\$79,476	\$1,965	\$2,948	\$389	\$97,399
Total Non-Discounted Benefits (Summed Across Container Type and Size Categories)										\$5,687,420	

^a Solid waste tipping fees based on average tipping fees in 13 states. The average across states was \$58/ton (2005\$). Hazardous waste tipping fees of \$233/ton (2005\$) were taken from the proposed container rule RIA (EPA, 1993) and adjusted for inflation to 2005 dollars. The cost savings achieved by diverting containers from the hazardous waste stream to the solid waste stream is therefore \$175/ton.

^b Totals may not add due to rounding.

5.3.2 Environmental Effects Avoided Due to Container-Related Pesticide Exposures

The failure or mishandling of pesticide containers and the resulting exposure to pesticides pose significant risks to the environment. Once the pesticide container rules are promulgated, however, the risk of such exposures will decrease due to reduced accidental spills, fewer leaks, less dripping, less frequent container stress failure, and proper rinsing prior to container disposal. The direct non-health benefit that results is therefore the damage reduction from fewer exposures of terrestrial and aquatic wildlife, including those in sensitive and critical habitats, to pesticides and residues. Unfortunately, a quantitative measure of the avoidance of such environmental damages related directly to the pesticide container regulations is very difficult to estimate.

The extent to which pesticide-related environmental incidents occur in the United States is not well documented. The primary clearinghouse for the reporting of such incidents is the Ecological Incident Information System (EIIS), a database maintained by the Ecological Fate and Effects Division of the Office of Pesticide Programs at EPA. The two primary sources of incident reports that are submitted to the EIIS are reports filed by pesticide registrants and government agencies. The container rule requires that pesticide registrants or manufacturers report to EPA any information related to known adverse environmental effects due to releases of their registered pesticides. Many of these ecological incidents are probably not observed or reported, however.

For example, the California Department of Pesticide Regulations (CDPR) is thought to be at the forefront of state agencies in terms of pesticide tracking, management, monitoring, and reporting. However, very few ecological incidents that occur in California are logged into the CDPR's database of priority investigations—the only statewide database that tracks such events (EPA, 2005). In California, pesticide-related releases are initially investigated by county agricultural commissioners. If a particular release is deemed to meet "priority investigation status," it is referred to the CDPR and logged into the database of priority investigations. An annual summary of all priority investigations, if any, is then provided to EPA for input into the EIIS. For non-health incidents, the current thresholds for categorizing an environmental incident as a priority investigation in California include:

Animals and Wildlife: Any pesticide incident with associated level of mortality that exceeds the following:

Non-Target Birds: 50 Non-Target Fish: 500

Listed Endangered or Threatened Species: 1

Domesticated, Game, or Other Non-Target Animals: 5

As one can see from the priority investigation criteria, it is likely that many pesticide-related incidents occur but never warrant priority investigation status. California maintains no records of such incidents, and of the records it does maintain and submit to EPA, only three spill-related environmental incidents were reported between 1968 and the present.

The spill/leak-related incidents are singled out in the EIIS since they are the incidents most likely to be avoided by the promulgation of the pesticide container regulations. Within the EIIS, there have been 43 spill/leak-related aquatic and terrestrial environmental incidents reported since its

inception in 1992 (with reports dating back to 1968). In total, 15 states have submitted spill-related environmental incident reports with varying degrees of severity. Incidents have ranged from an unknown number of species incapacitated to thousands of acute cases of animal mortality. Species affected include minnow, trout, catfish, largemouth bass, salmon, blue crab, banded water snake, American alligators, egrets, wood storks, and turkey vultures to name only a few. Of the spill-related incidents, however, the cause of only a handful can be categorized as potentially container-related.

In fact, of the 43 spill-related incidents in the EIIS database that had sufficient description in the incident report, only five could be considered container related. They are summarized as follows:

- Chlorpyrifos termicide leaked while a technician was repairing a tank. A significant quantity spilled onto the driveway. The technician washed the spilled chemical into a storm drain, which ran into a public duck pond resulting in a possible fish kill. The total number of species affected was not reported (EIIS #I001849-001).
- In California, approximately 100,000 carp and trout were killed as the result of endrin pesticide containers being discarded near an artesian well (EIIS #B0000-225-01).
- A 5-gallon can of Hydrothol 191 (endothall) was found dripping in a drain near Richvale, California. More than 1,000 fish were killed, mostly carp (EIIS #B0000-231-03).
- A fish kill occurred on a creek in Sangamon County, Illinois, due to a leaking sight valve on a 1,000 gallon tank. The type of pesticide was not reported (EIIS #I0000659-001).
- A fish kill occurred in a creek in Baton Rouge, Louisiana, due to a leaking 55-gallon drum of 2,4-D and bromacil and a leaking 55-gallon drum of degreaser. Approximately 600 fish were killed along 1.6 miles of the creek (EIIS #I004668-001).

The extent of national pesticide container-related environmental incidents reported in the EIIS is likely to be an underestimate of the actual number of container-related incidents. Therefore, caution should be taken in using EIIS to characterize the number and size of national container-based pesticide-related incidents that could be avoided once the container rules are in place. Though this type of benefit is not quantified in the current analysis, it should be noted that such benefits are likely to exist in association with the pesticide container rule.

5.3.3 Property Damage/Spill Cleanup Costs Avoided

For the same reasons we are unable to estimate the benefits associated with avoided environmental incidents (a lack of data from which to relate container-related spills to property damage and the related costs of cleanup), we are unable to draw any conclusions regarding the extent to which the pesticide container rules will prevent property damage or reduce the costs associated with unintended, container-related pesticide releases.

Data does exist, however, that tracks hazardous material releases. One primary database is the Accidental Release Information Program (ARIP) database, maintained by the Chemical Emergency Preparedness and Prevention Office (CEPPO) within the Office of Solid Waste and Emergency Response (OSWER), which contains 4,946 incident records from between 1986 and 1999. Most recently, EPA used the ARIP data and findings in support of the development of regulatory guidance for chemical accident prevention as mandated by the Risk Management

Program Rule (written to implement section 112(r) of the amended Clean Air Act). EPA discontinued the ARIP program in 1999 when EPA completed its regulatory guidance effort.

EPA administered the ARIP to learn about the causes and consequences of accidental releases of hazardous substances from fixed facilities and the actions that have been or could have been effective in preventing them from occurring. EPA used select releases collected in the Emergency Response Notification System database for the ARIP questionnaire, targeting those accidental releases at fixed facilities that resulted in off-site consequence or environmental damage. Unfortunately, a search of the database yielded no definitive pesticide container-related accidental releases.

We queried the database to extract all potential pesticide-related releases. We limited the search to the following SIC Codes:

- 2879 Pesticides & Agricultural Chemicals
- 2869 Industrial Organic Chemicals
- 2819 Industrial Inorganic Chemicals
- 2865 Cyclic Organic Crudes & Intermediates
- 2833 Medicinal Chemicals & Botanical Products
- 5261 Retail Nurseries & Lawn Supply Stores
- 5191 Farm Supplies
- 2491 Wood Preserving
- 2049 Food Preparations

There were 142 incidents recorded in the ARIP database associated with these SIC codes. Only 27 of these 142, however, were incidents related to "storage vessels" or "valves" that were caused by "equipment failure" rather than "operational error." Table 5.25 lists characteristics of these 27 incidents.

⁷⁵ The cause of release for 5 of the 27 incidents was not identified in the ARIP database. We therefore included these incidents in the "equipment failure" category.

Table 5.25. Characteristics of Potential Pesticide-Related Chemical Spills Recorded in the ARIP

Spills	6
Vapor Releases	17
Spills and Vapor Releases	4
Total	27
No Environmental Effects Recorded (Field Left Blank)	15
No Environmental Effects (Field Marked None)	9
Environmental Effects (Soil Contamination or Other)	3
Total	27
Injuries Recorded (Facility Employees, Contractors, General Public, and/or Responders)	7
No Injuries (Fields Marked Zero)	20
Total	27
Number of Facilities that Provided Cleanup Cost Information	8
Average Cleanup Cost (2000\$)	\$22,231
Minimum Cleanup Cost (2000\$)	\$1,438
Maximum Cleanup Cost (2000\$)	\$126,432
Primary Product or Service	Pesticides & Chemicals; Organic & Inorganic Chemicals & Pesticides; Agricultural Chemicals; Agricultural Products; Wood Preservation; Nursery Items (Fertilizer, Pesticides & Garden Tools); Medicinal Chemicals and Botanical Products; Manufacturing of Human Health Products, Pesticides, & Agricultural Chemicals; Industrial Organic Chemicals; Industrial Inorganic Chemicals
Chemicals Released	Sulfuric Acid, Nitric Acid, Methyl Chloride, Nitrogen Dioxide, Chlorine, Ammonia, Toluene, Hydrogen Chloride, Carbon Tetrachloride, Phosphoric Acid, Creosote, Ethylene Oxide, Ammonium Hydroxide

With the level of detail provided by ARIP, it is difficult to determine if a particular release would or would not be avoided due to the promulgation of the pesticide container regulations. We therefore provide the ARIP releases to demonstrate that chemical spills and other unintentional releases occur and that there is a cost associated with their cleanup. However, we are unable to draw any conclusions regarding the extent to which pesticide registrants and refillers will avoid cleanup costs due to the pesticide container regulations. Furthermore, it is impossible to draw any conclusions regarding the representativeness of the facilities surveyed by ARIP compared to the universe of all facilities that experience chemical releases. The criteria for selecting incidents to survey changed over time, and in the last few years of the survey (between 1997 and 1999), the ARIP survey effort scaled back its data collection efforts to only nine incidents surveyed per year, due to Paperwork Reduction Act requirements. We therefore cannot extrapolate the ARIP release information to represent a more broad estimate of potential pesticide container-related spills throughout the United States.

5.4 Summary of the Benefits of the Final Standards

As discussed above, the container design and residue removal standards are largely pollution prevention regulations that will safeguard workers and the environment by reducing the risk of exposure to concentrated pesticides. There are numerous types of human health-related benefits and non-human health-related benefits that will stem from such improvements because of relatively fewer expected spills, leaks, and other risks associated with exposure (e.g., handling by workers during disposal, discharges to the environment, and potential public exposures).

The expected benefits resulting from the proposed container design/residue removal regulations include: reduced pesticide-related illnesses and injuries, the cost savings associated with the disposal of rigid non-refillable containers as non-hazardous rather than hazardous waste, and the reduction in the number of accidental pesticide spills. Due to data limitations, we were only able to monetize the benefits associated with the first two benefit categories.

The largest monetary benefit of the container standards is the decrease in disposal costs of non-refillable containers. Large numbers of non-refillable containers that are currently disposed of in hazardous waste landfills will now be able to be disposed of in sanitary landfills at a much reduced cost (\$175/ton). This savings results in an annualized benefit of \$4,471,929 using a 3 percent discount rate and \$3,998,645 using a 7 percent discount rate.

The new standards will also have a positive effect on human health. It is estimated that 610 to 768 cases of illness will be avoided as a result of the container design and residue removal regulations each year. Assuming a 3 percent discount rate, this results in an annualized benefit of \$264,051 ("Low-End" scenario) to \$332,311 ("High-End" scenario). At a 7 percent discount rate, the health benefits range from \$236,635 to \$297,807. If the 51 "possible" cases in California are included, which increases the percentage of total pesticide product-related cases potentially avoided by 4.33 percent, the annual health benefits could be at five times this amount.

Therefore, the total monetized benefits of the container design and residue removal standards range from \$4,735,980 to \$4,804,240 at a 3 percent discount rate and \$4,235,280 to \$4,296,452 at a 7% discount rate.

The new container design and residual removal standards will also result in a decrease in the number of accidental pesticide spills that occur each year. This will have two benefits. First, large pesticide spills can have a significant effect on the environment. Second, by reducing the number of pesticide spills, the new standards will decrease response and clean up costs associated with these spills. We investigated several data sources to document the cause, environmental effect, and response and clean up costs associated with accidental pesticide spills. Although we were able to document that the new standards will likely prevent some future pesticide spills, and that these spills do have negative environmental consequences and result in clean-up costs, the data do not allow us to estimate the magnitude of these benefits. Though this type of benefit is not quantified in the current analysis, due to data limitations, these data are proof that such benefits are likely to result from the new standards.

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Appendix A. Compliance Costs for the Pesticide Container Standards

The inputs used to estimate fixed and unit variable compliance costs associated with the pesticide container rule are based upon information taken from four sources:

- (3) The Proposed Container Rule Regulatory Impact Analysis (RIA) (EPA, 1993). The assumptions used in that analysis were based on informal surveys of and consultations with pesticide registrants, refillers, and industry experts. The proposed container rule RIA also went through a review and comment period. The cost assumptions from the proposed EPA container rule are used as the primary source of cost information for the current analysis.
- (4) **An informal survey of registrants, refillers, and industry experts.** Where possible, cost assumptions transferred from the proposed EPA container rule RIA are updated with up-to-date information collected from an informal survey of registrants, refillers, and industry experts.
- (5) **Public comments.** Public comments to the 1994 proposed rule, 1999 Supplemental Notice (EPA, 1999), and 2004 comment period provided information and data in support of the assumptions made and data used in the economic analysis.
- (6) **Best professional judgment.** In cases where new information was not available, but a revision of the proposed EPA container rule assumptions seemed warranted, we used best professional judgment to estimate certain cost inputs.

The following section describes the source of each cost input and presents, in tabular form, the value of each cost assumption organized by the particular container standard, the size of the establishment, and the establishment's market sector.

Costs associated with the container standards are characterized in three ways. There are compliance period costs, capital costs, and recurring costs.

- Compliance period costs are associated with actions regulated entities must undertake to come into compliance with a particular regulation. It is assumed that affected entities will wait until the end of the compliance period to take these actions. The compliance periods for the various regulation categories are:
 - Non-refillable containers: 3 years;
 - Refillable containers: 5 years;
 - Refilling or repackaging: 5 years; and
 - Labeling: 5 years.
- Capital costs can be thought of as a one-time purchase of equipment and/or materials related to the compliance of a particular regulation. It is assumed that any capital equipment that must be acquired is purchased at the end of the compliance period.
- Recurring costs are those that regulated entities will incur on an annual or intermittent basis once the regulations are promulgated. Therefore, costs start in the first year after the end of the compliance period.

Not all pesticide container standards have costs associated with them. Table A-1 displays each of the container standards and lists whether there is a cost associated with compliance. If a cost is estimated related to the container standards, Table A-1 describes whether that cost is fixed or variable.

There are two reasons why a particular container standard would not have a cost associated with compliance. First, the container regulations state that pesticides that are considered Department of Transportation (DOT) hazardous materials must be packaged in containers that meet the DOT standards for hazardous materials. Therefore, any costs that regulated entities incur in complying with this standard for pesticides that are DOT hazardous materials are attributed to the DOT standards and not the container regulations. In other words, we consider the DOT standards for hazardous material containers to be in the compliance baseline for DOT hazardous materials. Second, it is assumed that there are containers available on the market today that comply with many of the regulations listed in Table A-1. This assumption is consistent with the proposed EPA container rule RIA which assumed that nearly all containers on the market met container closure and dispensing standards, and that most of the containers in use were DOTcompliant and that nearly all containers in production were DOT-compliant. These assumptions were confirmed for the final EPA container rule EA through additional discussions with pesticide registrants, refillers and industry experts. Compliance with the DOT-related standards was high for the proposed rule, and, given the increasing availability and use of DOT-compliant containers, the final rule assumes that those containers that were out of compliance have either been replaced or will be replaced with compliant containers within the compliance period at no extra cost 76

For those regulations where costs are associated with compliance, there are two inputs that many of the regulations share: labor rates and an inflation factor. First, many of the requirements, such as the administrative requirements (recordkeeping), container inspection, and marking of containers, involve labor costs. For this analysis, a base hourly wage of \$15.54 is used for administrative labor and \$48.22 is used for professional labor. These wages were calculated by averaging the hourly wage for each labor class across the agricultural chemical, industrial organic chemical, and miscellaneous chemical product industries. Using these average wages, we applied a 25 percent fringe adjustment to the hourly rate and a 50 percent overhead adjustment to the wage plus fringe. This results in an hourly rate of \$29.13 for administrative labor and \$90.42 for professional labor. The industry-specific occupational wage estimates are taken from the Bureau of Labor Statistics' Occupational Employment Statistics (BLS, 2000). All costs and cost inputs presented in this report are in 2005\$.

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Two DOT non-hazardous material packing standards had costs associated with them in the proposed EPA container rule RIA (the nonrefillable container marking and refillable container drop test standards). For the nonrefillable container marking requirement, the proposed rule estimated costs to mark containers with an EPA registration number and other statements. For the refillable container drop test requirement, the proposed rule RIA estimated costs to replace containers that were not in compliance with the drop test standard. The final EPA container rule EA estimates no compliance costs with these requirements because it is assumed that nearly all pesticide containers meet the DOT standards.

Table A-1. Compliance Costs Associated with the Container Standards

Container Standard	Cost Associated with Compliance?	Cost Type/ Reason for No Cost
DOT Packaging Standards - Hazardous Material	No.	Costs attributed to the DOT standards, not the container regulation standards.
DOT Packaging Standards – Non-Hazardous Material	No.	Containers that meet the standards are available on the open market at no extra cost.
Closure Standards	No.	Containers that meet the standards are available on the open market at no extra cost.
Standards for Container Dispensing Capability	No.	Containers that meet the standards are available on the open market at no extra cost.
Residue Removal Standards	Yes.	Fixed.
Administrative Requirements - Recordkeeping	Yes.	Fixed.
Standards for Container Marking	Yes.	Variable.
Standards for Openings	Yes.	Variable.
Bulk Container Standards	Yes.	Variable.
Inspection and Cleaning Standards	Yes.	Variable.
Language Changes	Yes.	Fixed.

A.1 Non-Refillable Container Costs

A.1.1 Residue Removal Standard

The cost of complying with the final standards for the removal of residues from non-refillable containers is attributed to the cost of ensuring that each non-refillable container design type and pesticide formulation combination meets the residue removal standard. The container regulations propose that every registrant test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable of attaining at least 99.99 percent removal of each active ingredient in the fourth rinsate after a triple rinse. In the proposed container rule RIA, EPA estimated that it costs \$3,425 to conduct the residue removal test using three containers, which is transferred to the current analysis.⁷⁷

In addition to the testing cost, it is necessary to know how many rigid container/dilutable formulation combinations there are per establishment to calculate the total residue removal compliance cost. It is assumed that the average establishment, regardless of size or market sector, uses three rigid container types per formulation, based on an assumption EPA made in its proposed container rule RIA. In an informal survey of pesticide registrants for the final rule economic analysis (EA), we determined that this was a reasonable assumption. Of nine responses across small, medium, and large registrants, four registrants indicated that on average

 $^{^{77}}$ Values quoted from the proposed container rule RIA have been updated to 2005\$ to make them comparable with values in this economic analysis.

they used three containers to package each of their formulations (from a range of 1 to 12 container types per formulation).

To develop the representative number of formulations for large and small registrants, the analysis begins by examining the active registrations for large companies, based on company registration information from EPA's Pesticide Product Information System (PPIS) database and Dun & Bradstreet data for determining company size. We downloaded the necessary container regulation Section 3 Product Information Files from the PPIS Web site (http://www.epa.gov/opppmsd1/PPISdata/) and then uploaded the files into a Microsoft Access database. We removed inactive registrations (and corresponding company data) from the database, and as a result, identified 1,804 registrants holding 16,407 active registrations (or formulations).

Based on the large pesticide registrant profile (see Appendix D), we matched approximately 4,600 registrations with the 146 large pesticide registrants identified in the industry profile. As a result, we calculated that each large registrant had on average 32 active registrations. We distributed the approximately 11,700 remaining active registrations (approximately 16,400 - 4,600) among the small registrants using best professional judgment by assigning on average more registrations to large-small companies (20) than medium-small companies (9) and small-small companies (3). Table A-2 summarizes the estimated number of registrations per company in each size category based on the approach described. The table also lists the assumptions made on the number of active registrations per registrant size category for the proposed rule, which was significantly higher due to less specific data available on the number of active registrations.

Table A-2. Estimated Number of Active Registrations (Formulations) per Registrant by Size Category: Current Versus Proposed Rule

Size Category	Estimated Number of Active Registrations (Formulations) per Registrant	Proposed Rule Estimate of the Number of Active Registrations (Formulations) per Registrant a
Large Registrants	32 ^b	430
Large-Small Registrants	20	430
Medium-Small Registrants	9	60
Small-Small Registrants	3	16

^a Estimates taken from the proposed container rule RIA (EPA, 1993).

As shown in Table A-3, by multiplying the number of active registrations per registrant by the number of registrants in each size category (see Table D-3), the total number of active registrations (15,438) and the percent of active registrations per size category can be calculated. This number is less than the actual number of active registrations (16,407) due to rounding in the per registrant size category.

^b Calculated by dividing the total number of active registrations (4,575) by the estimated number of registrants in each size category (146) and rounding the result up to the nearest integer (31.3 to 32).

Table A-3. Estimated Number of Active Registrations per Registrant Size Category

Size Category	Estimated Number of Active Registrations per Registrant ^a	Number of Registrants in Size Category b	Number of Active Registrations per Size Category	Percentage of Active Registrations per Size Category
Large Registrants	32	146	4,672	30%
Large-Small Registrants	20	166	3,320	22%
Medium-Small Registrants	9	495	4,455	29%
Small-Small Registrants	3	997	2,991	19%
Total ^c (Registrants or Active Registrations)	NA	1,804	15,438	100%

^a See Table A-2.

However, not all active registrations are subject to the residue removal standard. Only products that are subject to the full set of non-refillable container standards and that are flowable concentrate products in rigid containers are subject to the residue removal standard. The products that are subject to the full set of non-refillable container standards are those products that are not specifically exempt and that are: (1) classified in Toxicity Category I or II, and/or (2) are restricted use products (RUPs). Of the products that meet these criteria, only products that are formulated as flowable concentrates and that are packaged in rigid containers (i.e., not in bags) are subject to the residue removal standard.

An analysis of total number of products formulated as flowable concentrates that are Toxicity Category I and II and RUPs provides an estimate of the number of active registrations that are subject to the residue removal standard. Based on an analysis of EPA product registration data on the number and type of registered products, an estimated 105 (rounded up to 110) active registrations (products) are subject to the residue removal standard (Table A-4). The analysis first identified from EPA product registration data the total number of registered Toxicity Category I, II, III, and IV products, restricted use products, and antimicrobial products (column one of Table A-4). The analysis then estimated the percentage of these products that are subject to the residue removal standard (column two of Table A-4) by selecting from the EPA product registration data only those products formulated as flowable concentrates (346) and studying their labels to determine which of these products are Toxicity Category I and II and RUPs. Based on this analysis, an estimated 3 percent of Toxicity Category I, 3 percent of Toxicity Category II, and 6 percent of RUPs in Toxicity Category III/IV are subject to the residue removal standard (Table A-4). None of the identified flowable concentrate products are antimicrobial products.

^b See Table D-3.

^c May not add due to rounding. The estimated 15,438 products are less than the estimated total number of registrations based on EPA data due to rounding in per registrant estimates.

Table A-4. Estimated Number of Active Products Subject to the Residue Removal Standard

Product Category	Number of Products in Category ^a	Percentage of Products Subject to Residue Removal Standard ^b	Number of Products Subject to Residue Removal Standard ^c
Toxicity Category I (non-antimicrobial)	1,434	3%	43
Toxicity Category II (non-antimicrobial)	1,585	3%	48
Restricted Use Product in Toxicity Category III/IV (non-antimicrobial)	225	6%	14
Antimicrobial Products that are subject to non-refillable container standards ^d	1,350	0%	0
Total	4,594	NA	105 ^e

^a Based on information from EPA pesticide product databases.

Based on this information, Table A-3 can be amended to include the estimated number of active registrations (formulations) subject to the residue removal standard per registrant (Table A-5). This information is calculated by distributing the estimated 110 products subject to the residue removal standard among the four registrant size categories according to the same percentages as in Table A-3, and dividing the resulting value by the number of registrants in that size category. The result is a significant reduction in the number of active registrations subject to the residue removal standard. For example, for the average large registrant, the estimated number of active registrations subject to the residue removal standard drops from 32 to 0.23 (rounded up to 0.25) when considering only those products specifically subject to the residue removal standard. This value suggests that not every large registrant has an existing registration that will be subject to the residue removal standard. However, on average, across all registrants, each registrant has one-quarter of an existing registration subject to the residue removal standard. Table A-6 provides a comparison of the different estimates of the number of active registrations, considering all active registrations (column three of Table A-6), and considering only active registrations subject to the residue removal standard (column two of Table A-6).

^b Information on the percentage of active products subject to the residue removal standard was estimated by identifying all active flowable concentrate registrations and studying their labels to determine which products are Toxicity Category I and II and/or RUPs. This column represents the estimated percentage of the registered products that are Toxicity Category I and II and RUP flowable concentrates in rigid containers.

^c The number of products subject to the residue removal standard is calculated by multiplying the number of products in each category by the corresponding percentage of the sample subject to the residue removal standard. ^d None of the 346 active registered flowable concentrate products are antimicrobial products.

^e The number of products subject to the residue removal standard is rounded to 110 products in the analysis.

Table A-5. Estimated Number of Active Products Subject to the Residue Removal Standard by Registrant Size Category

Size Category	Percentage of Active Registrations per Size Category ^a	Number of Active Registrations Subject to Residue Removal Standard per Size Category b	Number of Registrants in Size Category ^c	Number of Active Registrations Subject to Residue Removal Standard per Average Registrant d
Large Registrants	30%	33	146	0.23
Large-Small Registrants	22%	24	166	0.14
Medium-Small Registrants	29%	32	495	0.06
Small-Small Registrants	19%	21	997	0.02
Total (Registrants or Active Registrations)	NA	110	1,804	NA

^a See Table A-3.

Table A-6. Comparison of the Estimated Number of Active Registrations (Formulations) per Average Registrant by Size Category

Size Category	Estimated Number of Active Registrations (Formulations) Subject to the Residue Removal Standard per Registrant ^a	Estimated Number of Active Registrations (Formulations) per Registrant ^c
Large Registrants	0.25	32
Large-Small Registrants	0.20	20
Medium-Small Registrants	0.10	9
Small-Small Registrants	0.05	3
Total Registrants	NA	NA

The proposed container rule RIA assumed that the number of new formulations per registrant per year that require testing was two for all entity sizes except small-small registrants, for which the RIA assumed one new formulation that requires testing each year. No new data are available with which to update the assumption about the number of new products per year. However, since there are so few existing registrations that are subject to the residue removal standard, this assumption must be adjusted to reflect the changes in the scope of the requirements from the proposed to the final rule. In the absence of data, the final rule EA makes the assumption that the number of new formulations subject to the residue removal standard per registrant per year is the same as the number of existing formulations subject to the residue removal standard per registrant. That is, for the final rule, it is assumed that there are 0.25 new formulations per registrant per year that require testing (or one every 4 years) for the large registrants; 0.20 new formulations per registrant per year that require testing (or one every 5 years) for the large-small

^b Equal to the percent of active registration per size category times the total number of active registrations (110). This analysis assumes that the number of active registrations subject to the residue removal standard is distributed by registrant size category in the same proportion as all active registrations.

^c See Table D-3.

^d Equal to the number of active registration subject to the residue removal standard divided by the number of registrants in each size category.

registrants; 0.10 new formulations per registrant per year that require testing (or one every 10 years) for medium-small registrants; and 0.05 new formulations per registrant per year that require testing (or one every 20 years) for the small-small registrants (Table A-7).

Table A-7. Non-Refillable Container Residue Removal Compliance Cost Inputs and Assumptions

Establishment Type	Testing Cost (2005\$) ^a	Container Types per Formulation ^a	Existing Formulations ^b	New Formulations ^b	Percent Re- tested ^c	"Me-Too" Scenario ^d		
Large-Small Establish	ments							
Agriculture	\$3,425	3	0.2	0.2	30%	75%		
I/C/G	\$3,425	3	0.2	0.2	30%	75%		
Home & Garden	\$3,425	3	0.2	0.2	30%	75%		
Medium-Small Establi	shments							
Agriculture	\$3,425	3	0.1	0.1	30%	75%		
I/C/G	\$3,425	3	0.1	0.1	30%	75%		
Home & Garden	\$3,425	3	0.1	0.1	30%	75%		
Small-Small Establish	ments							
Agriculture	\$3,425	3	0.05	0.05	30%	75%		
I/C/G	\$3,425	3	0.05	0.05	30%	75%		
Home & Garden	\$3,425	3	0.05	0.05	30%	75%		
Large Establishments								
Agriculture	\$3,425	3	0.25	0.25	30%	75%		
I/C/G	\$3,425	3	0.25	0.25	30%	75%		
Home & Garden	\$3,425	3	0.25	0.25	30%	75%		

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993: pg. IX-13). Costs were updated to 2005 dollars, and other assumptions were revised based on new data and discussions with industry experts.

Not all container/formulation combinations subject to the residue removal standard will be tested, however. In the proposed container rule RIA, EPA made this assumption because test data conforming to the residue removal protocol on a different non-refillable container/formulation combination may be used to demonstrate that a non-refillable container meets the residue removal standard. This is referred to as the "me-too" scenario. Because EPA did not know the extent to which "me-toos" applied, they assumed a lower range of 50 percent of all container/formulation combinations will be tested and an upper range of 100 percent of all such combinations will be tested. For this analysis, the midpoint of the range, 75 percent, is used since the extent to which "me-toos" will apply is not known.

^b Revised number of existing formulations per establishment based on analysis of the PPIS active registration database. The same value is estimated for new formulations.

^c The percent retested is based on residue removal testing studies of different container/formulation combinations. The retesting value is equal to the difference between the number of flowable concentrate container/formulation types failing the four-9s and five-9s standard.

^d The "Me-Too" Scenario refers to the percentage of formulations that will be tested—i.e., 25 percent of the container/formulation combinations are assumed not to be tested as a result of using test data from different container/formulation combinations that passed the protocol to demonstrate that these container/formulation combinations pass as well.

It is also assumed that a certain number of container/formulation combinations will fail the initial residue removal test, requiring a second test using a container carefully selected from the open market and expected to rinse more readily. Based on a study conducted for EPA, EPA assumed in the proposed container rule RIA that 13 percent of small, medium, and large agricultural containers and 3 percent of small and medium industrial/commercial/government containers would not pass a triple-rinse test where 99.999 percent (five-9s standard) of a given formulation would be removed after rinsing (EPA, 1992b). The proposed rule requires containers to pass only a four-9s standard (99.99 percent removed after rinsing). The preamble to the final rule summarizes the residue removal data from tests conducted using a standard testing procedure to test currently used formulations and container designs. The data show that all 26 of the flowable concentrate container formulations tested met the four-9s standard. However, 7 of the 26 container/formulation combinations tested (or 27 percent) failed to meet the five-9s standard. Because of the relatively large difference between the number of tests that meet the four-9s and the five-9s standards, we assume the difference (30 percent, rounded up from the 27 percent failure rate in the study) as the failure rate in the EA. In other words, the EA for the final rule assumes a 30 percent retesting rate due to failure in the first test for all registrant company sizes and market segments. It is assumed that all container/formulation combinations pass the retest.

Table A-7 displays the unit cost inputs and associated assumptions that comprise the residue removal standard compliance costs in this analysis. Table A-8 presents the compliance and annual costs associated with the residue removal standard. The costs associated with the testing of existing container/formulation combinations are considered to be compliance period costs incurred at the end of the third year (at the end of the compliance period for non-refillable containers), and the annual testing of new container/formulation combinations are annual costs incurred in each year after the end of the compliance period (years 4 through 20).

To demonstrate how costs in Table A-8 are calculated from the information in Table A-7, the cost inputs associated with large-small agricultural establishments are used. Initial testing costs of the existing formulations, and incurred in the compliance period, are calculated by multiplying the number of container types per formulation (3) by the number of existing formulations (0.2). Multiplying the number of existing formulation/container combinations (0.6) by the testing cost (\$3,425), and adjusting that result by the "me-too" adjustment factor (75 percent of container/formulation combinations tested), yields an initial testing cost of \$1,541. The retesting cost for existing container/formulation combinations are calculated by multiplying those combinations (0.6) by the percent retested factor (30 percent). This result (0.18) is then multiplied by the testing cost (\$3,425). The resulting retest cost incurred by large-small agricultural establishments in the compliance period is \$617. The same calculations apply for the initial testing and retesting costs for new container/formulation combinations (annual costs).

Table A-8. Non-Refillable Container Residue Removal Compliance Costs (2005\$)

Establishment Type	Initial Test Cost - Existing (Compliance) ^a	Initial Test Const - New (Annual) ^a	Re-test Cost - Existing (Compliance) ^b	Re-test Cost - New (Annual) ^b				
Large-Small Establish	ments							
Agriculture	\$1,541	\$1,541	\$617	\$617				
I/C/G	\$1,541	\$1,541	\$617	\$617				
Home & Garden	\$1,541	\$1,541	\$617	\$617				
Medium-Small Establ	ishments							
Agriculture	\$771	\$771	\$308	\$308				
I/C/G	\$771	\$771	\$308	\$308				
Home & Garden	\$771	\$771	\$308	\$308				
Small-Small Establish	ments							
Agriculture	\$385	\$385	\$154	\$154				
I/C/G	\$385	\$385	\$154	\$154				
Home & Garden	\$385	\$385	\$154	\$154				
Large Establishments	Large Establishments							
Agriculture	\$1,927	\$1,927	\$771	\$771				
I/C/G	\$1,927	\$1,927	\$771	\$771				
Home & Garden	\$1,927	\$1,927	\$771	\$771				

^a Initial test costs are calculated as follows: (Testing Cost) * (# Containers/Formulation) * (# of Formulations [Existing or New]) * (% "Me-Toos").

A.1.2 Administrative Requirements - Recordkeeping

For each pesticide product that a registrant handles, the container standards require the registrant to generate and maintain a number of records (listed in §165.86 of the container regulations) for as long as a particular non-refillable container design type is used to distribute or sell the pesticide product and for 3 years thereafter. Therefore, the costs associated with this recordkeeping are attributed to the administrative labor costs and the capital cost of acquiring a file cabinet to store the records. File cabinet costs are based on the average price of a four-drawer legal file cabinet surveyed across a number of office supply stores (\$229.65). The labor time assumptions are based on estimates used by EPA in the proposed container rule RIA. Since no new data are available to update these recordkeeping labor time estimates, they are left in place. It is assumed that these data are reasonable, however, based on the anticipated amount of recordkeeping required by the container regulations.

Table A-9 displays the cost inputs and assumptions that comprise the labor-related recordkeeping costs. Hours represent the total amount of time it takes to fulfill the recordkeeping requirements. For existing container/formulation combinations, the labor time is spent at the end of the compliance period (3 years for non-refillable container requirements). For new container/formulation combinations, the labor time is spent in each year (years 4 through 20) after the end of the compliance period. Note that the labor time assumptions change between establishment size categories, since the number of formulations handled by each establishment depends on the size of that establishment (see Table A-6 for the number of formulations by establishment type). The more container/formulation combinations, the longer it takes to

^b Retest costs are calculated as follows: (Testing Cost) * (# Containers/Formulation) * (# of Formulations [Existing or New]) * (% Retested).

complete the recordkeeping requirements. It is also assumed that administrative personnel will fill out the required paperwork. Therefore, the administrative cost of labor is applied in this analysis.

Table A-10 presents the capital, compliance, and annual costs for the residue removal standard. The cost associated with the acquisition of a file cabinet (\$229.65) is considered a capital cost that establishments incur at the end of the 3-year compliance period for the non-refillable container regulations. Generating the paperwork necessary for existing container/formulation combinations is a compliance period cost also incurred at the end of the 3-year compliance period. The annual generation and maintenance of paperwork for new container/formulation combinations is an annual cost that establishments incur each year between years 4 through 20.

To demonstrate how recordkeeping costs in Table A-10 are calculated from the information in Table A-9, the cost inputs associated with large-small agricultural establishments are used. Multiplying the administrative cost of labor (\$29.13) by the number of hours assumed that it will take a large-small agricultural establishment to fulfill its recordkeeping requirements for existing container/formulation combinations (40 hours), the compliance period cost for the non-refillable container requirements is estimated to be \$1,165.23 for large-small agricultural establishments. Using the same procedure to calculate recordkeeping costs for new container/formulation combinations, the administrative cost of labor (\$29.13) is multiplied by the recordkeeping labor time for new container/formulation combinations (4 hours). It is estimated to cost large-small agricultural establishments \$116.52 annually to fulfill the recordkeeping requirements for new container/formulation combinations.

Table A-9. Non-Refillable Container Recordkeeping Cost Inputs and Assumptions

Establishment Type	Recordkeeping Labor Time for all Cont./Form. Combs Existing (hours) ^a	Recordkeeping Labor Time for all Cont./Form. Combs New (hours) ^a	Labor Cost/Hour - Administrative (2005\$) ^b
Large-Small Establis	shments		
Agriculture	40°	4	\$29.13
I/C/G	40	4	\$29.13
Home & Garden	40	4	\$29.13
Medium-Small Estab	olishments		
Agriculture	36	3	\$29.13
I/C/G	36	3	\$29.13
Home & Garden	36	3	\$29.13
Small-Small Establis	hments		
Agriculture	24	2	\$29.13
I/C/G	24	2	\$29.13
Home & Garden	24	2	\$29.13
Large Establishment	S		
Agriculture	40	4	\$29.13
I/C/G	40	4	\$29.13
Home & Garden	40	4	\$29.13

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pg. IX-13).

^b The occupational wage estimates are taken from the Bureau of Labor Statistics' Occupational Employment statistics available on the BLS Web site, http://www.bls.gov/oes/2000, and updated from 2002\$.

^c Hours represent the time it takes to generate and maintain the records associated with the non-refillable container recordkeeping regulations in §165.86 of the FIFRA container regulations.

Table A-10. Non-Refillable Container Recordkeeping Costs

Establishment Type	File Cabinet Cost (Capital) ^a	Recordkeeping Cost - Existing (Compliance) b	Recordkeeping Cost - New (Annual) b
Large-Small Establishment	s		
Agricultural	\$229.65	\$1,165.23	\$116.52
I/C/G	\$229.65	\$1,165.23	\$116.52
Home & Garden	\$229.65	\$1,165.23	\$116.52
Medium-Small Establishme	ents		
Agricultural	\$229.65	\$1,048.71	\$87.39
I/C/G	\$229.65	\$1,048.71	\$87.39
Home & Garden	\$229.65	\$1,048.71	\$87.39
Small-Small Establishments	3		
Agricultural	\$229.65	\$699.14	\$58.26
I/C/G	\$229.65	\$699.14	\$58.26
Home & Garden	\$229.65	\$699.14	\$58.26
Large Establishments			
Agricultural	\$229.65	\$1,165.23	\$116.52
I/C/G	\$229.65	\$1,165.23	\$116.52
Home & Garden	\$229.65	\$1,165.23	\$116.52

^a File cabinet costs are based on the average price of a four-drawer legal file cabinet surveyed across a number of office supply stores.

