ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 165

[OPP–190001A; FRL–5776–3]

RIN 2070–AB95

Standards for Pesticide Containers and Containment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; partial reopening of the comment period.

SUMMARY: EPA issued a proposed rule in the **Federal Register** proposing container design and residue removal requirements for refillable and nonrefillable pesticide containers and standards for pesticide containment structures. (59 FR 6712, Feb. 11, 1994). EPA is today reopening the comment period to obtain public comment on three issues brought out in the comments on the proposed rule or by recently enacted legislation and on one other issue. EPA is considering changes that would reduce the scope of the container standards, add an exemption for certain antimicrobial pesticides, and adopt some of the Department of Transportation (DOT) hazardous materials regulations. EPA is also seeking comment on the definition for small business used to identify small pesticide formulators, agrichemical dealers and commercial pesticide applicators in the small entity impact analysis. These potential changes, if adopted in the final rule, would support EPA's goal of pollution prevention by promoting the use of refillable containers and would harmonize and promote consistency within the Federal packaging standards by adopting the DOT standards. In addition, the changes would decrease the estimated economic impact by reducing the number of pesticide products subject to the container requirements compared to the original proposal.

DATES: Comments, identified by the docket number OPP–190001A, must be received on or before December 20, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the ''SUPPLEMENTARY INFORMATION'' section of this notice.

FOR FURTHER INFORMATION CONTACT: Nancy Fitz, Office of Pesticide Programs (7506C), 401 M St., SW, Washington, DC 20460; telephone number (703) 305–7385; and e-mail address: fitz.nancy@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	SIC	Examples of Potentially Affected Entities
Pesticide formulators	32532	2879	Establishments that formulate and prepare insecticides, fungicides, herbicides, or other pesticides from technical chemicals or concentrates produced by pesticide manufacturing establishments. Some formulating establishments are owned by the large basic pesticide producers and others are independent.
Agrichemical dealers	44422	5191	Retail dealers that distribute or sell pesticides to agricultural users.
Independent commercial applicators	115112	0721	Businesses that apply pesticides for compensation (by aerial and/or ground application) and that are not affiliated with agrichemical dealers.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed above could also be affected. The Standard Industrial Classification (SIC) codes and the North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in Unit VII of this document and in §§ 165.100, 165.120, 165.122, 165.140, 165.141, and 165.142 of the original proposed rule (59 FR 6712, February 11, 1994). If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document and various support documents from the EPA internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register** - Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

2. *Fax on Demand.* You may request to receive a faxed copy of this document, as well as some supporting information, if available, by using a faxphone to call (202) 401–0527 and selecting item 6077. You may also follow the automated menu.

3. *In person.* The EPA has established an official record for this action under docket control number OPP–190001A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. A public version of this record, including printed, paper versions of any electronic comments submitted during the comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703–305–5805.

C. How and to Whom do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To

ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–190001A in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is 703–305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by the docket control number OPP–190001A. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI Information That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record by EPA without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult with the person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we discuss in this document, new approaches we haven't considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you use.
- Provide solid technical information and/or data to support your views.
- If you estimate potential burden or costs, explain how you arrive at the estimate.
- Tell us what you support, as well as what you disagree with.
- Provide specific examples to illustrate your concerns.
- Offer alternative ways to improve the rule.
- Make sure to submit your comments by the deadline in this notice.
- To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. Statutory Background

Sections 19(e) and (f) of the Federal Insecticide, Fungicide, and Rodenticide Act (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 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 reusing, whenever practicable, or disposing of rinse water and residue.

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

Section 19(f) provides that EPA, in its discretion, may exempt products intended solely for household use.

In addition, section 19(h), titled ''Relationship to Solid Waste Disposal Act,'' specifies that nothing in section 19 shall diminish the authorities or requirements of RCRA.

The Food Quality Protection Act (FQPA) of 1996 amended section 19(h) of FIFRA to add an exemption for certain antimicrobial pesticides. Since this new statutory language was not in existence at the time of the original proposed rule, EPA seeks comment on EPA's interpretation of how this statutory exemption applies to the proposed container regulations.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) requires an agency to prepare a regulatory flexibility analysis for any rule for which the agency is required to issue a notice of proposed rulemaking under the Administrative Procedures Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. For the purpose of analyzing potential impacts on small entities, section 601(6) of the RFA defines small entities to include small governments, small non-profit organizations, and small businesses, which are also further defined in section 601. The definition of small business provided in section 601(3) uses the definition of small business in section 3 of the Small Business Act, 15 U.S.C. 632, under which the Small Business Administration (SBA) establishes small business size standards. 13 CFR 121.201.

In analyzing potential impacts, the RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of the RFA provides that an agency may establish a different definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. In this document, EPA seeks comments on the ''small business'' definitions used to identify potentially affected small entities in the initial regulatory

flexibility analysis that was prepared for the 1994 proposed rule, i.e., for identifying small pesticide formulators, small agrichemical dealers, and small commercial pesticide applicators.

B. Regulatory Background

In a Notice of Proposed Rulemaking issued on February 11, 1994 (59 FR 6712) (Ref. 1), EPA proposed standards for pesticide containers and containment structures. This proposal included requirements for nonrefillable and refillable containers that would ensure the safe use and disposal of the containers. The proposal also included standards for containment structures, which would promote safe storage by facilitating the safe use, refill, and reuse of refillable containers. Additionally, the proposed rule contained amendments to the labeling regulations in 40 CFR part 156 to ensure adequate levels of residue removal from containers.

The public comment period for the proposed rule closed on July 11, 1994. EPA received about 1,900 pages of comments from over 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. A summary of these comments is available in the docket. (Ref. 2)

EPA received many comments during the public comment period on two of the issues being re-opened for comment in this document; specifically, 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. For each of these issues, a brief summary of the comments and a description of a modified regulatory option being considered are provided.

III. Scope of the Container Standards

A. Background on 1994 Proposal

In the February 1994 Notice of Proposed Rule Making (NPRM), EPA proposed that the container standards would generally apply to all pesticides and all containers, regardless of the pesticide market sector (e.g., agricultural, industrial, institutional, household, etc.), the type of pesticide (e.g., insecticide, herbicide, sanitizer, disinfectant, etc.), or the type of container (e.g., plastic jug, steel drum, paper bag, minibulk tank, etc.). Where appropriate, EPA proposed a limited applicability for specific requirements. For example, the proposed nonrefillable container dispensing capability standards would only apply to containers holding liquid pesticides, i.e., those containers that have the potential to drip or ''glug'' (the common industry term for not pouring in a continuous, coherent stream) during pouring.

During the public comment period, many commenters opposed the broad scope of the proposed container standards and requested EPA to exempt a specific subset of pesticides from the scope of the container requirements. The categories of pesticides that were suggested for exemption from the rule include: (1) Lower-risk pesticides; (2) nonagricultural pesticides in general; (3) antimicrobial pesticides; (4) swimming pool chemicals; (5) industrial biocides; and (6) disinfectants and/or sanitizers. To support the exemption requests, commenters generally argued that the pesticides suggested for exemption pose lower risk than agricultural pesticides (e.g., active ingredients that are less toxic, less persistent, more biodegradable, and/or at a lower concentration, and the pesticides are in smaller containers, etc.); that the containers suggested for exemption are handled differently than containers for agricultural pesticides; and/or it would be more burdensome for these pesticides/containers to come into compliance than for agricultural pesticides/containers. See the comment summary document (Ref. 2) for more information.

B. Regulatory Option Under Consideration

EPA is considering exempting some pesticides and containers from the final container rule. However, rather than exempting products based on the pesticide market sector or the type of pesticide, EPA believes it is more appropriate to exempt pesticides based on the relative risk they pose.

Under the regulatory option being considered for defining the general scope of the rule (i.e., for pesticides other than antimicrobial products that are eligible for exemption), a pesticide product would be subject to the container standards if the product met at least one of the criteria being considered: (1) The product is classified in Toxicity Category I or II; (2) the container capacity is greater than or equal to the container size criterion of 5 liters (1.3 gallons) or 5 kilograms (11 pounds); or (3) the product is intended for outdoor use and the label includes at least one of the specified environmental hazard statements. If the product does not meet any of these criteria, it would not be subject to the container standards. (See Unit IV of this document for a discussion of which antimicrobial pesticides would be subject to the container standards.)

C. Discussion

1. *General principle of risk.* When considering which pesticides should be subject to the pesticide container regulations, it is worth reviewing the goals of the proposed container standards, which include:

- Ensuring that pesticide containers are strong and durable to minimize container failures and the subsequent releases of pesticide to the environment
- Minimizing human exposure during container handling, e.g., loading and unloading the container, container cleaning, and management before disposal
- Facilitating container disposal and recycling
- Minimizing cross-contamination in refillable containers
- Codifying safe refilling management practices

Failure to attain any of these goals could lead to unreasonable adverse effects on the environment. For example, the first item relates to an event that can easily be visualized as causing people or the environment to be directly exposed to pesticides -- a container fails and releases the pesticide. Regarding the second item, a pesticide user could be exposed if pesticide splashes or drips from a container while the user is handling the container. Under exposure scenarios such as these (or under pesticide exposures during container disposal or recycling, from cross-contamination or from unsafe refilling practices), unreasonable adverse effects would be more likely to occur with pesticides that are higher-risk than with pesticides that are lower-risk. Therefore, EPA has considered several characteristics of pesticides and containers to distinguish between those that are higher-risk and those that are lower-risk in such situations.

2. *Toxicity criteria.* One factor in distinguishing higher-risk pesticides is the toxicity of the pesticide. EPA is considering the following criteria to identify the higher-toxicity, higher-risk pesticides for general inclusion in the container rule:

i. Toxicity Category I classification
ii. Toxicity Category II classification
iii. One of several environmental hazard statements (e.g. ''This pesticide is toxic to wildlife.'') on their labels.

The regulations in 40 CFR 156.10(h) define four categories that account for human toxicity, with Toxicity Category I including the most toxic pesticides and Toxicity Category IV the least toxic.

These categories are based on hazard information, including the oral LD_{50}, inhalation LC_{50}, dermal LD_{50}, eye effects, and skin effects of the pesticide. The following table 1 describes the hazard indicators defining each toxicity category as set out in § 156.10(h)(1), the human hazard signal word for each as required by § 156.10(h)(1)(i), and the precautionary statements regarding hazard to humans and domestic animals set forth in § 156.10(h)(2)(i)(B).

TABLE 1.—INFORMATION ON TOXICITY CATEGORIES AS SET OUT IN 40 CFR 156.10(h)

	Toxicity Categories			
	I	II	III	IV
Hazard Indicators.				
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5,000 mg/kg.	Greater than 5,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/kg.	From 0.2 thru 2 mg/kg	From 2 thru 20 mg/kg	Greater than 20 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2,000 mg/kg	From 2,000 thru 20,000 mg/kg.	Greater than 20,000 mg/kg
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.
Required Label Language.				
Human hazard signal word	''Danger''; and in some cases: ''Poison'' and the skull and crossbones.	''Warning''	''Caution''	''Caution''
Precautionary statements regarding hazard to humans and domestic animals: oral, inhalation, or dermal toxicity.	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.].	May be fatal if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Appropriate first aid statement required.].	Harmful if swallowed [inhaled or absorbed through skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	[No precautionary statements required.]
Precautionary statements regarding hazard to humans and domestic animals: skin and eye local effects.	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.	[No precautionary statements required.]

Because these categories cover the full range of toxicities in a continuum, it is difficult to make a clear-cut distinction among them. However, EPA is considering an option that would specify the two most hazardous groups -- Toxicity Categories I and II -- as criteria for pesticides that would be subject to the container standards. EPA believes it is appropriate to use classification in Toxicity Categories I and II as criteria for inclusion in the container standards, because it would include, by the definitions given in table 1, the most toxic pesticides. In addition, the specified label language seems to indicate a notable difference in the hazard posed by pesticides in Toxicity Category II and those in Toxicity Category III.

The United States is participating in a global effort to harmonize the classification and labeling of chemicals for human and environmental hazards, which is being lead by international agencies such as the Organization for Economic Cooperation and Development (OECD), World Health Organization, International Labor Organization and the United Nations Committee of Experts on the Transport of Dangerous Goods. OECD is the focal point for the harmonization of classification for health and environmental hazards, including toxicity endpoints for acute toxicity, reproductive toxicity, carcinogenicity, mutagenicity, sensitization, irritation and corrosion, and target organ effects and environmental endpoints for aquatic and terrestrial effects. The harmonized system is to be based on the intrinsic nature of all chemicals and mixtures regardless of their intended use (certain chemicals have both pesticide and non-pesticidal uses).