A.2 Refillable Container Costs

A.2.1 Administrative Requirements

If a registrant distributes or sells a pesticide product in refillable containers (either directly or to a refiller for repackaging), the regulations require that the registrant create certain documents and maintain a number of records. These documents include, for each pesticide product, a description of acceptable containers and a written residue removal procedure. (See §§165.164 and 165.190.) The registrant must maintain copies of the documents for the current operating year and 3 years after. (See §§165.176(a) and 165.194.) The registrant must also provide copies of the documents to independent refillers (§165.192). If the product will be repackaged by an independent refiller, the registrant must enter into a contract with the refiller and keep a copy of the contract (§§165.182 and 165.194). This kind of arrangement is currently standard operating practice because it is specified in EPA's Bulk Pesticide Enforcement policy. Therefore, the costs associated with the contract are not included as part of this economic analysis. It is worth noting that the administrative requirements are actually located in the repackaging regulations, but are included in the refillable container part of the cost analysis because they are borne by refillers.

The costs associated with the administrative requirements are attributed to administrative labor costs and the capital cost of acquiring a file cabinet to store the record. File cabinet costs are

^b Recordkeeping costs (compliance period or annual) are calculated as follows: Labor Time * Labor Cost. (See Table A-9.)

⁷⁸ This file cabinet is separate from the one used to store records associated with the non-refillable container requirements.

based on the average price of a four-drawer legal file cabinet surveyed across a number of office supply stores (\$229.65). The labor time assumptions are based on estimates used by EPA in the proposed container rule RIA. Since no new data are available to update these recordkeeping labor time estimates, these values are left in place.

Table A-11 displays the cost inputs and assumptions that comprise the labor-related administrative costs. Hours represent the total amount of time it takes to fulfill the refillable container administrative requirements. For existing container/formulation combinations, the labor time is spent at the end of the compliance period (5 years for refillable container and repackaging requirements). For new container/formulation combinations, the labor time is spent in each year (years 6 through 20) after the end of the compliance period. Note that the labor time assumptions change between establishment size categories, since the number of formulations handled by each establishment depends on the size of that establishment (see Table A-6 for the number of formulations by establishment type). The more refillable container/formulation combinations, the longer it takes to complete the administrative requirements. Since no new data are available to refute or validate these assumptions, they are left in place. It is also assumed that administrative personnel will fill out the required paperwork. The administrative cost of labor is, therefore, applied in this analysis.

Table A-12 presents the capital, compliance, and annual costs for the residue removal standard. We consider the cost associated with the acquisition of a file cabinet (\$229.65) a capital cost that establishments incur at the end of the five-year refillable container regulations compliance period. Generating the documents necessary for existing refillable container/formulation combinations is a compliance period cost also incurred at the end of the five-year compliance period. The annual generation and maintenance of paperwork is annual cost establishments incur each year between years six through 20.

To demonstrate how administrative costs in Table A-12 are calculated from the information in Table A-11, the cost inputs associated with large-small agricultural establishments are used. Multiplying the cost of administrative labor (\$29.13) by the number of hours it is assumed that it will take a large-small agricultural establishment to: (1) develop a description of acceptable refillable containers for use with each formulation (4 hours), and (2) revise or generate the written residue removal procedures for existing refillable containers (24 hours), it is estimated that the compliance period cost for the refillable container recordkeeping requirements will be \$815.66 for large-small agricultural establishments. Using the same procedure to calculate recordkeeping costs for new refillable container/formulation combinations, the administrative cost of labor (\$29.13) is multiplied by the equivalent recordkeeping labor time categories for new container/formulation combinations (1 hour + 2.4 hours). It is estimated that it costs large-small agricultural establishments \$99.04 annually to fulfill the recordkeeping requirements for new refillable container/formulation combinations.

Table A-11. Refillable Container Administrative Cost Inputs and Assumptions

		Administrative Labor Time (hours)					
Establishment Type	List of Acceptable Containers - Existing ^a	List of Acceptable Containers - New ^a	Written Res. Rem. Procedure - Existing ^a	Written Res. Rem. Procedure - New ^a	Labor Cost/hr – Administrative b		
Large-Small Establishments							
Agricultural	4	1	24	2.4	\$29.13		
I/C/G	4	1	24	2.4	\$29.13		
Home & Garden	4	1	24	2.4	\$29.13		
Medium-Small Estab	olishments						
Agricultural	3	0.5	16	1.5	\$29.13		
I/C/G	3	0.5	16	1.5	\$29.13		
Home & Garden	3	0.5	16	1.5	\$29.13		
Small-Small Establis	hments						
Agricultural	2	0.5	8	1	\$29.13		
I/C/G	2	0.5	8	1	\$29.13		
Home & Garden	2	0.5	8	1	\$29.13		
Large Establishment	Large Establishments						
Agricultural	4	1	24	2.4	\$29.13		
I/C/G	4	1	24	2.4	\$29.13		
Home & Garden	4	1	24	2.4	\$29.13		

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pg. IX-13).
^b The occupational wage estimates are taken from the Bureau of Labor Statistics' Occupational Employment statistics (BLS, 2000).

Table A-12. Refillable Container Administrative Costs (2005\$)

Establishment Type	File Cabinet Cost (Capital) ^a	Recordkeeping Cost - Existing (Compliance) b	Recordkeeping Cost - New (Annual) b
Large-Small Establishme	` • ·	(**** P ********************************	
	1	¢01 <i>5 ((</i>	¢00.04
Agricultural	\$229.65	\$815.66	\$99.04
I/C/G	\$229.65	\$815.66	\$99.04
Home & Garden	\$229.65	\$815.66	\$99.04
Medium-Small Establish	ments		
Agricultural	\$229.65	\$553.48	\$58.26
I/C/G	\$229.65	\$553.48	\$58.26
Home & Garden	\$229.65	\$553.48	\$58.26
Small-Small Establishme	nts		
Agricultural	\$229.65	\$291.31	\$43.70
I/C/G	\$229.65	\$291.31	\$43.70
Home & Garden	\$229.65	\$291.31	\$43.70
Large Establishments			
Agricultural	\$229.65	\$815.66	\$99.04
I/C/G	\$229.65	\$815.66	\$99.04
Home & Garden	\$229.65	\$815.66	\$99.04

^a File cabinet costs are based on the average price of a four-drawer legal file cabinet surveyed across a number of office supply stores.

A.2.2 Standard for Container Marking

Section 165.116 of the container regulations states that each refillable container must be durably marked with a serial number or other identifying code that will distinguish the individual container from all other containers. It is assumed that ink is the preferred method of applying the serial number and that all registrants already have the equipment (for example, stencils or printers) to apply the ink. This assumption is based on information presented in EPA's proposed container rule RIA. The RIA quoted a source (Bach, 1992) who stated that producers/formulators who package pesticides in refillable drums or barrels are already stenciling information on their containers before shipping and most, if not all, have stenciling equipment. It is assumed that this is still the case; most refillable containers in the current analysis are drum or barrel sized and larger. The container marking costs in this analysis, therefore, are the cost of acquiring the ink, the labor time it takes to apply the serial number to the container, and the number of containers that the serial number must be applied to. Because there is no new information to replace the assumptions used in the proposed container rule RIA, with the exception of the hourly wage of labor, all of the cost inputs and assumptions associated with this cost category are taken from the proposed container rule RIA.

EPA's contacts with industry experts and equipment and/or supply vendors determined that the cost of a gallon of ink was \$34.25; one gallon of ink could mark 70,000 containers; it takes

^b Recordkeeping costs (compliance period or annual) are calculated as follows: Labor Time (Design Standard Documentation + List of Acceptable Containers + Written Residue Removal Procedure) * Labor Cost.

approximately five minutes to add a serial number to each refillable container; and that a plastic refillable container lasts 5 years while a steel refillable container lasts 15 years. These assumptions are used to determine the two types of costs associated with the marking of refillable containers: the cost associated with marking existing refillable containers and, because refillable containers wear out, the cost of marking new containers that will need a serial number application over the course of the container regulations.

The costs associated with marking existing refillable containers are considered a compliance period cost, incurred by establishments at the end of the 5-year compliance period for the refillable container regulations. Though all plastic refillable containers, and one-third of steel refillable containers, will wear out and need replacement during the compliance period, it is assumed that the total inventory of refillable containers subject to the container marking regulations will not change by the end of the compliance period. By the end of the compliance period, therefore, all refillable containers will be subject to the container marking regulations and will need a serial number application. Though the marking of these existing containers will be phased in over the course of the 5-year compliance period, for consistency with other compliance period costs in the analysis, it is assumed that establishments incur the cost of marking existing refillable containers at the end of the compliance period in year 5.

The cost of marking new containers that will replace existing containers as they wear out after the compliance period are considered annual costs that establishments will incur yearly (in years 6 through 20). However, because only one-fifth of plastic containers and one-fifteenth of steel containers will require replacement each year, the annual unit marking costs are adjusted by the same factors.

Table A-13 displays the cost inputs and assumptions that comprise the container marking unit costs. Table A-14 presents the compliance period and annual costs associated with marking individual containers. To demonstrate how container marking costs in Table A-14 are calculated from the information in Table A-13, the cost inputs associated with large-small agricultural establishments are used. The unit cost associated with the ink needed to mark each container is calculated by dividing the cost of a gallon of ink (\$34.25) by the number of containers it is estimated to mark (70,000), resulting in a cost of \$0.00049 per container. The labor cost associated with the physical act of marking the containers is calculated by multiplying the time it takes to mark the container (five minutes, or 8.33 percent of an hour) by the administrative rate of labor (\$29.13/hour), which equals \$2.43 per container. The full ink and labor unit costs are applied to the containers subject to marking at the end of the compliance period, one-fifth of these unit costs are applied to the annual cost of marking plastic refillable containers, and one-fifteenth of these unit costs are applied to the annual cost of marking steel refillable containers. The annual cost per entity range from \$1 for small-small agricultural establishments to \$3,807 for large agricultural establishments (see Table A-14).

Table A-13. Refillable Container Marking Cost Inputs and Assumptions (2005\$)

Establishment Type	Ink (\$/gal.) ^a	# Containers Marked/gal. ^a	Stencil Time/ Container (hour) ^a	Labor Cost/hr - Administrative b	Refillable Container Lifespan - Plastic ^a	Refillable Container Lifespan - Steel ^a
Large-Small Estab	olishments					
Agricultural	\$34.25	70,000	0.0833	\$29.13	5	15
I/C/G ^c	\$34.25	70,000	0.0833	\$29.13	5	15
Home & Garden	\$34.25	70,000	0.0833	\$29.13	5	15
Medium-Small Es	tablishments	S				
Agricultural	\$34.25	70,000	0.0833	\$29.13	5	15
I/C/G ^c	\$34.25	70,000	0.0833	\$29.13	5	15
Home & Garden	\$34.25	70,000	0.0833	\$29.13	5	15
Small-Small Estab	lishments					
Agricultural	\$34.25	70,000	0.0833	\$29.13	5	15
I/C/G c	\$34.25	70,000	0.0833	\$29.13	5	15
Home & Garden	\$34.25	70,000	0.0833	\$29.13	5	15
Large Establishments						
Agricultural	\$34.25	70,000	0.0833	\$29.13	5	15
I/C/G ^c	\$34.25	70,000	0.0833	\$29.13	5	15
Home & Garden	\$34.25	70,000	0.0833	\$29.13	5	15

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pg. IX-13).

^b The occupational wage estimates are taken from the Bureau of Labor Statistics' Occupational Employment statistics (BLS, 2000).

^c Container marking is not required for refillable containers used for antimicrobials used in the swimming pool market, such as sodium hypochlorite. This adjustment is made to the number of refillable containers subject to the container marking regulations presented in the compliance profile and explained in Chapter 3 by considering the containers of swimming pool antimicrobials separately.

Table A-14. Refillable Container Marking Costs (2005\$)

Establishment Type	Unit Stencil Labor Cost - Plastic (Compliance/ Annual) ^a	Unit Stencil Labor Cost - Steel (Compliance/ Annual) ^a	Unit Ink Cost - Plastic (Compliance/ Annual) b	Unit Ink Cost – Steel (Compliance / Annual) b	Annual Cost per Entity ^d	
Large-Small Establishments						
Agricultural	\$2.43	\$2.43	\$0.00049	\$0.00049	\$27	
I/C/G ^c	\$2.43	\$2.43	\$0.00049	\$0.00049	\$3	
Home & Garden	\$2.43	\$2.43	\$0.00049	\$0.00049	\$0	
Medium-Small Establishmen	ts					
Agricultural	\$2.43	\$2.43	\$0.00049	\$0.00049	\$5	
I/C/G ^c	\$2.43	\$2.43	\$0.00049	\$0.00049	\$0	
Home & Garden	\$2.43	\$2.43	\$0.00049	\$0.00049	\$0	
Small-Small Establishments						
Agricultural	\$2.43	\$2.43	\$0.00049	\$0.00049	\$1	
I/C/G ^c	\$2.43	\$2.43	\$0.00049	\$0.00049	\$0	
Home & Garden	\$2.43	\$2.43	\$0.00049	\$0.00049	\$0	
Large Establishments						
Agricultural	\$2.43	\$2.43	\$0.00049	\$0.00049	\$3,807	
I/C/G ^c	\$2.43	\$2.43	\$0.00049	\$0.00049	\$356	
Home & Garden	\$2.43	\$2.43	\$0.00049	\$0.00049	\$0	

a Unit labor costs (compliance period costs) associated with refillable container markings are calculated as follows: Labor Time to Mark Each Container * Labor Cost. To calculate the annual labor cost of marking refillable containers, we adjust the compliance period unit cost by a factor to account for the life span of each container: Labor Time to Mark Each Container * Labor Cost ^b Unit ink costs (compliance period costs) associated with refillable container markings are calculated as follows: Ink Cost per Gallon ÷ # of Containers Marked per Gallon. To calculate the annual ink cost of marking refillable containers, we adjust the compliance period unit cost by a factor to account for the life span of each container: (Ink Cost per Gallon ÷ # of Containers Marked per Gallon) ^c Container marking is not required for refillable containers used for certain antimicrobials, including refillable containers filled with sodium hypochlorite, a common antimicrobial used in the swimming pool industry. This adjustment is made to the number of refillable containers subject to the container marking regulations presented in the compliance profile and explained in Chapter 3.

^d Average annual container marking compliance cost per firm. Annual cost is calculated by calculating the sum of the present discounted value of costs incurred from years 5 to 20, and then annualizing it using a 3 percent discount rate. The details of the calculations are presented in Chapter 4 in sections 4.5.6 through 4.5.8.

A.2.3 Standards for Openings

The container regulations limit access to the interior of liquid minibulk containers by requiring that each opening of a liquid minibulk container other than a vent have a one-way valve, a tamper-evident device, or both. EPA believes that one-way valves and tamper-evident devices will give repackagers reasonable assurance of the previous contents of the containers. Most agricultural minibulks and small volume returnable containers supplied by or purchased from registrants are equipped with either a one-way valve or a tamper-evident device (EPA, 1992b) and are therefore expected to be in compliance in the baseline. Agricultural minibulks obtained on the open market, rather than from registrants, usually lack tamper-evident devices or one-way valves, so refillers must add them (or something similar). The standards for openings are not applicable to bulk tanks.

The compliance rate for the standards for the openings for affected refillables is based on assumptions that EPA made for the proposed container rule RIA (EPA, 1993)⁷⁹. It is assumed that 65 percent minibulk containers are compliant in the agricultural market and 10 percent are compliant compliance for minibulk containers in the I/C/G market (assumes that tote bins are minibulks, but small volume returnables in the I/C/G market are not minibulks).

Because the compliance period for this regulation is 5 years, many refillable containers will reach the end of their life span by the time the rule is implemented. It is assumed that these containers will be replaced by compliant containers that are available on the open market at no extra cost. Using the same refillable life span assumption that was used to estimate container marking costs, it is assumed that plastic refillable containers must be replaced every 5 years and steel refillable containers every 15 years. As a result, no plastic refillable containers will incur the cost of modifying their container openings for the express purpose of complying with the regulation. Further, assuming that containers, which meet Container Rule standards, are available on the market for no extra cost, there will be no compliance costs associated with plastic containers.

Only one-third of existing steel refillable containers, however, will be replaced during the compliance period (5-year compliance period divided by the 15-year life span). To come into compliance with the regulation, two-thirds of existing steel refillable containers will need to add tamper-evident devices. It is assumed that all of these containers will require the tamper-evident modification. EPA estimated that the cost of such a modification, including labor and materials, was \$109.60. Establishments incur this cost at the end of the 5-year compliance period for the refillable container regulations.

Table A-15 presents the cost inputs and assumptions used to calculate the costs for this regulation. Table A-16 presents the one-time unit variable compliance cost of this regulation. To demonstrate how opening standard unit costs in Table A-16 are calculated from the information in Table A-15, the cost inputs associated with large-small agricultural establishments are used. There are no unit costs associated with the opening standards for plastic refillable containers because 100 percent of plastic refillable containers will be replaced by compliant

⁷⁹ Refer to the Proposed Container Rule RIA (EPA, 1993) Tables VII-8 and VII-9 and the table footnotes for information to substantiate the assumptions used in this analysis.

containers during the compliance period (5-year compliance period/5-year plastic refillable lifespan = 100% plastic refillable compliance). There are unit costs associated with the opening standards for steel refillable containers, however. Only 33 percent of steel refillable containers will be replaced with compliant containers during the compliance period (5-year compliance period/15-year steel refillable lifespan = 33.33% steel refillable compliance). The unit cost of complying with the container opening standard for steel refillables is therefore calculated by multiplying the modification costs for existing containers (\$109.60) by the percentage of steel refillable containers not in compliance with the opening standard (1 - 33.33% = 66.67%). The resultant unit cost is \$73.07. To compute the cost of the opening standard to the average pesticide refiller in each size category and market sector, the average cost per steel container (\$73.07) is multiplied by the number of steel containers the average refiller is assumed to have for each market sector and size category. The average cost per entity ranges from \$1 for small-small agricultural establishments to \$4,084 for large agricultural establishments. The details of the calculations are presented in Chapter 4, sections 4.5.6 through 4.5.8.

Table A-15. Cost Inputs and Assumptions for Refillable Container Openings (2005\$)

Establishment Type	Compliance Period (yrs)	Refillable Container Lifespan - Plastic ^a	Refillable Container Lifespan - Steel ^a	% of Containers Not Replaced During Compliance Period - Plastic b	% of Containers Not Replaced During Compliance Period - Steel ^b	Modification Costs for Existing Containers ^a
Large-Small Esta	1		1	1	1	
Agricultural	5	5	15	0%	67%	\$109.60
I/C/G ^c	5	5	15	0%	67%	\$109.60
Home & Garden	5	5	15	0%	67%	\$109.60
Medium-Small Es	stablishments					
Agricultural	5	5	15	0%	67%	\$109.60
I/C/G ^c	5	5	15	0%	67%	\$109.60
Home & Garden	5	5	15	0%	67%	\$109.60
Small-Small Estal	blishments			•		
Agricultural	5	5	15	0%	67%	\$109.60
I/C/G ^c	5	5	15	0%	67%	\$109.60
Home & Garden	5	5	15	0%	67%	\$109.60
Large Establishm	ents					
Agricultural	5	5	15	0%	67%	\$109.60
I/C/G ^c	5	5	15	0%	67%	\$109.60
Home & Garden	5	5	15	0%	67%	\$109.60

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pg. IX-13).

^b Calculated by dividing the length of the compliance period (5 years) by the assumed lifespan of a refillable container (plastic – 5 years, steel – 15 years).

^c Container marking is not required for refillable containers used for certain antimicrobials, including refillable containers filled with sodium hypochlorite, a common antimicrobial used in the swimming pool industry. This adjustment is made to the number of refillable containers subject to the container marking regulations presented in Chapter 3.

Table A-16. Refillable Container Openings Costs (2005\$)

Establishment Type	Opening Standard Unit Cost - Plastic (Compliance) ^a	Opening Standard Unit Cost - Steel (Compliance) b	Annual Cost per Entity ^d
Large-Small Establishments			
Agricultural	\$0.00	\$73.07	\$29
Industrial/Commercial/Government c	\$0.00	\$73.07	\$3
Home & Garden	\$0.00	\$73.07	\$0
Medium-Small Establishments			
Agricultural	\$0.00	\$73.07	\$5
Industrial/Commercial/Government ^c	\$0.00	\$73.07	\$1
Home & Garden	\$0.00	\$73.07	\$0
Small-Small Establishments			
Agricultural	\$0.00	\$73.07	\$1
Industrial/Commercial/Government c	\$0.00	\$73.07	\$0
Home & Garden	\$0.00	\$73.07	\$0
Large Establishments			
Agricultural	\$0.00	\$73.07	\$4,084
Industrial/Commercial/Government c	\$0.00	\$73.07	\$428
Home & Garden	\$0.00	\$73.07	\$0

^a Because it is assumed that all plastic refillable containers will be replaced with compliant containers by the end of the 5-year compliance period at no extra cost, there are no compliance period unit costs associated with plastic refillable containers under this regulation.

A.2.4 Bulk Container Standards

The bulk container standards (§165.120) require that bulk containers at independent refillers' establishments and their appurtenances be designed to resist extreme changes in temperature and be resistant to corrosion, puncture, or cracking, and that they also be capable of withstanding all operating stresses. It is assumed that the bulk containers currently used by refillers, and those that exist on the market today, comply with these basic design requirements. The bulk container standards also require that liquid bulk containers be equipped with a vent or other similar device, that external sight gauges be removed from bulk containers and replaced with another type of gauge, and that the containers be equipped with a shutoff valve that can be locked closed.

After conversations with industry experts, EPA assumed in its proposed container rule RIA that all dry bulk containers satisfy the bulk container standards and 75 percent of agricultural liquid

^b The unit cost of modifying a refillable steel container's opening is calculated as follows: Modification Cost * (1 - % of Containers Replaced During Compliance Period).

^c Container marking is not required for refillable containers used for certain antimicrobials, including refillable containers filled with sodium hypochlorite, a common antimicrobial used in the swimming pool industry. This adjustment is made to the number of refillable containers subject to the container marking regulations presented in the compliance profile and explained in Chapter 3.

^d Average annual container opening compliance cost per firm. Annual cost is calculated by calculating the sum of the present discounted value of costs incurred from years 5 to 20, and then annualizing it using a 3 percent discount rate. The details of the calculations are presented in Chapter 4 in sections 4.5.6 through 4.5.8.

plastic bulk containers, 20 percent of agricultural liquid steel bulk containers and 5 percent of all liquid bulk containers in the I/C/G market are in compliance with the bulk container standards.

For the current analysis, it is assumed that a float gauge will be chosen to comply with the bulk container regulations. EPA estimated that the cost of external sight gauge removal was \$68.50 per bulk tank and that the cost of float gauge installation was \$787.25 (updated to 2005\$). These costs are retained in this analysis. Table A-17 displays these one-time per-container compliance costs. It is assumed that establishments incur these costs at the end of the 5-year compliance period for refillable container regulations. The annual cost per entity ranges from \$1 for the small-small agricultural establishment to \$8,495 for the large I/C/G establishment. The annual cost are calculated as the sum of the present value of the costs incurred from year 5 to year 20, annualized using a 3 percent discount rate. The details of the annualization method are presented in Chapter 4, sections 4.5.6 through 4.5.8. The analysis assumes that all new bulk containers purchased will be in compliance with the regulations.

Table A-17. Bulk Container Standards Compliance Costs

Establishment Type	Cost of External Sight Gauge Removal (Compliance) a	Cost of Float Gauge Installation (Compliance) ^a	Annual Cost per Entity ^b
Large-Small Establishments			
Agricultural	\$68.50	\$787.25	\$24
Industrial/Commercial/Government	\$68.50	\$787.25	\$61
Home & Garden	N/A	N/A	N/A
Medium-Small Establishments			
Agricultural	\$68.50	\$787.25	\$4
Industrial/Commercial/Government	\$68.50	\$787.25	\$11
Home & Garden	N/A	N/A	N/A
Small-Small Establishments			
Agricultural	\$68.50	\$787.25	\$1
Industrial/Commercial/Government	\$68.50	\$787.25	\$2
Home & Garden	N/A	N/A	N/A
Large Establishments		·	
Agricultural	\$68.50	\$787.25	\$3,325
Industrial/Commercial/Government	\$68.50	\$787.25	\$8,495
Home & Garden	N/A	N/A	N/A

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pg. IX-13).

A.3 Refilling Compliance Costs

The standards for establishments that repackage pesticide products into refillable containers (refillers) require that these entities inspect, clean, and record information about the refillable containers that they refill (§§165.160–165.176, and §§165.200–165.218). The cost to do this is primarily associated with the labor time it takes to conduct the inspections, cleaning, and

^b Average annual bulk container standards compliance cost per firm. Annual cost is calculated by calculating the sum of the present discounted value of costs incurred from years 5 to 20, and then annualizing it using a 3 percent discount rate. The details of the calculations are presented in Chapter 4 in sections 4.5.6 through 4.5.8.

recordkeeping. Total costs also include the fixed capital cost of acquiring a file cabinet to store the required paperwork, the costs of which are the same as file cabinets acquired to store records associated with both the refillable and non-refillable container requirements (\$229.65).

Using our best professional judgment, based on estimates made by EPA in the proposed container rule RIA as a baseline (EPA, 1993, pg. IX-13), we estimated the labor time associated with inspecting, cleaning, and recordkeeping of a refillable container each time it is refilled. We estimated that it takes one minute to inspect the refillable container, 10 minutes to clean it, and two minutes to conduct the recordkeeping. This is a reasonable assumption on the median time take given that small containers are likely to take about one minute for inspection majority of the containers are small. It is assumed that these are administrative tasks; therefore, the administrative rate of labor (\$29.13/hour) is used to calculate costs. Unlike the majority of costs calculated in this analysis, the unit costs associated with the refilling regulations are calculated every time a container is refilled. The refilling rate assumptions, and associated discussion, are presented in Chapter 4.

Table A-18 presents the labor time assumptions for each of the refilling requirements and the hourly wage of administrative labor. Table A-19 presents the fixed capital cost of acquiring the file cabinet and the unit variable costs of complying with the inspection, cleaning, and recordkeeping requirements. The cost of the file cabinet is a one-time compliance period cost that refilling establishments will incur at the end of the 5-year compliance period for refiller regulations. The unit costs of inspection, cleaning, and recordkeeping of the containers that refilling establishments refill are considered annual costs that are incurred in years 6 through 20.

To demonstrate how refilling compliance costs in Table A-19 are calculated from the information in Table A-18, the cost inputs associated with large-small agricultural establishments are used. The unit cost associated with the inspection, cleaning, and recordkeeping of each container that is refilled is calculated based on the time it takes to complete each task (1, 10, and 2 minutes per refill, respectively) multiplied by the administrative cost of labor (\$29.13). The resulting unit (per refill) costs are therefore \$0.49 for container inspection, \$4.86 for container cleaning, and \$0.97 for container recordkeeping. The annual cost per entity ranges from \$14 for the small-small agricultural pesticide registrants to \$10,000 for the large swimming pool companies. Annual cost is calculated by calculating the sum of the present discounted value of costs incurred from years 5 to 20, and then annualizing it using a 3 percent discount rate. The details of the annualization proceedure are presented in Chapter 4 in sections 4.5.6 through 4.5.8.

⁸⁰ The recordkeeping involves recording the container's EPA registration number, amount of the pesticide product distributed or sold in the refillable container, the date of the repackaging, and the serial number of the refillable container.

Table A-18. Refilling Requirement Cost Inputs and Assumptions (2005\$)

Establishment Type	Inspection Time per Container Refill (min) ^a	Cleaning Time per Container Refill (min) ^a	Recordkeeping Time per Container Refill (min) ^a	Labor Cost/hr - Administrative ^b
Agricultural Pesticide	e Refillers			
Large-Small	1	10	2	\$29.13
Medium-Small	1	10	2	\$29.13
Small-Small	1	10	2	\$29.13
Large	1	10	2	\$29.13
Agricultural Pesticide	e Registrants			
Large-Small	1	10	2	\$29.13
Medium-Small	1	10	2	\$29.13
Small-Small	1	10	2	\$29.13
Large	1	10	2	\$29.13
Industrial/Commerci	al/Government - Pestic	ide Registrants		
Large-Small	1	10	2	\$29.13
Medium-Small	1	10	2	\$29.13
Small-Small	1	10	2	\$29.13
Large	1	10	2	\$29.13
Swimming Pool Supp	oly Companies - Antimi	crobial Applicators		
Large-Small	1	10	2	\$29.13
Medium-Small	1	10	2	\$29.13
Small-Small	1	10	2	\$29.13
Large	1	10	2	\$29.13

^a Using our best professional judgment, based on estimates made by EPA in the proposed container rule RIA as a baseline (EPA, 1993, pg. IX-13), we estimated the labor time associated with inspecting, cleaning, and recordkeeping of a refillable container each time it is refilled.

b The occupational wage estimates are taken from the Bureau of Labor Statistics' Occupational Employment

statistics (BLS, 2000).

Table A-19. Refilling Requirement Costs (2005\$)

Establishment Type	File Cabinet Cost (Compliance) a	Unit Variable Cost of Inspection (per refill) ^b	Unit Variable Cost of Cleaning (per refill) b	Unit Variable Cost of Recordkeeping (per refill) b	Annual Cost per Entity ^c
Agricultural Pesticide	Refillers				
Large-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$871
Medium-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$267
Small-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$43
Large	\$229.65	\$0.49	\$4.86	\$0.97	\$7,255
Agricultural Pesticide	Registrants				
Large-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$45
Medium-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$19
Small-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$14
Large	\$229.65	\$0.49	\$4.86	\$0.97	\$4,434
Industrial/Commercia	l/Government - P	esticide Registra	nts		
Large-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$40
Medium-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$18
Small-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$14
Large	\$229.65	\$0.49	\$4.86	\$0.97	\$3,828
Swimming Pool Suppl	y Companies - Ar	ntimicrobial App	licators		
Large-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$34
Medium-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$23
Small-Small	\$229.65	\$0.49	\$4.86	\$0.97	\$15
Large	\$229.65	\$0.49	\$4.86	\$0.97	\$10,000

^a File cabinet costs are based on the average price of a four-drawer legal file cabinet surveyed across a number of office supply stores.

A.4 Cost of Label Requirements

The container regulations, in addition to all of the compliance requirements detailed above, will also modify the labeling requirements in 40 CFR Part 156 (Labeling Requirements for Pesticides and Devices) by adding Subpart H, entitled "Container Labeling," and by modifying §156.10 (Labeling Requirements). The new labeling regulations will require that specific statements be placed on the label or container of all pesticide products and will also provide detailed residue removal instructions on the labels of some products. However, the final regulations exempt household products from the residue removal instructions.

The costs to comply with the labeling requirements are associated with the costs for a label change on virtually all formulated pesticide products, since much of the required information is

^b The unit costs of complying with the refilling requirements are calculated as follows: Labor Time (per refill) * Labor Cost.

^c Average annual refilling requirement cost per firm. Annual cost is calculated by calculating the sum of the present discounted value of costs incurred from years 5 to 20, and then annualizing it using a 3 percent discount rate. The details of the calculations are presented in Chapter 4 in sections 4.5.6 through 4.5.8.

not currently found on pesticide labels. Label changes must be made by the end of the 3-year compliance period for the labeling regulations.

Labeling cost inputs are based on the assumptions made in the proposed container rule RIA. In that analysis, EPA received label change cost data from a number of independent small, medium, and large pesticide formulators. Averaging across the responses received, EPA estimated that the label change costs for small facilities were \$1,918 per label change and \$5,069 per label change for medium and large facilities (in 2005\$). These costs represent the cost of the artwork or typesetting, two proof readings, and printing plates. The purchase of the labels themselves was considered an ordinary cost of doing business and was therefore not included in the label change costs. Also, the cost of disposing unused, non-compliant labels was not included in the label change costs because EPA assumed that each facility would be able to use up existing label inventory during the compliance period. Because there is no information to replace the assumptions used in the proposed container rule RIA, all of the cost inputs and assumptions associated with this cost category are taken from the proposed container rule RIA.

In the proposed container rule RIA, EPA assumed that because many pesticide labels routinely undergo changes every 1 to 3 years, facilities will change 50 percent of all their labels during the compliance period. For labels that undergo a routine change, EPA assumed that the additional language required by the labeling regulations would be incorporated at the same time. The entire cost of the label change, therefore, was not associated with the labeling requirements. Instead, EPA assumed that only one-third of the cost of the artwork changes was attributed to the labeling requirements (the cost of adding text to an already planned label change). The remaining 50 percent of the labels were assumed by EPA to require changing during the compliance period for one reason only: to come into compliance with the labeling requirements. Therefore, EPA attributed the full costs of changing the labels directly to the labeling requirements.

There are two slight differences between the current analysis and the proposed container rule RIA. First, in the current analysis, the label change costs for small facilities from the proposed container rule RIA are transferred to the small-small facilities, and the label change costs for medium and large facilities are transferred to medium-small, large-small, and large establishments. Second, the compliance period for the final labeling requirements is 3 years as opposed to the 2-year compliance period assumed in the proposed container rule RIA. Though the compliance period is now longer, there is not sufficient information to alter the proposed rule's assumption that 50 percent of all label changes that occur during the compliance period are routine (with only one-third of the total label change cost considered a cost of compliance), and that the other 50 percent are the result of the need to come into compliance with the regulation (with 100 percent of the total label change cost considered a cost of compliance). This assumption is therefore retained and applied to the current analysis.

The number of label changes that establishments must make is based on the number of formulations they package. It is assumed, as in the proposed container rule RIA, that each formulation requires one label change. The number of existing formulations per facility is the same as that used throughout the current analysis (see Table A-2). Table A-20 displays the cost

⁸¹ The proposed container rule RIA assumed a 2-year compliance period, though the proposed labeling requirements did not specify a definite compliance schedule or date.

inputs and assumptions used to calculate the label change costs, and Table A-21 displays the total facility-level compliance cost.

It is assumed that facilities incur the label change costs at the end of the compliance period for the 3-year labeling regulations. It is also assumed that once registrants make all of the labeling changes to existing labels by the end of the compliance period, establishments will incur no new labeling costs in the future; the artwork or typesetting and printing plates will have been modified to meet the labeling language requirements and will not need future modifications as a result of the labeling regulations. Also, facilities will be able to incorporate this labeling text into labels of new products at no additional cost.

To demonstrate how certification costs in Table A-21 are calculated from the information in Table A-20, the cost inputs associated with large-small agricultural establishments are used. The facility-level cost associated with routine label changes for existing formulations is calculated by multiplying the number of formulations (20) by the percentage of label changes considered routine (50 percent). The resulting number of existing formulations (10) is then multiplied by the cost of a routine label change (\$479.50 per label change). Routine label changes therefore cost large-small agricultural establishments \$4,795. The facility-level cost associated with necessary label changes for existing formulations is calculated similarly; the other half of existing formulations (10) is multiplied by the cost of a necessary label change (\$5,069 per label change). Necessary label changes therefore cost large-small agricultural establishments \$50,690.

Table A-20. Labeling Requirement Cost Inputs and Assumptions (2005\$)

	0 1	<u>-</u>	-	,
Establishment Type	Label Cost - Routine Change ^a	Label Cost - Necessary Change ^a	% of Label Changes Considered Routine ^a	Existing Formulations ^b
Large-Small Establis	hments			
Agricultural	\$479.50	\$5,069	50%	20
I/C/G	\$479.50	\$5,069	50%	20
Home & Garden	\$479.50	\$5,069	50%	20
Medium-Small Estab	lishments			
Agricultural	\$479.50	\$5,069	50%	9
I/C/G	\$479.50	\$5,069	50%	9
Home & Garden	\$479.50	\$5,069	50%	9
Small-Small Establis	hments			
Agricultural	\$205.50	\$1,918	50%	3
I/C/G	\$205.50	\$1,918	50%	3
Home & Garden	\$205.50	\$1,918	50%	3
Large Establishment	S			
Agricultural	\$479.50	\$5,069	50%	32
I/C/G	\$479.50	\$5,069	50%	32
Home & Garden	\$479.50	\$5,069	50%	32

^a Cost inputs based on assumptions made by EPA in the proposed container rule RIA (EPA, 1993, pp. X-1 through X-7). Only one-third of the total label change cost are considered routine cost of compliance.

^b Revised number of existing formulations per establishment based on analysis of the PPIS active registration

database. See Table A-2.

Table A-21. Labeling Requirement Costs (2005\$)

Establishment Type	Total Cost - Routine Change (Compliance) ^a	Total Cost - Necessary Change (Compliance) b
Large-Small Establishments		
Agricultural	\$4,795	\$50,690
I/C/G	\$4,795	\$50,690
Home & Garden	\$4,795	\$50,690
Medium-Small Establishments		
Agricultural	\$2,175	\$22,810.50
I/C/G	\$2,175	\$22,810.50
Home & Garden	\$2,175	\$22,810.50
Small-Small Establishments		
Agricultural	\$308.25	\$2,877
I/C/G	\$308.25	\$2,877
Home & Garden	\$308.25	\$2,877
Large Establishments		
Agricultural	\$7,672	\$81,104
I/C/G	\$7,672	\$81,104
Home & Garden	\$7,672	\$81,104

^a Facility-level routine labeling costs are calculated as follows: # of Existing Formulations * % of Label Changes Considered Routine * Routine Label Change Cost.

A.5 Waiver Costs

In addition to the costs associated with the container and labeling regulations, there are costs associated with the waiver applications that registrants may choose to submit to be exempted from particular regulations. For facilities that do submit a waiver, EPA assumed in the proposed container rule RIA that it took a facility manager 4 hours to complete the waiver. We assume this is a reasonable amount of time to compose and submit a waiver for one or all regulations eligible for exemption. This labor time multiplied by the assumed hourly wage of professional labor equaled the facility-level cost of completing a waiver. EPA assumed in the proposed container rule that this cost was the same across all market sectors and facility sizes. These assumptions are retained in the current analysis, using the updated professional labor wage of \$90.42/hour. The total cost facilities incur when applying for a waiver is therefore labor time (4 hours) multiplied by labor cost (\$90.42/hour), which equals \$361.69. It is assumed that facilities will apply for waivers, and therefore incur waiver costs, in the first year that the container rules are promulgated.

^b Facility-level necessary labeling costs are calculated as follows: # of Existing Formulations * % of Label Changes Considered Necessary * Necessary Label Change Cost.

Appendix B. Compliance Profile Estimation Details

B.1 Assumptions and Procedure for Converting Pesticide Volume and Weight into Number of Refillable Containers in Use

The number of refillable containers in the agricultural market is calculated by converting the formulated volume (in gallons) and formulated weight (in pounds) of pesticides reported in the 1996 American Crop Protection Association (ACPA) Container Survey (ACPA, 1997) into the number of refillable containers in use. We assumed the following in order to convert pesticide volume and weight used into the estimated number of refillable containers in use for the agricultural market:

Assumed representative non-bulk container sizes per category (Paulson, 2002):

Liquid refillables

- 5–25 gallon plastic/steel: 15 gal;
- 26–60 gallon plastic/steel: 45 gal, based on average between common sizes of 30 and 60 gallons;
- 61–125 gallon plastic/steel: 85 gal, based on mid-point across range of sizes between 60 and 110 gallons;
- 126–250 gallon plastic: 180 gal, based on mid-point across range of sizes between 140 and 220 gallons; and
- 126–250 gallon steel: 225 gal, based on average between common sizes of 200 and 250 gallons.

Dry refillables

- <100 pound non-bulks: 75 lbs, based on mid-point across range of sizes between 50 and 100 pounds; and
- 101–2,500 pound non-bulks: 1,100 lbs, based on mid-point across common range of sizes between 1,000 and 1,200 pounds.

Assumed refill rates (Paulson, 2002):

- Small and large liquid refillables are estimated to be refilled on average 2–2.5 and 1.5–2 times annually, respectively. As a result, the refill rate for 5–25 gallon containers was 2.25 times annually and for 26–250 gallon container sizes was 1.75 times annually.
- Dry non-bulk refillables are estimated to be refilled on average 1.5–2 times annually, with 1.75 used in the analysis.
- Bulk liquid and dry containers are assumed to be refilled on average 1–1.5 times annually, with 1.25 used in the analysis.

These estimates include the assumption that not all containers are refilled to capacity.

Assumed representative bulk container sizes (Paulson, 2002):

- Liquid: 2,500 gallons; and
- Dry: 2,501 pounds.

We used the following procedure to estimate the number of agricultural refillable containers in use:

- (7) **Estimate the number of new, non-bulk containers:** Divide the formulated amount in use based on the 1996 ACPA Container Survey by the assumed average non-bulk container size for that category and round the estimate to the nearest hundred. For example, there are an estimated 34,700 new "5–25 gallon plastic" refillables in existence based on a formulated volume of 519,842 gallons divided by the representative container size of 15 gallons (34,656 rounded to 34,700). New refillables are assumed to be filled initially by a pesticide registrant at the manufacturing or formulating facility.
- (8) **Estimate the number of existing non-bulk containers:** Refillables repackaged with pesticide product are assumed to be refilled primarily by agricultural pesticide refillers. Pesticide product refilled into existing refillables is assumed to pass through the bulk containers considered in the 1996 ACPA Container Survey. Therefore, the ratio of formulated volume (or weight) for a given container size category versus the total non-bulk container formulated volume (or weight) was multiplied by the total liquid (or dry) formulated volume (or weight) in use and divided by the representative container size times the annual refill rate. For example, we estimated there are 93,200 existing "5–25 gallon plastic" refillables in use based on the following equation:

(519,842/7,589,197)*45,923,755/(15*2.25)

(total volume in 5-25 gallon plastic category/total non-bulk volume) * total liquid volume in use/(representative container size*refill rate)

- (9) Sum the new and existing refillables for each size category: For example, the total number of "5–25 gallon plastic" refillables in use was estimated to be 127,900 (34,700 new plus 93,200 existing containers).
- (10) **Estimate the number of bulk containers:** There does not appear to be an observable increasing or decreasing trend in the formulated volume and weight of annual pesticide use over the 1989 through 1996 ACPA Container Survey period. Therefore, no net change in the number of bulk containers is assumed to have occurred since the 1996 survey.

The 1996 ACPA Container Survey bulk container formulated amount represents the amount of pesticides distributed from pesticide manufacturers and formulators to retailers through stationary bulk containers in 1996. The method in which the pesticide is transported from the manufacturer or formulator to the retailer (i.e., via tank car or tanker truck) is not important to the analysis. The number of containers taken out of circulation annually is unknown. Based on this information, we divided the 1996 bulk container formulated amount by the representative bulk container size (2,500 gallons or 2,501 pounds) multiplied by the

⁸² The 1996 APCA Container Survey defined bulk containers as containers larger than 250 gallons.

refill rate mid-point estimate (1.25 times annually). As a result, the total estimated number of liquid and dry bulk containers in use was 14,700 and 5,600, respectively.

The estimated numbers of liquid (>500 gallons) and dry (>4,000 pounds) retail bulk tanks (as defined in this economic analysis) are 13,400 (12,060 plastic and 1,340 steel) and 175, respectively. These estimates were considered reasonable by EPA and Don Paulson (2002) and are consistent with the estimates used for the economic analysis of the containment rule. ⁸³ Of the remaining 1,300 liquid minibulk tanks (251-500 gallons), we assume that 90 percent (or 1,170) are plastic and 10 percent (or 130) are steel. There are 5,425 dry minibulk containers assumed in the analysis (5,600 - 175).

B.2 Number of Refillables in Use by the Pool Industry: A Separate Discussion and Consideration

Sodium hypochlorite is an antimicrobial that is exempt from certain container requirements (see Chapter 3). Public commenters on the 1994 proposed container rule (EPA,1994) and 1999 Supplemental Notice (EPA, 1999), including pool supply companies, industry associations, and an antimicrobial manufacturer, specifically addressed the impact that the container regulations would have on refillable containers currently used to distribute sodium hypochlorite for swimming pool/spa use. It is assumed that the estimated number of refillable containers in use in the industrial/commercial/government (I/C/G) and home and garden (H&G) markets does not include the refillables used in the swimming pool industry. This assumption is based on the comments received and EPA's understanding of the source data used to derive container estimates for the proposed container rule RIA and subsequent updates to the estimates for this analysis.

Currently, based on comments to the 1999 Supplemental Notice submitted by relevant trade associations (i.e., the Chlorine Institute, National Spa and Pool Institute, and Swimming Pool Chemical Manufacturers Association), we estimate that more than 38 million gallons of sodium hypochlorite are estimated to be distributed each year in refillable containers ranging in size from jugs (1 and 2.5 gallons) to drums (30 and 55 gallons) to minibulks (220 and 330 gallons). The comments also suggest that the average number of refillings and is eight. A smaller refilling rate of four was assumed for larger containers. This refilling rate was used with the data on volume from the comments (38 million gallons of sodium hypochlorite in use for pools in spas annually) to arrive at the total number of containers.

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⁸³ A separate economic analysis is written for the requirements for bulk containment structures. The containment regulations apply only to stationary bulk containers at retail facilities, custom applicators, and custom blenders, while the bulk container standards apply only to bulk containers at independent refillers.

Appendix C. Regulation-Specific Cost Schedules

Table C-1. Undiscounted Costs ^a of Complying with the Residue Removal Standards for Non-Refillable Containers Under the Current Rule ^b

					C			
Establishment				Yea	r			
	3	4	5	6	7	8	9	10
Large-Small Establishments								
Agricultural	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158
I/C/G	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158
Home & Garden	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158
Medium-Small Establishments								
Agricultural	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079
I/C/G	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079
Home & Garden	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079
Small-Small Establishments								
Agricultural	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539
I/C/G	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539
Home & Garden	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539
Large Establishments								
Agricultural	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697
I/C/G	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697
Home & Garden	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697

Table C-1 (Continued). Undiscounted Costs ^a of Complying with the Residue Removal Standards for Non-Refillable Containers Under the Current Rule ^b

Establishment					Y	ear				
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158
I/C/G	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158
Home & Garden	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158	\$2,158
Medium-Small Establishments										
Agricultural	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079
I/C/G	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079
Home & Garden	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079	\$1,079
Small-Small Establishments										
Agricultural	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539
I/C/G	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539
Home & Garden	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539	\$539
Large Establishments										
Agricultural	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697
I/C/G	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697
Home & Garden	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697	\$2,697

^a Costs are rounded to the nearest dollar.

^b Compliance with the Residue Removal Standards involves only fixed costs.

^c The compliance period for non-refillables is 3 years. The analysis assumes that costs are incurred beginning at the end of the third year.

Table C-2. Undiscounted Costs ^a of Complying with Recordkeeping Requirements for Non-Refillable Containers Under the Container Rule ^b

Establishment				Year	c				
	3	4	5	6	7	8	9	10	
Large-Small Establishments									
Agricultural	\$1,165	\$117	\$117	\$117	\$117	\$117	\$117	\$117	
I/C/G	\$1,165	\$117	\$117	\$117	\$117	\$117	\$117	\$117	
Home & Garden	\$1,165	\$117	\$117	\$117	\$117	\$117	\$117	\$117	
Medium-Small Establishments									
Agricultural	\$1,049	\$87	\$87	\$87	\$87	\$87	\$87	\$87	
I/C/G	\$1,049	\$87	\$87	\$87	\$87	\$87	\$87	\$87	
Home & Garden	\$1,049	\$87	\$87	\$87	\$87	\$87	\$87	\$87	
Small-Small Establishments									
Agricultural	\$699	\$58	\$58	\$58	\$58	\$58	\$58	\$58	
I/C/G	\$699	\$58	\$58	\$58	\$58	\$58	\$58	\$58	
Home & Garden	\$699	\$58	\$58	\$58	\$58	\$58	\$58	\$58	
Large Establishments									
Agricultural	\$1,165	\$117	\$117	\$117	\$117	\$117	\$117	\$117	
I/C/G	\$1,165	\$117	\$117	\$117	\$117	\$117	\$117	\$117	
Home & Garden	\$1,165	\$117	\$117	\$117	\$117	\$117	\$117	\$117	

Table C-2 (Continued). Undiscounted Costs ^a of Complying with Recordkeeping Requirements for Non-Refillable Containers

Under the Container Rule ^b

Establishment					Yo	ear				
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117
I/C/G	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117
Home & Garden	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117
Medium-Small Establishments										
Agricultural	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87
I/C/G	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87
Home & Garden	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87	\$87
Small-Small Establishments										
Agricultural	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58
I/C/G	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58
Home & Garden	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58
Large Establishments										
Agricultural	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117
I/C/G	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117
Home & Garden	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117	\$117

^a Costs are rounded to the nearest dollar.

^b Compliance with the Other Administrative Requirements (recordkeeping) involves only fixed costs.

^c The compliance period for non-refillables is 3 years. The analysis assumes that costs are incurred beginning at the end of the third year.

Table C-3. Undiscounted Costs ^a of Complying with the Container Marking Standards for Refillable Containers Under the Container Rule ^b

Establishment			Year	. с		
	5	6	7	8	9	10
Large-Small Establishments						
Agricultural	\$166	\$27	\$27	\$27	\$27	\$27
I/C/G	\$15	\$3	\$3	\$3	\$3	\$3
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Medium-Small Establishments						
Agricultural	\$31	\$5	\$5	\$5	\$5	\$5
I/C/G	\$3	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Small-Small Establishments						
Agricultural	\$7	\$1	\$1	\$1	\$1	\$1
I/C/G	\$1	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Large Establishments						
Agricultural	\$23,231	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720
I/C/G	\$2,072	\$356	\$356	\$356	\$356	\$356
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A

Table C-3 (Continued). Undiscounted Costs ^a of Complying with the Container Marking Standards for Refillable Containers Under the Container Rule ^b

Establishment	Year									
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27	\$27
I/C/G	\$3	\$3	\$3	\$3	\$3	\$3	\$3	\$3	\$3	\$3
Home & Garden	N/A									
Medium-Small Establishments										
Agricultural	\$5	\$5	\$5	\$5	\$5	\$5	\$5	\$5	\$5	\$5
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A									
Small-Small Establishments										
Agricultural	\$1	\$1	\$1	\$1	\$1	\$1	\$1	\$1	\$1	\$1
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A									
Large Establishments										
Agricultural	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720	\$3,720
I/C/G	\$356	\$356	\$356	\$356	\$356	\$356	\$356	\$356	\$356	\$356
Home & Garden	N/A									

 ^a Costs are rounded to the nearest dollar.
 ^b Compliance with the Container Marking Standards involves only variable costs.
 ^c The compliance period for refillables is 5 years. The analysis assumes that costs are incurred beginning at the end of the fifth year.

Table C-4. Undiscounted Costs ^a of Complying with the Standards of Openings (for Liquid-Minibulk Containers Only) for Refillable Containers Under the Container Rule ^b

Establishment			Year ^c			
	5	6	7	8	9	10
Large-Small Establishments						
Agricultural	\$519	\$0	\$0	\$0	\$0	\$0
I/C/G	\$54	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Medium-Small Establishments						
Agricultural	\$96	\$0	\$0	\$0	\$0	\$0
I/C/G	\$10	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Small-Small Establishments						
Agricultural	\$20	\$0	\$0	\$0	\$0	\$0
I/C/G	\$2	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Large Establishments						
Agricultural	\$72,555	\$0	\$0	\$0	\$0	\$0
I/C/G	\$7,605	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A

Table C-4 (Continued). Undiscounted Costs^a of Complying with the Standards of Openings (for Liquid-Minibulk Containers Only) for Refillable Containers Under the Container Rule^b

Establishment					Year					
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medium-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Small-Small Establishments										ļ
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Large Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

^aCosts are rounded to the nearest dollar.

^bCompliance with the Standards for Openings (for liquid minibulk containers only) involves only variable costs.

^cThe compliance period for refillables is 5 years. The analysis assumes that costs are incurred beginning at the end of the fifth year. The analysis also assumes that compliant containers can be purchased at no extra cost at the end of the compliance period.

Table C-5. Undiscounted Costs^a of Complying with the Bulk Container Standards for Refillable Containers Under the Container Rule^b

Establishment			Year ^c			
	5	6	7	8	9	10
Large-Small Establishments						
Agricultural	\$423	\$0	\$0	\$0	\$0	\$0
I/C/G	\$1,080	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A
Medium-Small Establishments						
Agricultural	\$78	\$0	\$0	\$0	\$0	\$0
I/C/G	\$200	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A
Small-Small Establishments						
Agricultural	\$17	\$0	\$0	\$0	\$0	\$0
I/C/G	\$43	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A
Large Establishments						
Agricultural	\$59,063	\$0	\$0	\$0	\$0	\$0
I/C/G	\$150,914	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A

Table C-5 (Continued). Undiscounted Costs^a of Complying with the Bulk Container Standards for Refillable Containers

Under the Container Rule^b

Establishment					Year					
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Medium-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Small-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Large Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden ^d	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

^aCosts are rounded to the nearest dollar.

^bCompliance with the Bulk Container Standards involves only variable costs.

^cThe compliance period for refillables is 5 years. The analysis assumes that costs are incurred beginning at the end of the fifth year. The analysis also assumes that bulk containers purchased after the five-year compliance period will be in compliance at no extra cost.

^dCompliance costs for Home & Garden establishments are not applicable because the number of bulk containers in Home & Garden establishments is zero.

Table C-6. Undiscounted Costs^a of Complying with Administrative Requirements for Refillable Containers Under the Containment Rule^b

Establishment			Year ^c			
	5	6	7	8	9	10
Large-Small Establishments						
Agricultural	\$1,133	\$128	\$128	\$128	\$128	\$128
I/C/G	\$1,133	\$128	\$128	\$128	\$128	\$128
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Medium-Small Establishments						
Agricultural	\$841	\$73	\$73	\$73	\$73	\$73
I/C/G	\$841	\$73	\$73	\$73	\$73	\$73
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Small-Small Establishments						
Agricultural	\$550	\$58	\$58	\$58	\$58	\$58
I/C/G	\$550	\$58	\$58	\$58	\$58	\$58
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A
Large Establishments						
Agricultural	\$1,133	\$128	\$128	\$128	\$128	\$128
I/C/G	\$1,133	\$128	\$128	\$128	\$128	\$128
Home & Garden	N/A	N/A	N/A	N/A	N/A	N/A

Table C-6 (Continued). Undiscounted Costs^a of Complying with Administrative Requirements for Refillable Containers Under the Containment Rule^b

Establishment					Year					
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128
I/C/G	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128
Home & Garden	N/A									
Medium-Small Establishments										
Agricultural	\$73	\$73	\$73	\$73	\$73	\$73	\$73	\$73	\$73	\$73
I/C/G	\$73	\$73	\$73	\$73	\$73	\$73	\$73	\$73	\$73	\$73
Home & Garden	N/A									
Small-Small Establishments										
Agricultural	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58
I/C/G	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58	\$58
Home & Garden	N/A									
Large Establishments										
Agricultural	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128
I/C/G	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128	\$128
Home & Garden	N/A									

^aCosts are rounded to the nearest dollar.

^bCompliance with the Other Administrative Requirements (preparing certain documents and recordkeeping) involves only fixed costs.

^cThe compliance period for refillables is 5 years. The analysis assumes that costs are incurred beginning at the end of the fifth year.

Table C-7. Undiscounted Costs^a of Complying with the Labeling Requirements for All Containers Under the Container Rule^b

Establishment	Year ^c										
	3	4	5	6	7	8	9	10			
Large-Small Establishments	·					•	•				
Agricultural	\$55,485	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
I/C/G	\$55,485	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Home & Garden	\$55,485	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Medium-Small Establishments											
Agricultural	\$24,968	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
I/C/G	\$24,968	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Home & Garden	\$24,968	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Small-Small Establishments											
Agricultural	\$3,185	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
I/C/G	\$3,185	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Home & Garden	\$3,185	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Large Establishments											
Agricultural	\$88,776	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
I/C/G	\$88,776	\$0	\$0	\$0	\$0	\$0	\$0	\$0			
Home & Garden	\$88,776	\$0	\$0	\$0	\$0	\$0	\$0	\$0			

Table C-7 (Continued). Undiscounted Costs^a of Complying with the Labeling Requirements for All Containers Under the Container Rule^b

Establishment		Year								
	11	12	13	14	15	16	17	18	19	20
Large-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Medium-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Small-Small Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Large Establishments										
Agricultural	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
I/C/G	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Home & Garden	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

^aCosts are rounded to the nearest dollar.

^bCompliance with the Labeling Requirements involves only fixed costs.

^cThe compliance period for non-refillables is 3 years. The analysis assumes that labeling costs are incurred beginning at the end of the third year. The analysis also assumes no costs after the compliance period because existing labels will be in compliance and new labeling text will be incorporated into the labels of new products at no additional cost.

Appendix D. Profile of Industries Regulated by the Pesticide Container Regulations

This appendix provides descriptive and quantitative information about the three regulated entities estimated to be affected by the current container regulations: (1) registrants, (2) agricultural pesticide refillers, and (3) swimming pool supply companies. Relevant details on the economic and financial characteristics associated with all regulated entities are discussed. This information is necessary to assess the potential impacts of regulatory compliance costs associated with the container regulations.

Two industry sectors considered in the 1999 Supplemental Notice were pesticide formulators and agrichemical dealers. These regulated entities correspond with pesticide registrants and agricultural pesticide refillers, respectively, in this analysis.

Tables 3.3 and 3.4 illustrate which regulated entities are responsible for which pesticide container regulations, and provide a brief overview showing how each of the regulated entities identified and characterized in Chapter 3 will be affected by the container rule.

Another purpose of this appendix is to identify the small entities that are potentially affected by the container regulations. A small entity is defined as:

- A small business as defined in the Small Business Administration (SBA) regulations at 13 CFR §121.201—the SBA defines small businesses by category of business using North American Industry Classification System (NAICS) codes;
- 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
- Any small, not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

This economic analysis evaluates an alternative definition of small entities or businesses potentially affected by the container regulations. As discussed by EPA in the 1999 Supplemental Notice on Standards for Pesticide Containers and Containment (EPA, 1999), the alternative definition disaggregates the SBA-defined small businesses into three size categories: small-small (SS), medium-small (MS), and large-small (LS) businesses. EPA is concerned that using an overly broad definition of small business in the economic analysis of the container regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector.

D.1 Pesticide Registrants

According to §165.42, §165.92, and §165.142 of the container regulations, registrants that distribute or sell a pesticide product in non-refillable or refillable containers, and/or distribute or sell pesticide products to a refiller (that is not part of the same entity) for repackaging into refillable containers, constitute a business that must comply with the standards. Pesticide active ingredient (PAI) manufacturers may or may not be subject to the container regulations because §165.46, §165.96, and §165.146 of the container regulations indicate that the standards do not apply to manufacturing use products. However, many PAI manufacturers are vertically integrated to pesticide formulating facilities through direct ownership or wholesale distribution of PAIs to independent formulators. Also, registrants are responsible for complying with the label requirements in 40 CFR Part 156.

Pesticide registrants are basically required to ensure that all non-refillable and refillable containers meet the container construction and design standards, develop and provide information to refillers, and ensure that labels include the specified information. Pesticide registrants are responsible for procedural and handling activities for approximately 10 percent of the refillables in the agricultural market (Paulson, 2002) and all of the refillables in the I/C/G market. Inadequate data are available to differentiate pesticide registrants that are or are not engaged directly in pesticide refilling activities.

The total universe of affected pesticide registrants used in this analysis was derived based on the number of unique companies holding active Section 3 and/or Section 24(c) pesticide registrations. EPA queried the Pesticide Product Information System (PPIS) database in July 2002 and determined that 1,956 companies with unique EPA company numbers held more than 16,000 Section 3 and 24(c) pesticide registrations. The PPIS database contains information for all pesticide products registered in the United States, including registrant name and address, chemical ingredients, toxicity category, product names, distributor brand names, site/pest uses, pesticidal type, formulation code, and registration status.

The registrant universe was reduced by consolidating companies that have recently merged and combining companies that are considered subsidiaries or part of a larger "parent" company. Companies were consolidated in four ways:

• We matched unique companies with EPA company numbers to company information and financial data from the Dun & Bradstreet (D&B) database. The D&B data included information on the company total number of employees; most recent sales and revenue information; and primary business classifications—NAICS code and Standard Industrial Classification (SIC) code where possible. In order to link registrants in the PPIS sample data set with the D&B database, we identified each company's Data Universal Numbering System (DUNS) number. The D&B DUNS number is a unique identifier for a single business entity, which also links together the corporate family structure. Using the corresponding DUNS

⁸⁴ Don Paulson recently retired from Ciba/Novartis and currently is a consultant to Syngenta and CropLife America, formerly the American Crop Protection Association (ACPA). Mr. Paulson was very active in the ACPA packaging task force in the 1990s and co-surveyed the number of agricultural pesticide containers for ACPA with Tom Gilding between 1989 and 1996.

numbers, we "rolled up" or consolidated companies to the Global Ultimate DUNS number or "parent" level.

- In some cases company information in D&B did not reflect recent mergers; therefore, we consolidated the registrant universe manually by adjusting for known company mergers. For example, Aventis CropScience was acquired by Bayer CropScience in June 2002.
- We matched and consolidated company names for all EPA company numbers based on the likelihood that the company numbers actually reflect one company and/or based on EPA recommendations.

As a result, the set of 1,956 unique company numbers in EPA's PPIS database was reduced to 1,804 unique companies. These 1,804 companies represent the pesticide registrant universe for this analysis. Table D-1 illustrates this process numerically.

Table D-1. Estimated Number of Pesticide Registrants Affected by the Pesticide Container Regulations

Pesticide Registrants	Estimated Number of Entities
Number of unique companies in EPA's PPIS database holding Section 3 and/or Section 24(c) registration(s)	1,956 ^a
Total number of duplicate companies	243 ^b
Consolidated number of duplicate companies	91
Total	1,804

^a As of July 2002.

D.1.1 Pesticide Registrants' NAICS Codes

A company's total employees and revenue information is required to break down the estimated total number of affected pesticide registrants into entity size categories according to SBA and EPA alternative definitions of company size specifications and to determine the impact of the container regulations on pesticide registrants. The company size specifications are based on the SBA definition for the primary NAICS code for pesticide registrants.

To confirm the primary NAICS code designation for pesticide registrants, we counted the number of pesticide registrants associated with each NAICS codes, which were available from D&B for 804 (out of an estimated 1,804 total) pesticide registrants. The eight most common six-digit NAICS codes designated in D&B for the set of registrants (399 out of 804) are presented in Table D-2. A total of 184 six-digit NAICS codes are associated with at least one of the 804 registrants.

b Number of all companies with unique EPA company numbers that were consolidated based on the following criteria: (1) matching of EPA company numbers with Dun & Bradstreet DUNS and Global Ultimate DUNS numbers; (2) consolidation as a result of recent mergers and acquisitions; or (3) matching of company names associated with unique EPA company numbers.

Table D-2. Most Common NAICS Codes Associated with Sample of 804 Pesticide Registrants

NAICS CODE	Count of NAICS Code	U.S. Industry Title	SBA Threshold
325320 ^a	88	Pesticide and Other Agricultural Chemical Manufacturing	500 employees
422690	84	1997 NAICS - Otr Chem & Allyd Prdct Whlslrs	100 employees
422910	65	1997 NAICS - Farm Supplies Wholesalers	100 employees
325612	62	Polish and Other Sanitation Good Manufacturing	500 employees
325998	30	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 employees
325188	27	All Other Basic Inorganic Chemical Manufacturing	1,000 employees
453998	22	All Other Miscellaneous Store Retailers (except Tobacco Stores)	\$6 million in revenue
325412	21	Pharmaceutical Preparation Manufacturing	750 employees

^a NAICS code 325320 was considered the primary NAICS code associated with pesticide registrants in the proposed container rule RIA (EPA, 1993). The 325- NAICS series is used to designate types of "Chemical Manufacturing" industries.

D.1.2 Analysis of Large Pesticide Registrants

Company information on some pesticide registrants is unknown or unavailable. However, D&B data are more likely to be available for large companies than for small companies, based on the way D&B collects company financial information and on the availability of the required data.

To estimate the total number of large pesticide registrants, we assumed that D&B data are available for all large firms. A total of 146 companies were considered to be large based on the company's defined NAICS code and associated SBA definitions. This estimate was derived by collecting information from the D&B database for companies at the parent company level as of November 2002. In some cases a company identified with a unique DUNS number is ultimately part of a larger "parent" company, a corporation that owns more than 50 percent of another company, at the Global Ultimate DUNS number level. We identified the parent company in D&B using the Global Ultimate DUNS number associated with each company listing. Global Ultimate DUNS numbers in the D&B database are the highest parent company level containing revenue and employee number information.

Additionally, we made modifications to the large pesticide registrant universe based on knowledge of the industry. For example, at the time of analysis in fall 2002, D&B contained financial information for both Aventis and Bayer CropScience. Bayer CropScience recently acquired Aventis, and these companies are now consolidated. This and other modifications

⁸⁵ D&B data for certain large pesticide registrants may not be readily available, and all parent companies considered to be large may not have been identified. In addition, mergers and acquisitions may slightly reduce the number of large registrants considered in the analysis. Given this uncertainly, it is assumed that the estimated number of large pesticide registrants is reasonable.

condensed the number of large pesticide registrants slightly. Table D-3 illustrates the results of the large pesticide registrant economic profile. The average revenue for a large pesticide registrant is estimated to be \$6,882 million with an average number of employees of approximately 19,300.

D.1.3 Analysis of Small Pesticide Registrants

We generated a random sample of firms from the PPIS database to determine the breakdown of the remaining 1,658 firms, which are SBA-defined small firms. A randomly selected set of 1,000 unique companies identified in PPIS as holding one or more Section 3 registrations was used for determining the number and financial characteristics of small pesticide registrant entities. Because PPIS data do not contain information on the financial aspects of the registrants, we matched the 1,000 randomly selected firms with company information and financial data from D&B.

We identified DUNS numbers for 853 of the 1,000 firms in the PPIS sample data set using firm name, address, and primary line of business. The additional identifiers, beyond firm name, were necessary in many cases where D&B listed several companies with the same name. Of the 853 registrants in the PPIS sample data set, only 615 companies had sufficient information on total revenue and number of employees to be included in this analysis.

We queries the D&B database using the DUNS numbers of the 615 potentially affected entities to retrieve the ultimate parent company name (i.e., Global Ultimate DUNS number), annual sales, total employees, and primary NAICS code. 86

Based on total employees and financial data from D&B, we determined the entity size and average sales revenue of pesticide registrants in the PPIS sample data set as illustrated in Table D-3. We identified a total of 568 unique parent companies, of which 449 or 79 percent were considered small businesses by SBA definitions. Of the SBA-defined small pesticide registrants, approximately 60 percent (270) were small-small, 30 percent (134) were medium-small, and 10 percent (45) were large-small, based on EPA's alternative small business definitions.

global ultimate parent is the highest-level firm within the company's structure. For example, a major pesticide manufacturer may be headquartered in Chicago, but have facilities in Memphis and St. Louis. The company information from PPIS may list the Memphis or St. Louis facility locations, and/or the D&B database may include company financial information from facility level up to the global ultimate parent company level. D&B data may make it possible to determine that all three of these locations are owned by the same parent company.

⁸⁶ All financial information in this industry profile is summarized at the global ultimate parent company level. The global ultimate parent is the highest-level firm within the company's structure. For example, a major pesticide

Table D-3. Economic Profile of Pesticide Registrants by Entity Size

			PF	PIS Registrant Da		Pe	esticide Registra	nts	
Entity Size Category	Definition	Total Companies	Percentage of Small Companies	Total Revenue for All Companies (million)	Average Revenue per Company (million)	Average Number of Employees per Company	Total Entities	Total Revenue for All Entities (million) b	Percentage of Total Revenue
SBA-Defined Siz	zes								
Large	501 or more employees	146	NA	\$1,075,106	\$7,364	19,266	146	\$1,075,106	98.6%
Small	500 or fewer employees	449 °	NA	\$4,239	\$9.44	39	1,658	\$15,651	1.4%
Total		NA	NA	NA	NA	NA	1,804 ^d	\$1,090,757	100.0%
EPA Alternative	Small Business	Sizes ^e							
Large-Small	100 to 500 employees	45	10.0%	\$2,370	\$52.68	217	166	\$8,753	0.8%
Medium-Small	20 to 99 employees	134	29.8%	\$1,307	\$9.76	44	495	\$4,829	0.4%
Small-Small	1 to 19 employees	270	60.1%	\$561	\$2.08	8	997	\$2,070	0.2%
Total		449	NA	\$4,239	\$9.44	39	1,658	\$15,651	1.4%

^a Sufficient Dun & Bradstreet company information and financial data were assumed to be available for all SBA-defined large pesticide registrants, based on the set of 1,804 unique pesticide registrants identified as having one or more Section 3 or Section 24(c) pesticide registrations. The total number of pesticide registrants that met this criteria and were considered to be large companies was 146. For SBA-defined small businesses, a random sample of 1,000 unique pesticide registrants was used to develop the economic profile. A total of 565 unique parent companies were identified as having sufficient financial information at the Global Ultimate DUNS number level to be included in the analysis, of which 449 or 79 percent were considered small businesses by SBA definitions.

^b Calculated as the average revenue per company multiplied by the total number of entities for the respective size category.

^c SBA-defined small businesses identified out of a random sample of 1,000 unique companies with one or more active Section 3 or Section 24(c) registrations.

^d Number of all companies with unique EPA company numbers that were consolidated based on the following criteria: (1) matching of EPA company numbers with D&B DUNS and Global Ultimate DUNS numbers; (2) as a result of recent mergers and acquisitions; (3) matching of company names associated with unique EPA company numbers; or (4) recommended by EPA to be consolidated based on nearly identical name matching and/or prior knowledge.

^e EPA discussed alternative definitions of small businesses for some industry sectors in the 1999 Supplemental Notice on Standards for Pesticide Containers and Containment (EPA, 1999). EPA is concerned that using an overly broad definition of small business in the economic analysis of container regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on those facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector.

The relative percentages for the EPA alternative small business categories from the sample of 449 small pesticide registrants with sufficient D&B data were applied to the total universe of 1,658 small registrants from the PPIS database. As a result, the SBA-defined small pesticide registrant universe was estimated to include 997 small-small registrants, 495 medium-small registrants, and 166 large-small registrants, based on the EPA alternative small business definitions.

The D&B data for the 449 unique small companies with sufficient financial data were used to determine size (by SBA definition) and to estimate average or typical annual revenue to generate the economic profile for potentially affected small pesticide registrant entity size categories (SBA-defined and EPA alternative definitions for small businesses). The data from the random sample of small pesticide registrants are summarized in Table D-3 and the economic profile is applied to the total universe of 1,658 small pesticide registrants.

D.1.4 Container Profile for Registrants by Market Sector and Size Category

The procedure for mapping pesticide containers and associated regulatory requirements to pesticide registrants is shown in Table D-4. To the extent that certain antimicrobials are exempt from consideration, the number of containers associated with each pesticide registrant size category and ultimately with individual representative entities will vary. The container profile is used to estimate the average number of containers for a given size category and type that can be associated with a given pesticide registrant size (by SBA large and small definitions and by EPA alternative definitions for small businesses) and market sector (agricultural, industrial/commercial/government, and home and garden).

The procedure described in steps 3 and 4 of Table D-4 was duplicated for all non-refillable and refillable container types and sizes. In the pesticide container regulations cost analysis (Chapter 4), the number of containers associated with each representative entity size category of pesticide registrants is used in combination with the regulation compliance rates (see Chapter 3) to derive costs of compliance and anticipated SBA small business impacts.

Table D-4. Procedure Used to Establish Market-Specific Regulated Entities

Step 1. Distribute the pesticide registrants across market sectors (agricultural, I/C/G, and H&G) based on volume of pesticides used by each sector according to the *Pesticide Industry Sales and Usage: 2000 and 2001 Market Estimates* (EPA, 2002b).

From EPA's pesticide use and sales report, we know the amount of pesticide product used in each market sector. The total amount of pesticide product considered includes conventional pesticides, other pesticides, and an EPA estimate of 29.8 percent of the antimicrobial products (wood preservatives, chlorine/hypochlorites, and specialty biocides) subject to the container regulations. The total number of SS, MS, LS, and large pesticide registrant entities is distributed among market sectors, based on the relative amount of the assumed pesticide product subject to the container regulations used by each sector in 2001.

Example: 2001 total pesticide use is as follows: 40% agricultural, 30% I/C/G, and 30% H&G. Accordingly, the number of pesticide registrants by size and market sector is as follows:

	SS	MS	LS	Large
Agricultural	399	198	66	58
I/C/G	299	148	50	44
H&G	299	148	50	44
Total	997	495	166	146

Step 2. Derive total revenue by pesticide registrant size category and determine the revenue ratio for each pesticide registrant size category by market sector to the total revenue for that market sector.

Sum the total revenue for SS, MS, LS, and large pesticide registrants based on PPIS sample data set analysis results for average revenue by pesticide registrant size category. Multiplying the average revenue by the total number of registrants in each category yields the total.

Example: Total revenue for SS, MS, LS, and large firms in the PPIS sample data set were \$2,070 million, \$4,829 million, \$8,753 million, and \$1,075,106 million, respectively.

Determine the revenue ratio for each pesticide registrant size category based on the total revenue per size category compared to the revenue for the total universe of registrants. The revenue ratios for the registrant size categories are applicable to each market sector.

	Total Revenue (million)	Revenue Ratio
SS	\$2,070	0.2%
MS	\$4,829	0.4%
LS	\$8,753	0.8%
Large	\$1,075,106	98.6%
Total	\$1,090,757	100.0%

Step 3. Distribute the containers that are affected by the container regulations in each size/type category into entity size categories for each market sector (agricultural, I/C/G, and H&G).

For each liquid and dry product pesticide container size category, apply the revenue ratio to allocate the containers to SS, MS, LS, and large entities for each market sector. Repeat example procedure to the right for every container category (size, type, material).

Example: The 199,434 potentially affected 30–55 gallon plastic non-refillable containers in the agricultural market sector are distributed as follows:

as follows.							
	SS	MS	LS	Large			
Agricultural	378	883	1,600	197K			

Step 4. Determine the number of containers per representative pesticide registrant by entity size for each market sector.

Calculate the number of containers for an average (or representative) pesticide registrant for each size category in each market sector by dividing the number of each type of container in each market sector (step 3) by the number of companies in each market sector (step 1). Repeat example procedure to the right for every container category (size, type, material).

Example: Using the above example, the number of plastic 30-55 gal. containers for the Agricultural (market sector) firms is as follows:

	SS	MS	LS	Large
Agricultural	1	4.5	24	3,389

Numbers may not add due to rounding.

D.2 Agricultural Pesticide Refillers

The agricultural pesticide refiller entity is analogous to agricultural chemical dealers who generally supply pesticide products to farmers or other end users in refillable containers for large-scale application. Agricultural pesticide refillers are subject to the repackaging requirements each time a pesticide is repackaged into a refillable container. Generally, this regulated entity is responsible for inspecting, rinsing, and properly labeling containers prior to reuse, and maintaining appropriate records.

Agricultural pesticide refillers repackage and supply the majority of pesticides to farmers and other agricultural end users. It is estimated that 90 percent of agricultural pesticide product distributed in refillable containers is distributed or sold by agricultural pesticide refillers, and the remaining 10 percent is distributed or sold directly by registrants (Paulson, 2002). Agricultural pesticide refillers are generally represented under NAICS 422910 (Farm Supplies and Wholesale Sector), which consists of "establishments primarily engaged in wholesaling farm supplies, such as animal feeds, fertilizers, agricultural chemicals, pesticides, plant seeds and plant bulbs" (U.S. Department of Commerce, 1997).

This analysis considers only agricultural pesticide refillers, even though the regulations do not prohibit refilling by companies other than registrants in non-agricultural markets. To represent current business practices, we assumed that all pesticides in the I/C/G market are repackaged by the registrants and that there are no refillables used in the H&G market/

We extracted the revenue and employee data directly from the D&B database for all establishments with NAICS 422910 designations to generate the industry profile for agricultural pesticide refillers. It is assumed that the financial information extracted from D&B for the NAICS 422910 market sector is representative of the agricultural pesticide refiller entities subject to the container regulations. As a result, we pulled 24,360 records from the D&B database, with 21,599 establishments having sufficient financial data to be included in the analysis. We consolidated these data by Domestic Ultimate DUNS number in order to aggregate facilities by parent company designation, resulting in a total of 12,511 unique companies identified. In a few instances where discrepancies arise in revenue and employee information at the Domestic Ultimate DUNS level, we used the maximum values for the D&B data fields "Employees Total" and "Sales Volume (US\$)" associated with each Ultimate DUNS number.

We then broke down the D&B sample data set into small and large entity size according to the SBA small business definition for NAICS 422910 (i.e., SBA defines a small business for NAICS 422910 as having 100 employees or fewer). As illustrated in Table D-5, 99 percent of the 12,511 unique parent companies we identified were considered small by the SBA definition. Based on the EPA alternative small business definitions presented in Table 3.3, approximately 83 percent were small-small, 14 percent were medium-small, and 2 percent were large-small (see Table D-5).⁸⁷

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⁸⁷ Regulated facilities in this analysis are companies rather than individual facilities.

Table D-5. Economic Profile of Agricultural Pesticide Refillers by Entity Size

			D&B Sample Data Set for NAICS 422910						Agricultural Pesticide Refillers	
Entity Size Category	Definition	Total Companies	Percent of Total Companies	Total Revenue for All Companies (million)	Percent of Total Revenue	Average Revenue per Company (million)	Average Number of Employees per Company	Total Entities ^a	Total Revenue for All Entities (million) b	
SBA-Defined Siz	ees									
Large	101 or more employees	114	0.9%	\$21,842	47.1%	\$191.60	448	153	\$29,322	
Small	100 or fewer employees	12,397	99.1%	\$24,670	52.9%	\$1.99	6	16,642	\$33,050	
Total		12,511	100.0%	\$46,416	100.0%	\$3.71	10	16,795 °	\$62,372	
EPA Alternative	Small Business S	Sizes d								
Large-Small	50 to 100 employees	187	1.5%	\$4,246	9.2%	\$22.71	71	251	\$5,700	
Medium-Small	10 to 49 employees	1,784	14.3%	\$12,006	25.9%	\$6.73	19	2,395	\$16,118	
Small-Small	1 to 9 employees	10,426	83.3%	\$8,341	18.0%	\$0.80	3	13,996	\$11,232	
Total		12,397	99.1%	\$24,670	52.9%	\$1.99	6	16,642	\$33,050	

^a The percentage of total companies in the D&B sample data set was applied to the estimated number of agricultural pesticide refillers used in the analysis.