The global harmonization effort is still under negotiation. A basic principle of the effort is that the level of protection should not be reduced. Hazard categories will be defined, but countries will select elements deemed appropriate for regulating transport, worker and environmental protection. However, there may be new definitions of each toxicity category, particularly with regard to inhalation toxicity, and the number of products captured by each may expand or contract. Since in this notice EPA is considering an approach of exempting certain pesticide products from the container standards based on

their toxicity category, any change in the toxicity classification may change the universe of products subject to the container rule. If the final criteria for toxicity categories differ significantly from those currently used by EPA, a clarification of the products subject to the container standards can be included in the final rule.

EPA believes it is important and necessary to also account for environmental factors when evaluating the risk posed by pesticide containers. The approach EPA is currently considering is to rely on whether or not at least one of the environmental hazard statements is included on the label. Some environmental hazard statements are required by 40 CFR 156.10(h)(2)(ii). For the purposes of the regulatory option being considered here, EPA is looking at the following environmental hazard statements (label statements) or similar warnings or precautionary statements pertaining to wildlife, fish, birds, or groundwater:

- This pesticide is toxic (or extremely toxic) to wildlife.
- This pesticide is toxic (or extremely toxic) to fish.
- This pesticide is toxic (or extremely toxic) to birds.
- This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.
- This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

EPA believes it is appropriate to consider only realistic environmental exposure scenarios. For example, it is possible that the label of a pesticide product for indoor use could have one of the environmental hazard statements, such as ''This pesticide is toxic to fish.'' In this case, the chance of fish in the environment being exposed if the container fails is very small, since the container would most likely be stored and the pesticide used inside. Therefore, in the regulatory option being considered, the environmental hazard criterion would apply only to pesticides intended for outdoor use.

EPA is considering specifying several environmental hazard criteria in addition to the label statements listed earlier. Some pesticides are classified as restricted use for environmental or ecological reasons. EPA is considering adding this criterion (classification as restricted use for environmental or ecological reasons) to help distinguish the higher-risk pesticides in terms of environmental risk. However, EPA believes that pesticides that meet this criterion would most likely have at least one of the specified environmental hazard statements on their labels. EPA is also considering adding a criterion for ''biological activity'' or phytotoxicity to include pesticides that are applied at low application rates. Low application rate pesticides may not trigger the container size criterion since only small volumes are used. However, a small release of a low application rate herbicide may still pose significant risks in the environment, because such pesticides are designed and intended to be effective in low doses. These potential criteria are not included in the draft regulatory language in this document, although EPA may decide to include one or both of them in the final rule.

3. *Container size criterion*. In addition, EPA is concerned that even products that don't meet any of the higher-toxicity criteria may pose a significant risk if they are present in large enough quantities. Therefore, EPA is also considering container size as a criterion for defining the scope of the container standards. EPA is currently considering a size criterion of 5.0 liters (1.3 gallons) for containers holding liquid formulations and 5.0 kilograms (11.0 pounds) for containers holding solid formulations. These sizes were selected to be consistent with the limited quantity exceptions in the DOT Hazardous Materials Regulations (HMR) in 49 CFR parts 171–180. As described in Unit V of this document, many commenters strongly urged EPA to be consistent with the DOT HMR which would include adopting the DOT limited quantity exceptions. Therefore, EPA believes it is appropriate to base a container size criterion on the package sizes delineated in the DOT limited quantity exceptions.

4. *General discussion*. The flow chart below depicts the changes being considered for the scope of the container standards for pesticides other than antimicrobial pesticides that are eligible for exemption. The changes to the scope and applicability provisions would be the same for nonrefillable containers (in proposed subpart F) and refillable containers (in proposed subpart G). Under the approach being considered for the general scope (and as shown in the flow chart), the container standards would not apply to manufacturing use products, as proposed in 1994. Regarding products other than manufacturing use products, if the pesticide product meets at least one of the criteria being considered (i.e., Toxicity Category I, Toxicity Category II, greater than (or equal to) the minimum container size, or outdoor use products with one of the label environmental hazard statements) then the product would be subject to the container standards. If the product did not meet any one of these criteria, it would not be subject to the container standards. Potential alternative regulatory text that is being considered for the final rule is provided in Unit VII of this document.

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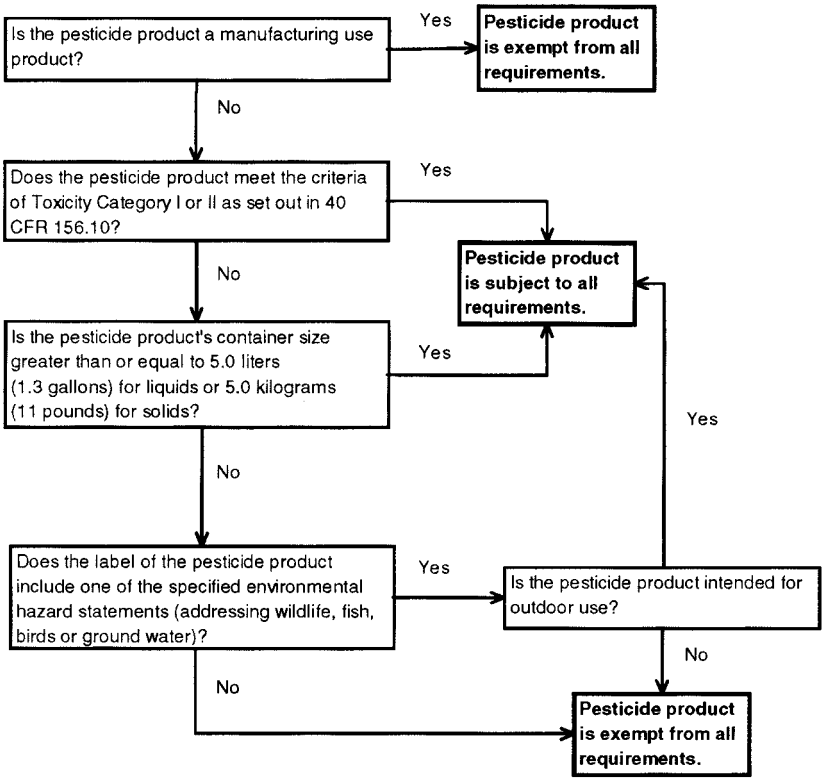

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EPA believes that it has authority to reduce the scope of these regulations. FIFRA section 19(e) requires EPA to promulgate regulations that promote the safe storage and disposal of pesticides. FIFRA section 19(f) requires EPA to promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal, but provides the EPA with much discretion in accomplishing this goal. In addition, FIFRA section 25(b) allows EPA to exempt (by regulation) any pesticide from the requirements of FIFRA if EPA determines that pesticide to be of a character which is unnecessary to be subject to FIFRA in order to carry out the purposes of FIFRA.