^b The average revenue of agricultural pesticide refillers for each entity size category was multiplied by the total number of entities for the given size category.

^c EPA estimate based on state estimates where available; otherwise, SIC 5191.02 + 5191.14 from the American Business Information Lists of 9 Million Businesses, 1990. The same total number is estimated as presented in the 1999 Supplemental Notice on Standards for Pesticide Containers and Containment (EPA, 1999).

^d EPA discussed alternative definitions of small businesses for some industry sectors in the 1999 Supplemental Notice on Standards for Pesticide Containers and Containment (EPA, 1999). EPA is concerned that using an overly broad definition of small business in the economic analysis of the container regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on those facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector.

Based on information collected by EPA (see footnote c to Table D-5), it was determined that no one NAICS code was unique to agrichemical dealers or agricultural pesticide refillers. Therefore, the economic profile for the sample of 12,511 companies was applied to the total universe of 16,795 agricultural pesticide refillers. The estimated number of agricultural pesticide refillers potentially affected (16,795 companies) is based on the information presented in the 1999 Supplemental Notice (EPA, 1999) and the proposed container rule RIA. This estimate is considered to be a reasonable estimate for the current total number of entities potentially affected.

The number and types of refillable containers associated with agricultural pesticide refillers that are subject to the repackaging regulations are assumed to be approximately 90 percent of the total for each container size category (Paulson, 2002). We duplicated the procedure described in steps 3 and 4 of Table D-4 to determine the number of refillable containers associated with a representative agricultural pesticide refiller in each SBA and EPA alternative size category. The total number of containers that fall within the scope of the container regulations is presented by market sector in Chapter 4 (Table 4.7).

D.3 Swimming Pool Market

EPA has determined that certain antimicrobial products are exempt from the container regulations (EPA, 2002a). Container requirements for antimicrobial products that are subject to the rule will primarily affect pesticide registrants. However, applicators of sodium hypochlorite used to disinfect pool and spa water (i.e., swimming pool supply companies) have been identified as regulated entities that will be required to comply with some refillable container and repackaging requirements. Refillable containers for the products must comply with the adopted DOT standards and bulk container standards (if applicable), but not the marking or one-way valve/tamper-evident device requirements. Swimming pool supply companies must meet certain refilling requirements, but not all. Refillables are required to be inspected and cleaned (unless specified conditions in §165.170 are met) and must be properly labeled. Swimming pool supply companies must maintain certain records, but not all. Copies of the residue removal procedures for refilling and description of acceptable containers must be on file, but a record of certain information recorded each time a container is refilled (e.g., product, amount) is not required. The partial set of repackaging (refilling) requirements and compliance rates are detailed in Chapter 3.

A readily available data source that could be used to characterize the swimming pool chemical industry impacts associated with the container regulations does not exist. There is no current NAICS code that is specifically devoted to the swimming pool supply industry. Additionally, the Chlorine Institute, National Spa and Pool Institute, and the Swimming Pool Chemical Manufacturers Association were unable to provide adequate information. Based on EPA data, we generated a list of 472 company names associated with registered sodium hypochlorite products. The primary NAICS code associated with these companies is 453998 (All Other Miscellaneous Store Retailers [except Tobacco Stores] – 7.6 percent), and 235990 (All Other Special Trade Contractors – 5.9 percent). To keep SBA small/large business distinctions from becoming too complex, we used establishment records with the most common NAICS code designation to characterize the swimming pool chemical industry.

We consolidated the establishment records with the same Domestic Ultimate DUNS number to estimate the number of potentially affected swimming pool supply companies (322) at the parent company level. All parent companies having sufficient revenue and employee data were divided into small and large businesses based on the SBA small business size standard for NAICS 453998, which is no more than \$6 million in revenue. Once the D&B parent companies were grouped into small and large SBA defined size categories, we divided the SBA small businesses into the three EPA alternative small business size categories based on the criteria presented earlier in Table 3.3.

Table D-6 illustrates the number of affected swimming pool supply companies, by size, and the financial information associated with the average company for each given entity size category. The total number of swimming pool supply companies subject to the refilling requirements is 322, with nearly all (94.7 percent) of those entities considered SBA small businesses.

Information is not readily available to estimate which swimming pool chemical companies use refillable containers for sodium hypochlorite. Therefore, it is assumed that all swimming pool chemical companies identified will likely be subject to the repackaging requirements. The number of refillable containers associated with representative swimming pool supply companies were found for each size category based on steps 3 and 4 described in Table D-4. The total number of containers that fall within the scope of the container regulations is presented by market sector in Chapter 4 (Table 4.7).

Table D-6. Economic Profile of Swimming Pool Supply Companies a by Entity Size

		D&B/InfoUSA Data Set for 472 Selected Companies with Registered Sodium Hypochlorite						
Entity Size Category	Definition	Total Companies	Percentage of Total Companies	Total Revenue for all Companies (millions)	Percentage of Total Revenue	Average Revenue per Company	Average Number of Employees per Company	
SBA-Defined Size	es ^c							
Large	Revenues greater than \$6.0 million	17	5.3%	\$41,445	98.9%	\$2,437,954,281	12,119	
Small	Revenues up to \$6.0 million	305	94.7%	\$455	1.1%	\$1,492,653	13	
EPA Alternative	Small Business Sizes d							
Large-Small	50 or more employees	14	4.4%	\$72	0.17%	\$5,113,298	70	
Medium-Small	10 to 49 employees	117	36.3%	\$298	0.71%	\$2,544,285	20	
Small-Small	1 to 9 employees	174	54.0%	\$86	0.21%	\$494,205	4	
Total ^e		322	NA	\$41,900	NA	\$130,125,720	652	

^a Currently, only refillable containers used in the pool chemical industry are considered. These are primarily used for repackaging sodium hypochlorite for commercial and residential pool servicing.

^b Based on EPA analysis of sodium hypochlorite pesticide registrations.

^c The SBA small business size standard is no more than \$6 million in revenue for NAICS 453998. The analysis divided the SBA small businesses into the three EPA alternative small business size categories regardless of employee or revenue totals once the regulated entity passed the SBA-defined small business screening.

^d EPA has not previously proposed alternative definitions of small businesses for swimming pool supply companies. However, EPA is concerned that using an overly broad definition of small business in the economic analysis of the container regulations may result in significant economic impacts on smaller entities that will be camouflaged when combined with information about potential impacts on those facilities that meet the SBA size standard for small business but are not typical of a small business in that industry sector.

^e No employee or revenue data were available for 140 companies out of the initial 472 companies considered. As a result, these companies have not been included in this summary table. In addition, 10 companies in the data collected were also removed from consideration because they proved to be duplicates of another record (i.e., they were found to have the same Domestic Ultimate parent company).

Appendix E. 1994 Proposed Rule Container Standards Costs and Benefits

E.1 Estimated Cost of Proposed Rule Container Standards

Three regulatory options are evaluated in the proposed container and labeling standards: (1) Regulatory Option 1, a low stringency option, (2) Regulatory Option 2, representing EPA's proposed minimum standards, and (3) Regulatory Option 3, a more stringent option. Under all three options, non-refillable containers must meet general integrity standards; must be marked with the EPA registration number of the pesticide and the name, symbol, or code of the material(s) from which the container is constructed; must be designed so that the container pours in a continuous, coherent stream (doesn't glug), drippage is eliminated, and the container recloses securely; and must have one of four standardized closures to encourage and expedite the use of closed handling systems (if the container is used to hold a pesticide labeled for use in the production of an agricultural commodity). In addition, under Regulatory Option 1, each container/formulation combination must meet a five-9s (99.999 percent) residue removal standard following a prescribed protocol for testing and analyzing the rinsate from a fourth rinse. Under Regulatory Options 2 and 3, a more stringent residue removal standard of six-9s (99.9999) percent) must be met. Under Regulatory Option 3, non-refillable containers with a capacity of greater than 5 gallons that are used to contain liquid pesticides are prohibited; any such container must be a refillable container and must meet the standards for refillable containers. And finally, certain certification and recordkeeping requirements are consistent among all three regulatory options. We analyzed two different scenarios under all three regulatory options, with Scenario 1 assuming that 50 percent of all non-refillable/dilutable formulation combinations will be tested for the residue removal standard, whereas Scenario 2 represents a works-case analysis in that 100 percent of all container/formulation combinations are assumed to be tested for the standard.

Additional requirements for refillable containers include, under Regulatory Option 1, no drop tests; under Regulatory Option 2, all minibulk refillable containers must undergo a drop test of 2.6 feet to 3.9 feet, depending on whether the pesticide contained is dry or liquid; and under Regulatory Option 3, all minibulk refillable containers refillable containers must undergo drop tests per DOT standards, as well as a vibration test, lifting device test, stacking device test, hydrostatic test, and leakage test. Additional requirements for registrants include certification, recordkeeping requirements, and provision of certain materials to refilling establishments, including written residue removal procedures and a written list of acceptable refillable containers for each product. Requirements for refilling establishments relative to refillable containers are the same under all three regulatory options, including obtaining specified authorization/information from the registrant(s), container inspection procedures, repackaging procedures, and recordkeeping/inspection requirements.

Table E-1 and Table E-2 summarize the estimated costs of the proposed container standards for representative formulator and refiller facilities by market, respectively. Both the annual cost and annual cost as a proportion of annual sales are summarized for all three regulatory options and for both scenarios in the Tables. Table E-3 summarizes the total costs of the proposed container standards. Costs are aggregated by regulatory option and scenario for all facilities for both the container and labeling standards.

Table E-1. Summary of Annual Revenue Requirements (ARR) ^a and ARRs as a Percentage of Sales for Representative Formulating Facilities in Each Market Sector Under Regulatory Options 1, 2, and 3 ^b and Scenarios 1 and 2 ^c for the Proposed Pesticide Container Standards (2005\$)

Market/Representative Formulator Facility Type		Regulatory Option 1 Regula		Regulator	Regulatory Option 2		Regulatory Option 3	
Securic Secu		Regulator	у орион т	iteguiatoi	J Option 2			
Securic Secu	Markat/Dannagantativa	ARR	ARR/sales	ARR	ARR/sales	ARR	ARR/sales	
Scenario 1 Agricultural Market Small Agricultural Facility \$133 0.6 \$35 0.64 \$94 1.71 Medium Agricultural Facility \$126 0.46 \$135 0.49 \$223 0.81 Large Agricultural Facility \$726 0.19 \$796 0.21 \$913 0.24 Large Agricultural Facility 2 \$801 0.21 \$871 0.23 \$988 0.26 Large Agricultural Facility 3 \$3,331 0.87 \$3,401 0.89 \$3,518 0.92 Large Agricultural Facility 4 \$822 0.21 \$892 0.23 \$1,009 0.26 Industrial Market Small Industrial Facility \$45 0.82 \$46 0.84 \$304 5.55 Medium Industrial Facility \$184 0.67 \$190 0.69 \$703 2.56 Institutional Market Small Institutional Facility \$133 0.49 \$139 0.51 \$451 1.65 Household Market Small Household Facility \$128 0.47 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$134 0.49 \$135 0.49 \$135 0.45 \$135								
Agricultural Market Small Agricultural Facility \$33 0.6 \$35 0.64 \$94 1.71	, , , , , , , , , , , , , , , , , , ,	(\$000)	(70)	(\$000)	(70)	(\$000)	(70)	
Small Agricultural Facility \$33 0.6 \$35 0.64 \$94 1.71								
Medium Agricultural Facility \$126 0.46 \$135 0.49 \$223 0.81 Large Agricultural Facility 1 \$726 0.19 \$796 0.21 \$913 0.24 Large Agricultural Facility 2 \$801 0.21 \$871 0.23 \$988 0.26 Large Agricultural Facility 4 \$822 0.21 \$892 0.23 \$1,009 0.26 Industrial Market Small Industrial Facility \$45 0.82 \$46 0.84 \$304 5.55 Medium Industrial Facility \$40 0.67 \$190 0.69 \$703 2.56 Institutional Facility \$40 0.72 \$41 0.75 \$197 3.6 Medium Institutional Facility \$133 0.49 \$139 0.51 \$451 1.65 Household Market Small Possehold Market Small Household Facility \$128 0.47 \$134 0.49 \$134 0.49 Scenario 2 Agricultural Facility \$72 1.3	0	\$33	0.6	\$35	0.64	\$94	1.71	
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Small Institutional Facility \$70 1.28 \$74 1.35 \$230 4.19 Medium Institutional Facility \$228 0.83 \$241 0.88 \$553 2.02 Household Market Small Household Facility \$67 1.23 \$71 1.3 \$71 1.3	Medium Industrial Facility	\$279	1.02	\$292	1.07	\$805	2.94	
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Household Market Small Household Facility \$67 1.23 \$71 1.3 \$71 1.3	Small Institutional Facility	\$70	1.28	\$74	1.35	\$230	4.19	
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Medium Household Facility \$223 0.81 \$236 0.86 \$236 0.86	Small Household Facility	\$67		\$71		· ·	1.3	
	Medium Household Facility	\$223	0.81	\$236	0.86	\$236	0.86	

^a One method for analyzing uneven cost streams is to calculate their equivalent, constant-level cost per year. This equivalent cost is referred to as the annual revenue requirement (ARR) because the present value of such an annual revenue stream would just offset or equal the present value of the cost stream.

Table E-1 (Continued). Summary of Annual Revenue Requirements (ARR) ^a and ARRs as a Percentage of Sales for Representative Formulating Facilities in Each Market Sector Under Regulatory Options 1, 2, and 3 ^b and Scenarios 1 and 2 ^c for the Proposed Pesticide Container Standards (2005\$)

^b Regulatory Option 1:

- Five-9s residue removal standard for non-refillables
- No drop test required for refillables
- Other EPA-proposed requirements.

Regulatory Option 2:

- Six-9s residue removal standard for non-refillables
- Other EPA-proposed requirements.

Regulatory Option 3

- Six-9s residue removal standard for non-refillables
- Non-refillables greater than 5 gallons prohibited for liquid pesticides
- Extensive container integrity tests for container design
- Other EPA-proposed requirements.

Table E-2. Summary of Annual Revenue Requirements (ARR) ^a and ARRs as a Percentage of Sales for Representative Agricultural Refilling Facilities in Regulatory Options 1, 2, and 3 ^b for the Proposed Pesticide Container Standards (2005\$)

	Regulate	ory Option 1	Regulatory Option 2 and 3		
Representative Agricultural Refilling Facility	ARR (\$)	ARR/Sales (%)	ARR (\$)	ARR/Sales (%)	
Small Refilling Facility	\$314	0.013	\$637	0.026	
Medium Refilling Facility	\$618	0.008	\$1,263	0.016	
Large Refilling Facility	\$1,491	0.005	\$2,999	0.01	

^a One method for analyzing uneven cost streams is to calculate their equivalent, constant-level cost per year. This equivalent cost is referred to as the annual revenue requirement (ARR) because the present value of such an annual revenue stream would just offset or equal the present value of the cost stream.

- No drop test required for refillables
- Other EPA-proposed requirements.

Regulatory Option 2: Other EPA-proposed requirements.

Regulatory Option 3:

- Extensive container integrity tests for container design
- Other EPA-proposed requirements.

^c Scenario 1: 50% of container/formulation combinations tested for residue removal. Scenario 2: 100% of container/formulation combinations tested for residue removal.

^b Regulatory Option 1:

Table E-3. Total Cost (Annual Revenue Requirement or ARR) of the Proposed Pesticide Container and Labeling Standards

	Container Standards		Labeling S	Standards	
Regulatory Option/ Scenario ^a	Formulating Industry (million \$)	Refilling Industry (million \$)	Formulating Industry (million \$)	End User b (million \$)	Total ARR (million \$)
Regulatory Option 1					
Scenario 1	\$21.4	\$2.6	\$5.1	\$8.2	\$37.3
Scenario 2	\$30.4	\$2.6	\$5.1	\$13.6	\$51.6
Regulatory Option 2					
Scenario 1	\$22.2	\$4.7	\$5.1	\$8.2	\$40.1
Scenario 2	\$32.2	\$4.7	\$5.1	\$13.6	\$55.5
Regulatory Option 3					
Scenario 1	\$87.8	\$4.7	\$5.1	\$8.2	\$105.8
Scenario 2	\$97.8	\$4.7	\$5.1	\$13.6	\$121.1

^a Regulatory Option 1:

- Five-9s residue removal standard for non-refillables
- No drop test required for refillables
- Other EPA-proposed requirements.

Regulatory Option 2:

- Six-9s residue removal standard for non-refillables
- Other EPA-proposed requirements.

Regulatory Option 3:

- Six-9s residue removal standard for non-refillables
- Non-refillables greater than 5 gallons prohibited for liquid pesticides
- Extensive container integrity tests for container design
- Other EPA-proposed requirements.

Scenario 1: 50% of container/formulation combinations tested for residue removal. Scenario 2: 100% of container/formulation combinations tested for residue removal

^b For end users only, Scenarios 1 and 2 are not defined as in Footnote a. Rather, Scenario 1 assumes a 60% compliance rate by end users for triple rinsing certain container that have a triple rinse requirement for the first time, and Scenario 2 assumes a 100% compliance rate for triple rinsing the same universe of containers. Household end users account for approximately 85% of the total cost under each scenario, and institutional end users account for approximately 15%.

E.2 Estimated Benefits of the Proposed Rule Container Standards

The RIA for the proposed container and labeling standards estimates both direct and indirect benefits (See Chapter 5 for details). The direct benefits (see Table E-4) include: (1) health- and environment-related benefits resulting from a reduction in the incidents of container failure and the risks posed by accidental spills of pesticide, leaks, dripping, and the residue remaining in pesticide containers; (2) a quantitative estimate of disposal-related benefits resulting from lower costs for non-refillable container disposal as non-hazardous waste after triple rinsing (versus disposal as hazardous waste); and (3) several additional categories of qualitative benefits (e.g., increased worker productivity and reduced property damage).

The estimated indirect benefits are associated with the switch from use of non-refillable containers to refillable containers, which are expected (not required) as a result of the container standards. The types of indirect cost savings estimated as a result of the switch to refillable containers include: (1) container cost savings, (2) container disposal cost savings, and (3) substantial labor savings associated with triple rinsing of used non-refillable pesticide

containers. The sum of indirect benefits is estimated to range from \$36.4 million to \$109.1 million with a midpoint of \$72.8 million.

Table E-4. Estimated Benefits of the Proposed Container and Labeling Standards

Benefits Estimated in the Proposed Container Rule RIA	Type of Benefit	Estimated Benefits
Direct Benefits	Health- and Environment- Related Effects	EPA estimated that 1,650 to 2,250 acute illness incidents caused by container design/residue removal problems could potentially be avoided annually throughout the United States. In addition, a potentially significant number of unreported acute pesticide poisoning incidents and environmental incidents may be avoided.
	Non-Refillable Container Disposal Effects	\$5,649,880 to \$6,904,800
	Other Container Design/Residue Removal and Labeling Effects	In addition to these quantitative benefit estimates, several additional categories of benefits were qualitatively presented, including potential reductions in liability/insurance costs, increased worker productivity, creation of a lower at-risk work environment, and the potential for reduced property damage from pesticide accidents and improved pesticide management.
Indirect Benefits	Refillable Container Cost-Saving Effects	\$29,535,145 to \$88,605,435
	Refillable Container Disposal Cost-Saving Effects	\$545,945 - \$1,637,835
	Refillable Container Labor-Saving (Rinsing) Effects	\$6,280,765 - \$18,842,295

Appendix F. Nationwide and State Regulations and Standards for Pesticide Containers

This section will examine the following nationwide regulations or standards:

- U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR) (i.e., 49 CFR Parts 107-179);
- United Nation (UN) Recommendations on the Transport of Dangerous Goods (UN, 1999);
- Mid America CropLife Association: MACA-75 Manufacturer Specifications and User Guidelines for Liquid Pesticides and Other Agri-Chemicals Not Subject to U.S. DOT Specification Packaging (MACA, 1992); and
- Existing EPA policy applicable to pesticide containers.

UN recommendations and the MACA-75 specifications, which are voluntary, are included because research has shown that the majority of container manufacturers produce containers meeting one or both of these standards. These are viewed by major container manufacturers as necessary rather than optional standards.

Regulations affecting containers and packaging that have been specifically excluded are the Resource Conservation and Recovery Act (RCRA) regulations (40 CFR §261.7(b)(3)). Because the container regulations address the usage rather than disposal of containers, there is very little overlap with the RCRA regulations. The only overlap occurs at the time of container disposal. It is EPA's intent that containers that are triple rinsed as provided in the container regulations will meet the requirements for "empty" under RCRA at 40 CFR §261.7(b)(3). While there is no specific final residue removal standard for refillable containers, users will likely meet one of the removal requirements at §261.7(b) if their container holds a hazardous waste and they wish to avoid regulation under RCRA.

This appendix is organized into seven sections. The first three sections (F.1, F.2, and F.3) present a brief overview of the three major regulations/standards (DOT HMR, UN recommendations, and MACA-75 specifications, respectively). Section F.4 describes the container population affected by each of the three major regulations/standards. Section F.5 presents the requirements of the major regulations/standards as they compare with the container regulations. Section F.6 presents a summary of existing EPA policies and regulations that affect the baseline container regulation compliance rate. The final section (F.7) presents a summary of existing state regulations and standards for pesticide containers.

F.1 Department of Transportation Hazardous Materials Regulations

The DOT HMR apply to the interstate (and in some cases, intrastate) transportation of hazardous materials in commerce (DOT, 1996). In general, the DOT HMR specify requirements for packaging, classification, handling, transport, hazard communication, and incident reporting of hazardous materials. The HMR are enforced by the Federal Highway Administration, the Federal Aviation Administration, the Federal Railroad Administration, and the U.S. Coast Guard.

The DOT HMR hazard class definitions are generally aligned with nine risk classes used in the UN recommendations described in the next subsection. Under this classification system,

pesticides primarily fall under Hazard Class 6, Division 6.1, although some may also meet the criteria for flammable materials (RTI, 1989). Hazard Class 6 uses a definition related to oral, dermal, and inhalation toxicity, similar to that for the UN recommendations. The HMR also contain 20 UN performance-oriented packaging standards for non-bulk containers. These requirements contain general standards for specific types of packaging such as plywood drums, plastic drums and jerricans, ⁸⁸ fiber drums, and steel jerricans. In addition, there are testing standards that apply to all non-bulk packaging types. These requirements follow the UN recommendations for non-bulk containers and include the following tests: drop, leakproofness, hydrostatic pressure, and stacking. Non-bulk packaging used for hazardous materials in the United States must also be capable of withstanding a vibration standard that is not included in the UN recommendations.

The HMR prescribe various performance levels in packaging hazardous materials based on the level and nature of hazards posed by the material to be packaged. All packaging, regardless of type, must be designed so that under normal conditions of transport, no contents will be released. Also, the containers must be designed so that the effectiveness of the packaging will not be substantially altered by temperature.

The DOT HMR requirements apply regardless of whether the container is refillable. If a container is refillable, it must also meet the reuse provisions found at 49 CFR §173.28, which require inspections before reuse, and the following provisions for non-bulk containers: retesting of liquid packaging for leakproofness, durable marking, and minimum thickness criteria for metal and plastic drums and jerricans. The DOT HMR also contain requirements regarding the reconditioning and remanufacturing of non-bulk packaging.

Portable tanks are subject to 49 CFR §173.32, which addresses "Qualification, maintenance and use of portable tanks other than Specification IM portable tanks." These provisions contain recordkeeping, retesting, and container/material compatibility requirements, some of which are required by tank specification (e.g., DOT Specifications 56, 57, and 60). There are special requirements for containers constructed before May 15, 1950, as well as provisions addressing deteriorated, damaged, and unused tanks. There are also additional requirements for these tanks at 49 CFR §§173.32a, 173.32b, and 173.32c addressing the approval of Specification IM portable tanks, the periodic testing and inspection of these tanks, and requirements regarding their use.

F.2 United Nations Recommendations on the Transport of Dangerous Goods

The UN Recommendations on the Transport of Dangerous Goods were developed by the UN Committee of Experts on the Transport of Dangerous Goods (1999). While these recommendations address dangerous goods that are shipped internationally, they also affect containers shipped domestically. Many packaging manufacturers are beginning to follow portions of these recommendations for containers shipped domestically. Additionally, some companies ship both domestically and internationally, and the containers used meet both the UN recommendations and the DOT HMR discussed in the previous subsection. The DOT design

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⁸⁸ A jerrican, as defined by the DOT HMR, is a metal or plastic "packaging" of rectangular or polygonal cross-section (49 CFR 171.8).

specification packaging system was accepted in international transport under transitional provisions which expired on December 31, 1990; after that date, the packaging for most hazardous materials in international transport were required to conform to the UN standards (55 FR 52404). As of October 1996, UN performance-oriented packaging standards added to the DOT Hazardous Materials Regulations (HMR) by HM-181 were fully in effect (Deadrick, 1992; 55 FR 52408 and 52473-52474).

The UN recommendations classify dangerous goods into nine risk classes. For each class, there is a set of criteria; any substance meeting those criteria is considered in that class. Class 6— Poisonous (toxic) and Infectious Substances—is the class where many pesticides would fall. A material is a Class 6 poison if it is "liable to either cause death or serious injury or to harm human health if swallowed, inhaled or by skin contact" (UN Committee of Experts on the Transport of Dangerous Goods, 1999, p. 97). Division 6.1 specifically addresses poisonous (toxic) substances; Chapter 2.6 in the guidance document on the UN recommendations (UN Committee of Experts on the Transport of Dangerous Goods, 1999), which addresses Division 6.1, includes a section that allows shippers of pesticides to determine which of three Packing Groups is appropriate for their material. Many of the pesticides listed are insecticides because they tend to be more toxic to humans than either herbicides or fungicides. The three Packing Groups—I, II & III—are based on toxicity classifications: the lethal dose to 50 percent of the sample population (LD₅₀s) for oral and dermal activity and the lethal concentration to 50 percent of the population (LC₅₀) for inhalation activity. Packing Group I contains the most toxic materials. The criteria for these groups are shown in Table F-1.

Table F-1. Grouping Criteria for Administration Through Oral Ingestion, Dermal Contact, and Inhalation of Dusts and Mists

Packing Group	Oral Toxicity LD ₅₀ (mg/kg) ^a	Dermal Toxicity LD ₅₀ (mg/kg) ^a	Inhalation Toxicity by Dusts and Mists LC ₅₀ (mg/l) ^b
Ι	≤5	≤40	≤0.5
II	>5-50	>40-200	>0.5-2
III °	Solids: >50-200 Liquids: >50-500	>200-1,000	>2-10

Source: UN Committee of Experts on the Transport of Dangerous Goods (1999).

^b Lethal concentration to 50% of the sample population.

^a Lethal dose to 50% of the sample population.

^c Tear gas substances should be included in Packing Group II even if their toxicity data correspond to Packing Group III values.

⁸⁹ Some may meet the criteria for a flammable substance and be placed in either Class 3 - Flammable liquids or Class 4 - Flammable solids, or possibly Class 8 - Corrosives (RTI, 1989; EPA, 2005).

The UN recommendations contain standards for two different container size groups:

- Non-bulk packaging, which has a net mass of 882 lbs (400 kgs) or less, and whose capacity is 119 gals (450 L) or less, and
- Intermediate bulk containers (IBCs), which are rigid or flexible portable packagings with a capacity of not more than 500 gals and are not included in non-bulk packaging. ⁹⁰

The recommendations for both non-bulk containers and IBCs include permanent marking, construction standards, and performance testing—including drop, leakproofness, hydraulic pressure, and stacking tests. IBCs must also meet bottom lift and top lift testing. There are also special tests that flexible containers (e.g., bags) must meet (UN Committee of Experts on the Transportation of Dangerous Goods, 1999).

F.3 Mid America CropLife Association (MACPA): MACA-75 Manufacturer Specification and User Guidelines for Portable Agrichemical Tanks

The Mid America CropLife Association has adopted the MACA-75 standards for the conglomerate of regional crop protection associations represented at the national level. MACPA was formerly known as the Midwest Agricultural Chemicals Association (MACA); hence the MACA-75 standards have retained their title by recognition of the association's former name. These specifications were developed by MACA's Bulk Pesticide Task Force Committee. because MACA recognized that the majority of pesticides sold were not considered DOT hazardous material.⁹¹ The lack of regulation could result in certain tanks (especially minibulks) being used to transport pesticides even though the tanks were not of a design or construction that allowed for safe movement over the highway (MACA, 1986). The eventual consequences of this lack of regulation could be environmental pollution, severe government regulation, bad publicity, and potentially large civil liabilities to the pesticide industry. To avoid these consequences, MACA developed the MACA-75 tank specifications, which apply to containers of 60 to 660 gallons. While MACA is only one of several regional agricultural chemical associations across the country, its tank specifications and user guidelines have become accepted nationally and are the standards used by many container manufacturers (MACA, 1992, 1986; Bartenhagen, 1992; Snyder Industries, 1992).

The MACA-75 specifications include general construction requirements regarding minimum strength, openings that allow for internal visual inspection, and handling characteristics (tie-down/loading design features). Standards are also included to address appurtenances, closures, plumbing connected to the tank, and emergency pressure relief devices. Tanks designed under MACA-75 specifications must meet a series of qualification tests, including vibration, leakproofness, drop, lifting device, base support structure, stacking, and hydrostatic testing.

⁹⁰ In the UN Recommendations on the Transport of Dangerous Goods (UN, 1999) no lower limit is given for IBCs, but the definition of IBCs states "other than those [non-bulk packagings] specified in Chapter 6.1." Thus, it would appear that the IBC's lower capacity limit is 450 L.

^{9f} At the time the MACA standards were developed, DOT used a different classification system from the nine hazard classes introduced by HM-181. Then, pesticides considered DOT hazardous materials were mostly classified as Class B poisons, flammable liquids, or combustible liquids. EPA felt that the number of pesticides covered was 20-25 percent of all pesticides; HM-181 has probably increased the number of pesticides included. Herbicides still comprise a major portion of those pesticides not covered because they tend not to be as toxic to mammals as many insecticides.

F.4 Container Population Affected by the container regulations and the Three Major National Regulations/Standards

To better understand the compliance baseline, we compared the affected pesticides and pesticide container populations of the three major regulations/standards (i.e., DOT HMR, UN Recommendations on the Transport of Dangerous Goods, and MACA-75 Guidelines) to the container regulations. Table F-2 summarizes the affected container population for the three major sets of regulations/standards.

Both the DOT HMR and UN recommendations cover pesticide containers that (1) are transported, and (2) hold pesticides that are highly toxic (i.e., LD₅₀ of 200 mg/kg or less for solids and 500 mg/kg or less for liquids) or meet the DOT HMR/UN criteria for a flammable or corrosive material. The DOT HMR regulate these containers, either through direct regulation or exemption, regardless of container size or whether the container is refillable. The MACA-75 specifications primarily affect containers that (1) contain liquid agricultural pesticides of lower toxicity (e.g., most herbicides, and certain fungicides and insecticides that are not considered DOT hazardous materials) that are not DOT HMR flammable or corrosive materials, (2) are of sizes 60 to 660 gallons, and (3) are used in the agricultural market. Thus, based on this combination of requirements, recommendations, and voluntary standards, those containers that are currently not subject to marking, construction, or performance standards include:

- Containers of 60 gallons or less, holding liquid pesticides that are used in the agricultural market and are not DOT hazardous materials;
- Containers holding dry pesticides that are used in the agricultural market and are not DOT hazardous materials;
- Containers of any size holding liquid and dry pesticides that are used in non-agricultural markets and are not DOT hazardous materials; and
- Bulk containers containing any pesticides that are not transported. (Some states have standards for stationary bulk containers.)

These containers are subject to the full effects of the final container regulations in that they are effectively starting from a "no standards" baseline and will become subject to the full requirements of the regulations.

Table F-2. Scope of Container Regulations Versus Scope of Other National Regulations and Standards

	Container Regulations	DOT Hazardous Materials Regulations (49 CFR Parts 100-199)	UN Recommendations on the Transport of Dangerous Goods	MACA-75 Manufacturer Specification and User Guidelines
Pesticides				
Affected	Other than manufacturing use products (MUPs), plant-incorporated protectants, and exempt antimicrobial products, all pesticide products are subject to the non-refillable container regulations. A product is subject to all non-refillable container requirements if it satisfies at least one of the following criteria: (1) It meets the criteria of Toxicity Category I. (2) It meets the criteria of Toxicity Category II. (3) It is a restricted use product. If it doesn't meet any of these criteria, the product is subject to only the basic DOT requirements in the non-refillable container regulations. Other than MUPs, plant-incorporated protectants, and exempt antimicrobial products, all pesticide products are subject to all of the refillable container and repackaging regulations.	Pesticides that meet the definition of a hazardous material in 49 CFR §171.8	Those meeting UN risk class definitions 1–9 (i.e., most in class 6, Division 6.1 Toxic Substances). Includes pesticides with oral LD ₅₀ <500 mg/kg for liquids and 200 mg/kg for solids. DOT Packing Group I and II pesticides are primarily included. Some pesticides may also meet criteria of flammable or corrosive material.	Agricultural pesticides, with exceptions (see below).

Table F-2 (Continued). Scope of Container Regulations Versus Scope of Other National Regulations and Standards

	Container Regulations	DOT Hazardous Materials Regulations (49 CFR Parts 100-199)	UN Recommendations on the Transport of Dangerous Goods	MACA-75 Manufacturer Specification and User Guidelines
Unaffected	The following three categories of pesticide products are not subject to the non-refillable container, refillable container, and repackaging 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 the container regulations Section 2(mm), or it has antimicrobial properties, as defined in the container regulations 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. • It is not specifically included in the regulations by EPA.	Pesticides that <i>do not</i> meet the hazardous material definition in 49 CFR §171.8.	Those pesticides that do not meet UN risk class definitions 1-9.	Liquid pesticides and other agrichemicals subject to DOT specification packaging.
Container Ty	<u> </u>		ı	1
Refillable	All containers filled and refilled with eligible product more than once.	No distinction between refillable and non- refillable containers with regard to specific	No distinction between refillable and non-refillable containers	No distinction between refillable and non-

Table F-2 (Continued). Scope of Container Regulations Versus Scope of Other National Regulations and Standards

	Container Regulations	DOT Hazardous Materials Regulations (49 CFR Parts 100-199)	UN Recommendations on the Transport of Dangerous Goods	MACA-75 Manufacturer Specification and User Guidelines
Non- Refillable	Containers that are designed and constructed for one-time filling only with eligible pesticide.	requirements; however, DOT refers to "reuse" of containers.	with regard to specific requirements.	refillable containers with regard to specific requirements.
Non-Bulk	No regulatory distinction between non-bulk and bulk with regard to requirements.	Packaging that has: (1) a maximum capacity of 450 L (119 gallons) or less as a receptacle for a liquid; (2) a maximum net mass of 400 kg (882 pounds) or less and a maximum capacity of 450 L (119 gallons) or less as a receptacle for a solid; or (3) a water capacity of 454 kg (1,000 pounds) or less as a receptacle for a gas as defined in §173.115. (§171.8)	Net mass ≤400 kg Capacity ≤450 L (6.1.1.1)	Does not specify.
Bulk	No regulatory distinction between non-bulk and bulk with regard to requirements.	Bulk packaging means a packaging, other than a vessel or a barge, including a transport vehicle or freight container, in which hazardous materials are loaded with no intermediate form of containment and which has: (1) A maximum capacity greater than 450 L (119 gallons) as a receptacle for a liquid; (2) A maximum net mass greater than 400 kg (882 pounds) and a maximum capacity greater than 450 L (119 gallons) as a receptacle for a solid; or (3) A water capacity greater than 454 kg (1,000 pounds) as a receptacle for a gas as defined in §173.115. (§171.8)	IBC defined as rigid or flexible portable packagings other than those specified in Division 6.1 that (A) have a capacity of: (i) Not more than 3,000 L for solids and liquids of Packing Groups (PG) II and II; (ii) Not more than 1.5 m³ for solids of PG I when packed in flexible, rigid plastics, composite, fiberboard, and wooden IBCs; (iii) Not more than 3.0 m³ for solids of PG I when packed in metal IBCs; and (iv) Not more than 3.0 m³ for radioactive material of Class 7. (1.2.1)	60–660 gallons

F.5 Detailed Comparison of the Pesticide Container Regulations and the Three Major Regulations/Standards

The container regulations under consideration include several components. This section details 13 major components of the container regulations and compares them to the relevant requirements of the DOT HMR, UN recommendations, and MACA-75 specifications. Each component is discussed separately below.

F.5.1 Design Standards

The container regulations adopt the DOT HMR packaging standards for pesticides classified as DOT hazardous materials. Pesticides that are not classified as DOT hazardous materials are required to be packaged in accordance with the specified design and construction standards that would apply to a DOT Packing Group III material. Under the container regulations, sale or distribution of pesticides in containers not meeting the DOT standards for design, construction, and markings is prohibited, and registrants are held responsible for, but are not required to report, the design standards.

The container regulations incorporate a provision similar to the DOT limited quantity exceptions that provide exceptions parallel to those in the DOT HMR. The integrity use and compatibility standards of the DOT HMR are incorporated into the container regulations with the exception of additional requirements in the container regulations for bulk refillable containers for appurtenances and listing of compatible containers for pesticide formulations.

The UN recommendations and the MACA-75 specifications are much more specific. The UN recommendations contain detailed construction requirements by container/material grouping. These requirements address which construction materials can be used; the design of openings and closures; seams; and, in some cases, minimum allowable material thickness. MACA-75 specifications are somewhat more general, but the requirements are more detailed than the container regulations and address minimum strength, handling characteristics, and draining/cleaning capability.

F.5.2 Permanent Markings

All of the current regulations/standards examined require some form of permanent marking on each container; however, each regulation/standard varies somewhat in the information required. The container regulation requirements for *non-refillables* and *refillables* refer to and adopt the DOT standards. Additionally, container regulations require a serial number or other identifying code for each non-refillable container.

The information requirements that are common between the *refillable* container requirements and the regulatory/standards baseline are: manufacturer name or symbol, year of manufacture, and name or symbol (code) of materials the container is made from. The UN IBC recommendation calls for a marking that signifies conformity to design type. Serial number and capacity rating are required only under the EPA requirements and MACA-75 specifications.

F.5.3 Dispensing Capability

The container regulations stipulate that containers with a capacity greater than 20 liters (5.3 gallons) need to be designed to eliminate the splash and leakage during normal pouring of the contents, closing or resealing of the container, and storage and cleaning of the container.

The other three regulations/recommendations primarily mention dispensing capability in terms of cleaning and storing. MACA-75 recommends that tanks be designed so that, when necessary, they can be totally drained.

F.5.4 Closures

Safe use of pesticide containers extends to closed systems (also known as closed transfer systems). All four nationwide standards are similar in that they each discuss regulations/ recommendations for proper container closures. Each standard specifies in some fashion that containers must be equipped with closures that will be secure and leakproof. However, EPA's regulations are the most specific about specific closure sizes (see Table F-3 for more details).

F.5.5 Residue Removal Design Standard

Only the MACA-75 guidelines specify a standard for residue removal for non-refillable containers. The MACA-75 standard applies to bulk tanks and states that containers should be designed to allow the product to completely drain out of the tank. With regard to non-refillable containers, the container requirements specify that each rigid/dilutable container/formulation combination must achieve a certain laboratory performance standard (a reduction of the original active ingredient concentrate to .01 percent in a fourth rinse or equivalent to 99.99 percent removal). This specification, of course, does not guarantee that these containers will be rinsed to this level by the end user in the field before container disposal.

While the UN recommendations, the DOT HMR, and the MACA-75 specifications all address residue removal from refillable containers, the container regulations are the most specific regarding how much must be removed and how it should be removed. The UN recommendations state only that the container should be "purged" of its former contents before refilling; no procedures are specified. The DOT HMR state that before the container is refilled, it must "be free from incompatible residue." The MACA-75 specifications recommend that each portable tank be kept in dedicated service to one product "in order to reduce contamination and content-disposal problems." If the container must be used for another product, the container must be examined "to determine presence of previous product and then "all of the residue from the former loading" must be cleaned out.

The container regulations require that the every registrant test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable of attaining at least 99.99 percent removal of each active ingredient in the fourth rinsate after a triple rinse.

F.5.6 Production Testing

The container regulations do not specify production testing requirements. However, by adopting DOT HMR design standards, the container regulations indirectly include production testing for

performance of drop, leakproofness, hydrostatic pressure, stacking, and cooperative tests (as applicable) for each new or different packaging.

For non-bulk containers, DOT HMR (or the container regulations) and UN recommendations require sampling of 3–6 containers, whereas the MACA-75 guidelines do not specify. For bulk containers, the container and DOT regulations require representative samples of all design types, while the UN recommendations and MACA-75 specifications suggest using one container. The DOT HMR (or container regulations) filling requirements are the same as the UN recommendations and similar to the MACA-75 specifications. Drop testing requirements for DOT (or container regulations) are similar to the UN recommendations, while the MACA-75 specifications only state that the standard is two feet.

F.5.7 Production Retesting

Rather than directly specifying, the container regulations adopt DOT HMR standards for an interval for repeating production testing. The product retesting intervals for DOT HMR bulk is every year, but varies according to the container specifications. For example, each IBC must be tested in accordance to the leakproofness test and visually inspected every 2.5 years. Under the UN recommendations, retesting of a particular container design must be conducted at intervals established by a "competent authority." The MACA-75 specifications do not address product retesting for the container design.

The non-bulk DOT HMR is the only set of requirements requiring a leakproofness test before reuse of each container. The MACA-75 specifications and the UN recommendations specify rerunning a leakproofness test on tanks at least every 2 years and 2.5 years, respectively. The DOT HMR specifications for non-bulks require that each tank must be fully retested every 2 years.

F.5.8 Reconditioning

Only the UN recommendations and the DOT HMR have specific reconditioning standards. Under the UN recommendations, containers (including non-bulks) must be capable of passing all appropriate performance tests, and each one must undergo the leakproofness test before it can be reused for transport. The DOT HMR contain specific requirements for reconditioning metal drums and require that all other reconditioned containers be capable of meeting all non-bulk performance standards. A reconditioned container must have a permanent mark representing a certification that the reconditioned container conforms to the DOT HMR standards for that container design.

F.5.9 Waiver

None of the nationwide standards except the container regulations specify a procedure for obtaining a waiver for all or parts of the regulation or standard. The container regulations include procedures for allowing a waiver of compliance for portions of the regulation based on the registrant's capacity to demonstrate that the container meets or exceeds DOT standards for hazardous materials.

F.5.10 Recordkeeping

EPA container records requirements are more extensive than those of the baseline. The regulations require several types of recordkeeping. The first addresses the documentation that the container used meets each aspect of the non-refillable container design standards. For non-refillables, the period extends for as long as the container design type is used with the registered pesticide product, plus 3 years. The second type of recordkeeping requirement involves records kept by the registrants regarding repackaging. The registrants are required to keep copies of the contracts or authorizations, residue removal procedures for refilling, and list of acceptable containers for the current operating year and for 3 years after.

The third type of recordkeeping involves refillers keeping copies of the documents identified in the previous paragraph for the registrants for the current operating year and for 3 years after (as with the registrant recordkeeping). The fourth type of recordkeeping involves information the refillers have to record when they repackage and when they receive refillable containers. Refillers must record three pieces of information when a pesticide is repackaged. No recordkeeping is required when a refillable container is received. These records must be kept for 3 years.

The UN recommendations, the DOT HMR, and the MACA-75 specifications have no requirements analogous to the second type of recordkeeping. Relative to the first type, however, the UN recommendations for IBCs do include recordkeeping provisions but only to the extent that a report should be kept of each inspection. This report should be retained at least until the date of the next inspection. Testing records also are recommended. The MACA-75 standards are similar, stipulating written records of the annual inspections. The results of the 2-year test for leakproofness must also be kept by tank serial number. The DOT HMR currently require records only for non-bulk packaging. These records are limited to information regarding the design qualification testing, including documenting the types of tests conducted; dates; locations; packaging specifications; test specifics (e.g., drop heights, hydrostatic pressures); results; and test operators' names or name of the person responsible for testing each packaging at each location where that packaging was manufactured; and at each location where design qualification tests are conducted. This information must be retained for as long as the packaging is produced and for at least 2 years thereafter. Similar information must be kept for periodic retesting. This information must be kept until such tests are performed successfully again and for at least 2 years from the date of each test.

F.5.11 Refilling

The container regulations contain a great amount of detail regarding refilling, including specific guidelines for registrants and refillers. For example, registrants who directly sell or distribute pesticide products in *refillables* or sell or distribute pesticide products to refillers for repackaging are held responsible for providing instructions and documentation for refilling. Refillers who package or repackage pesticide products into refillable containers for distribution or sale must comply with the residue removal procedure for refilling developed by registrants and repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, refillers must inspect the exterior and interiors of the containers to ensure that the container meets the necessary criteria with respect to container integrity, required markings, and openings; and clean each refillable container according to the pesticide product's

residue removal procedure for refilling before repackaging the product, unless certain criteria are met

With regard to refilling, the UN and DOT regulations are much less detailed than the container regulations. They both specify that each package must be inspected before reuse. The MACA-75 specifications also refer to refilling recommendations only in terms of inspection. They recommend that fillers examine the tank to determine the presence of any residue of the previous product to prevent contamination and clean out residue of the former lading if the tank must be refilled with another product.

An inspection prior to refilling is required under the container regulations and under each of the regulations/standards included in the baseline. The container regulations and the MACA-75 standards are the most detailed with regard to how the inspection should be conducted. The MACA-75 standards also specify a thorough exterior/interior inspection annually (or at the beginning of each use season), and on a 2-year basis, an inspection that includes retesting for leakproofness. The UN recommendations for non-bulk containers include inspection before each filling, and, for certain container types, (e.g., rigid metal and plastic containers) inspections every 2.5 years to the "satisfaction of the competent authority" with regard to external conditions of the container and proper functioning of service equipment. Every 5 years, these containers are also inspected to the satisfaction of the competent authority, to determine:

- Conformance to design type, including marking;
- Internal and external conditions, and
- Proper functioning of service equipment.

DOT standards (both the specifications and non-bulk packaging) indicate that on inspection the container must not show a reduction in integrity (non-bulks) and must be "free from incompatible residues, rupture or other damage which reduces its [the container's] structural integrity." The container regulations require a tamper-evident device for containers holding liquids, and the MACA-75 standards specify an anti-backfilling device for such containers. These devices must be checked before each refilling.

F.5.12 Labeling

Labeling requirements were originally considered under the proposed container and containment regulations in the 1994 proposed container rule. In this section, labeling requirements are compared with existing standards as referenced in the 1994 Proposed Rule.

The Proposed Rule adopted PR Notice 83-3 recommendations (EPA, 1983), which provided the pesticide user certain statements and instructions on the container label for pesticide and container storage and removal. Additionally, container regulations require container labels to include the product's intended use and registration number and container type information.

The DOT HMR require containers to be labeled with general specifications pertaining to the nature of the hazard of the product. UN recommendations also requires a statement on the label regarding the primary and secondary risks of the product. The DOT HMR or UN recommendations do not contain labeling specifications for product or container storage and

disposal nor a unique identifier to track the product. MACA-75 specifications do not include labeling.

Table F-3 presents a side-by-side comparison of the 13 requirement categories and subcategories between the container regulations and the three major regulations/standards.

Table F-3. Comparison of Container Regulations with Other National Regulations and Standards

	Container Requirements		DOT Hazardous Materials Regulations (49 CFR Parts 100-199)		UN Recommendation	MACA-75 Manufacturer Specification and User Guidelines		
D	N D #11 11		fillable	n II IVDC	N D II	N D II	ID C	D 11
Requirement	Non-Refillable	Minibulk	Bulk	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Design Standards Requirements	Prohibit distribution or sale of pesticide product in non-refillable container unless the container met standard. (§165.42) Container must meet DOT standards for design, construction, and markings in accordance with Packing Group III material as defined by DOT. (§§165.60–165.64)	product in refillab container met stan (§165.92) Container must me for design, constru	eet DOT standards action, and markings a Packing Group III d by DOT.	Specific construction requipackaging types, including sizes and types, compatibil materials, construction mat 173.24) 178, 180)	seams, opening/closing lity of container and	Specific construction standards by container type (e.g., steel drums, plastic drums, and jerricans), including: opening size, seams, construction materials, etc. (6.1.4)	(1) Resistant to or protected from deterioration. (2) Constructed so that contents can't escape under normal conditions. (3) Gaskets made of materials not subject to attack by the contents of the IBCs. (4) All service equip. positioned or protected to minimize risk of escape or contents owing to damage. (5) Designed to withstand internal pressure of contents and stresses of normal handling and transport. (6) Specific construction requirements by container type. (7) Each IBC capable of passing relevant performance tests. (6.5.1.5)	Examples: (1) Construction materials (1.2.1) (2) Minimum strength requirements (1.3.1) (3) Inspection openings (1.3.2) (4) Fork-liftable (1.3.3) (5) Fastening/blocking for transport (1.3.4) (6) Pressure release valve (1.4.4) (7) Seal to verify tank/content integrity (1.4.5) (8) Appurtenance protection (1.4.3) (9) Draining/cleaning capability (1.3.6)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requiren	nents		aterials Regulations rts 100-199)		ons on the Transport of ous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Ref	fillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Reporting	No reporting under these regulations. Refer to standards under the container regulations 6(a)(2) to determine if incidents involving containers are reportable to EPA. (§165.80)	Refer to standards under the container regulations 6(a)(2) to determine if incidents involving containers are reportable to EPA. (§165.130)		Each carrier that transports hazardous materials shall report in writing to DOT when there has been an unintentional release of hazardous materials or any quantity of hazardous materials has been discharged during transportation. (§171.16)		None.	A report of each inspection of conformity to design type kept until date of next inspection. (6.5.1.6.4(b))	Not specified.
Responsibility	Registrants. (§165.42)	pro		Manufacturer or any person who performs a function prescribed in this part shall perform that function in accordance with this part. $\S178.2(a)(2)$		Not specified.	Not specified.	Not specified.
Integrity - Use	Not specified.	Not specified.	Each liquid and dry bulk container and its appurtenances must meet the following standards: (1) Be resistant to extreme changes in temperature and constructed of materials adequately thick to not fail and be resistant to corrosion, puncture, or cracking; and (2) Capable of withstanding all operating stresses. (§165.120(a))	Each package used for the shipment of hazardous materials shall be designed, constructed, maintained, filled, its contents so limited, and closed, so that under conditions normally incident to transportation: (1) Except as otherwise provided, there will be no identifiable (without the use of instruments) release of hazardous materials to the environment; (2) The effectiveness of the package will not be substantially reduced; for example, impact resistance, strength, packaging compatibility,	Each package used for the shipment of hazardous materials shall be designed, constructed, maintained, filled, its contents so limited, and closed, so that under conditions normally incident to transportation- (1) Except as otherwise provided, there will be no identifiable (without the use of instruments) release of hazardous materials to the environment; (2) The effectiveness of the package will not be substantially reduced; for example, impact resistance, strength,	Specific requirements according to packaging type relating to containers designed so that they remain secure and leakproof under normal conditions of transport. (6.1.4)	Resistant to and protected from deterioration from external environment. (6.5.1.5.1) None of the contents can escape under normal conditions of transport. (6.5.1.6.2, 6.5.1.5.6)	Minimum strength requirements and handling requirements. (1.3)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	Co	ontainer Requirements	DOT Hazardous Materials Regulations (49 CFR Parts 100-199)		UN Recommendations on the Transport of Dangerous Goods		MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable Refillable		Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
			etc. must be maintained for the minimum and maximum temperatures encountered during transportation; (3) There will be no mixture of gases or vapors in the package which could, through any credible spontaneous increase of heat or pressure, significantly reduce the effectiveness of the packaging. (§173.24(b)) (4) Additional integrity requirements for Intermediate Bulk Containers (§178.704)	packaging compatibility, etc. must be maintained for the minimum and maximum temperatures encountered during transportation; (3) There will be no mixture of gases or vapors in the package which could, through any credible spontaneous increase of heat or pressure, significantly reduce the effectiveness of the packaging. (§173.24(b))			

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requirements	DOT Hazardous Ma (49 CFR Pai			ons on the Transport of ous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Refillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Integrity - Compatibility	Not specified.	Registrants develop a description of acceptable containers, which are those that meet the standards in Subpart D and are compatible with the pesticide formulation. (§§165.164(b) and 165.190(b))	part, it is, nevertheless, the responsibility of the		Construction should be appropriate to its intended use (6.1.4)	IBCs and closures constructed with materials compatible with their contents so not liable (1) to be attacked by contents so as to make their use dangerous or (2) cause contents to react or decompose, or form harmful or dangerous compounds with IBCs (6.5.1.5.3)	Each tank must be made of materials having performance characteristics suitable to their application (1.2.1)
			(4) Mixed contents. Hazard packed or mixed together in packaging with other hazar materials if such materials and dangerously with each other or dangerous evolution of he evolution of flammable, pogases; or formation of unstable or co (5) Packagings used for sol liquid at temperatures likely transportation, must be cap hazardous material in the li	n the same outer dous or non-hazardous are capable of reacting er and causing combustion neat; isonous, or asphyxiant rrosive materials. ids, which may become y to be encountered during able of containing the			

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

Requirement	Non-Refillable	Container Requirements Refillable	DOT Hazardous Materials Regulations (49 CFR Parts 100-199) Bulk and IBC Non-Bulk		UN Recommendation Danger Non-Bulk	MACA-75 Manufacturer Specification and User Guidelines Bulk	
Permanent Markings	Not specified.	Serial number or other identifying code for each container (§165.116)	Each packaging represented DOT specification or a UN on a non-removable compwith specification marking applicable specification, at (1) In an unobstructed are numerals identifying the statement (e.g., UN 1A1, DOT 4B24 (2) Unless otherwise specification, and address or symbol manufacturer or, where specification or support of the company of the compa	and as manufactured to a solution of the packaging ges conforming to the and with the following: a, with letters, and tandards or specification 10ET, etc.). iffied in this part, with the sol of the packaging ecifically authorized, the ency certifying compliance sols, if used, must be ate Administrator for ty. Duplicate symbols are estamped, embossed, se marked on the uate accessibility, legibility so as to be	(1) UN packaging symbol (2) Code designating type of packaging (3) Letter of designation (4) Relative density for which the design type has been tested. (5) Either letter "S" denoting that packaging intended for transport of solids or inner packagings or for packagings intended to contain liquids, hydraulic test pressure which packaging has shown to withstand (6) Last 2 digits of the year which packaging was manufactured. (7) State authorizing allocation of the mark (8) Name of manufacturer or other ID of packaging (9) Specific marking according to packaging type (10) Reconditioning markings (6.1.3.1)	(1) UN packaging symbol. (2) Code designating type of IBC (3) Letter designating the packing groups for which the design type has been approved. (4) Month and year of manufacture (5) State authorizing allocation of the mark. (6) Name or symbol of manufacturer and other ID of the IBC as specified by competent authority (7) Stacking test load (8) Maximum permissible gross mass. (9) Conformity to design type (10) Additional markings for certain categories of IBCs (6.5.2.1)	(1) Tank manufacturer (2) Specification-MACA 75 (3) Material of construction (4) Design pressure (5) Test pressure (6) Rated gross weight (7) Volumetric capacity (8) Serial number (9) Tare weight (10) Production date (11) Other specifications according to tank type (2.1.1)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	Container Requirements Non-Refillable Refillable				DOT Hazardous Materials Regulations (49 CFR Parts 100-199)		UN Recommendations on the Transport of Dangerous Goods	
Requirement	Non-Refillable	Re	fillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
				(4) Unless otherwise specimust be at least 12.0 mm (except that for packagings L (7.9 gallons) capacity for pounds) capacity for solids 6.0 mm (0.2 inches). For p capacity of 5 L (1 gallon) cletters and numerals must I (5) For packages with a grikg (66 pounds), the marking must appear on the top or C (6) A UN standard packagimarkings are permitted proapplicable standards. (7) Authorized exemptions (§178.3, §178.503(a), §178.503(a), §178.503(a), §178.503(a),	0.47 inches) in height of less than or equal to 30 r liquids or 30 kg (66 s the height must be at least ackagings having a or 5 kg (11 pounds) or less, be of an appropriate size. ross mass of more than 30 ngs or a duplicate thereof on a side of the packaging. ing marking or multiple povided container meets all s allowed.			
Dispensing Capability	If container has capacity of 30 L or less & if container holds a liquid pesticide, container must: (1) Allow contents of nonrefillable container to pour out in a continuous, coherent stream (2) Minimize dripping (§165.68)	Not specified.	Not specified.	Closures on packagings shall be so designed and closed that under conditions normally incident to transportation: (1) Except as provided in paragraph (g) of this section, there is no identifiable release of hazardous materials to the environment from the opening to which the closure is applied; and (2) The closure is secure and leakproof. (§173.24(f))	Must be leakproof (6.1.4)	No contents should esca conditions (6.5.1.5.2)	pe under normal	Each tank must be designed so that, when necessary, it may be totally drained (1.3.6)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requiren			MACA-75 Manufacturer Specification and User Guidelines			
Requirement	Non-Refillable	Ret	fillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Closures	Four closure sizes are specified for containers that meet all of these criteria: (1) rigid container; (2) capacity greater than or equal to 3.0 liters (0.79 gal.); (3) holds liquid agricultural pesticide; (4) is not an aerosol container; (5) is not a pressurized container. (§165.66) Final rule should not overlap with child-resistant packaging requirements.	Each opening of each liquid minibulk container must have a one-way valve, a tamperevident device, or both (§165.118)	(1) Each liquid bulk container must A) be equipped with a vent or other device designed to relieve excess pressure, prevent losses by evaporation, exclude precipitation. (2) External sight gauges are prohibited. (3) Container connections except for vents must be equipped with a shutoff valve which can be locked closed (§165.120(b))	(1) Closures on packagings shall be so designed and closed that under conditions (including the effects of temperature and vibration) normally incident to transportation- (i) Except as provided in paragraph (g) of this section, there is no identifiable release of hazardous materials to the environment from the opening to which the closure is applied; and (ii) The closure is secure and leakproof. (2) Except as otherwise provided in this subchapter, a closure (including gaskets or other closure components, if any) used on a specification packaging must conform to all applicable requirements of the specification. (§173.24 (f)) §178.601(g)(5)	Specific construction standards according to type. For example, closure device must be designed so it remains secure and leakproof under normal conditions of transport (6.1.4)	Constructed so that none escape under normal cor		Closure must protect against leakage or accidental opening that might be caused by vibration, corrosion, temperature, or other circumstances normally encountered during transportation or sue. The tank structure may be used to provide this protection. (1.4.1)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	Container Requirements Non-Refillable Refillable		DOT Hazardous Materials Regulations (49 CFR Parts 100-199) Rulk and IRC Non Rulk		UN Recommendations on the Transport of Dangerous Goods		MACA-75 Manufacturer Specification and User Guidelines	
Requirement	Non-Refillable	n-Refillable Refillable Bulk and IBC Non-Bulk Non-Bulk IBC		Bulk				
Residue Removal Design Standard	For rigid containers with dilutable pesticide, container must be capable of 99.99% removal of each active ingredient. 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 according to a formula. (§165.70)	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.	Each tank must be designed so that, when necessary, it may be totally drained and thoroughly drained out (1.3.6)
Design Standard Responsibility	Registrant	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not specified.

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

				DOT Hazardous Materials Regulations (49 CFR Parts 100-199)			tions on the Transport of erous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Re	fillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Procedure	Conduct rinsing (triple and/or pressure) on the label if rigid container & dilutable pesticide.	product placed in a refillable container that is adequate to maintain product integrity. (§§165.164(a) and		To be considered empty and not subject to DOT requirements, packaging must be "sufficiently cleaned to remove any potential hazard." (§173.29(b)(2)(ii)) Must be free from incompatible residue for reuse. (§§173.28(a))		Not specified-	Not specified-	Examine to determine presence of previous product. Each portable agrichemical tank should be kept in dedicated service; however, if tank must be refilled with another product, clean out all residue of the former lading. (2.1.2)
Procedure Responsibility	End user	(which could be the disposal: whoever	e registrant, refiller,	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.
Production Testing	No	No	No	Yes	Yes	Yes	Yes	Yes
Sampling	No			IBC-Samples of all intermediate bulk container design types (§178.810(c))	3-6 containers (§178.602)	3-6 containers (6.1.5.3.1)	1 container (says the same or different IBC may be used for each drop (6.5.4.9.3))	1 container (1.7.1)
Filling Requirements	No	No	No	Filled at least: solids- 95%, liquid-98% (§178.602, §178.810)	Filled at least: solids- 95%, liquid-98% (§178.602)	Filled to at least: solids-95%; liquid- 98% (6.1.5.2.1)	Filled to at least: solids- 95%; liquid-98% (6.5.4.9.2)	Filled to rated gross weight but not over 98% of volume (1.7.1.2)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

Requirement	Container Requirements Non-Refillable Refillable		DOT Hazardous Materials Regulations (49 CFR Parts 100-199) Bulk and IBC Non-Bulk		UN Recommendatio Danger Non-Bulk	MACA-75 Manufacturer Specification and User Guidelines Bulk		
Drop Test	No	No No		The drop test must be conducted for the qualification of all packaging design types and performed periodically as specified in §178.601(e) Drop heights are determined according to the packing group; for liquids, if the test is performed with water, there are specific requirements (§178.603, §178.810)	The drop test must be conducted for the qualification of all packaging design types and performed periodically as specified in §178.601(e). Drop heights, measured as the vertical distance from the target to the lowest point on the package, must be determined as follows: (1) For solids and liquids, if the test is performed with the solid or liquid to be transported or with a non-hazardous material having essentially the same physical characteristic, the drop height must be determined according to packing group and (2) Specific requirements if for liquids, the test is performed with water (§178.603(e)).	If test performed with materials to be carried or with another substance having essentially same physical characteristics, 0.8 m - 1.8 m depending on packing group. Other heights will apply based on relative density (6.1.5.3.4)	Depends on relative density: (1) 1.8m, 1.2 m, 0.8m if relative density 1.2 or (2) density * 1.5m/d * 1.0m/d * 0.67m if relative density > 1.2. (6.5.4.1.3)	2 ft. (1.7.1.2)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requirem	nents	DOT Hazardous Materials Regulations (49 CFR Parts 100-199)		UN Recommendation	MACA-75 Manufacturer Specification and User Guidelines	
Requirement	Non-Refillable	Ref	illable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Production Retesting	Not specified, however DOT standards are referred to and adopted. (49 CFR Parts 178 and 180)	Not specified, however DOT standards are referred to and adopted. (49 CFR Parts 178 and 180)	Not specified, however DOT standards are referred to and adopted. (49 CFR Parts 178 and 180)	Manufacturer-periodic retesting §178.601(e) -Each IBC intended to contain liquids or solids that are loaded or discharged under pressure must be tested in accordance with the leakproofness test prescribed in §178.813 of this subchapter and visually inspected every 2.5 years, starting from the date of manufacture or the date of a repair (§180.352b)	The performance of the drop, leakproofness, hydrostatic pressure, and stacking tests. (§178.601(c)(2)) The packaging manufacturer shall achieve successful test results for the periodic retesting at intervals established by the manufacturer of sufficient frequency to ensure that each packaging produced by the manufacturer is capable of passing the design qualification tests. Changes in retest frequency are subject to the approval of the Associate Administrator for Hazardous Materials Safety. For single or composite packagings, the periodic retests must be conducted at least once every 12 months. For combination packagings, the periodic retests must be conducted at least once every 24 months. (§178.601(e))	At intervals established by competent authority. (6.1.5.1.3) Retesting before reuse every 2.5 years (§173.32(e))	At intervals established by competent authority. (6.5.4.1.4) All packages subject to the leakproofness test with air prescribed in §178.604 must be checked for leakproofness before reuse. (§173.28(b) (2))	Every 2 years perform leak test immediately prior to the use season for the tank. (2.1.4) At minimum, check at two year inspection fill with non-hazardous liquid and be sure tank does not leak. (2.1.4)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requiren	nents	DOT Hazardous M (49 CFR Pa	aterials Regulations rts 100-199)		ons on the Transport of ous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Ref	fillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Reconditioning	No. However, may be applicable to drums.	No	No	Packagings and receptacles used more than once must be in such condition, including closure devices and cushioning materials, that they conform in all respects to the prescribed requirements of this subchapter. Before reuse, each packaging must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage which reduces its structural integrity. (§173.28)	(1) Reconditioning of metal drums is: cleaning, restoring and inspecting. Packagings that have visible signs of deterioration must be rejected. (§173.28) (2) Reconditioning of a non-bulk packaging other than a metal drum or a UN 1H1 plastic drum includes: removal of former contents, cleaning, inspecting, replacing non-integral parts with new or refurbished parts, and restoring to meet standards. (§173.28) (3) A person who reconditions a packaging must mark and certify the package before reuse. (§178.503(c)(d))d (d) The marking may different than the original but must not identify a greater container capacity. (4) Packagings which have significant defects which cannot be repaired may not be reused. (§173.28c)	(1) Requires leakproofness test (4.1.1.12 (2) Must be able to pass all tests (4.1.1.9)	(1) Requires leakproofiness test (4.1.1.12) (2) Must be able to pass all tests (6.5.1.6.6)	No
Miscellane ous								Additional guidelines in leakproofness (1.8.1), hydrostatic (1.7.2.2), stacking (1.7.1.5), vibration (1.7.1.1), base support (1.7.1.4), and lifting device (1.7.1.3).

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requiren	nents		aterials Regulations arts 100-199)		ons on the Transport of ous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Ret	fillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Waiver	Yes. May be issued by EPA for the following reasons: (1) if registrant demonstrates container safety standard meets or exceeds DOT standards for hazardous materials; (2) necessary or similarly protective non-standard closure; (3) or other reasons as necessary. Waiver must be obtained in writing. (§§165.72, 165.74)	Yes. May be issued by EPA if registrant demonstrates container safety standard meets or exceeds DOT standards for hazardous materials. Waiver must be obtained in writing. (§§165.122, 165.124)	Not specified.	Not specified.	Not specified.	Not specified.	Not applicable.	
Certification	Not required	Not required.	DOT or UN marking (1) All requirements or UN standard are n (2) All functioned pe the person whose nar part of the marking of	of the DOT specification	A transport certificate and attesting that container des (5.4.1.6)		A certificate and mark shall be issued attesting that design type including its equipment meets the standards. (6.5.1.6.3)	No

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

Record For ea pestic produc	n-Refillable each	Refillable		rts 100-199)		ons on the Transport of rous Goods	Specification and User Guidelines
keeping pestici produc	each		Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
for as non-recontaitype is distrib the per production of the per per per per per per per per per pe	duct, ntain records as long as the -refillable tainer design e is used to ribute or sell pesticide duct and for 3 as thereafter. It keep the owing ords: Idame and A registration aber of the cicide product description of design type ne non- llable tainer in ch pesticide duct is ributed or l opy of the ification as cribed in 65.82 and 84 decord to tument upliance with requirement closures in 5.66 decord to tument upliance with pensing dards in 5.68.	Keep a copy of the certification for as long as a refillable container is used to distribute the product and for 3 years after. (§165.136)	Bulk and IBC Yes, relative to testing for IBCs. (§178.801(1)) Page 25:	Yes, relative to testing for refillables. (§178.601(1))	Non-Bulk Yes, relative to testing. (6.1.5.8.9)	Yes, relative to inspections and tests. (6.5.4.14.4, 6.5.1.6.5)	Bulk Yes, relative to maintenance and inspection. (2.1.5, 2.2.6)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	Container Requirements			laterials Regulations arts 100-199)		ons on the Transport of rous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Refillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Refilling Transfer	Not Applicable.	Replaces the Bulk Pesticides Enforcement Policy with §165.182 and §165.200. Provides that registrants may allow a refiller to prepackage the registrant's pesticide product into any size refillable container and distribute or sell under the registrant's registration (provided all conditions of the rule are met). Require registrants to submit to EPA acknowledgement that they have entered into a repackaging agreement with a refiller and they are responsible for the integrity of the repackaged product.	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.
Responsibility - Registrant that distributes or sells products in refillable containers	Not applicable.	(1) Product not adulterated or different from composition described. (§165.162) (2) Registrant would be required to develop written residue removal procedure for refilling each pesticide product. (§165.164) (3) Registrant required to develop a written list of acceptable containers for each registered pesticide. (§165.164) (4) Refiller at establishment must use approved container(s) (§165.166), have required documentation (§165.168), clean and inspect containers before refilling (§§165.170–165.174), and appropriately label the containers (§165.176). (5) Keep and make available to EPA records on pesticide products distributed or sold and information on container history and use. (§165.178)	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requirements		Materials Regulations Parts 100-199)		tions on the Transport of erous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Refillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Responsibility - Registrant that distributes or sells products to refillers for repackaging	Not applicable.	(1) Repackaging results in no change to pesticide formulation and occurs at an EPA approved location. (§165.182) (2) Registrant must provide refiller with a written contract/authorization. (§165.186) (3) Registrant responsible for product integrity (§165.188) (4) Registrant required to provide refiller with a written residue removal procedure for refilling each pesticide product before or at the time of distribution or sale. (§§165.190, 165.192) (5) Registrant required to provide refiller with a written list of acceptable containers for each registered pesticide. (§§165.190, 165.192) (6) Keep and make available to EPA records on contracts entered into with refillers, residue removal procedure, and list of acceptable containers for the current operating year and 3 years after that. (§165.194)	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.
Responsibility - Refiller	Not applicable.	(1) Required to possess necessary written authorizations. (§165.200) (2) Product not adulterated or different from composition described. (§165.204) (3) Refiller at establishment must use approved container(s) (§165.206), have required documentation (§165.208), clean and inspect containers before refilling (§§165.210–165.214), and appropriately label the containers (§165.216). (4) Keep and make available to EPA records on pesticide products distributed or sold and information on container history and use. (§165.218)	Not specified.	Not specified.	Not specified.	Not specified.	Not specified.

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requirements		aterials Regulations rts 100-199)		ons on the Transport of ous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Refillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Inspection	Not applicable.	Inspection prior to packaging or refilling (§§165.174 and 165.214)	Before reuse, each packaging must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage which reduces its structural integrity. (§173.28, §178.601(c)(g))	Refillables-inspection prior to refill. (§173.28, §180.352) Before reuse, each packaging must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage which reduces its structural integrity. (§173.28, §178.601(c)(g))	Inspection before each fill (4.1.1.9)	Before each refill. (4.1.1.9) For some types of packaging, inspection by a competent authority required, thorough every 5 years and less thorough every 2.5 years. (6.5.1.6.4)	Before each refill; annual and 2 yr. inspections more thorough. (2.1.1, 2.1.2, 2.1.4) Before loading a product into any tank, the filler should perform the following: (1) verify for anti back-filling device or other filling control device on the discharge opening. (2) Examine the tank to determine the presence of any residue of the previous product to prevent contamination. Clean out reside of the former lading if tank must be refilled with another product. (3) Examine tank and support structure for any significant structural damage(2.1.2)

Table F-3 (Continued). Comparison of Container Regulations with Other National Regulations and Standards

	C	ontainer Requirements	DOT Hazardous M (49 CFR Pa	aterials Regulations rts 100-199)		ons on the Transport of ous Goods	MACA-75 Manufacturer Specification and User Guidelines
Requirement	Non-Refillable	Refillable	Bulk and IBC	Non-Bulk	Non-Bulk	IBC	Bulk
Labeling	(1)Identify container type + recycle statement (156.140(a)) (2) Residue removal statement (156.144(d))	(1) Reserve space for net weight of contents (156.10(d)(7)) (2) Reserve space for EPA establishment number (156.10(f)) (3) Identify container type (156.140(b)) (4) Residue removal statement	Except as specified in §172.400a, each person who offers for transportation or transports a hazardous material in any of the following packages or containment devices, shall label the package or containment device with labels specified for the material in §172.101 and §172.400 Examples: (1) general label specifications (2) codes indicating the primary hazard of the material (3) codes indicating subsidiary hazards (4) specific labels according to hazard class or division (§172.101(g), §172.400)	Labels of primary and subsidiary risk (5.2.2.1)	1. Precautionary markings (1.1.1) 2. Marked in accordance with applicable provisions of the container regulations (1.2.1) 3. Tanks designed, constructed, or tested under these guidelines aren't required to be labeled or marked as prescribed by DOT Haz. Mat. Regs unless they contain DOT regulated hazardous materials (1.1.3) 4. Containers over 119 gallons capacity, containing combustible liquids, must be marked and placarded as required to DOT HMR (1.1.4)	Not specified	Not specified

F.6 Existing EPA Policy Applicable to Pesticide Containers

Existing EPA regulations, recommendations, and programs have an effect on the baseline compliance rate of the container regulations. Three policies that are examined to estimate this effect are the child-resistant packaging requirements already specified under container regulations, the Consumer Labeling Initiative, and the Bulk Pesticide Enforcement Policy. It is important to estimate the impacts of these policies in order to determine the level of adjustments and changes that the affected market sectors will make to come into compliance under the container regulations. Each of these current policies affects some but not all of the components of the container regulations. Below is a summary of each policy and its relevant impacts on the container regulations. Following the policy summaries, Table F-4 provides a side-by-side comparison of the relevant components of the container regulations.

F.6.1 Child-Resistant Packaging (40 CFR Part 157)

Subpart B of 40 CFR Part 157 prescribes requirements for child-resistant packaging (CRP) of pesticide products and devices under authority of the container regulations Sections 25(a)(1) and 25(c)(3). The purpose of this regulation is to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated under the container regulations. The CRP requirements are targeted toward products that meet toxicity criteria and are intended for residential use. Table F-4 details the toxicity criteria used to determine eligibility. Pesticides classified for restricted use or that are packaged in large sizes are exempt.

The CRP standards are set for effectiveness, compatibility, and durability and must be certified by EPA. Registrants must keep on record a (1) description of the container, (2) copy of the certification statement, (3) document verifying the package is child-resistant, (4) written evidence verifying that the container has been tested, and (5) an explanation of why the container and closure are compatible in cases where the components are purchased separately.

F.6.2 Consumer Labeling Initiative

EPA's Consumer Labeling Initiative (CLI) is a voluntary, cooperative partnership effort among federal, state, and local government agencies, the pesticide and cleaner industry, environmental groups, and other interested groups. CLI was promulgated by a Pesticide Registration (PR) Notice posted in the *Federal Register* (EPA,1996). The purpose of CLI is to make labels easier to read and understand on indoor insecticides, outdoor pesticides, and household hard surface cleaners (i.e., floor and basin, tub and tile), some of which are registered antimicrobials/disinfectants.

CLI has undergone two phases. Phase I began in early 1996 and ended on September 30, 1996. It was comprised of three components: qualitative consumer research, a literature review of relevant publications and reports of studies available in the public domain or provided by various stakeholders, and a review of extensive stakeholder comments solicited through the *Federal Register* Notice.

Phase II, which began in October 1996, resulted from this first phase of research. Phase II addressed issues that Phase I did not complete or include, including conducting in-depth

quantitative consumer research, finding ways to improve labels by using clearer wording and storage and disposal information, and identifying other information about ingredients that consumers want and need on labels. This phase also included the development of a consumer education campaign.

Pesticide Regulation Notices are issued by EPA's Office of Pesticide Programs to inform pesticide registrants and other interested persons about important policies, procedures, and regulatory decisions. The labeling recommendations of the Phase I and II reports, some of which have been included in PR Notices, are as follows:

- Include emergency telephone numbers on product labels;
- Use common chemical names, not formal chemical names;
- Use the heading "Other Ingredients" instead of the little understood term "Inert Ingredients";
- Use the more readily understood heading "First Aid," instead of "Statement of Practical Treatment";
- Include simplified, medically correct First Aid Statements;
- List only meaningful ingredient identification;
- Provide consistent and clear directions for storage and disposal; and
- Specify label recommendations according to pesticide type.

The CLI affects a relatively small portion of the pesticides included in the scope of the container regulations. This class of products includes outdoor pesticides under Toxicity Categories I or II, which are not exempt as eligible antimicrobials. It appears unlikely that outdoor pesticides in Toxicity Categories III and IV, which meet container regulations, were intended for use in the scope of the CLI. The CLI targets the home and garden sector whereas the container regulations are intended for eligible containers used by all market sectors. Table F-4 below compares the requirements of the 1994 Proposed Rule regulations for container labeling with the CLI recommendations.

F.6.3 Bulk Pesticide Enforcement Policy

The Bulk Pesticide Enforcement Policy was published in July 1977 (41 FR 55932). This policy was developed to define when bulk shipments and transfer practices were allowable without a separate registration. The commercial transfer of pesticides in bulk can involve changing the container at various stages of the distribution process; however, "repackaging" ("transferring a pesticide formulation from one container to another without a change in the composition of the formulation or the labeling for sale or distribution," 40 CFR §165.3) is considered "production" of a pesticide as defined in 40 CFR §167.3. A registration is needed for distribution or sale of a repackaged product. The Bulk Policy clarifies that a separate registration is not needed, as long as "the transfer of a registered product in 'bulk' involves *only* the changing of the product container with *no* change:

- (1) "to the pesticide formulation,
- (2) to the product's accepted labeling [with exceptions regarding information required by the policy regarding the repackaging establishment and package content], *and*
- (3) to the identity of the party accountable for the product's integrity."