Under the changes being considered to the scope of the container rule, the standards would not apply to small containers holding pesticides in Toxicity Category III or IV that don't have any of the environmental hazard statements on their labels or that have at least one of the environmental hazard statements but are not intended for outdoor use. EPA believes it is appropriate to exclude these groups of pesticides and containers from regulation because the relatively small risk to humans and the environment if the container fails, due to their low toxicity, small quantity and/or limited exposure to the environment, is not commensurate with the costs of imposing the standards on these pesticides and containers.

These potential changes to the scope of the proposed rule are being considered only for the container design and residue removal standards in subparts F and G -- not for the proposed modifications to the 40 CFR part 156 label provisions. EPA believes that it is appropriate to have container cleaning and disposal instructions on the labels of all pesticides because of safety and environmental protection considerations for recycling operations. It is necessary for pesticide containers to be properly emptied and cleaned prior to being recycled to protect workers who handle the recyclable material and to prevent releases of pesticides to the environment. Because pesticide containers from all segments of the pesticide industry are currently being recycled, container cleaning and disposal instructions are needed on the labels of all pesticides. EPA believes that FIFRA sections 19(e) and (f) provide the Agency with the authority to make this determination.

D. Request for Comments

EPA solicits comments on the potential modifications to the scope and applicability of the container standards. In addition to any general comments on the approach being considered, EPA requests comments on the following specific issues. (1) Is it appropriate to apply the container standards only to the higher-risk pesticides? (2) Are the criteria being considered by EPA to distinguish between higher-risk and lower-risk pesticides appropriate? (3) In particular, is container size a reasonable factor to consider and, if so, is the suggested size criterion appropriate or should EPA adopt a different size limit? (4) Should alternative or additional environmental hazard criteria, such as those described in Unit III.C.2 of this document be considered? (5) Are there certain container types (e.g., glass containers) that are sufficiently unsafe that such container types should be regulated for all pesticides? (6) Should the potential modifications to the scope be made to the container-related provisions only or should the changes also be made to the proposed label standards?

IV. Antimicrobial Exemption

A. Statutory Background

The Food Quality Protection Act (FQPA) of 1996, Public Law No. 104–170, amended section 19 of FIFRA to exempt certain types of antimicrobial pesticides from the pesticide container provisions under certain circumstances. Specifically, FQPA added the following to FIFRA section 19(h):

A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal

Act (42 U.S.C. 6901 et seq.) shall not be subject to the provisions of subsections (a), (e), and (f), unless the Administrator determines that such product must be subject to such provisions to prevent an unreasonable adverse effect on the environment.

Since this language was added after the pesticide container and containment rule was proposed, EPA believes it is appropriate to solicit public comment on the applicability of this provision to the proposed container regulations. In addition, EPA must interpret the antimicrobial exemption provision to answer two broad questions. First, what is the scope of ''household, industrial, or institutional antimicrobial product[s] that [are] not subject to regulation under the Solid Waste Disposal Act''? Second, which ''product[s] must be subject to [the container] provisions to prevent an unreasonable adverse effect on the environment''?

B. Scope of the Antimicrobial Exemption

1. *Regulatory option under consideration*. EPA believes that a ''household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act'' is a pesticide product that meets all of the following criteria. (i) The product meets the definition of ''antimicrobial pesticide'' in section 2(mm) of FIFRA; (ii) the product is classified in at least one of the following antimicrobial product use categories: (a) food handling/storage establishments premises and equipment; (b) commercial, institutional, and industrial premises and equipment; (c) residential and public access premises; (d) medical premises and equipment; (e) materials preservatives; (f) industrial processes and water systems; (g) antifouling coatings; (h) wood preservatives; or (i) swimming pools; and (iii) the product is not subject to regulation under the Resource Conservation and Recovery Act as a hazardous waste when it becomes a waste.

2. *Discussion*. The first criterion above requires an ''antimicrobial product'' to be an ''antimicrobial pesticide,'' as defined in FIFRA. Section 2(mm) of FIFRA provides the following definition for an antimicrobial pesticide.

(1) IN GENERAL.--The term 'antimicrobial pesticide' means a pesticide that--

(A) is intended to-- (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section 409 of such Act.

(2) EXCLUDED PRODUCTS.--The term 'antimicrobial pesticide' does not include --

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) INCLUDED PRODUCTS.--The term 'antimicrobial pesticide' does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

Because this is a very complex definition, EPA considered using a more straightforward definition for ''antimicrobial product.'' Specifically, EPA considered defining ''antimicrobial product'' to be any product covered under section (1)(A) of the definition of ''antimicrobial pesticide'' in FIFRA section 2(mm), without taking the remainder of that definition into account. However, EPA rejected this approach because the Agency is unaware of evidence that indicates Congress intended ''antimicrobial products'' to be different than ''antimicrobial pesticides.'' Additionally, EPA believes that distinguishing between ''antimicrobial products'' and ''antimicrobial pesticides'' could be confusing to regulators and the regulated industry and could pose enforcement problems. If a pesticide product is not included in the definition of antimicrobial pesticide (e.g., if it is excluded by paragraph (2) of the definition), it is not eligible for the antimicrobial product exemption from the container standards and, thus, is subject to the general scope criteria as discussed in Unit III of this document.

The second criterion for defining the scope of the antimicrobial exemption states that a pesticide product is a ''household, industrial, or institutional'' product if it is classified in at least one of nine specified antimicrobial product use categories.

In response to other FQPA provisions pertaining to antimicrobial pesticides, EPA is developing regulations on the registration of antimicrobial pesticides and the associated data requirements. In its proposal on data requirements (that would amend 40 CFR part 158), EPA intends to categorize all antimicrobial uses into one of the following 12 use categories. All currently registered antimicrobial use patterns are included in one of these larger use classifications for data requirement purposes, but EPA has not to date classified the existing use patterns in this organized fashion.