If the above three conditions are met, the repackaged product is considered to be encompassed within the terms of the original product registration. The policy details when a new registration is needed and how to satisfy the third criterion regarding "accountability" for product integrity. Primarily, this criterion is met if the repackager has written authorization from the registrant allowing the repackager to repackage the pesticide at a registered establishment and to use the registrant's label.

The Bulk Pesticides Enforcement Policy is often referred to as the "55-gallon" policy because it defines the term "bulk" to mean any volume of pesticide greater than 55 gallons or 100 pounds held in an individual container. This policy may have discouraged repackaging smaller amounts (i.e., it placed a lower limit on the quantity of pesticide that could be introduced into refillable bulk containers and on the capacity of the containers because such quantities could not be repackaged without a new registration). On March 4, 1991, this policy was amended to allow the repackaging of any quantity of pesticides into refillable containers, provided that:

- (4) "The container is designed and constructed to accommodate the return and refill of greater than 55 gallons liquid or 100 lb. dry materials; and
- (11) 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 to the container in order to avoid cross-contamination; and
- (12) All other conditions of the July 11, 1977 policy are met."

The Bulk Pesticides Enforcement Policy does not include any container construction or performance standards. With regard to labeling and marking, the policy indicates that the registrant's label must be used for the repackaged material, and this label must reflect the establishment number of the establishment that repackaged the material and the appropriate net content statement. Permanent marking is not required.

The refillable container requirements do not change the conditions under which repackaging a pesticide can occur without requiring a new registration. The safeguards specified in the Bulk Pesticides Enforcement Policy are incorporated into the final container regulations through the requirements regarding registrant and refilling establishment repackaging responsibilities. The Bulk Pesticides Enforcement Policy will be rescinded after the container regulations are final. The final regulations make the following general changes:

- (5) Repackaging is allowed for any quantity of pesticide into any size of container, as long as that container meets the standards for a refillable container, and
- (6) Specific labeling, marking, design, and performance standards are established for refillable containers.

Table F-4. Comparison of Container Regulations with Other EPA Policies

Category	Container Regulations	Child-Resistant Packaging (49 CFR Part 157)	Consumer Labeling Initiative (FR 61:12011)	Bulk Pesticide Enforcement Policy (40 CFR Part 167)
Scope	(1) The product is classified in Toxicity Category I or II, or (2) The container capacity is greater than or equal to the container size criterion of 5 L (1.3 gallons) or 5 kg (11 lbs), or (3) The product is intended for outdoor use and the label includes at least one of the specified environmental statements (FR 64:203, Table 5) Exempt: Antimicrobials eligible for exemption (FR 64:203, Table 5)	(1) The product has toxicity of: 1.5 g/kg LD50 oral; 2,000 mg/kg LD50 acute dermal; or 2 mg/l LC50 acute inhalation; or (2) The product is corrosive to the eye, causes corneal irritation persisting 21+ days; or (3) The product is corrosive to the skin or causes severe skin irritation at 72 hrs; or (4) EPA determines packaging could significantly reduce serious hazard or injury. and (5) Product intended for residential use. Exempt: Product classified for restricted use or packaged in large sizes.	(1) Indoor insecticides (2) Household surface cleaners (3) Outdoor pesticides Some of these pesticides are registered antimicrobials.	Separate registration is not needed to transfer a registered product from one container to another (repackaging) as long as the composition of the formulation and labeling for sale or distribution remains the same.
Design Standards	Major component of regulation developed for refillable and non-refillable container standards (refer to Table F-3 above).	 (1) Effectiveness: meets specification in 16 CFR §170.20. (2) Compatibility: product does not interfere with the child-resistant packaging or is detrimental to the integrity of the container. (3) Durability: child-resistant packaging meets standards over lifetime of container. 	Not applicable.	The container is designed and constructed to accommodate the return and refill of >5 gallon liquid or 100 lb of dry material. (1991 amendment to the policy)
Certification	Not required.	Child-resistant packaging device must be certified by EPA along with compatibility with container.	Not applicable.	None.
Recordkeeping	Record of container certifications must be kept while container is in use.	Record of CRP and container certifications must be kept while container is in use.	Not applicable.	None.

Table F-4 (Continued). Comparison of Container Regulations with Other EPA Policies

Category	Container Regulations	Child-Resistant Packaging (49 CFR Part 157)	Consumer Labeling Initiative (FR 61:12011)	Bulk Pesticide Enforcement Policy (40 CFR Part 167)
Labeling	Labeling regulations pertain to: (1) For refillables, reserve space for net contents and EPA establishment number. (2) Residue removal instructions. (3) Identification of container types.	Not specified.	Voluntary labeling recommendations pertain to: (1) Simplifying and clarifying language, ingredient listings, and first aid statements. (2) Providing useful storage and disposal information.	The original registered label must be attached to the transferred product. Also it must reflect the establishment number of the establishment at which the product was transferred.

F.7 State Regulations and Standards

State regulations and standards have an important role in managing pesticide containers. Just as nationwide regulations/standards affect the baseline compliance rate of container regulations, state-level regulations/standards also have an impact on the baseline compliance rate. States have developed container-related regulations varying from no or weak standards to stringent requirements. This suggests that adjustments to the nationwide compliance rate are necessary to compensate for variability in state-level container regulations.

While a comprehensive state-level container standards analysis is beyond the scope of this economic analysis, this section will discuss some of the applicable state regulations and guidelines that focus on container performance standards and the rinsing, disposal, and storage of pesticide containers. To obtain information on state pesticide regulations, we conducted a survey of Internet literature for eight states located in different regions of the United States. The main source of information used for this section was the National Agricultural Safety Database (NASD) maintained by the Centers for Disease Control and Prevention (CDC). The NASD includes pesticide container-related articles and brochures contributed by professionals and organizations from states across the country. Additional information collected and summarized in this section comes from state agencies responsible for pesticide container standards and university extension programs providing recommendations.

The results of the eight-state analysis are summarized in the following sections by requirement category. Following the summaries is Table F-5, which includes state-by-state details of the rinsing, disposal, and storage guidelines from the eight states evaluated.

F.7.1 Container Design and Performance Standards

States are prohibited from imposing any requirements for pesticide packaging in addition to, or different from, those required under the container regulations (Section 14(b)). The container regulations require pesticides that are considered DOT hazardous materials to be packaged in containers that meet the DOT hazardous materials regulations, which contain performance, design, and management standards. Most, if not all, states have adopted the DOT HMR in some form and, in this way, regulate pesticide containers holding DOT hazardous materials. These requirements must be at least as stringent as the federal requirements.

F.7.2 Refilling Requirements

Some states have adopted bulk pesticide storage regulations that by definition allow repackaging and transfer into refillable containers with the assurance that certain standards are being met. Such standards may address, depending on the state, refillable storage containers and appurtenances, secondary containment, operational area containment (mixing/loading/refilling activities), security, inspection and maintenance, open burning of agrichemical containers, and other issues. Iowa and South Dakota have effectively incorporated EPA's 1977 Bulk Pesticides Enforcement Policy.

Applicators can purchase small quantities of pesticides in containers that are refilled by the registrant. Several registrants market pesticides in these small refillable containers (e.g., 15 or 30 gallons) in compliance with both federal and state law. They do this by having the containers

returned to them for refilling, rather than to a dealer. Registrants are able to trace and ensure return of these containers by numbering each one and requiring a deposit.

F.7.3 Transfer of Pesticides Between Containers

California has regulations requiring the use of closed systems when (1) employees handle any liquid pesticide or liquid mix or dilution of pesticide displaying the signal word "DANGER" on the label or (2) employees handle any minimal exposure pesticide. California defines a "closed system" as "a procedure for removing a pesticide from its original container, rinsing the empty container and transferring the pesticide product and dilutions and rinse solution through connecting hoses, pipes, and couplings that are sufficiently tight to prevent exposure of any person to the pesticide or rinse solution" (CalEPA, 1998). Employees must receive training in the proper use and safety precautions of closed systems. Employees who only handle up to one gallon of product per day in original containers of up to one gallon in size are exempted from the closed system requirement.

California has found its closed-system requirement difficult to implement because of the variety of container sizes, shapes, and materials. Additionally, not all reusable containers are adaptable to closed systems. The container regulations do not address the use of closed systems for either the registrant or the refilling establishment, but the requirement for use of standardized closures for non-refillable containers should encourage and expedite the use of closed systems. EPA's final container regulations do not specify that refillable containers must conform to the use of standardized closures.

F.7.4 Residue Removal Procedures

A number of states have developed residue removal procedures for users. These are sometimes part of a regulatory requirement or are published as recommendations in Cooperative Extension circulars or bulletins. The removal procedures vary by state and typically include triple rinsing and/or pressure rinsing. Table F-5 contains descriptions of the residue removal procedures, either required or recommended, for those states that have such procedures.

F.7.5 Container Collection and Disposal Procedures

A number of states have instituted some form of pesticide container disposal program. The primary function of these programs is to provide pesticide users with a secure and environmentally controlled site for returning empty containers, so that uncontrolled disposal and dumping of pesticide containers is reduced. These programs also help to ensure that residues have been properly removed from empty containers. States commonly recommend that rinsed, empty pesticide containers be disposed of in approved, sanitary landfills. Pesticide container collection sites and toxic waste cleanup days are also common. South Dakota, for example, establishes 19 sites across the state during the summer for pesticide container collection. Some states, including Florida and Nebraska, allow for some pesticide containers to be disposed of by open burning. Opening burning of pesticide containers is prohibited by state statute in Michigan. Florida and Nebraska also permit the burial of properly rinsed pesticide containers in open fields, with regulations that the burial be a minimum of 18 inches deep and in a location where surface and groundwater will not be polluted. California prohibits the burial of pesticide containers.

F.7.6 Pesticide Storage Guidelines

Pesticide storage guidelines are similar from state to state. Generally, states recommend that pesticides and pesticide containers should be stored in a clean, dry, well-ventilated, insulated, fireproof structure that can be locked and monitored by responsible personnel. Storage guidelines commonly specify that only pesticide and pesticide containers should be stored together to avoid the contamination of other products. Visible signs on all entrance points with the words "danger," "warning," or "keep out" are also recommended. Michigan has special storage guidelines for bulk pesticides which specify permissible locations of storage facilities based on distance from water supplies. The Iowa State University Extension is promoting "Zero Pesticide Storage" to encourage farmers to inventory and properly dispose of all unneeded or unusable pesticides in 2 to 3 years.

Table F-5. Eight-State Analysis of Pesticide Container Guidelines

Rinsing Guidelines	Disposal Guidelines	Storage Guidelines	Source
FLORIDA			
Triple-rinse, or jet-rinse, applicable to metal, glass, and plastic containers, with the exception of aerosol cans: 1. Empty container into spray tank and drain in vertical position for 30 seconds 2. Add a measured amount of rinse water (or other dilutant) so container is 1/5 to 1/4 full 3. Rinse container thoroughly, pour into tank, and drain for 30 seconds. 4. Repeat step three times 5. Puncture container before final drain 6. Crush pesticide container immediately; sell as scrap for recycling or bury 7. Bury triple-rinsed containers a minimum of 18 inches deep but well above the ground water table (never bury in wetlands or sinkholes).	Florida state law allows for some pesticide containers to be disposed of by open burning. Strict regulations apply. Farmers may bury triple-rinsed containers on their own property. Containers should be buried at least 18 inches deep but well above the ground water table, and never in sinkholes and wetlands. Farmers should receive permission from the landowner before burying containers on rented property. Non-farmers who bury empty pesticide containers on the their own property must notify their local Department of Environmental Regulation of the burial.	 Safe storage rules: Keep pesticides and other poisons locked in a cabinet, room, or separate building designated solely for their storage. Post the cabinet, room, or building with a sign, "PESTICIDES—POISONS, KEEP OUT," or similar signs Control access to the facility to one to three highly trusted, responsible individuals Never store pesticides where food, feed, seed, fertilizers, or other products may become contaminated Only store pesticides in their original containers Facility shall be reasonably fireproof and well-ventilated; temperatures should be kept between freezing and 100 degrees F Concrete block walls, sealed concrete floors with no floor drains, and metal shelves are recommended over wooden structures Store dry pesticides on the top shelves, liquids on the lower shelves Electrical fixtures should be dust- and explosion-proof.	NASD: http://www.cdc.gov/nasd/
MICHIGAN			
Triple-rinse, or pressure-rinse, applicable to all empty pesticide containers. After triple-rinsing, puncture metal and plaster containers.	Metal and plastic containers should be punctured after they are properly rinsed. Rinsed glass, metal, and plastic containers may be buried in approved sanitary landfills. Open burning of pesticide containers is prohibited by state statute. Michigan has had an agricultural plastic pesticide container recycling program in operation since 1992. This program facilitates grinding and recycling of clean, plastic containers.	Safe storage rules: Keep a separate structure for pesticide storage Structure should be locked at all times and protected from temperature extremes, high humidity, and direct sunlight Structure should be dark, cook, dry, well-ventilated, insulated to prevent freezing, and constructed to state and local fire codes for storing flammable/combustible materials Never store pesticides near feed, seed, food, or fertilizers. Storage guidelines for bulk pesticides also exist in Michigan. The guidelines specify permissible locations of storage facilities, based on distance from water supplies.	NASD: http://www.cdc.gov/nasd/ Michigan Department of Agriculture: http://www.michigan.gov/mda

Table F-5 (Continued). Eight-State Analysis of Pesticide Container Guidelines

Rinsing Guidelines	Disposal Guidelines	Storage Guidelines	Source
IOWA			
Triple-rinse, or pressure-rinse, applicable to all empty pesticide containers: 1. Fill container about 20 percent full of water, replace the cap securely, and shake the container 2. Pour rinse water into a spray tank 3. Drain for at least 30 seconds 4. Repeat two times 5. Puncture all containers.	Empty pesticide containers that have been properly rinsed may be disposed of in approved landfills.	The Iowa State University Extension recommends that pesticide users try to achieve "Zero Pesticide Storage" in 2 to 3 years. The following initial steps are suggested: Determine what pesticides are in storage; banned pesticides such as DDT or Chlordane should be disposed of by professionals at the next Toxic Waste Cleanup Day Set aside all pesticides that are no longer wanted or that are unusable (unusable pesticides may be ineffective or dangerous to use due to poor storage conditions); store them properly until the next Toxic Waste Cleanup Day.	NASD: http://www.cdc.gov/nasd/
KANSAS			
Triple-rinse applicable to all empty containers of liquid pesticides.			NASD: http://www.cdc.gov/nasd/
Wash the inside of the tractor with detergent and water and change the cab's filters when finished applying pesticides.			
MARYLAND			
Triple-rinse pesticide containers and return the rinsate to the spray tank.	Puncture thoroughly rinsed pesticide containers so they cannot be reused. Pesticides containers may be disposed of in a licensed sanitary landfill.	Pesticides should be stored in their original containers in a cool, well-ventilated, locked location away from pumps and water sources.	Maryland Cooperative Extension: httphttp://www.pesticide.u md.edu/Leaflets.html Leaflet #9 Protecting Groundwater from Pesticides

 Table F-5 (Continued). Eight-State Analysis of Pesticide Container Guidelines

Rinsing Guidelines	Disposal Guidelines	Storage Guidelines	Source
SOUTH DAKOTA			
Containers must be either triple-rinsed or pressure-rinsed prior to recycling or disposal. Triple rinse: Remove cover from container; empty pesticide into the sprayer tank; let container drip and drain for an extra 30 seconds once it is empty Fill the container 1/5 to 1/4 full with water Secure the cover on the container Remove cover and empty rinsate into the sprayer tank; let container drip and drain for an extra 30 seconds Repeat two more times Leave container open to air dry Inspect container for cleanliness – pay close attention to threads and the outside of the container (more rinsing may be necessary).	Pesticide containers are collected at approximately 19 sites across South Dakota during the summer. Containers are inspected before acceptance. Acceptable containers are recycled, while containers with visible residue are rejected. Applicators with unacceptable containers are asked to properly clean and return them. A person shall not construct a bulk pesticide storage facility, for the storage of more than 300 gallons, without a secondary means of containment. Plans and specifications for the facility must be submitted to the Secretary of Agriculture for review and approval prior to construction.	Reduce the amount of pesticides kept in storage at any one time, storing it no longer than necessary.: Rotate pesticide supply, using the oldest products first Store pesticides under proper conditions; most pesticides require storage temperatures between 40 and 100 degrees F under relatively dry conditions Store in a location away from occupied areas and on an impermeable floor, such as concrete, to allow detection and containment of spills.	South Dakota Department of Agriculture: http://www.state.sd.us/doa/das/pest_was.htm http://www.state.sd.us/doa/das/pest_sum.htm
NEBRASKA			
All empty pesticide containers must be either triple-rinsed or pressure-rinsed. Triple-rinsing (applicable for plastic, non-pressurized metal, and glass containers): Remove cap from container; empty remaining pesticide into the spray tank, allowing container to drain for 30 seconds Fill container 10% to 20% full of water or rinse solution Secure the pesticide container cap Swirl liquid within the container to rinse all inside surfaces Remove cap; add rinsate from container to spray tank and allow to drain for at least 30 seconds Repeat two more times Replace cap and dispose of container properly.	Nebraska has community landfills and other sites that accept empty plastic agricultural pesticide containers that have been pressure- or triple-rinsed. All containers are thoroughly inspected before acceptance. Pesticide containers are divided into three groups: Group I: combustible containers that held all pesticides except for heavy metals Group II: noncombustible containers (metal, glass, and plastic) that held all pesticides except for heavy metals Group III: both combustible and noncombustible containers used for pesticides containing heavy metals. Group I containers may be disposed of by: Burning in a special high-temperature pesticide incinerator Burial in a specially designated disposal landfill Burning small quantities (50 pounds or one day's accumulation, whichever is less) if local ordinances permit Burial singly in open fields at least 18 inches below the surface, but only in locations where surface and	Store pesticides and pesticide containers in a fire-resistant structure with a concrete floor and good ventilation Post weatherproof signs stating "Danger – Pesticides, Keep Out!" or a similar warning on each door of the facility and over all windows Use pesticide storage area ONLY for pesticides Good lighting—both natural and artificial—is necessary in storage area; some liquid pesticides, for example, are subject to photodecomposition and therefore should not be stored in direct sunlight Insulate storage areas to avoid temperature extremes An electrically shielded exhaust-type ventilating fan may be needed in the storage area to reduce the temperature and concentrations of toxic fumes	NebGuide, Cooperative Extension, Institute of Agriculture and Natural Resources, University of Nebraska— Lincoln http://www.ianr.unl.edu/pubs/pesticides

Table F-5 (Continued). Eight-State Analysis of Pesticide Container Guidelines

Rinsing Guidelines	Disposal Guidelines	Storage Guidelines	Source
Pressure-rinsing (applicable for plastic and non-pressurized metal containers): Remove cap from container; empty pesticide into spray tank, allowing container to drain for 30 seconds Insert pressure-rinser nozzle by puncturing through the lower side of the container Hold container upside down over the spray tank openings Rinsate will run into the spray tank Rinse for the length of time recommended by the manufacturer (at least 30 seconds); rotate the nozzle to rinse all inside surfaces Rinse caps in a bucket of water for more than one minute and pour this rinse water into spray tank Replace cap and dispose of container properly.	subsurface water will not be polluted; containers should not be buried in locations likely to be used as future building sites or where animals might uncover them while rooting or digging. Group II containers may be disposed of by: Burial in a sanitary landfill If group II containers are not properly rinsed, they can only be disposed of by burial in a specially designated landfill. Group III containers may be disposed of by: Disposal in a sanitary landfill, if the container has been triple-rinsed and punctured to facilitate draining	recommended; provide floor plan and records of the location and nature of pesticides in storage to the police or county sheriff, fire department, and public health department Provide wooden pallets or metal shelves for storing granular and dry formulations packaged in sacks, fiber drums, boxes, or other waterpermeable containers.	

Table F-5 (Continued). Eight-State Analysis of Pesticide Container Guidelines

Rinsing Guidelines	Disposal Guidelines	Storage Guidelines	Source
CALIFORNIA			
Each emptied container that held less than 28 gallons of a liquid pesticide diluted for use shall be rinsed by the user at the time of use. There are two rinsing procedures: Procedure 1: • For containers smaller than 5 gallons, use enough water to fill the containers 1/4 full; for larger containers, use enough water to fill it 1/5 full • Close the container securely and agitate • Drain the solution into the mix tank; allow the container to empty completely • Repeat steps a minimum of 2 more times.	Dispose of all empty pesticide containers in a manner approved by the CalEPA, Department of Toxic Substances Control. Glass, plastic, and metal containers should be disposed of in an approved disposal site. No pesticide container should be buried. Disposal requirements may differ by county. In many counties, people must possess a permit or certificate issued by the local agricultural commissioner to dispose of rinsed containers.	Safe storage guidelines: Keep pesticides and empty containers under direct personal control at all times Acceptable pesticide storage areas include: (1) a locked, fenced area, (2) a lockable storage compartment, (3) a locked truck or trailer with side racks (the tops of the racks should be at least six feet above the ground) Keep storage areas clean, dry, ventilated, and adequately lighted Keep pesticides and fertilizers separate in storage area Post warning signs on all storage areas containing pesticides (or empty containers) with the signal words "DANGER" or "WARNING" on the label; post signs on all directions of approach, if possible; sign must be readable from 25 feet away.	Worker Health and Safety Branch, CalEPA, "Pesticide Safety Information Series A" http://www.cdpr.ca.gov/docs/whs/pdf/hs1 743.pdf
Procedure 2: Turn the empty container over and place the opening over a nozzle; this nozzle must be located in the opening of the mix tank so the liquid will drain into the tank; the nozzle must be able to rinse all inner surfaces of the container Turn the nozzle on and rinse until the water coming from the container is clear; use a minimum of ½ the container volume of water. Other rinsing methods may be used, if approved by the Department of			

Appendix G. Comparison of the Final Container Regulations with the 1994 Proposed Container Regulations

The final container regulations differ significantly from the 1994 proposed regulations. The final regulations are narrower in scope than the proposed regulations, exempt certain antimicrobial pesticides, and adopt some of the Department of Transportation (DOT) hazardous materials regulations. As a result, the economic impacts on the regulated community will be different under the final regulations than under the proposed regulations.

EPA received approximately 1,900 pages of comments from more than 200 commenters (e.g., trade associations, pesticide manufacturers, pesticide retailers, and many state regulatory agencies) on the proposed rule. In response, two significant issues were readdressed, and the comment period was reopened in 1999. The two issues were: (1) the scope of the container standards; and (2) the relationship between the 1994 proposed rule and the DOT standards for hazardous materials packaging. In the final rule (as discussed below), EPA has revised the scope of the container standards to be risk-based with exemptions, and has adopted many of the design and construction standards that would apply to DOT Packing Group III materials. These and other changes made to each standard are as follows.

The following is a comparison of the proposed and final container requirements under consideration by EPA for 11 major sections of the container regulations. Each category is discussed in a separate section below:

G.1 Scope

The proposed regulations generally affected all containers used to package pesticide products, without regard to industry, use, risk, or container type and size. Only manufacturing use products were exempt from the proposed regulations.

The final CONTAINER regulations affect a significant number but not all of the total containers used in the pesticide industry. The scope criteria of the final regulations are based on the characteristics and/or human risk associated with the pesticide product contained. All manufacturing use products, all plant-incorporated protectants, and certain antimicrobial products are not subject to the final regulations. In particular, antimicrobial pesticide products that satisfy all four of the following criteria are exempt from the regulations:

- The product is an antimicrobial pesticide, as defined in the container regulations Section 2(mm), or it has antimicrobial properties, as defined in the container regulations 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 the regulations to prevent an unreasonable adverse effect on the environment.

As set out in the last bullet, the final regulations include a provision to require a specific antimicrobial product or group of products to comply with the container regulations if a problem

becomes evident. EPA may consider evidence such as 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.

Other than MUPs, plant-incorporated protectants, and exempt antimicrobial products, all pesticide products are subject to the non-refillable container, refillable container, repackaging and labeling regulations.

However, the scope of the non-refillable container regulations is different in that only "higher-risk" products are subject to all of the non-refillable container requirements. The "lower-risk" products are subject only to the basic DOT requirements. In particular:

- A product is subject to *all* non-refillable container requirements if it is classified in at least one of the following categories:
 - Toxicity Category I
 - Toxicity Category II
 - 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.

For the refillable container and repackaging regulations, all products (that are not specifically exempt) are subject to the full set of requirements. The only exception is that antimicrobial products used in swimming pools and closely related sites are subject to a reduced number of requirements.

To estimate the number of containers affected by the container rule, EPA estimated the percentage of pesticide products in Toxicity Categories I and II, and the percentage of antimicrobial pesticides. Based on an analysis of information in an Office of Pesticide Programs database (EPA, 1998a), EPA estimated the percentage of pesticide products in Toxicity Category I used on agricultural crops and forestry and ornamental turf/plants to be 20 and 10 percent, respectively. Toxicity Category II pesticide products were estimated to be 15 percent used on agricultural crops and forestry and ornamental turf/plants. Fifteen percent of all pesticide products used for agricultural products and forestry and ornamental turf/plants were in Toxicity Category II.

For comparison purposes, EPA estimated that 70 percent of antimicrobial pesticides eligible for exemption are classified in Toxicity Category I and 15 percent in Toxicity Category II. The antimicrobial pesticide exemption applies only to non-agricultural pesticide use. EPA estimated that an additional 10 to 20 percent of pesticide products above and beyond those affected by the toxicity criteria would also be affected by the hazard statement scope criteria and an additional 15 to 25 percent affected by the container size criteria. In the end, approximately 50 to 90 percent of pesticide containers were expected to be affected by the scope criteria.

G.2 Design Standards

Design standards were very general in the proposed regulations. The final container standards adopt a subset of the Department of Transportation Hazardous Materials Regulations (DOT

HMR) packaging standards at the Packing Group III level for pesticides not classified as DOT hazardous materials. Pesticides that are classified as DOT hazardous materials must comply with all applicable DOT regulations. For the purpose of enforcing the pesticide container regulations, the final rule identifies the DOT requirements for all three packing groups that are "equivalent" to the Packing Group III requirements applicable to products that are not DOT hazardous materials. Under the regulations, sale or distribution of pesticides in containers not meeting all of the standards (the specifically listed ones in the pesticide regulations and the adopted DOT packaging standards) is prohibited. Both non-refillable and refillable pesticide containers must meet these standards.

G.3 Permanent Markings

Proposed container regulations specified permanent marking requirements for non-refillable and refillable containers. *Non-refillables* required the EPA registration number and the name, symbol, or code of materials used to make the container, and *refillables* required several pieces of information including the statement, "Meets EPA standards for refillable containers." The final regulations for *non-refillables* and *refillables* refer to and adopt the DOT standards, which include marking requirements. Additionally, the final regulations require a serial number or other identifying code to be durably marked on each refillable container.

G.4 Dispensing Capability

The proposed regulations stipulated that all non-refillable containers for liquids be designed to eliminate the splash and leakage during normal pouring of the contents, closing or resealing of the container, and storage and cleaning of the container. The final regulations apply only to liquid non-refillable containers with a capacity greater than 20 liters (5.3 gallons) and are the same except the resealing criterion was replaced by a DOT equivalent. No dispensing capability requirements are specified in either the proposed or final container regulations for refillable containers.

G.5 Closures

The final requirements for container closures are essentially the same as the proposed closure standards. Four closures are specified for non-refillable rigid containers having a capacity greater than 3.0 liters for liquid agricultural pesticides. The proposed and final regulations should not overlap with the child-resistant packaging requirements. Liquid minibulk *refillables* require a one-way valve, tamper-evident device, or both on each opening. Liquid bulk refillable containers must be equipped with a pressure-relieving device and locking shutoff valve and cannot have external sight gauges.

G.6 Residue Removal Design Standard

With regard to non-refillable containers, the proposed regulations specified that registrants must demonstrate that each rigid/dilutable container/formulation combination achieves a "six-9s" laboratory performance standard (a reduction of the original active ingredient concentrate to .0001 percent in a fourth rinse or equivalent to 99.9999 percent removal). The final regulations require only a "four-9s" standard, where rigid containers with dilutable pesticides must be capable of 99.99 percent removal of each active ingredient. Percent removal represents the

percentage 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 according to a formula.

The final regulations require that every registrant test three containers from each rigid container/dilutable formulation combination to determine that the containers are capable of attaining at least 99.99 percent removal of each active ingredient in the fourth rinsate after a triple rinse.

The proposed regulations required that a minimum of 19 randomly selected containers be sampled for residue removal compliance and required the testing to be done according to the full GLP rule.

Residue removal procedures for the final and proposed regulations are the same, except that household products are exempt from the residue removal labeling requirements for non-refillables. For non-refillable, rigid containers with dilutable pesticides, triple and/or pressure rinsing is required prior to disposal, and the procedure is specified on the pesticide label. Additionally, for refillables, registrants are required to develop written residue removal procedures for each pesticide product, and refillers are required to follow the procedures before each refill.

G.7 Design Qualification Testing⁹²

The proposed regulations specified several container design qualification testing requirements; in particular, residue removal testing for non-refillable containers and drop testing for refillable minibulk containers. The final regulations do not specifically require residue removal testing for non-refillable containers, although in reality the registrants will have to conduct some testing to be able to show that their containers meet the residue removal standard. The details of the testing procedure will be included in an OPP testing guideline. The final regulations do not provide the specific details of a drop test for minibulks as the proposed regulations did. Instead, the final rule adopts the DOT HMR design standards for non-refillable and refillable containers, thereby incorporating DOT's design qualification testing for drop, leakproofness, hydrostatic pressure, stacking, and cooperative tests (as applicable) for each new or different packaging.

G.8 Production Testing and Periodic Retesting⁹²

The proposed regulations did not address production testing or periodic retesting, whereas the final regulations require production testing and periodic retesting by adopting DOT HMR standards. Depending on the kind of container, the DOT HMR specify the retesting intervals (e.g., every 12 or 24 months for DOT non-bulk packages). In addition, the DOT HMR specify

⁹² The titles of Sections G.7 and G.8 are consistent with the DOT definitions of design qualification testing, periodic retesting, and production testing (49 CFR §178.601(c)). For the sake of completeness:

[&]quot;Design qualification testing is the performance of the drop, leakproofness, hydrostatic pressure, stacking, and cooperage tests, as applicable, prescribed in sections..., for each new or different packaging, at the start of production of that packaging.

Periodic retesting is the performance of the drop, leakproofness, hydrostatic pressure, and stacking tests, as applicable, prescribed in sections..., at the frequency specified in §178.601(e) of this subpart.

Production testing is the performance of the leakproofness test prescribed in §178.604 of this subpart on each single or composite packaging intended to contain a liquid."

production testing (testing each and every container for compliance with the leakproofness test) for some types of containers.

G.9 Reconditioning

The proposed regulations did not address reconditioning of containers. The final rule incorporates DOT requirements (such as 49 CFR §173.28) that allow and account for reconditioning.

G.10 Waiver

The proposed rule provided for waivers from the standard closure and residue removal standards for non-refillable containers. The final rule includes provisions for these two waivers, plus waivers from the container dispensing requirements (for non-refillable containers) and from the cross-referenced DOT requirements (for non-refillable and refillable containers.)

G.11 Certification

The proposed regulations required registrants to certify that the non-refillable and refillable containers used for distribution or sale of pesticides meet the regulatory standards. As proposed, the certification needed to contain information including the EPA registration number and the name of company official who certified the container. The final rule does not require certification.

G.12 Recordkeeping

The proposed and final regulations require several types of recordkeeping. The first addresses the documentation that the container used meets each aspect of the EPA design standards. In the proposed rule, the records for non-refillable container design specified six pieces of information and required the records to be kept for as long as the container design type was used with the registered pesticide product, plus 3 years. The final recordkeeping requirements are similar, although only five pieces of information must be kept. In the proposed rule, the records for refillable containers included documentation of compliance with the drop test and a copy of the certification and needed to be kept for as long as the registrant allowed the container to be used, plus 3 additional years. The final rule does not include any refillable container design recordkeeping because the standards for which records were proposed are not being finalized.

The second type of recordkeeping requirement involves records kept by the registrants regarding repackaging. The proposed rule required registrants to keep copies of the contracts or authorizations, residue removal procedure for refilling, and list of acceptable containers for as long as the registrant distributes or sells a product to a refiller and for 3 years thereafter. The final rule requires registrants to keep the same records, but changes the time period to the current operating year and for 3 years thereafter.

The third type of recordkeeping requires refillers to keep copies of the documents identified in the previous paragraph for the registrants. The same documents are specified in both the proposed and final regulations, although the time period for maintaining the records in the final rule was changed to the current operating year and for 3 years after (as for the registrant recordkeeping).

The fourth type of recordkeeping involves information that refillers have to record when they repackage and when they receive refillable containers. The proposed rule required refillers to record six pieces of information each time a pesticide was repackaged into a refillable container and four pieces of information each time a refiller received a refillable container. These records were to be kept for 3 years. The final rule maintains the same time frame, but significantly decreases the amount of information that refillers must keep. In the final rule, refillers must record only three pieces of information when a pesticide is repackaged, and no recordkeeping is required when a refillable container is received.

G.13 Refilling

The proposed and final regulations contain nearly the same requirements for refilling, including specific guidelines for registrants and refillers. For example, registrants that directly sell or distribute pesticide products in *refillables* or sell or distribute pesticide products to refillers for repackaging are held responsible for providing instructions and documentation for refilling. Refillers that repackage pesticide products into refillable containers for distribution or sale must comply with the residue removal procedure for refilling developed by registrants and can repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, refillers must inspect the exterior and interiors of the containers to ensure that the container meets the necessary criteria with respect to container integrity, required markings, and openings. Refillers must also clean each refillable container according to the pesticide product's residue removal procedure for refilling (supplied by the registrant) before repackaging the product, unless certain criteria are met. Both the proposed and final regulations set out conditions for allowing registrants and refillers to engage in repackaging. The final rule has the same general structure of these conditions, although the final rule changes two of the conditions to: (1) require a contract between the parties (rather than a contract or an authorization as proposed); and (2) allow repackaging at an end user location under certain circumstances (rather than requiring the repackaging to be conducted at a registered establishment as proposed).

G.14 Labeling

Labeling requirements under the final regulations are generally more flexible than the proposed regulations because they provide a range of specific statements. The scope of the labeling requirement (proposed and final) includes all labels for all pesticide products, not just those that fall within the container rule scope. However, the final regulations exempt household products from the residue removal instructions. Labels may include blank areas, which are more specifically described in the final regulations, to allow a refiller to put any amount of product into a refillable, designate on the label the amount, and add its EPA establishment number. This is an option in the final rule, but was required in the proposal. Other information to be included on the label is a description of the container type (intended purpose, such as a refillable or non-refillable statement) and detailed residue removal instructions. Changes between the final and proposed regulations include clarifying that durable permanent marking is acceptable versus permanent marking, adding alternatives for the recycling and reuse statements for refillables, exempting household products from including residue removal instructions, and several minor changes that offer greater flexibility and clarity.

Table G-1 presents a side-by-side comparison of the 14 requirement categories and subcategories between the final and proposed regulations for the three major container types (non-refillable, refillable minibulk, and refillable bulk). In the table (as in the previous discussion), only substantial changes in the requirements are mentioned. For the purposes of this analysis, substantial changes are modifications that would change the costs and/or the assumptions made in the proposed container rule RIA. All changes, including those made for clarification purposes, are described in the preamble of the final rule.

Table G-1. Comparison of Final Container Regulations with Proposed Container Regulations

	Final Containe	er Requirements		1994 Proposed Conta	ainer Requirements	
		Refil	lable		Refilla	ble
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks
1. Ѕсоре	The following three categories of pesticide products are not subject to the non-refillable container, refillable container, and repackaging regulations: (1) Manufacturing use products (MUPs), (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 the container regulations Section 2(mm), or it has antimicrobial properties, as defined in the container regulations 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 the regulations to prevent an unreasonable adverse effect on the environment.			MUPs are exempt. All other pesticide proc	lucts affected.	
	Other than MUPs, plant-incorporated protectants, and exempt antimicrobial products, all pesticide products <i>are subject to</i> the non-refillable container regulations. A product <i>is subject to</i> all non-refillable container requirements if it satisfies at least one of the following criteria: (1) It meets the criteria of Toxicity Category I. (2) It meets the criteria of Toxicity Category II. (3) It is a restricted use product. If it does not meet any of these criteria, the product <i>is subject to</i> only the basic DOT requirements in 49 CFR §173.24.	Other than MUPs, pl protectants, and exer products, all pesticid subject to all of the r and repackaging regr	npt antimicrobial e products <i>are</i> efillable container			
2. Design Standards (general)	Prohibit distribution or sale of pesticide product in non-refillable container unless the container meets the standards. (§165.42) Container must meet certain DOT standards for design, construction, and markings in accordance with Packing Group III material as defined by DOT. (§\$165.60–165.64)	Prohibit distribution product in refillable container meets the s Container must meet standards for design, markings in accordar Group III material as (§§165.110–165.114 Same general integri containers as propos	container unless standards. (§165.92) certain DOT construction, and nee with Packing s defined by DOT.) ty standards for bulk	Cannot sell or distribute pesticide in a non-refillable container unless container meets the standards. (§165.102(a)(1)). General integrity requirements.	Can't sell or distribute refillable container un meets the standards. (General integrity requ minibulks. Different standards for bulk con	less container §165.124(a)(1)). irrements for general integrity

Table G-1 (Continued). Comparison of Final Container Regulations with Proposed Container Regulations

	Final Containe	er Requirements		1994 Proposed Container Requirements			
		Refi	llable		Refi	llable	
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks	
3. Permanent Markings	Incorporates DOT marking.	Incorporates DOT marking. Also, serial number or other identifying code marked durably on each container. (§165.116)		Permanent only: EPA registration number and the name, symbol, or code of material(s) used to make container. (§165.102(c))	Permanent only: name of container manufacturer, model number, date of manufacture, capacity, the name, symbol or code of material(s) used to make container, serial number, and the statement, "Meets EPA standards for refillable containers." (§165.124(b))		
4. Dispensing Capability	If container has capacity of 20 L or less and if container holds a liquid pesticide, container must: (1) Allow contents to pour out in a continuous, coherent stream, and (2) Minimize dripping. (§165.68)	Not specified.		Require all containers that hold liquid pesticide to: (1) Allow contents to pour in continuous, coherent stream, (2) Dispense without leaking or dripping, and (3) Once container has been resealed, not allow the pesticide to escape during storage or agitation. (§165.102(d))	Not specified.		
5. Closures	Similar to proposed rule requirements. (§165.66)	Same as proposed rule requirements. (§165.118)	Same as proposed rule requirements. (§165.120(b))	Four closure sizes are specified for containers that meet all of these criteria: (1) rigid container; (2) capacity greater than or equal to 3.0 liters (0.79 gal.); (3) holds liquid agricultural pesticide; (4) is not an aerosol container; (5) is not a pressurized container. (§165.102(e)) Final rule should not overlap with childresistant packaging requirements.	Each opening of each liquid minibulk container must have a one-way valve, a tamper-evident device, or both. (§165.124(e))	For liquid bulk containers: (1) The container must be equipped with a vent or other device designed to relieve excess pressure, prevent losses by evaporation, exclude precipitation. (2) External sight gauges are prohibited. (3) Container connections except for vents must be equipped with a shutoff valve that can be locked closed. (§165.124(f))	

Table G-1 (Continued). Comparison of Final Container Regulations with Proposed Container Regulations

	Final Containe	er Requirements		1994 Proposed Conta	iner Requirements	
		Refi	llable		Refill	able
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks
6. Residue Removal Design Standard	The final regulations require only a "four-9s" standard, where rigid containers with dilutable pesticides must be capable of 99.99 percent removal of each active ingredient. Percent removal represents the percentage 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 according to a formula. The final regulations require that every registrant test three containers from each rigid container/dilutable formulation combination.	Not specified.	Not specified.	For rigid containers with dilutable pesticide, registrant must demonstrate that container achieves 99.9999% removal of each active ingredient. Testing done according to full GLP regulations. (§165.104) Testing done by sampling of a minimum 19 random containers for residue removal compliance. (§165.105(b)(1))	Not specified.	