- Agricultural premises and equipment
- Food handling/storage establishments premises and equipment
- Commercial, institutional, and industrial premises and equipment
- Residential and public access premises
- Medical premises and equipment
- Human drinking water systems
- Materials preservatives
- Industrial processes and water systems
- Antifouling coatings
- Wood preservatives
- Swimming pools
- Aquatic areas

The list of the 12 use categories with all of the appropriately classified use sites is included in the docket (Ref. 3).

In today's document, EPA is considering the approach of identifying nine of these use categories to identify ''household, industrial, or institutional'' antimicrobial products. Specifically, EPA believes that the following nine use categories generally fit within the common understanding of household, industrial and institutional uses:

- Food handling/storage establishments premises and equipment
- Commercial, institutional, and industrial premises and equipment
- Residential and public access premises
- Medical premises and equipment
- Materials preservatives
- Industrial processes and water systems
- Antifouling coatings
- Wood preservatives
- Swimming pools

The other three categories, which are listed below, would not be considered household, industrial, or institutional uses because they fall outside the common understanding of these uses:

- Agricultural premises and equipment
- Human drinking water systems
- Aquatic areas

EPA considered developing definitions for household, industrial, and institutional use, but rejected this approach because of the difficulty in distinguishing among these pesticide market sectors. EPA believes that relying on the antimicrobial product use categories in the antimicrobial registration data requirements rule to distinguish between ''household, industrial, and institutional antimicrobial products'' and all others

for the purposes of the container rule will offer a consistent approach to the definitional issues involved with this criterion. There may be implementation issues with this approach since it is unlikely that the pesticide container and containment rule and the rule on antimicrobial pesticide registration data requirements will be finalized at the same time. However, EPA will coordinate between these rules to ensure consistency and proper notice to the public on the issue of antimicrobial product use categories.

The third criterion for defining the scope of the antimicrobial exemption establishes that a pesticide product ''is not subject to regulation under the Solid Waste Disposal Act'' if it is not subject to regulation under the Resource Conservation and Recovery Act as a hazardous waste when it becomes a waste. The Solid Waste Disposal Act (SWDA) is the Federal waste management statute, which is commonly referred to as the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 to 6992k. (Technically, RCRA was the name of the law that extensively amended the SWDA in 1976.) The terms ''RCRA'' and ''SWDA'' are used synonymously in this document.

EPA believes that the intent of the statutory language in question -- ''that is not subject to regulation under the SWDA'' -- is to include in the antimicrobial exemption household, industrial, or institutional antimicrobial products that are not subject to regulation under RCRA as hazardous wastes when they become wastes. If a household, industrial, or institutional antimicrobial product would be classified as a hazardous waste when it becomes a waste (either by being on one of the RCRA hazardous waste lists or by meeting one of the hazardous waste characteristics), then the product would not be eligible for the FIFRA section 19(h) exemption. An initial review showed that none of the ''listed hazardous waste pesticides'' are antimicrobial pesticides. EPA believes that most household, industrial, and institutional antimicrobial products would not be subject to regulation under RCRA as hazardous wastes when they become wastes and, therefore, would be eligible for the FIFRA section 19(h) exemption.

EPA considered several other interpretations of the SWDA reference, but rejected them because the group of pesticides that would be exempt did not appear to be an accurate or realistic representation of Congress's intent. One alternative interpretation is based on the fact that household, industrial, or institutional antimicrobial products are products and not wastes. Pesticide products are regulated by FIFRA; pesticide wastes are regulated by RCRA. Under this interpretation, no household, industrial, or institutional antimicrobial products would or could ever be subject to regulation under the Solid Waste Disposal Act, and, therefore, they all would be eligible for the FIFRA section 19(h) exemption. However, EPA believes that the scope of the exemption under this interpretation is too broad to realistically represent the Congressional intent.

Another alternative would be to include in the exemption only household, industrial, or institutional antimicrobial products that are not subject to any regulation under RCRA (i.e., as solid waste or hazardous waste) when they become wastes. However, this interpretation would appear to eliminate the exemption altogether, because all antimicrobial product waste (including liquids) would fit into the RCRA regulatory definition of ''solid waste.'' Therefore, all of the household, industrial, or institutional antimicrobial products would be subject to regulation under the Solid Waste Disposal Act. Under this interpretation, none of these products would be eligible for the FIFRA section 19(h) exemption. It seems reasonable to presume that Congress did not intend this result, as it would clearly nullify the exception that Congress had crafted for antimicrobial pesticides. It would seem to be an absurd interpretation that Congress intended this section to have no effect. Further, it is reasonable to presume, given the structure and regulatory history of SWDA, that Congress intended its reference to regulation under SWDA to mean regulation as a hazardous waste under SWDA. Though SWDA does provide for regulation of solid waste (in particular, restrictions on ''open dumping''), hazardous waste has been subject to much more extensive regulation and has been to a significant degree the focus of Federal regulation under SWDA. (Ref. 4) It is therefore likely that the most reasonable interpretation of this provision is to interpret ''subject to regulation under the Solid Waste Disposal Act'' to mean ''subject to regulation as a hazardous waste under the Solid Waste Disposal Act.''

In summary, EPA believes that the scope of ''household, industrial, or institutional antimicrobial products that are not subject to regulation under the Solid Waste Disposal Act'' includes pesticide products that: (1) Meet the definition of antimicrobial pesticide in FIFRA section 2(mm); (2) fall within one of the specified antimicrobial product use categories; and (3) are not subject to regulation under RCRA as hazardous wastes when they become wastes. Throughout the remainder of this document, these pesticides are referred to as ''eligible antimicrobial pesticides,'' i.e., those pesticides that are eligible for the antimicrobial exemption.

3. *Request for comments.* EPA requests comments on this interpretation of the statutory antimicrobial exemption. In addition to general comments, EPA solicits comments on the following specific questions.

i. Is it appropriate to adopt the statutory definition for ''antimicrobial pesticide'' to define ''antimicrobial product'' for the purposes of the pesticide container and containment rule? If an alternative definition of antimicrobial product should be adopted, please explain why and provide an alternative definition.

ii. Is it appropriate to rely on antimicrobial product use categories developed for data requirement purposes to distinguish among household, industrial, and institutional antimicrobials and all others for container regulatory purposes or should EPA adopt another approach such as defining each of these pesticide use sectors?

iii. Is EPA's interpretation of the statutory reference to the SWDA appropriate or should EPA adopt an alternative interpretation?

In addition, EPA requests information about which antimicrobial pesticides, if any, are subject to regulation as hazardous wastes under RCRA when they become wastes.