Table G-1 (Continued). Comparison of Final Container Regulations with Proposed Container Regulations

	Final Containe	r Requirements		1994 Proposed Conta	iner Requirements	
		Refil	llable		Refil	lable
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks
Procedure	Same as proposed rule requirements, but household products are exempt.	Same as proposed rule requirements.		Conduct rinsing (triple and/or pressure) on the label if rigid container & dilutable pesticide. (156.144(d))	Registrant develops a written residue removal procedure for each pesticide product placed in a refillable container that is adequate to maintain product integrity. (§§165.164(a) and 165.190(a)) Before refilling, the refiller (which could be a registrant) must clean each refillable container by conducting the pesticide product's residue removal procedure for refilling unless certain conditions are met. (§§165.170 and 165.210) Before disposal, conduct the rinsing procedure on the label. (§156.144(e))	
Procedure Responsibility	Same as proposed rule requirements.	Same as proposed rule requirements.		End user.	Before refilling: registrant and refiller (which could be the registrant). Before disposal: whoever disposes of container, could be registrant, refiller, end user or someone else.	
7. Design Qualification Testing	Residue removal testing not required, but registrants will have to do some testing to show they comply with the standard. Incorporates DOT design qualification tests.	Incorporates DOT design qualification tests.	Incorporates DOT design qualification tests.	Yes, required residue removal testing	Yes, required drop test for minibulks	No.
Sampling	Three containers for residue removal test, as described in OPP test procedure. Sampling for DOT tests as set out in the DOT regulations.	As set out in DOT regulations.	As set out in DOT regulations.	Nineteen random containers at a minimum (for residue removal). (§165.105(b)(1))	One random container; drop testing.	No.
Drop Test	Incorporates drop test (and other tests) in DOT regulations. (49 CFR Parts 178 and 180)	Incorporates drop test (and other tests) in DOT regulations. (49 CFR Parts 178 and 180)	Incorporates drop test (and other tests) in DOT regulations. (49 CFR Parts 178 and 180)	No.	Solids - 2.6 ft, and liquids - 3.9 ft. (§165.125(c-e))	No.

Table G-1 (Continued). Comparison of Final Container Regulations with Proposed Container Regulations

	Final Containe	r Requirements		1994 Proposed Conta	iner Requirements	
		Refil	llable		Ref	illable
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks
8. Production Testing and Periodic Retesting	Incorporates production testing and periodic retesting in DOT regulations. (49 CFR Parts 178 and 180)	Incorporates production testing and periodic retesting in DOT regulations. (49 CFR Parts 178 and 180)	Incorporates production testing and periodic retesting in DOT regulations. (49 CFR Parts 178 and 180)	No.	No.	No.
9. Reconditioning	Incorporates DOT regulations that provide for reconditioning. (49 CFR §173.28)	No.	No.	No. However, may be applicable to drums.	No.	No.
10. Waiver	Yes. Provisions to waive: (1) adoption of the subset of DOT standards (new); (2) standard closure requirement (as proposed); (3) container dispensing standards (new); and (4) residue removal standard (as proposed) if the specified criteria are met. Waiver must be obtained in writing. (§§165.72, 165.74)	Yes. There is a provision to waive adoption of the DOT standards if the specified criterion is met. (New) waiver must be obtained in writing. (§§165.122, 165.124) Yes. May be issued by EPA if registrant can demonstrate that waiving compliance with residue removal procedure does not result in unreasonable risk. (§165.104(c)) There is also the option to request approval of a non-standard closure, which is ultimately a waiver (§165.102(e)(2))				
11. Certification	No	No		Yes. (§165.111(a))	Yes. (§165.126(a))	
12. Recordkeeping For Container Design Requirements	Similar to proposed rule requirements, but copy of certification is not required. (§165.86)	No recordkeeping re	quired.	For each pesticide product, maintain records for as long as the non-refillable container design type is used to distribute or sell the pesticide product and for 3 years thereafter. Must keep the following records: (1) Name and EPA registration number of the pesticide product (2) Description of the design type of the non-refillable container in which pesticide product is distributed or sold (3) Copy of the certification (4) Record to document compliance with the requirement for closures (5) Record to document compliance with dispensing standards (6) Record to document compliance with residue removal standard. (§165.107)	For each product d refiller for repacka containers, maintai as a refillable contadistribute the productive records: (1) Description of a container(s) (2) Record to docu with the drop test fapplicable) (3) Copy of the cer (§165.128)	ging into refillable n records for as long ainer is used to act and for 3 years seep the following the refillable ment compliance for minibulks (if

Table G-1 (Continued). Comparison of Final Container Regulations with Proposed Container Regulations

	Final Co	ntainer Requirements		1994 Proposed Container Requirements			
		Refil	lable		Refi	llable	
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks	
For Repackaging Requirements	Not applicable.	Registrant records: N records, but for a dif (current operating ye thereafter.) (§§165.1	ferent time period ear and for 3 years	Not applicable.	Registrant records: registrant distribute to a refiller and for the registrant must contract or authoriz removal procedure of acceptable conta	s or sells a product 3 years thereafter, keep copies of: the ation, residue for refilling, and list	
			nal" records: Must ls, but for a different operating year and). (§§165.176(a)		long as a refiller dis product in refillable	containers and for the refiller must keep ct or authorization, occdure for refilling,	
		Refiller repackaging records: Each time a refiller repackages into a refillable container for sale or distribution, must generate and maintain the following for 3 years: product information; date of repackaging; serial number of container. (§§165.176(b) and 165.218(b))			Refiller repackaging records: Each time a refiller repackages into a refillable container for sale or distribution, must generate and maintain the following for 3 years: product information; date of sale; name & address of consignee; serial number of container; record of inspection; record of cleaning. (§165.136(c))		
		Refiller container ret required in final rule			Refiller container retime a refiller received container, must received following for 3 year of person providing number of containe was received; producontainer. (§165.13	ves a refillable ord and maintain the rs: name & address container; serial r; date the container act last sold in	

Table G-1 (Continued). Comparison of Final Container Regulations with Proposed Container Regulations

	Final Containe	er Requirements		1994 Proposed Conta	ainer Requirements	
		Refil	lable		Refi	llable
Requirement	Non-Refillable	Minibulks	Bulks	Non-Refillable	Minibulks	Bulks
13. Refilling Transfer	Not Applicable.	Same general structure as proposed rule requirements, but the final rule changes two of the conditions to require a contract between the parties rather than a contract or authorization and to allow repackaging at an end user location if conducted by a registered establishment. (§§165.182 and 165.202)		Not applicable.	Replaces the Bulk I Enforcement Policy Provides that registr refiller to repackage pesticide product in refillable container sell under the regist (provided all condit met). Also establish responsibilities of refillers for various process.	with §165.129. rants may allow a the registrant's to any size and distribute or rant's registration ions of the rule are hes the
Responsibility for Product Integrity	Not applicable.	Same as proposed ru (§165.162, 165.188	1	Not applicable.	Both the registrant a responsible for inte- repackaged product related roles regard- repackaging. (§§16.	grity of the ; different but ing label and
Inspection	Not applicable.	Same as proposed ru (§§165.168 and 165.		Not applicable.	Refiller inspects pri (§165.134(e))	or to repackaging.
14. Labeling	Similar to and more specific and flexible than proposed requirements. Additional/amended requirements include: (1) Durable markings acceptable (§156.140) (2) Non-refillable statement includes alternatives for recycling and reuse directions (§156.140(a)) (3) Exempt household products from requiring residue removal instructions. (§156.144(c)) (See residue removal procedures above.) (4) Rinsing procedure includes "or equivalent." (§156.146(a)) (See residue removal procedures above.)	Similar to and more than proposed requir Additional/amended include: (1) Durable marking (§156.140) (2) More specific de blank space on label and EPA establishm number, and makes optional ("may inclu (3) Container type re an alternative statem (4) Residue removal (§156.156) (See resi procedures above.)	ements. requirements s acceptable scription of use of s for net contents ent registration blank spaces ide") (§156.10(d)(f)) equirement includes ent. (§156.140(b)) statement	(1) Identify container type + recycle + do not reuse statement (§156.140(a)) (2) Residue removal statement (§156.144(d)) (See residue removal procedures above.)	(1) Reserve space for contents (§156.10(c) (2) Reserve space for establishment numb (3) Identify contain (§156.140(b)) (4) Residue remova (§156.144(e)) (See procedures above.)	D(7)) or EPA oer (§156.10(f)) er type

Appendix H. Characterization of Unintentional Human Pesticide and Antimicrobial Exposures and Health Effects in the TESS Database

H.1 General Characterization of Unintentional Human Pesticide and Antimicrobial Exposures

One of the strengths of TESS information is that it provides a perspective on the extent of pesticide exposures occurring throughout the country. For example, we have information on the distribution of the age of unintentional pesticide exposure victims by the reason of exposure (Table H-1). Generally, children less than 6 years of age comprised 54 percent of the overall exposure cases seen. Thirty-seven percent of the incidents involved adults over 19 years old, followed by young children 6 to 12 years old (6 percent), and young adults 13 to 19 years old (3 percent). Overall, in children under 6 years of age most cases (64.05 percent) were observed as a result of "general" unintentional exposure causes.

Table H-1. Percent Distribution of Age of Exposure Case by Reason of Exposure

Exposure Reason	≤5 Years Old	6-12 Years Old	13-19 Years Old	≥ 20 Years Old	Unknown	Total ^a
General	64.05%	5.14%	2.21%	27.83%	0.76%	81.21%
Environmental	17.12%	8.78%	4.92%	67.40%	1.78%	8.11%
Occupational	0.04%	0.04%	6.93%	91.54%	1.45%	3.24%
Therapeutic Error	22.55%	21.72%	8.13%	46.43%	1.16%	0.74%
Misuse	6.38%	7.87%	5.26%	79.97%	0.52%	6.20%
Bite/sting	19.64%	7.14%	3.57%	66.07%	3.57%	0.07%
Food poisoning	9.52%	4.76%	47.62%	38.10%	0%	0.05%
Unknown	29.29%	5.72%	5.39%	58.59%	1.01%	0.37%
Total	54.10%	5.57%	2.85%	36.62%	0.86%	100.00%

Source: AAPCC (2002, Report 31 "Reason by Age (Adults Lumped)").

As expected, adults sustained the majority (91.54 percent) of exposures occurring in occupational environments. Although adults comprised only 36.62 percent of the overall victim population, they made up the largest proportion of exposures in each specific reason of exposure category, except for "general."

Table H-2 below shows a similar breakdown of these unintentional exposures categories by exposure chronicity. Of all the unintentional pesticide and antimicrobial exposures observed in 2001, the overwhelming majority (97 percent) of them were considered "acute" exposures. Chronic exposures comprised 1.4 percent of all unintentional pesticide and antimicrobial exposures, acute-on-chronic exposures represented approximately one percent, and cases in which the chronicity could not be determined accounted for 0.2 percent of overall unintentional exposures.

^a Represents column percent where total number of cases is 80,978; other percentages represent row percent.

Table H-2. Percent Distribution of Exposure Chronicity to Reason of Exposure

Exposure Reason	Acute ^a	Acute-on- chronic ^b	Chronic ^c	Unknown ^d	Total ^e
General	98.84%	0.52%	0.50%	0.14%	81.27%
Environmental	88.66%	3.12%	7.56%	0.65%	8.11%
Occupational	88.99%	2.70%	7.20%	1.10%	3.24%
Therapeutic Error	90.05%	4.31%	5.47%	0.17%	0.74%
Misuse	95.56%	2.01%	2.21%	0.22%	6.20%
Bite/sting	94.64%	1.79%	3.57%	0%	0.07%
Food poisoning	100.00%	0%	0%	0%	0.05%
Unknown	93.60%	2.36%	2.02%	2.02%	0.37%
TOTAL	97.40%	0.93%	1.44%	0.22%	100.00%

Source: AAPCC (2002, Report 42 "Reason by Exposure Chronicity").

H.2 Characterization of Health Effects Associated with Unintentional Human Pesticide and Antimicrobial Exposure Cases

TESS data also offer some insight into the type or degree of outcome or clinical effects and the location of the activities performed to manage the exposure. We evaluated these data and determined the appropriate stratification with which to estimate the number of unintentional pesticide-related illnesses expected per year. This section characterizes the overall patterns seen among unintentional pesticide exposures.

The general distribution of exposure cases by medical outcome is presented for both the "with concomitants" and "without concomitants" categories in Table H-3. In this case, the distribution of medical outcome does not vary significantly between the two categories.

^a Acute: a single, repeated or continuous exposure occurring over a period of 8 hours or less.

^b Acute-on-chronic: single exposure that was preceded by a continuous, repeated, or intermittent exposure occurring over a period exceeding 8 hours.

^c Chronic: a continuous, repeated, or intermittent exposure to the same substance lasting longer than 8 hours.

^dUnknown: unable to determine whether the exposure is acute or chronic.

e Represents column percent where total number of cases is 80,978; other percentages represent row percent.

Table H-3. Profile of Unintentional Pesticide and Antimicrobial Exposures by Medical Outcome

Medical		With Con	comitants ^a		hout nitants ^b
Outcome	Description	Number	Percent	Number	Percent
No effect	Patient developed no signs or symptoms as a result of exposure	18,385	22.70%	17,888	23.03%
Minor effect	Patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved with no residual disability or disfigurement	12,084	14.92%	11,295	14.54%
Moderate effect	Patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms (usually some form of treatment is indicated)	2,164	2.67%	1,876	2.42%
Major effect	Patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement	111	0.14%	87	0.11%
Death	Patient died as a result of the exposure or as a direct complication of the exposure	2	0%	2	0%
No follow-up, nontoxic	No follow-up calls were made to determine the patient's outcome because the substance implicated was nontoxic, the amount implicated was insignificant, or the route of exposure was unlikely to result in a clinical effect	13,773	17.01%	13,612	17.52%
No follow-up, minimal toxicity	No follow-up calls were made to determine the patient's outcome because the exposure was likely to result in only minimal toxicity of a trivial nature	25,388	31.35%	24,482	31.52%
No follow-up, potentially toxic	Patient was lost to follow-up, refused follow- up, or was not followed, but the exposure was significant and may have resulted in a moderate, major, or fatal outcome	2,378	2.94%	2,229	2.87%
Unrelated effect	Exposure was probably not responsible for the effect	6,693	8.27%	6,201	7.98%
	Total	80,978	100.00%	77,672	100.00%

Source: AAPCC (2002, Report 22 "Medical Outcome" and p. 6 "Field Definitions").

We evaluated only the unintentional pesticide and antimicrobial exposures "with concomitants" to include all the cases in which a pesticide was involved. The majority of cases reported showed no effect (23 percent) or was an exposure in which minimal toxicity concerns were involved (31 percent).

^a "With Concomitants" indicates that a pesticide substance was implicated in the exposure case but could have involved another substance that may or may not have been another pesticide.

b "Without concomitants" indicates that only one pesticide substance was implicated in the exposure.

Table H-4 displays the severity of symptoms associated with exposures distributed by age. As described earlier, young children account for the majority of the exposed population (54 percent) in the 80,978 reported cases. However, from Table H-4, we see that they also account for the majority of the individuals who showed no effect from the reported exposure (75 percent) as well as of the individuals involved in nontoxic exposures (77 percent). By contrast, adults were among the majority of victims exhibiting minor, moderate, or major medical effects. More severe outcomes ("major effect") also occurred in the adult (over 19 years old) category. Results for the exposures resulting in death appear to be equally distributed between less-than-6-year-olds and over-19-year-olds, but this is representative of the two deaths reported in 2001.

Table H-4. Percent Distribution of Age of Exposure Patient by Symptom Severity of Medical Outcome Among "With Concomitants" Exposure Cases

Medical Outcome	≤5 Years Old	6-12 Years Old	13-19 Years Old	≥20 Years Old	Unknown	Total ^a
No effect	74.57%	5.32%	1.68%	17.97%	0.46%	23.70%
Minor effect b	24.90%	7.15%	4.97%	62.20%	0.78%	14.92%
Moderate effect b	11.23%	3.51%	4.16%	80.18%	0.93%	2.67%
Major effect b	27.93%	5.41%	9.01%	55.86%	1.80%	0.14%
Death	50.00%	0%	0%	50.00%	0%	0%
No follow-up, nontoxic	77.02%	4.94%	1.68%	15.72%	0.64%	17.01%
No follow-up, minimal toxicity	53.39%	5.90%	3.06%	36.64%	1.01%	31.35%
No follow-up, potentially toxic	43.82%	4.12%	2.86%	45.75%	3.45%	2.94%
Unrelated effect	24.07%	4.62%	3.35%	67.00%	0.97%	8.27%
Total	54.10%	5.57%	2.85%	36.62%	0.86%	100.00%

Source: AAPCC (2002, Report 51a "Medical Outcome by Age (Adults Lumped)").

Table H-5 shows the tendency for increasing duration of the clinical effects with more severe outcomes among those exhibiting minor, moderate, or major medical outcomes. Although these outcome categories were defined above in Table H-3, some examples of common symptoms demonstrated in each group may include:

- Minor effect: self-limited gastrointestinal symptoms, drowsiness, skin irritation, first-degree dermal burn, transient cough;
- Moderate effect: corneal abrasion, high fever, disorientation, isolated brief seizures that respond readily to treatment; and
- Major effect: repeated seizures, respiratory compromise during intubation, cardiac or respiratory arrest.

^a Represents column percent where total number of cases is 80,978; other percentages represent row percent.

^b The duration of the clinical effects observed in these outcome categories are highlighted in Table H-5 below.

Table H-5. Duration of Clinical Effects by Symptom Severity Among Those "With Concomitant" Cases Exhibiting Minor, Moderate or Major Medical Outcomes

Duration	Minor Effect	Moderate Effect	Major Effect	Total
≤2 hours	48.49%	14.93%	5.41%	43.10%
> 2 and 8 hours	18.55%	19.69%	7.21%	18.64%
> 8 and 24 hours	12.34%	16.54%	19.82%	13.03%
$>$ 24 hours and \leq 3 days	6.30%	14.60%	23.42%	7.68%
$>$ 3 days and \leq 1 week	2.97%	10.17%	9.01%	4.10%
> 1 week and ≤ 1 month	1.12%	3.79%	5.41%	1.55%
> 1 month	0.27%	1.39%	4.50%	0.47%
Anticipated permanent	0.02%	0.28%	4.50%	0.10%
Unknown	9.93%	18.62%	20.72%	11.32%
Total ^a	84.16%	15.07%	0.77%	100.00%

Source: AAPCC (2002, Report 23 "Duration of Clinical Effects by Medical Outcome").

Most minor effects lasted less than 2 hours, and as expected, victims with major effects tended to experience more prolonged effects.

Table H-6 gives more insight regarding the severity of reported cases and the medical resources required to manage them. The majority of all unintentional pesticide exposures (77 percent) reported to poison centers were managed in a non-health care facility, such as at the site of the exposure (which could be the patient's home). Treatment in health care facilities was involved in 20 percent of the reported cases and was recommended in another 1.27 percent of patients.

Table H-6. Percent Distribution of Symptom Severity of Medical Outcome by Management Site Among "With Concomitant" Exposure Cases

Medical Outcome	Non-Health Care Facility	Health Care Facility	Other	Refused Referral	Unknown	Total ^a
No effect	76.57%	22.49%	0.36%	0.55%	0.03%	22.70%
Minor effect	66.44%	29.93%	1.02%	2.35%	0.26%	14.92%
Moderate effect	23.94%	69.18%	1.57%	4.81%	0.51%	2.67%
Major effect	9.01%	81.98%	5.41%	3.60%	0%	0.14%
Death	0%	100%	0%	0%	0%	0%
No follow-up, nontoxic	93.25%	6.43%	0.25%	0.03%	0.05%	17.01%
No follow-up, minimal toxicity	88.03%	10.32%	0.81%	0.37%	0.47%	31.35%
No follow-up, potentially toxic	28.17%	46.01%	3.11%	14.00%	8.70%	2.94%
Unrelated effect	61.09%	34.87%	1.00%	1.51%	1.52%	8.27%
Total	77.29%	20.10%	0.75%	1.27%	0.60%	100.00%

Source: AAPCC (2002, Report 39 "Medical Outcome by Management Site").

^a Represents row percent where total number minor, moderate and major effects is 14,359; other percentages represent column percent.

^a Represents column percent where total number of cases is 80,978; other percentages represent row percent.

Table H-4 above showed that the majority of victims experiencing minor, moderate, or major effects were over 19 years old. According to Table H-6, the majority of victims with moderate and major effects are managed in a health care facility. Table H-7 provides the distribution of the victims that were treated in health care facilities, where children less than 6 years old and adults over 19 years of age were most often treated and released when they were evaluated at a health care facility. However, adults over 19 years of age were also approximately twice as likely as children less than 6 years old to be admitted to the hospital for their exposure.

Table H-7. Percent Distribution of Management Site by Age of "With Concomitant" Exposure Patient

Management Site	≤5 Years Old	6-12 Years Old	13-19 Years Old	≥20 Years Old	Unknown	Total ^a
Non-health care facility	56.75%	5.99%	2.73%	33.71%	0.81%	77.29%
Health care facility	45.80%	3.75%	3.22%	46.43%	0.79%	21.36%
Treated/released	52.01%	3.98%	2.84%	40.68%	0.48%	16.24%
Admitted, critical care	28.84%	5.03%	4.23%	61.11%	0.79%	0.47%
Admitted, non-critical care	32.50%	2.12%	7.31%	57.88%	0.19%	0.64%
Admitted, psychiatry	1.85%	1.85%	20.37%	74.07%	1.85%	0.07%
Lost to follow-up/left against medical advice	25.33%	3.26%	3.59%	65.10%	2.72%	2.69%
Refused Referral	24.98%	2.34%	3.90%	67.90%	0.88%	1.27%
Other	34.26%	13.61%	5.90%	41.48%	4.75%	0.75%
Unknown	32.37%	5.19%	2.28%	56.02%	4.14%	0.60%
TOTAL	54.10%	5.57%	2.85%	36.62%	0.86%	100.00%

Source: AAPCC (2002, Report 45a "Management Site by Age - Row %").

^a Represents column percent where total number of cases is 80,978; other percentages represent row percent.

Appendix I. Benchmark Costs for Physician Office Visits by Current Procedural Terminology, Fourth Edition (CPT-4) Code

Table I-1. Benchmark Costs for Physician Office Visits by Current Procedural Terminology, Fourth Edition (CPT-4) Code

CPT-4 Code	Brief Description	Cost (Year 2000\$)	Cost (Year 2005\$) a
99201	New patient requiring: 1. Problem focused history 2. Problem focused examination 3. Straightforward medical decision-making	\$30.61	\$31.68
99202	New patient requiring: 1. Expanded problem focused history 2. Expanded problem focused examination 3. Straightforward medical decision-making	\$48.44	\$50.14
99203	New patient requiring: 1. Detailed history 2. Detailed examination 3. Medical decision-making of low complexity	\$66.95	\$69.30
99204	New patient requiring: 1. Comprehensive history 2. Comprehensive examination 3. Medical decision-making of moderate complexity	\$99.58	\$103.07
99205	New patient requiring: 1. Comprehensive history 2. Comprehensive examination 3. Medical decision-making of high complexity	\$125.15	\$129.54
99211	Established patient. May not require a physician. Presenting problems are minimal (5 minutes).	\$13.46	\$13.93
99212	Established patient requiring 2 of these 3 components: 1. Problem focused history 2. Problem focused examination 3. Straightforward medical decision-making	\$26.58	\$27.51
99213	Established patient requiring 2 of these 3 components: 1. Expanded problem focused history 2. Expanded problem focused examination 3. Medical decision-making of low complexity	\$38.02	\$39.35
99214	Established patient requiring 2 of these 3 components: 1. Detailed history 2. Detailed examination 3. Medical decision-making of moderate complexity	\$57.53	\$59.55
99215	Established patient requiring 2 of these 3 components: 1. Comprehensive history 2. Comprehensive examination 3. Medical decision-making of high complexity	\$90.83	\$94.01

Source: Online division of Intellimed, accessible at www.myhealthscore.com.

^a Prices provided at www.myhealthscore.com were year 2000 dollars, as of October 23, 2002. These costs were converted to 2005 dollars by applying the Medicare Physician Fee Schedule conversion factors: [2005 conversion factor] ÷ [2000 conversion factor] = \$37.8975 ÷ \$36.6137 = 1.0351.

Appendix J. Case Summaries of 1999 California Incidents That Would Have Been Prevented by the Container Regulations

In Chapter 5, we described the state data used to derive the percentage of pesticide illnesses potentially related to the container standards. This section provides a more detailed view of the underlying cases in California in 1999 that were used in the calculation of the percentage. First, we provide a breakdown of the cases based on the likelihood of prevention by the regulation and whether the pesticide involved is subject to the regulations. This is followed by individual case summaries for each of the cases used by EPA to estimate the percentage of potentially avoidable pesticide illnesses as a result of the regulation.

Table J-1 shows the number of cases associated with the incidents in California in 1999 that were considered by EPA to have been "very likely" or "possibly" prevented by the container regulations. Sixteen cases were considered "very likely," and 51 cases were considered "possible." Table J-2 presents the specific case summaries, along with two columns of information critical to the calculations described in Chapter 5.

Table J-1. Number of Cases in California in 1999 Considered by EPA as "Very Likely" or "Possibly" Preventable by the Container Regulations

		Likelihood of Incident Prevention					
Regulated Pesticide Category	Very Likely	Possibly	Total				
Other Pesticide	7	15	22				
Antimicrobial	9	30	39				
Antimicrobial (unclear whether subject to regulations)	3	3	6				
Total	19	48	67				

Note: Shaded areas denote the 51 "possible" cases, which if included, would increase the annual health benefits by an additional 1,950 to 2,451 cases, as described in Section 5.2.5.3. The three unclear antimicrobial cases are included in the "Possible" incidents

The first column of interest is "Reg Impact," which designates EPA's evaluation of the regulatory impact. In addition to this condition of whether the incident was likely to have been prevented by the regulations, EPA also considered whether the chemical involved was subject to the regulations (noted in the column "Product Category"). Here, EPA determined that cases involving non-antimicrobial agents were subject to the regulations ("Not A"). For the remaining cases, where the antimicrobial pesticide was known, EPA determined whether it would be subject to the regulations ("A-in" if subject to regulations, otherwise exempt and omitted from the table).

However, in six cases antimicrobial pesticides were involved, but it was not clear from the California Department of Pesticide Regulations (CDPR) information available whether the pesticide is subject to the container regulations (denoted "A?" in Table J-2). Three of these cases were initially categorized as "very likely" and three were "possibly" prevented by the regulations, as shown in Table J-1. Due to the limited data and the uncertainties surrounding these cases, we regrouped the three former cases as "possibly" for a conservative approach to

deriving the percentage of pesticide illnesses potentially related to the container design and residue removal standards.

Additional cases avoided if possible cases are included

Similar to calculations described in 5.2.4 and 5.2.5, we estimate the additional cases avoided if the 51 "possible" cases were also considered. The 51 "possible" cases (from CDPR) corresponds to 4.33 percent of the total unintentional pesticide product cases in CDPR (i.e., 51 / 1,179 = 4.33 percent). In 2001, 64 poison control centers participated in TESS, reporting more than 2 million human exposure cases, which represent an estimated 98.8 percent of all poison exposures reported to poison centers in the U.S. To scale up to 100 percent, we need the inverse of 98.8 percent, which is 1.012)

Avoided illnesses with clinical effects = 19,492 * 4.33% * 1.012 = 853 cases, where 19,492 is the number of nationwide illnesses resulting from unintentional pesticide-related exposures (from TESS); used for "low-end" scenario. To calculate the "high-end" scenario, we go through the same steps using 24,531 (19,492 related cases + 5039 unknown if related) "high-end" cases as the basis from TESS, which results in 1,074 cases avoided.

From Table 5.10, we have that 43.86% of exposures resulted in clinical effects (including minor, moderate, major effects, and death) and 56.14% of exposures resulted in "no effect." Assuming these same ratios between exposures with clinical effects and exposures with "no effect," than we can estimate the number of cases with "no effect" avoided by the rule would be:

$$\frac{853}{43.86\%} = \frac{x}{56.14\%} \Rightarrow x = 1,092$$

Therefore, the total number of additional cases that could have been avoided if the 51 "possible" cases were considered from the CDPR data, is 1,945 (853 + 1,092 = 1,945). This number represents the "low-end" scenario. To calculate the "high-end" scenario, we go through the same steps using 1,074 "high-end" cases resulting in clinical effects, which results in 2,449 "high-end" cases avoided.

$$\frac{1,074}{43.86\%} = \frac{x}{56.14\%} \Rightarrow x = 1,375$$

Table J-2. Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

	CDPR	Product			Days off	Days in	Reg	
Case No.	Relation ^a	Category b	Medical Description	Pesticide(s)	Work	Hosp	Impact c	Comments
				HANDLING CONTAIN	NER FOI	R APPLI	ICATION/	USE
Opening o	r closing co	ntainer (othe	r than drops)		<u> </u>	T	1	
99-44	def	A-in	red, irritated eye	sodium hypochlorite	0	0	Р	After removing the cap to a bleach bottle, a restaurant manager poked a hole in the inside seal causing a drop of bleach to splash into his eye. He flushed the eye; failed to wear provided eye protection.
99-121	pro	A-in	red, irritated eyes	sodium hypochlorite	0	0	P	According to the manager, a bus boy splashed sanitizer into his eyes when he opened a 5-gallon sanitizer container prior to connecting it to the dishwasher. His eyes felt irritated so a coworker drove him to the hospital.
99-176	def	A-in	red, burning eye, blurred vision	sodium hypochlorite	0	0	P	Kennel technician flicked a drop of bleach into her eye as she pulled the inner seal from a new bottle of bleach. She flushed her eye; failed to wear employer-provided gloves & eye wear.
Handler o	pens contair	ner and then	drops it					
99-840	def	A-in	& dry eyes, blurred vision, sluggishly reactive pupils	sodium hypochlorite	1	0	V	As a worker poured pool chlorine into a dispensing barrel, the container's handle broke off in his hands. The container fell into the barrel and splashed liquid chlorine onto his face. The liquid ran down behind his goggles and into his eyes.
Transfer p	esticide fro	m container,	unspecified					
99-334	def	A-in	red eye, superficial corneal burn	sodium hypochlorite	0	0	P	School food service worker splashed bleach in her eye while pouring a sanitizer from a gallon container into a small spray bottle. She acknowledged having been trained to wear rubber gloves & goggles, but failed to do so.
99-783	def	A-in	scratchy, burning, red eyes	sodium hypochlorite	2	0	Р	Liquid pool chlorine sprayed into the faces of a delivery driver and his assistant when the assistant uncapped a hose incautiously. They rinsed eyes & were taken to a hospital. Both recovered fully within 5 days.
99-995	def	A-in	red, burning eye	sodium hypochlorite	0	0	Р	When a camp maintenance worker poured liquid chorine into a cistern to treat the camp's drinking water, some of the liquid splashed up into his eye. He flushed the eye and sought medical attention.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No. 99-1121	CDPR Relation ^a def	Product Category b A-in	Medical Description red, dry and burning eye, blurred vision burning eye	Pesticide(s) sodium hypochlorite sodium hypochlorite	Days off Work 0	Days in Hosp 0	Reg Impact ^c P	Comments When a hurried correctional officer tried to pour bleach from a 5-gallon container into a cup, she splashed some bleach into her eye. She failed to wear label-required eye protection. As employee poured disinfectant into a spa, some liquid contacted his hand. He then touched the contaminated hand to his eye, which began burning, so he flushed it before seeking medical attention.
			oading; exposure involv		0			
99-719	pro	A ?	burning eye	peroxyacetic acid	0	0	Р	Sterilant failed to completely drain from its packet into a sterilizer when a medical technician submerged the packet in water and cut it open. She accidentally splashed a drop of liquid into her eye. She flushed it with water.
Handler is	exposed wh	ile mixing/lo	ading; exposure involv	ves the transfer equipm	ent			
99-395	pro	A-in	burning, irritated skin on face, neck, shoulder; headache, brief transient eye irritation	sodium hypochlorite	0	0	Р	A pool chlorine delivery driver asked a swimming pool employee to shut a valve during the transfer process. When the employee attempted to close the valve, it broke. Liquid chlorine splashed on his body.
99-613	def	A-in	redness, burning sensation in eye, slightly blurred vision	sodium hypochlorite	0	0	P	Employee attempted to dislodge what he believed was a blockage in the disinfectant discharge tube when the disinfectant splashed toward his face and into his eye. He flushed the eye with water and sought medical attention.
99-715	def	A-in	redness, stinging & burning pain in eyes	sodium hypochlorite	0	0	P	Mobile home park manager investigated problem with pool chlorinator. During inspection, a line blew off and sprayed liquid chlorine in his face. Force of spray lifted his goggles. He had no pesticide training.
99-854	def	A-in	irritated, burning eye	sodium hypochlorite	1	0	P	As a prison employee attempted to connect a bleach hose to a water treatment tank, the hose popped off and splashed bleach into his eye. He flushed it with water and went to the infirmary, which sent him to a doctor.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No.	CDPR Relation ^a	Product Category ^b	Medical Description	Pesticide(s)	Days off Work	Days in Hosp	Reg Impact ^c	Comments
Handler is	exposed wh	nile mixing/lo	ading; exposure does i	not involve the containe	r and/or	transfer	equipmen	t
99-402	def	A-in	burning, irritated eye	sodium hypochlorite	0	0	Р	As a housekeeper cleaned the restroom, she poured bleach into a bucket of water and splashed some in her eye. She developed symptoms and sought medical attention. She failed to wear the provided eye protection.
99-635	def	A-in	red & irritated eye	sodium hypochlorite	17	0	P	As a meat packing plant employee filled a machine with cleaner & disinfectant, some solution splashed into his eye. He sought medical attention. He failed to wear provided eye protection.
99-779	pos	Not A	itchy, red, burning rash on face and neck	propargite, adjuvant	0	0	P	Worker mixed, loaded & applied propargite to a grape vineyard for 3 or 4 days. He first noticed his neck feeling hot while loading the propargite in the spray tank. He saw a doctor the next day when symptoms worsened.
99-819	def	A-in	red, burning eye	sodium hypochlorite	0	0	Р	When a custodian poured bleach into bucket, some of it splashed into his eye. He developed symptoms and sought medical attention. He failed to wear provided eye protection.
99-865	pro	Not A	red, burning, itching and papular lesion on penis	not determined, metolachlor, trifluralin	0	0	P	After mixing/loading herbicides, an applicator urinated w/o washing his hands. He developed symptoms and saw a doctor 2 hours later. Grower & worker have conflicting statements about application dates and protective gear.
99-1005	def	A-in	burning, painful and slightly red eye	sodium hypochlorite	0	0	Р	Veterinary assistant prepared to mop the floor of the clinic. As she poured bleach into the mop bucket, some splashed up into her eye. She sought medical attention.
99-1047	def	A ?	red, burning eye	unknown	0	0	Р	As restaurant employee poured liquid sanitizer into water, some of it splashed up into his eye. He developed symptoms and sought medical attention. Restaurant switched to granular sanitizer.
99-1135	def	A-in	red, burning, painful eye	sodium hypochlorite	5	0	Р	When a shop employee poured bleach into a bucket, she splashed some into her eye. She flushed it and sought medical attention. The bucket contained cleaning towels.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No.	CDPR Relation ^a	Product Category ^b	Medical Description	Pesticide(s)	Days off Work	Days in Hosp	Reg Impact ^c	Comments
99-1146	def	A-in	red, painful eye	sodium hypochlorite	0	0	P	While preparing a bleach solution to wash walls, a custodian splashed the liquid into his eye. He flushed the eye with water and continued work. He sought medical attention the next day.
Use or app	olication							
99-120	def	A-in	red, irritated eye	sodium hypochlorite	0	0	P	Amusement park worker splashed sanitizer in his eye as he poured the liquid into a sink of dishes. The eye remained irritated after flushing it, so he went to a hospital emergency room.
99-406	pro	A-in	red, burning eye	sodium hypochlorite	0	0	P	Hospital housekeeper splashed bleach in her eye while cleaning a toilet. She flushed her eye with water before seeking medical attention in the hospital emergency room.
99-674	def	Not A	mildly swollen eyelid, irritated eye	permethrin	5	0	P	SPCO removed safety glasses to examine a plugged nozzle. While manipulating the nozzle, it unplugged and sprayed permethrin into his eye. He flushed the eye with water and saw a doctor the next day.
99-682	def	A-in	red, burning eye, blurred vision, small erosions over right cornea	sodium hypochlorite	1	0	P	As a swimming instructor poured chlorine into the pool, some liquid splashed up into her eye. She flushed the eye & sought medical attention. Label instructions were almost illegible.
99-713	pro	A ?	water & burning eyes, irritated throat, brief wheezing headache	peroxyacetic acid	0	0	V	As an LVN placed a sterilant container into a sterilizing machine, the lid broke. She removed the container and poured sterilizer into an adjacent sink according to instructions. She exposed herself to fumes & developed symptoms.
99-1128	def	A-in	burning eye	sodium hypochlorite	0	0	P	Pool serviceman ignored explicit company policy by failing to wear provided PPE. As he poured pool chlorine into a spa, liquid splashed up into his eye. He flushed it and sought medical attention.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No.	CDPR Relation ^a	Product Category ^b	Medical Description	Pesticide(s)	Days off Work	Days in Hosp	Reg Impact ^c	Comments
Miscellane	eous							
99-288	pro	Not A	red, irritated eyes	adjuvant	0	0	P	As employee put away a spreader-binder container, he set it down hard, causing the material to splash up into his eyes. The cap was not screwed on tight. He rinsed his eyes with water and went home for the day. He saw a doctor the next day.
99-320	pos	Not A	red, burning, painful eye	not determined, diuron, glyphosate, oxyfluorfen, simazine	0	0	P	Farm worker felt something in right eye while hand-pouring a herbicide into a spray tank equipped with a boom sprayer and a hand wand. He wore safety glasses with brow and temple protection. He is unsure what got into his eye.
				OTHER CON	TAINER	HAND	LING	
Handling t	that seems to	o be related t	to use					
99-196	def	Not A	red and burning skin on the palm of the left hand	not determined, 2,4-D, diquat, fluazifop-butyl, mecoprop	?	0	V	A herbicide leaked onto a homeowner's left hand as she adjusted the nozzle on a ready-to-use product. Her hand began to burn so she rinsed it with water for 15 minutes before seeking medical attention. She failed to wear the required rubber gloves.
99-296	pro	Not A	severe burning & pain in eyes	glyphosate	0	0	P	While holding a glyphosate container, homeowner contaminated his hand with residue on the container. He rubbed his eyes and developed symptoms. He irrigated the eyes and sought medical attention.
99-689	pro	Not A	headache, nausea, lightheadedness, slight difficulty breathing	glyphosate	4	0	р	As an employee talked to an unhappy customer, he took the lid off a hand pump sprayer and accidentally splashed some of the pesticide onto her arms. The sprayer was left in her work area where she smelled the fumes. She developed symptoms.
Moving co	ntainers on	a cart						
99-1048	pro	A-in	red, burning eye	sodium hypochlorite	0	0	P	While cleaning a co-worker's cart, a janitor reached for a bottle of bleach with a loosened cap. The cap came off and spilled bleach into her eye. She flushed it and was taken for medical evaluation.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No.	CDPR Relation ^a	Product Category ^b	Medical Description	Pesticide(s)	Days off Work	Days in Hosp	Reg Impact ^c	Comments
Miscellane	eous							
99-340	def	Not A	red, irritated eyes	fipronil	0	0	P	Child grabbed flea treatment product from her grandfather's hands. She meant to apply it, but squirted it in her eyes while trying to open it. Her grandparents rinsed her eyes immediately and took her to the emergency room.
99-1177	def	A-in	redness, temporary loss of vision	sodium hypochlorite	3	0	P	As employee changed the disinfectant container for a dishwasher, some of the liquid splashed up into his eye. He flushed it & sought medical attention. His employer provided no eye protection.
				S	TORAG	E		
Stock man	agement							
99-90	def	A-in	red, burning eye	sodium hypochlorite	1	0	V	As a worker stacked liquid pool chlorine cases onto a hand truck, some liquid from the bottom of a case splashed up into his eye. He immediately flushed his eye with water and sought medical attention; failed to wear provided safety glasses.
99-546	def	A ?	nausea, headache, vomiting	unknown	?	0	V	As employee lifted boxes of disinfectant containers, bottom fell out of one box. Container broke upon impact and contents splashed up into his face. He developed symptoms and sought medical attention the next day.
99-1001	def	A-in	red, irritated eye, blurred vision	sodium hypochlorite	0	0	V	Pool chlorine leaked and wet its carton. When the store manager moved the carton, it caught on a nail & tore. The chlorine containers fell out and liquid splashed into his eye. He flushed it & sought medical attention.
99-1105	def	Not A	2 dime-sized blisters on the hand between fingers	not determined, chloropicrin, methyl bromide	0	0	P	While prepping empty fumigant cylinders for return to manufacturer, a grower placed safety cap back on a cylinder. He noticed wetness on his hand & smelled chloropicrin. Within a few hours, he noticed blisters on his hand.
Leaking/b	roken conta	iner on shelf	causes exposure					
99-560	def	A-in	red, burning, itchy eyes, temporary blindness	sodium hypochlorite	1	0	V	Liquid from a cracked disinfectant container splashed into an employee's eyes as he stocked shelves at a retail store. He developed symptoms & sought medical attention.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