C. Preventing Unreasonable Adverse Effects on the Environment

1. *Regulatory option under consideration.* Under the regulatory option being considered, EPA has determined that eligible antimicrobial products classified in Toxicity Category I must be subject to a substantial majority of the container provisions to prevent an unreasonable adverse effect on the environment. As discussed in greater detail below, eligible Toxicity Category I antimicrobial products would be subject to all of the nonrefillable and refillable container standards with two exceptions. First, eligible Toxicity Category I antimicrobial products would be exempt from the nonrefillable residue removal standard. Second, eligible Toxicity Category I antimicrobial products that are used in swimming pools would be exempt from certain refillable container standards (including, but not limited to serial

number markings, one-way valves or tamper-evident devices, and some recordkeeping) that would greatly interfere with the current wide use of refillable containers in that industry segment.

2. *Description of options.* EPA considered a wide range of options for determining which eligible antimicrobial products must be subject to the container provisions to prevent an unreasonable adverse effect on the environment. The four options that EPA preliminarily believes to be the most appropriate are described in Units IV.C.2.i - iv of this document. The options are listed in the order of how many eligible antimicrobial products would be exempt, where option 1 would exempt the most and option 4 would exempt the least. Options 2 and 3 would exempt the same number of products, but would apply different sets of standards to the products that would be included.

This section of the document is intended to provide a brief summary of the options. The following unit provides a comparison, analysis, and more detailed explanation of the options and explains why option 3 is put forth as EPA's preferred option.

i. *Option 1. Exempt all eligible antimicrobials, but include a provision to require a specific product or group of products to comply with the container regulations if a problem becomes evident.* Eligible antimicrobials (i.e., household, industrial, or institutional antimicrobial products that are not subject to regulation under the Solid Waste Disposal Act) would be exempt from the pesticide container regulations, unless EPA specifically includes the antimicrobial product or products. EPA could make a case-by-case determination that a specific product or group of products must be subject to the container standards to prevent an unreasonable adverse effect on the environment. The regulations could include a provision such as the following to allow such case-by-case decisions to be made: ''EPA may determine that an antimicrobial product or products must comply with the container standards. EPA may consider evidence such as field studies, use history, accident data, monitoring data, or other pertinent evidence in deciding whether the product must comply with the container standards to prevent an unreasonable adverse effect on the environment.''

The overall criterion that would be used to make product-specific inclusion decisions is that the antimicrobial product would cause an unreasonable adverse effect on the environment unless it complied with the container standards. EPA would consider requiring a specific antimicrobial product to comply with the container standards in situations where EPA became aware of situations such as, but not limited to: (1) An antimicrobial product with a non-negligible number of containers that leaked or otherwise accidentally released pesticide to the environment; (2) an antimicrobial product with a non-negligible number of container-related documentable exposures to persons using the product, particularly if there are significant health effects to the pesticide users; or (3) the use of refillable containers to distribute antimicrobial products has expanded into new market segments and use sites, where the safeguards of the proposed regulations are necessary to prevent exposure and unreasonable risks to pesticide users and human health and the environment in general. In situations such as these, EPA could decide to require just the specific product in question to comply with the container regulations. However, EPA could also require similar products distributed in similar containers to comply with the container standards if the Agency could reasonably expect the same problems from these other antimicrobial products.

A provision such as this could be added to any of the other options to account for new information about problems with specific products that might not be included by the general criteria. In order to simplify this discussion, EPA chose not to add such a provision to create a ''suboption'' for each of the following options. In the final rule, however, EPA may decide to add a ''case-by-case provision'' to one of the following options.

ii. *Option 2. Subject eligible antimicrobials classified in Toxicity Category I to all of the container regulations.* Eligible antimicrobials classified in Toxicity Category I would be included in the pesticide container regulations. Other eligible antimicrobials (i.e., those in Toxicity Categories II, III, and IV) would be exempt from the container regulations. Under this option, EPA would make a determination that eligible antimicrobials classified in Toxicity Category I must be subject to all of the container regulations to prevent an unreasonable adverse effect on the environment.

iii. *Option 3. Subject eligible antimicrobials classified in Toxicity Category I to a subset of the container regulations.* This option is similar to option 2 in that eligible antimicrobials classified in Toxicity Category I would be included in the pesticide container regulations and other eligible antimicrobials (i.e., those in Toxicity Categories II, III, and IV) would be exempt from the container standards. EPA would make an unreasonable adverse effects determination similar to that in option 2. Under this option, however, only a subset of the container standards would apply to eligible antimicrobial pesticides in Toxicity Category I.

Specifically, eligible Toxicity Category I antimicrobial products would be subject to all of the nonrefillable container standards except for the residue removal standard (which was proposed as § 165.104). Also, eligible Toxicity Category I antimicrobial products that are used in swimming pools would be exempt from certain refillable container standards (including, but not limited to serial number markings, one-way valves or tamper-evident devices, and some recordkeeping). All other eligible Toxicity Category I antimicrobial products would have to comply with all of the refillable container standards. The full list of requirements that would apply under this approach is provided in the potential alternative regulatory text in Unit VII of this document. The exemptions from specific requirements are discussed in more detail in Unit IV.C.3 of this document.

iv. *Option 4. Apply the scope criteria being considered for other pesticides (as discussed in Unit III of this document) to eligible antimicrobials.* Eligible antimicrobials would be subject to the same exclusion/inclusion criteria as other pesticides, according to the modifications being considered for the scope of the container regulations. As discussed in Unit III of this document, EPA is considering criteria based on: (a) Classification in Toxicity Categories I or II; (b) container size; and (c) environmental hazard statements on the labels of outdoor pesticides to distinguish between higher-risk and lower-risk pesticides. Under this approach, EPA would make a determination that eligible antimicrobials that meet any of the criteria must be subject to the container regulations to prevent an unreasonable adverse effect on the environment.

3. *Discussion.* One issue regarding these options is whether EPA can set general criteria for making an unreasonable adverse effect determination or if such a determination must be made on a case-by-case basis. EPA believes that the statutory language ''unless the Administrator determines that [an eligible antimicrobial] product must be subject to [the container]

provisions to prevent an unreasonable adverse effect on the environment'' does not preclude the adoption of either approach (general criteria or a case-by-case decision). Section 19(h) provides the Agency with considerable flexibility to make a reasonable interpretation of the statutory language. EPA believes that the Agency can set general criteria and/or make case-by-case decisions in making unreasonable adverse effect determinations.

Another issue regarding these options is estimating how many products would be included in the regulations by each of the options. (Ref. 5) EPA estimates that there are about 5,000 registered antimicrobial end-use products being marketed in the United States. While not all of these products would be household, industrial, or institutional antimicrobial products that are not subject to regulation under the SWDA, this analysis will use 5,000 products as a reasonable upper limit. To estimate the percentage of eligible antimicrobial pesticides classified in Toxicity Categories I and II, EPA analyzed information in an Office of Pesticide Programs data base. Based on this analysis, EPA estimates that about 70% of eligible antimicrobial products are classified in Toxicity Category I and an additional 15% are classified in Toxicity Category II. The number and percent of eligible antimicrobial products that would have to comply with the container standards under the four options is summarized in the following table 2.

TABLE 2.— SUMMARY OF OPTIONS FOR EXEMPTING CERTAIN ANTIMICROBIAL PRODUCTS

Option Number	Description	Products Included		Products Exempted	
		Number	Percent	Number	Percent
Option 1	Exempt all except case-by-case	some	> 0	most (< 5,000)	< 100
Option 2	Include Toxicity Category I	3,500	70	1,500	30
Option 3	Include Toxicity Category I	3,500	70	1,500	30
Option 4	Include Toxicity Category I & II, container size, environmental criteria.	4,250 – 4,500	85 – 90	500 – 750	10 – 15

Under option 1, eligible antimicrobials would be exempt from the pesticide container regulations, unless EPA made a case-by-case determination that a specific product or group of products must be subject to the container standards to prevent an unreasonable adverse effect on the environment. This option would exempt nearly all eligible antimicrobials from the container rule. Therefore, this option would have the lowest economic costs since the economic costs of the rule are directly related to the number of products that would be regulated.

EPA rejected option 1 because the Agency believes that the risk of exempting nearly all eligible antimicrobial products is too high. Under this approach, few, if any, antimicrobial pesticides would initially be subject to these regulations, even those antimicrobial pesticides that are in Toxicity Category I. A high percentage, about 70%, of eligible antimicrobials are classified in Toxicity Category I (mostly because they meet the criteria for eye and/or skin effects). This is a significantly larger percentage than for other segments of the pesticide industry. Based on an analysis of information in an Office of Pesticide Programs data base (Ref. 5), EPA estimates that about 20% of agricultural pesticides are classified in Toxicity Category I (with an additional 15% in Toxicity Category II) and about 10% of pesticides for forestry and ornamental turf and plants are classified in Toxicity Category I (with an additional 15% in Toxicity Category II). This information is summarized in the following table 3.

TABLE 3.— COMPARISON OF HIGHLY TOXIC PRODUCTS IN DIFFERENT PESTICIDE MARKET SEGMENTS

Pesticide Industry Segment	Percentage of Products		
	Toxicity Category I	Toxicity Category II	Toxicity Category I or II
Forestry and ornamental turf and plants	10	15	25
Agricultural crops	20	15	35
Eligible antimicrobials	70	15	85

In addition, the large quantity of antimicrobial products used each year supports including some of these products within the scope of the container requirements. The following table 4 summarizes the U.S. usage of different types of pesticides in 1995. (Ref. 6) According to this information, eligible antimicrobial pesticides account for over 40% of all pesticides used in 1995 (on a weight basis).

TABLE 4.— PESTICIDE USAGE IN THE UNITED STATES IN 1995

Type of Pesticide	Quantity of Pesticide Used	
	Millions of pounds active ingredient	Percent
Non-antimicrobial pesticides		
Conventional pesticides	973	21

TABLE 4.— PESTICIDE USAGE IN THE UNITED STATES IN 1995—Continued

Type of Pesticide	Quantity of Pesticide Used	
	Millions of pounds active ingredient	Percent
Sulfur, petroleum (oil, distillates, etc.), sulfuric acid and other miscellaneous chemicals used as pesticides	249	6
Subtotal	**1222**	**27**
Eligible antimicrobial pesticides		
Wood preservatives [1]	718	16
Specialty biocides by end use.		
Swimming pools, spas, individual water treatment [2]	175	4
Disinfectants and sanitizers [3]	32	1
Other [4]	50	1
Chlorine/hypochlorites.		
Bleaching disinfectant and pools	925	20
Subtotal	**1,900**	**42**
Non-eligible antimicrobial pesticides [5]		
Chlorine/hypochlorites.		
Disinfection of potable and waste water	1,390	31
Subtotal	**1,390**	**31**
TOTAL [6]	**4,512**	**100**

[1] Includes water and air borne preservatives and creosote/coal tar/petroleum preservatives. The original report (Ref. 6) also included 7 million pounds of fire retardants in the category of wood preservatives. The 7 million pounds of fire retardants are not included as wood preservatives in this table.

[2] Specialty biocides only. Does not include hypochlorite or chlorine consumption, which is reported separately.

[3] Includes industrial/institutional applications and household cleaning products. Specialty biocides only. Does not include hypochlorite or chlorine consumption, which is reported separately.

[4] Includes biocides for adhesives and sealants, leather, synthetic latex polymers, metalworking fluids, paints and coatings, petroleum products, plastics, and textiles. Does not include: hospital and medical antiseptics, food and feed preservatives, and cosmetics/toiletries. These latter types of usage are not included (in Ref. 6), as they are regulated largely by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act rather than FIFRA. The FDA and EPA share regulatory responsibilities over some of the specialty biocide usage reported in the table.

[5] This category of chlorine/hypochlorites usage is not considered a ''household, industrial, or institutional use.'' See the discussion of antimicrobial use product use categories in Unit IV.B.2 of this document.

[6] The total is 7 millions pounds less than in Ref. 6 because 7 million pounds of fire retardants were removed from the original estimate of wood preservatives. See footnote 1.

Because most eligible antimicrobial products pose a high (Toxicity Category I) or relatively high (Toxicity Category II) hazard to humans and the large quantity of eligible antimicrobials used annually (over 40% of pesticides used in 1995, based on pounds of active ingredient), EPA believes that it is appropriate and necessary to require certain eligible antimicrobial products to comply with the container standards to prevent unreasonable adverse effects on the environment.

In option 2, EPA would require eligible antimicrobial products in Toxicity Category I to comply with the container standards. EPA believes it is appropriate to include these products because they present the highest hazards to humans. Subjecting these highest-risk pesticides to the container standards that are intended to ensure the safe storage, use, refill/reuse and disposal of pesticides would provide benefits, by lowering the overall risk to man and the environment, that would not be obtained by option 1.