					Days	Days	8	
Case No.	CDPR Relation ^a	Product Category b	Medical Description	Pesticide(s)	off Work	in Hosp	Reg Impact ^c	Comments
99-580	pro	Not A	nausea, upset stomach	not determined, 2,4-D, dichlorprop, mecoprop	0	0	V	When a customer picked up a leaking herbicide bottle from a shelf, he contaminated his hand. He bought another bottle and drove home. While driving home, he became nauseous so he washed his hands upon arriving home. He saw a doctor the next day.
99-610	def	Not A	red, burning eye	metolachlor	0	0	V	Shop foreman splashed a concentrated herbicide in his eye when he investigated a wet package. He had received applicator training. After the incident, his employer directed him to wear PPE in all dealings with chemicals.
99-1354	pro	A ?	rough, dry skin on fingers, itchy & burning hands	phenolic disinfectants	0	0	V	Hospital service technician developed skin irritation through repeated contact with leaking containers, one of which is a disinfectant. He saw a nurse practitioner who instructed him to wear protective gloves when handling containers.
Container	falls off she	lf or is dropp	oed after being taken f	rom a shelf				
99-903	pro	Not A	burning eyes, nose, throat and chest	MSMA	0	0	V	Sales clerk dropped a bottle of herbicide while stocking shelves. Upon impact, the lid popped off and the herbicide splashed into his face & eyes. He flushed them & sought medical attention.
Stocking s	helves or dis	splays	1					
99-275	def	A-in	pain & corneal abrasion in eye	sodium hypochlorite	0	0	Р	As employee stocked the grocery shelves with disinfectant, he accidentally squeezed the trigger nozzle on a bottle and squirted the disinfectant into his eye. A co-worker immediately drove him to a medical clinic for treatment.
Retail – ex	posure occu	ırs at cashier	/check out stand					
99-128	def	A-in	pain, irritation in eyes	sodium hypochlorite	1	0	V	When a cashier dropped a bleach bottle, some of the liquid splashed up into her eyes. She flushed her eyes and saw a doctor, who noted normal exam except for eyelid opening.
Retail – ex	posure fron	n handling re	eturns					
99-56	pro	Not A	red, watery eyes and burning sensation of eyes and face	cypermethrin	0	0	P	A courtesy clerk dropped a can of insecticide as she returned it to the shelf. When she picked it up, it exploded in her face. She washed but developed symptoms 30 minutes later.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No.	CDPR Relation ^a	Product Category b	Medical Description	Pesticide(s)	Days off Work	Days in Hosp	Reg Impact ^c	
99-510	def	A-in	red, burning, tearing eye, red eyelids	sodium hypochlorite	0	0	P	As grocery store employee handled a returned gallon of bleach, a loose cap allowed some to spill on a roll of tape. When she picked up the tape, the liquid splashed into her eye. She flushed her eye with water.
99-891	def	Not A	blurred vision, light sensitivity in the eye	malathion	3	0	P	Dissatisfied customer slammed a plastic bag containing a broken malathion bottle onto the returns counter causing malathion to splatter into the cashier's eye. She flushed her eye and saw a doctor the next day.
Retail – ot	her							
99-720	pro	A-in	mildly red, burning pain in eye	calcium hypochlorite	0	0	V	When a grocery store clerk picked up a leaking bag of granular pool chlorine, some of the product blew up into her eye. Her eye began burning so a co-worker took her to a doctor.
99-786	pro	A-in	itchy, red, burning skin on arm, sensitive to light touch, nausea	sodium hypochlorite	0	0	V	Pool sanitizer spilled from a leaking bottle onto a retail clerk's arm. She felt her skin immediately begin to burn so she washed it with soap & water. Her skin reddened and she felt nauseous.
99-889	pos	A-in	watery, irritated, bloodshot eye	sodium hypochlorite	0	0	V	Retail clerk handled a wet box of liquid pool chlorine. She said it did not smell like chlorine. Later, her eye became irritated. She flushed it with water and was sent to a doctor.
99-1159	pos	A-in	red, burning in eye	copper naphthenate	0	0	V	Retail clerk rubbed his eye after carrying an unopened can of wood preservative. The eye began to burn and he flushed it immediately with water.
				TRAN	SPORTA	TION		
Exposure	while loadin	g or unloadi	ng a vehicle					
99-133	pos	Not A	nausea, lightheadedness, slightly dry mouth, difficulty breathing, sluggishness	diazinon	0	0	V	Farm supply company driver picked up a bag of diazinon powder. Bag split open and powder poofed up into his face. He washed face, removed shirt, developed symptoms that night. His family had the flu at the time.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No. Container 99-168	CDPR Relation ^a leaks or spi	Product Category ^b Ils during tra Not A	Medical Description ansport burning testicle and abdomen skin, leg numbness	Pesticide(s) trifluralin	Days off Work	Days in Hosp	Reg Impact ^c	An unopened box with 2 containers fell off a truck as 2 employees drove to an application site. One employee contaminated himself with pesticide & developed symptoms. He saw a doctor 4 hours later.
Transport	 ation – acci	ldent	<u> </u>				<u> </u>	The saw a doctor 4 flours fater.
99-1353	pro	A-in	red, burning eyes, difficulty breathing, burning lungs & facial skin	sodium hypochlorite	0	0	P	Two police officers spent 30 minutes directing traffic at vehicular accident site involving a pool service company truck. The chemicals spilled and formed a whitish cloud to which the officers were exposed.
					OTHER	•		
Repackagi	ng - transfe	rring pesticio	de from one container	to another (not for app	lication o	r use)		
99-1219	pro	A-in	difficulty breathing, pain upon deep breathing	calcium hypochlorite	0	0	P	As a pool maintenance worker transferred granular pool chlorine from a large container to a small one, he inhaled the fumes. He developed symptoms and sought medical attention. He smokes 4–5 packs of cigarettes per week.
Spill – vari	ious causes	(not drop, no	t moving, not falling o	ff shelves)	•	•	•	
99-1441	pro	A-in	coughing, breathing difficulty, eye irritation, dizziness	not determined, hydrogen chloride, sodium hypochlorite	15	0	P	Contractor was checking on a nearby tank when he noticed the cloud of greenish gas and shouted for people to clear the area. He reported that one of his employees also was present and experienced similar symptoms.
Mix up coi	ntainers/mis	stake/mis-lab	eled containers					
99-541	pro	A ?	burning in throat, chest heaviness, transient shortness of breath	unknown	0	0	P	Someone apparently poured an unknown liquid into a broken container of granular pool chlorine causing generation of fumes. Upon investigating an odor complaint, a store manager discovered the problem, inhaled the fumes & developed symptoms.
Cleanup								
99-785	pos	Not A	nausea, sleepiness, eye irritation	oxyfluorfen	0	0	Р	Public works employee developed symptoms after helping to clean up a herbicide spill. He went home to rest. His supervisor went to his home and took him for medical care.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Case No. Miscellane 99-1055		Product Category b old exposures A-in	Medical Description s red, irritated eye	Pesticide(s) sodium hypochlorite	Days off Work	Days in Hosp	Reg Impact ^c	When a worker added disinfectant bleach to a load of laundry, some bleach splashed up into her eye. She rinsed the eye and continued working. The eye still bothered her 23 days later and she sought medical attention.
				SPECIFIC PESTIC	CIDES O	R CON	TAINERS	
Fogger								
99-284	def	Not A	coughing, sore throat, burning eyes, rash on head		?	0	V	Homeowner successfully activated 2 insecticide foggers, but the tab snapped off the third and sprayed the insecticide into her face. She rinsed her face and eyes with a garden hose and sought medical attention. Her symptoms resolved within a few days.
Aerosol co	ntainer – ex	posure occu	rs during application (use of the container)				
99-1411	pos	Not A	nausea, vomiting, diarrhea, mild sweating, abdominal pain, possible mild tremor	chlorpyrifos	?	0	Р	Man developed symptoms after spraying an aerosol insecticide in his room. He reportedly inhaled some as well as getting some on his skin.
Spray bott	tle – spray n	nechanism ar	nd bottle separate, caus	sing exposure				
99-511	def	Not A	bad taste in mouth, nauseam eye irritation	glyphosate	0	0	V	While preparing to spray weeds, a homeowner pulled up on the plunger of a ready-to-use glyphosate container. The plunger handle broke off, allowing glyphosate to spray up into his face. He felt irritant symptoms, so he showered and sought medical attention.
99-1365	pro	Not A	burning eyes, blurred vision	unknown	0	0	Р	Homeowner treated a crape myrtle with an old dormant spray, thought to contain copper & oil. When the nozzle tip came off the hand pump sprayer, the wind blew pesticide stream into his face & eyes. He washed up & saw a doctor.

Table J-2 (Continued). Case Summaries of Incidents in California in 1999 Considered by EPA to Have Been "Very Likely" or "Possibly" Prevented by the Container Regulations

Source: EPA (2005).

^a "CDPR Relation" refers to the California Department of Pesticide Regulation (CDPR) evaluation of the degree of correlation between pesticide exposure and resulting symptoms, where the term "pesticide-related" refers to cases that fall into one of the three following relationships:

Definite (def): High degree of correlation between pattern of exposure and resulting symptoms. Requires both medical evidence (such as measured cholinesterase inhibition, positive allergy tests, characteristic signs observed by medical professional) and physical evidence of exposure (environmental and/or biological samples, exposure history) to support the conclusions.

Probable (pro): Relatively high degree of correlation exists between the pattern of exposure and the resulting symptoms. Either medical or physical evidence is inconclusive or unavailable.

Possible (pos): Some degree of correlation evident. Medical and physical evidence are inconclusive or unavailable.

^b "Product Category" refers to the following codes, developed and assigned by EPA regarding the type of pesticide involved and whether it is subject to the Container Regulations given the information provided in the CDPR case summary:

Not A: not an antimicrobial, assumed to be subject to the regulations.

A-in: antimicrobial that is subject to the regulations (i.e., antimicrobial that is "in" the scope of the regulations).

A ?: antimicrobial, but it is unclear whether or not it will be subject to the regulations, either because there is not enough information, or it is not clear how all of the regulatory criteria would apply to it.

^c "Reg Impact" refers to whether EPA determined the incident to be "very likely" (V) or "possibly" (P) prevented by the container regulations.

Appendix K. Pesticide Container and Refilling Requirements Cost Analysis Tables

Table K-1a. Number of Containers Within the Scope of the Rule by Container Type, Entity Size, and Market Sector: Non-Refillable Liquid Pesticide Containers

	30-55	Gallons	5 Gall	lons	1 to < 5 G	Gallons		< 1 Gallon		Water S Pacl		Bag in	Aerosol	Subtotal Liquid
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Glass	PVA Packets	Barrier Packs	Box	Cans	Containers
Small-Small	Establisl	nments												
Agricultural	378	141	71	35	34,128	0	1,233	0	0	667	101	1	0	36,755
I/C/G	1,610	2,335	14,139	966	21,208	1,449	20,693	161	242	0	0	262	23,350	86,415
Home & Garden	0	0	0	0	30,186	8,625	112,120	12,937	8,625	0	0	0	215,615	388,107
Medium-Sm	all Estab	lishments												
Agricultural	883	330	166	82	79,623	0	2,876	0	0	1,555	235	1	0	85,752
I/C/G	3,757	5,448	32,987	2,254	49,481	3,381	48,279	376	564	0	0	611	54,478	201,616
Home & Garden	0	0	0	0	70,427	20,122	261,587	30,183	20,122	0	0	0	503,052	905,494
Large-Small	Establis	hments												
Agricultural	1,600	598	301	149	144,339	0	5,214	0	0	2,820	425	2	0	155,449
I/C/G	6,811	9,876	59,799	4,086	89,698	6,130	87,518	681	1,022	0	0	1,107	98,756	365,483
Home & Garden	0	0	0	0	127,669	36,477	474,198	54,715	36,477	0	0	0	911,918	1,641,453
Large Estab	lishment	S												
Agricultural	196,572	73,449	36,958	18,327	17,728,446	0	640,408	0	0	346,332	52,251	299	0	19,093,042
I/C/G	836,533	1,212,973	7,344,760	501,920	11,017,139	752,880	10,749,449	83,653	125,480	0	0	135,937	12,129,728	44,890,451
Home & Garden	0	0	0	0	15,680,901	4,480,257	58,243,346	6,720,386	4,480,257	0	0	0	112,006,434	201,611,581

Table K-1b. Number of Containers Within the Scope of the Rule by Container Type, Entity Size, and Market Sector: Non-Refillable Solid Pesticide Containers

	11-44 lb Bags	45 - 55	lb Bags	11 - 44 II	o Bags	1 - 10 1	b Bags	J	ugs	Water S Pack	0 - 0 - 0 - 0	Bulk
	Paper/ Plastic	Plastic	Paper	Plastic	Paper	Plastic	Paper	2.5 Gallons	1 qt to < 2.5 Gal	PVA Packets	Barrier Packs	> 101 lb
Small-Small	Establishn	nents										
Agricultural	0	2,264	9,991	4,609	2,714	403	7,015	32	2,783	53,951	14,542	526
I/C/G	0	0	0	1,127	0	0	0	0	372	1,308	433	0
Home & Garden	0	0	0	42,584	0	0	0	0	539	0	0	0
Medium-Sm	all Establis	hments	_									
Agricultural	0	5,282	23,309	10,753	6,331	939	16,367	75	6,492	125,874	33,929	1,227
I/C/G	0	0	0	2,630	0	0	0	0	869	3,053	1,010	0
Home & Garden	0	0	0	99,353	0	0	0	0	1,258	0	0	0
Large-Small	Establishn	nents										
Agricultural	0	9,575	42,255	19,493	11,477	1,703	29,669	137	11,769	228,181	61,506	2,224
I/C/G	0	0	0	4,768	0	0	0	0	1,575	5,534	1,830	0
Home & Garden	0	0	0	180,104	0	0	0	0	2,280	0	0	0
Large Establ	lishments											
Agricultural	0	1,175,993	5,189,922	2,394,278	1,409,603	209,151	3,644,096	16,776	1,445,534	28,026,402	7,554,447	273,121
I/C/G	0	0	0	585,573	0	0	0	0	193,448	679,683	224,818	0
Home & Garden	0	0	0	22,121,271	0	0	0	0	280,016	0	0	0

Table K-1b (Continued). Number of Containers Within the Scope of the Rule by Container Type, Entity Size, and Market Sector: Non-Refillable Solid Pesticide Containers

	Fiber Dı	ums		Subtotal	
	> 30 lb	< 30 lb	Other	Dry Containers	Total
Small-Small Estab	lishments				
Agricultural	15	159	4,214	103,217	139,972
I/C/G	1,288	0	0	4,529	90,944
Home & Garden	0	0	0	43,123	431,230
Medium-Small Est	ablishments	•			
Agricultural	35	370	9,832	240,816	326,568
I/C/G	3,006	0	0	10,567	212,183
Home & Garden	0	0	0	100,610	1,006,105
Large-Small Estab	lishments				
Agricultural	64	671	17,822	436,544	591,993
I/C/G	5,449	0	0	19,155	384,638
Home & Garden	0	0	0	182,384	1,823,837
Large Establishme	ents	•			
Agricultural	7,811	82,428	2,189,025	53,618,588	72,711,631
I/C/G	669,226	0	0	2,352,749	47,243,200
Home & Garden	0	0	0	22,401,287	224,012,868

Table K-1c. Number of Containers Within the Scope of the Rule by Container Type, Entity Size, and Market Sector: Refillable Liquid Pesticide Containers

	"Large Tai		Bulk (> 250 C		126 - Gall		61 - 125 (Gallons	26 - 60 G	Sallons	5 - 25 G	allons	Other	Subtotal Liquid
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Sizes	Containers
Small-Small Esta	blishme	nts												
Agricultural	23	3	2	0	66	13	327	109	93	8	243	189	0	1,076
I/C/G	14	2	22	5	14	2	14	2	270	7	133	0	1,897	2,380
Home & Garden	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swimming Pool Industry	3	0	10	1	0	0	0	0	287	0	144	0	2,052	2,498
Medium-Small E	Stablish	ments						_		_		_		
Agricultural	53	6	5	1	154	30	764	255	216	18	566	442	0	2,510
I/C/G	33	4	51	12	32	4	32	4	630	16	310	0	4,427	5,553
Home & Garden	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swimming Pool Industry	12	1	33	4	0	0	0	0	996	0	498	0	7,112	8,655
Large-Small Esta	ablishme	nts												
Agricultural	97	11	9	1	279	54	1,385	462	392	32	1,026	801	0	4,549
I/C/G	60	7	92	22	58	6	58	6	1,142	28	562	0	8,025	10,067
Home & Garden	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swimming Pool Industry	3	0	8	1	0	0	0	0	241	0	120	0	1,718	2,091
Large Establishn	nents													
Agricultural	11,887	1,321	1,153	128	34,301	6,604	170,123	56,773	48,100	3,943	126,065	98,368	0	558,766
I/C/G	7,313	813	11,282	2,736	7,146	794	7,146	794	140,310	3,478	68,996	0	985,651	1,236,458
Home & Garden	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swimming Pool Industry	1,602	178	4,629	514	0	0	0	0	138,476	0	69,238	0	989,117	1,203,756

Table K-1d. Number of Containers Within the Scope of the Rule by Container Type, Entity Size, and Market Sector: Refillable Solid Pesticide Containers

	"Large" Bulk	Bulk (> 2,501 lbs)	101 - 2,500 lbs	< 100 lb	Other	Subtotal Dry	Total
	Tank	Paper/Plastic	Paper/Plastic	Paper/Plastic		Containers	
Small-Small Establishme	nts						
Agricultural	0	10	25	1,286	0	1,322	2,398
I/C/G	0	0	0	0	0	0	2,380
Home & Garden	0	0	0	0	0	0	0
Swimming Pool Industry	0	0	0	0	0	0	2,498
Medium-Small Establish	ments						
Agricultural	1	24	59	3,001	0	3,084	5,594
I/C/G	0	0	0	0	0	0	5,553
Home & Garden	0	0	0	0	0	0	0
Swimming Pool Industry	0	0	0	0	0	0	8,655
Large-Small Establishme	nts						
Agricultural	1	44	107	5,439	0	5,591	10,140
I/C/G	0	0	0	0	0	0	10,067
Home & Garden	0	0	0	0	0	0	0
Swimming Pool Industry	0	0	0	0	0	0	2,091
Large Establishments							
Agricultural	172	5,347	13,109	668,074	0	686,703	1,245,469
I/C/G	0	0	0	0	0	0	1,236,458
Home & Garden	0	0	0	0	0	0	0
Swimming Pool Industry	0	0	0	0	0	0	1,203,756

Table K-2a. Number of Containers Out of Compliance for the Average Registrant, by Requirement, Market Sector, and Entity Size (Nonrefillable Containers)

	DOT Packaging Standards, Hazardous Material	DOT Packaging Standards, Non- hazardous Material	Closure Standards	Dispensing Standards	Labeling	Recordkeeping
Small Establishments	S					
Agriculture	0	0	39	81	1,596	1,596
Indust./Comm./Govt.	0	0	0	272	1,383	1,383
Home & Garden	0	0	0	511	6,556	6,556
Total	0	0	39	865	9,535	9,535
Small-Small Establish	hments					
Agriculture	0	0	9	18	351	351
Indust./Comm./Govt.	0	0	0	60	304	304
Home & Garden	0	0	0	112	1,442	1,442
Total	0	0	9	190	2,097	2,097
Medium-Small Estab	lishments					
Agriculture	0	0	40	84	1,650	1,650
Indust./Comm./Govt.	0	0	0	281	1,429	1,429
Home & Garden	0	0	0	529	6,778	6,778
Total	0	0	40	894	9,857	9,857
Large-Small Establis	hments					
Agriculture	0	0	217	453	8,906	8,906
Indust./Comm./Govt.	0	0	0	1,519	7,716	7,716
Home & Garden	0	0	0	2,854	36,586	36,586
Total	0	0	217	4,825	53,208	53,208
Large Establishment	s				_	
Agriculture	0	0	30,404	63,288	1,245,062	1,245,062
Indust./Comm./Govt.	0	0	0	212,341	1,078,612	1,078,612
Home & Garden	0	0	0	398,927	5,114,449	5,114,449
Total	0	0	30,404	674,556	7,438,123	7,438,123

Table K-2b. Number of Containers Out of Compliance for the Average Registrant, by Requirement, Market Sector, and Entity Size (Refillable Containers)

		(-	Keimabie Ce	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	DOT Packaging Standards, Hazardous Material	DOT Packaging Standards, Non- hazardous Material	Labeling	Recordkeeping	Container Markings	Minibulk Container Openings	Bulk Container Standards
Small Establishments							
Agriculture	0.00	0.00	27.34	27.34	27.34	4.18	0.09
Indust./Comm./Govt.	0.00	0.00	36.19	36.19	1.09	6.02	0.23
Home & Garden	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	63.53	63.53	28.43	10.20	0.31
Small-Small Establish	ments						
Agriculture	0.00	0.00	6.01	6.01	6.01	0.92	0.02
Indust./Comm./Govt.	0.00	0.00	7.96	7.96	0.24	1.32	0.05
Home & Garden	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	13.97	13.97	6.25	2.24	0.07
Medium-Small Establ	ishments						
Agriculture	0.00	0.00	28.26	28.26	28.26	4.32	0.09
Indust./Comm./Govt.	0.00	0.00	37.41	37.41	1.13	6.23	0.23
Home & Garden	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	65.67	65.67	29.39	10.55	0.32
Large-Small Establish	ments						
Agriculture	0.00	0.00	152.56	152.56	152.56	23.33	0.49
Indust./Comm./Govt.	0.00	0.00	201.94	201.94	6.10	33.61	1.26
Home & Garden	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	354.50	354.50	158.66	56.94	1.75
Large Establishments							
Agriculture	0.00	0.00	21326.52	21326.52	21326.52	3261.93	68.98
Indust./Comm./Govt.	0.00	0.00	28229.63	28229.63	853.30	4698.55	176.25
Home & Garden	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	49556.14	49556.14	22179.81	7960.48	245.23

Table K-3. Number of Refillable Containers by Type of Refilling Entity

Type of Refilling Entity	Number of C	ontainers with of the Rule	nin the Scope
	Liquid	Dry	Total
Agriculture	566,900	696,700	1,263,600
Agricultural Pesticide Refillers	510,210	627,030	1,137,240
Agricultural Pesticide Registrants	56,690	69,670	126,360
I/C/G Pesticide registrants	37,458	0	37,458
Swimming Pool Industry Antimicrobial Applicators	1,217,000	0	1,217,000
Home & Garden	0	0	0
Total	2,388,258	696,700	2,518,058

Table K-4a. Annual Refillings per Refiller Currently Not in Compliance with Inspection Requirement by Container Type, Entity Size, and Market Sector

					Contain	er Tvr	e: Liau	id Pro	ducts					Co	ntaine	r Type	: Dry Pr	oducts	
	"Large" Bulk Tanks	Steel		(> 520 Gallons)	Plastic	·	Plastic		Plastic	Steel	Plastic Plastic		Other	"Large" Bulk Tank	Bulk (> 2,501 lbs) Paper/Plastic	101 - 2,500 lbs Paper/Plastic	< 100 lb Paper/Plastic	Other	Total
Agricultural Pesticide			Tastic	Sieci	Tiastic	Sicci	Tastic	Sicci	1 lastic	Sicci	Tastic	Steel							
Large-Small	2.0	0.2	0.2	0.0	8.0	1.5	39.6	13.2	11.2	0.9	37.7	29.4	0.0	0.0	0.9	3.1	155.4	0.0	303.4
Medium-Small	0.6	0.1	0.1	0.0	2.4	0.5	11.7	3.9	3.3	0.3	11.2	8.7	0.0	0.0	0.3	0.9	46.1	0.0	89.9
Small-Small	0.1	0.0	0.0	0.0	0.3	0.1	1.4	0.5	0.4	0.0	1.3	1.0	0.0	0.0	0.0	0.1	5.5	0.0	10.7
Large	16.7	1.9	1.6	0.2	67.3	13.0	334.0	111.5	94.4	7.7	318.3	248.3	0.0	0.2	7.5	25.7	1311.8	0.0	2560.2
Agricultural Pesticide	Registra	nts																	
Small	0.0	0.0	0.0	0.0	0.1	0.0	0.3	0.1	0.1	0.0	0.2	0.2	0.0	0.0	0.0	0.0	1.0	0.0	2.0
Large-Small	0.1	0.0	0.0	0.0	0.3	0.1	1.5	0.5	0.4	0.0	1.4	1.1	0.0	0.0	0.0	0.1	5.7	0.0	11.2
Medium-Small	0.0	0.0	0.0	0.0	0.1	0.0	0.3	0.1	0.1	0.0	0.3	0.2	0.0	0.0	0.0	0.0	1.1	0.0	2.1
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.4
Large	10.2	1.1	1.0	0.1	41.1	7.9	203.9	68.1	57.7	4.7	194.3	151.6	0.0	0.1	4.6	15.7	800.8	0.0	1562.9
I/C/G Pesticide regi	strants																		
Small	0.3	0.0	0.3	0.1	0.3	0.0	0.3	0.0	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.7
Large-Small	1.5	0.2	1.7	0.6	1.9	0.2	1.9	0.2	0.6	0.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	9.6
Medium-Small	0.3	0.0	0.3	0.1	0.3	0.0	0.3	0.0	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.8
Small-Small	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4
Large	208.8	23.2	243.6	81.2	261.0	29.0	261.0	29.0	84.7	127.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1348.7
Swimming Pool Suppl	ly Compa	nies	Antimicro	bial Ap	plicators				1		,	1							
Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	14.2		0.0	0.0	0.0	0.0	17.3
Large-Small	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	6.9	0.0	3.4	0.0	49.1	0.0	0.0	0.0	0.0	0.0	59.6
Medium-Small	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	3.4	0.0	1.7	0.0	24.3	0.0	0.0	0.0	0.0	0.0	29.5
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7	0.0	0.3	0.0	4.7	0.0	0.0	0.0	0.0	0.0	5.7
Large	18.9	2.1	54.5	6.1	0.0	0.0	0.0	0.0	3258.3	0.0	1629.2	0.0	23274	0.0	0.0	0.0	0.0	0.0	28242.9

Table K-4b. Annual Refillings per Refiller Currently Not in Compliance with Container Cleaning Requirement by Container Type, Entity Size, and Market Sector

					Contain	er Typ	e: Liquid	l Produ	ıcts					Container Type: Dry Products					
	"Large" Bulk	Lanks	Bulk Tanks	(> 250 Gallons)	126 - 250 Gallons		61 - 125 Gallons		26 - 60 Gallons		5-25 Gallons		Other	"Large" Bulk Tank	Bulk (> 2,501 lbs) Paper/Plastic	101 - 2,500 lbs Paper/Plastic	< 100 lb Paper/Plastic	Other	Total
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel		· ,,					
Agricultural Pesticid			Ţ								· · · · · · · · · · · · · · · · · · ·						1		
Large-Small	0.4	0.0	0.0	0.0	1.6	0.3	7.9	2.6	2.2	0.2	7.5	5.9		0.0	0.2	0.6	31.1	0.0	60.7
Medium-Small	0.1	0.0	0.0	0.0	0.5	0.1	2.3	0.8	0.7	0.1	2.2		0.0	0.0	0.1	0.2	9.2	0.0	18.0
Small-Small	0.0	0.0	0.0	0.0	0.1	0.0	0.3	0.1	0.1	0.0	0.3	0.2		0.0	0.0	0.0	1.1	0.0	2.1
Large	3.3	0.4	0.3	0.0	13.5	2.6	66.8	22.3	18.9	1.5	63.7	49.7	0.0	0.0	1.5	5.1	262.4	0.0	512.0
Agricultural Pesticid	e Registr	ants																	
Small	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.4
Large-Small	0.0	0.0	0.0	0.0	0.1	0.0	0.3	0.1	0.1	0.0	0.3	0.2	0.0	0.0	0.0	0.0	1.1	0.0	2.2
Medium-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.4
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Large	2.0	0.2	0.2	0.0	8.2	1.6	40.8	13.6	11.5	0.9	38.9	30.3	0.0	0.0	0.9	3.1	160.2	0.0	312.6
I/C/G Pesticide reg	istrants																		
Small	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3
Large-Small	0.3	0.0	0.3	0.1	0.4	0.0	0.4	0.0	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.9
Medium-Small	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Large	41.8	4.6	48.7	16.2	52.2	5.8	52.2	5.8	16.9	25.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	269.7
Swimming Pool Supp	oly Comp	anies -	- Antimic	robial	Applicat	tors						•					•		
Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Large-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Medium-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		0.0	0.0	0.0	0.0	0.0	0.0	0.0
Large	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table K-4c. Annual Refillings per Refiller Currently Not in Compliance with Container Tracking (Recordkeeping)
Requirement by Container Type, Entity Size, and Market Sector

	Container Type: Liquid Products													Cor					
	"Large" Bulk Tanks		_ <u> </u>		126 - 250 Gallons		61 - 125 Gallons		26 - 60 Gallons		5 - 25 Gallons		Other	"Large" Bulk Tank	Bulk (> 2,501 lbs) Paper/Plastic	101 - 2,500 lbs Paper/Plastic	< 100 lb Paper/Plastic	Other	Total
	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Plastic	Steel	Ot	Т,,	Bu Pa	101 Pap	< 1 Pa	Ot	${ m To}$
Agricultural Pesticide Refillers																			
Large-Small	4.9	0.5	0.5	0.1	20.0	3.8	99.0	33.0	28.0	2.3	94.3		0.0	0.1	2.2	7.6	388.6	0.0	758.5
Medium-Small	1.5	0.2	0.1	0.0	5.9	1.1	29.3	9.8	8.3	0.7	27.9	21.8	0.0	0.0	0.7	2.3	115.2	0.0	224.8
Small-Small	0.2	0.0	0.0	0.0	0.7	0.1	3.5	1.2	1.0	0.1	3.3		0.0	0.0	0.1	0.3	13.7	0.0	26.8
Large	41.7	4.6	4.0	0.4	168.4	32.4	835.1	278.7	236.1	19.4	795.6	620.8	0.0	0.6	18.7	64.3	3279.4	0.0	6400.4
Agricultural Pesticid	Agricultural Pesticide Registrants																		
Small	0.0	0.0	0.0	0.0	0.1	0.0	0.7	0.2	0.2	0.0	0.6		0.0	0.0	0.0	0.1	2.6	0.0	5.0
Large-Small	0.2	0.0	0.0	0.0	0.7	0.1	3.6	1.2	1.0	0.1	3.5	2.7	0.0	0.0	0.1	0.3	14.3	0.0	27.9
Medium-Small	0.0	0.0	0.0	0.0	0.1	0.0	0.7	0.2	0.2	0.0	0.6	0.5	0.0	0.0	0.0	0.1	2.7	0.0	5.2
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.6	0.0	1.1
Large	25.4	2.8	2.5	0.3	102.8	19.8	509.8	170.1	144.1	11.8	485.7	379.0	0.0	0.4	11.4	39.3	2001.9	0.0	3907.2
I/C/G Pesticide reg	istrants																		
Small	0.7	0.1	0.8	0.3	0.8	0.1	0.8	0.1	0.3	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.3
Large-Small	3.7	0.4	4.4	1.5	4.7	0.5	4.7	0.5	1.5	2.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	24.1
Medium-Small	0.7	0.1	0.8	0.3	0.9	0.1	0.9	0.1	0.3	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.5
Small-Small	0.1	0.0	0.2	0.1	0.2	0.0	0.2	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0
Large	522.1	58.0	609.1	203.0	652.6	72.5	652.6	72.5	211.7	317.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3371.7
Swimming Pool Supp	Swimming Pool Supply Companies Antimicrobial Applicators																		
Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Large-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Medium-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Small-Small	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Large	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table K-5a. Present Discounted Value of Compliance Costs per Entity for Refilling Requirement, 3% Discount Rate

	Year															
	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Agricultural Pesticide Refillers																
Large-Small	\$1215	\$987	\$958	\$930	\$903	\$877	\$851	\$826	\$802	\$779	\$756	\$734	\$713	\$692	\$672	\$652
Medium-Small	499	293	284	276	268	260	252	245	238	231	224	218	211	205	199	193
Small-Small	234	35	34	33	32	31	30	29	28	28	27	26	25	24	24	23
Large	8776	8328	8085	7850	7621	7399	7184	6974	6771	6574	6383	6197	6016	5841	5671	5506
Agricultural Pesticide Registrants																
Small	205	7	6	6	6	6	6	5	5	5	5	5	5	5	4	4
Large-Small	236	36	35	34	33	32	31	30	30	29	28	27	26	26	25	24
Medium-Small	205	7	7	6	6	6	6	6	5	5	5	5	5	5	5	4
Small-Small	200	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Large	5434	5084	4936	4792	4652	4517	4385	4258	4134	4013	3896	3783	3673	3566	3462	3361
Industrial/Commercial/	Governm	ent Pest	icide Re	gistrants												
Large-Small	230	31	30	30	29	28	27	26	26	25	24	23	23	22	21	21
Medium-Small	204	6	6	5	5	5	5	5	5	5	4	4	4	4	4	4
Small-Small	199	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Large	4717	4387	4259	4135	4015	3898	3784	3674	3567	3463	3362	3264	3169	3077	2987	2900
Swimming Pool Supply	Compani	es – Ant	imicrobi	ial Appli	cators											
Large-Small	223	24	24	23	22	22	21	20	20	19	19	18	18	17	16	16
Medium-Small	210	12	12	11	11	11	10	10	10	9	9	9	9	8	8	8
Small-Small	200	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Large	12026	11484	11149	10825	10509	10203	9906	9618	9337	9065	8801	8545	8296	8055	7820	7592

Table K-5b. Present Discounted Value of Compliance Costs per Entity for Refilling Requirement, 7% Discount Rate

	Year															
	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Agricultural Pesticide Refillers																
Large-Small	\$1004	\$785	\$734	\$686	\$641	\$599	\$560	\$523	\$489	\$457	\$427	\$399	\$373	\$349	\$326	\$305
Medium-Small	413	233	218	203	190	178	166	155	145	135	127	118	111	103	97	90
Small-Small	193	28	26	24	23	21	20	18	17	16	15	14	13	12	12	11
Large	7254	6626	6193	5787	5409	5055	4724	4415	4126	3856	3604	3368	3148	2942	2750	2570
Agricultural Pesticide Registrants																
Small	169	5	5	5	4	4	4	3	3	3	3	3	2	2	2	2
Large-Small	195	29	27	25	24	22	21	19	18	17	16	15	14	13	12	11
Medium-Small	169	5	5	5	4	4	4	4	3	3	3	3	3	2	2	2
Small-Small	165	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0
Large	4492	4045	3780	3533	3302	3086	2884	2695	2519	2354	2200	2056	1922	1796	1678	1569
Industrial/Commercial/	Governm	ent Pest	icide Re	gistrants												
Large-Small	190	25	23	22	20	19	18	17	16	15	14	13	12	11	10	10
Medium-Small	169	5	4	4	4	4	3	3	3	3	3	2	2	2	2	2
Small-Small	165	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0
Large	3899	3491	3262	3049	2849	2663	2489	2326	2174	2032	1899	1774	1658	1550	1448	1354
Swimming Pool Supply	Swimming Pool Supply Companies – Antimicrobial Applicators															
Large-Small	184	19	18	17	16	15	14	13	12	11	10	10	9	9	8	7
Medium-Small	174	10	9	8	8	7	7	6	6	6	5	5	5	4	4	4
Small-Small	166	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1
Large	9940	9137	8539	7981	7459	6971	6515	6088	5690	5318	4970	4645	4341	4057	3792	3544