However, EPA prefers option 3, a variation of option 2, because it offers some cost and environmental benefits over option 2. Option 3 would exempt eligible antimicrobial products in Toxicity Category I from certain container requirements.

To ease the economic impact on registrants of antimicrobial pesticides, option 3 would exempt eligible antimicrobial products from the nonrefillable residue removal standard, which was proposed as § 165.104. While representatives from all sectors of the pesticide industry commented that the proposed nonrefillable residue removal standard would be a burdensome and costly requirement, the antimicrobial industry pointed out some characteristics of their containers and products that pose particular difficulties with respect to residue removal. Commenters stated that antimicrobial products tend to have extremely low active ingredient concentrations, which makes it difficult to make the measurements needed to determine compliance with the proposed standard. In addition, commenters said that antimicrobial formulations often contain ingredients that create foam when containers are shaken during the triple rinsing procedure, making it more difficult to comply with the proposed residue removal standard. (Ref. 2) Based on the comments, EPA believes these problems are more prevalent with antimicrobials than with other pesticides. EPA also believes that the ''unreasonable adverse effect'' language of section 19(h), which requires review of costs and benefits, allows EPA more flexibility to exempt antimicrobial pesticides from these requirements than does the language in section 19(e) and (f) which is more directed at risk. Therefore, under the regulatory approach under consideration, eligible antimicrobial products would not have to comply with the nonrefillable residue removal standard. Please note that EPA is considering a range of modifications to the residue removal standard in the final rule that take into account all of the comments on the proposed standard. This document is not soliciting additional comments on the proposed nonrefillable residue removal standard.

Another significant concern with the proposed rule that was raised in the public comments was that the refillable container standards posed many impediments to the extensive and successful use of refillable containers that are currently used to distribute swimming pool chemicals. The swimming pool chemical industry commented that the following proposed requirements would require significant and costly changes to the many refillable containers currently used: the serial number marking; one-way valves or tamper-evident devices; relabeling the container; and recordkeeping. (Ref. 2) EPA agrees that applying these requirements to swimming pool pesticides would disrupt the current refillable container system for swimming pool chemicals and would probably cause the refillables to be replaced by millions of single-use, nonrefillable containers. EPA believes that adding millions of pounds of these nonrefillable containers to the waste stream is inconsistent with the goals of section 19(e) of FIFRA, particularly that the regulations facilitate the safe refill and reuse of containers.

In addition, many of the proposed refillable container standards in question are intended to minimize the possibility of cross-contamination in refillable containers. Cross-contamination is less of a concern for swimming pool pesticides than for agricultural pesticides for several reasons. First, several commenters indicated that the refillable containers in the swimming pool market are only used to distribute sodium hypochlorite and not other kinds of antimicrobial pesticides. (Ref. 2) Second, these antimicrobial pesticides are used on the same site, i.e., swimming pools. EPA evaluates the risks posed by swimming pool pesticides at the concentrations at which they are used. Therefore, low levels of contamination from other swimming pool chemicals would pose little additional risk to humans or the environment because of the low concentrations and because the contaminant is intended to be used in swimming pools. In other words, the contaminant would not be applied to a site, pest, or crop for which it wasn't intended, which could easily happen in an agricultural setting. [Note: this does not exempt swimming pool chemicals from complying with the product chemistry registration requirements and related policies, including PR Notice 96–8 ''Toxicologically Significant Levels of Pesticide Active Ingredients'' (Ref. 7)].

Therefore, this option would exempt swimming pool antimicrobial pesticides from certain refillable container standards.

As described above in the discussion of options 2 and 3, EPA believes it is appropriate to require eligible antimicrobial products that are in Toxicity Category I to comply with most of the container standards. About 70% of eligible antimicrobials would therefore have to comply with most of the container standards. This might be considered too large a percentage of antimicrobial products to be subject to the regulation. Therefore, EPA is requesting comments on possible ways to divide the eligible antimicrobial products in Toxicity Category I into subcategories, for the purposes of regulating the products that pose the highest risk and exempting the others. For example, the formulation of the product may be related to the exposure of the handler when dispensing a product from a container. For example, liquid formulations may cause higher exposures than solid formulations due to dripping, glugging, and leaking. In this example, EPA could choose to require only liquid eligible antimicrobial products in Toxicity Category I to comply with most of the container standards. EPA requests comments on whether it is appropriate to divide eligible antimicrobial products in Toxicity Category I into subcategories and, if so, EPA requests suggestions on reasonable criteria for making such a distinction.

Option 4 would apply the same exclusion/inclusion criteria being considered for other pesticides to eligible antimicrobials. As discussed in Unit III of this document, EPA is considering criteria based on (1) classification in Toxicity Categories I or II; (2) container size; and (3) environmental hazards to distinguish between higher-risk and lower-risk pesticides. Subjecting a larger group of higher-risk pesticides to the container standards would provide more benefits -- by further lowering the overall risk to man and the environment -- than for options 2 and 3. However, EPA rejected option 4 mainly because the Agency believes that the FQPA amendment to FIFRA section 19(h) indicates a Congressional intent for EPA to regulate eligible antimicrobial products differently than all other pesticide products. In particular, the standard set for subjecting antimicrobial products to the container standards by FIFRA section 19(h) is ''to prevent an unreasonable adverse effect on the environment.'' On the other hand, the mandates in FIFRA sections 19(e) and (f) establish a level of ''safety,'' e.g., ''safe storage and disposal'' and ''safe use.'' In addition, Congress's revision to section 19(h) indicates that Congress was particularly concerned about the economic impacts of section 19(e) and (f) on the manufacture and use of antimicrobial pesticides. Therefore, EPA believes that Congress intended that eligible antimicrobial products should not be regulated unless there is an extremely serious risk to humans or the environment if exposed during a container incident, as there would be for Toxicity Category I products. EPA believes a Toxicity Category I product would pose a serious risk in such a situation regardless of whether it is classified in Toxicity Category I because of its systemic toxicity, e.g., oral or dermal LD_{50} or inhalation LC_{50}, or because of its eye and/or skin effects.

Because of the many questions raised by the statutory antimicrobial exemption, it is instructive to review the approach EPA is considering to implement this exemption. The following flow chart depicts EPA's potential approach for implementing the antimicrobial exemption as discussed above.

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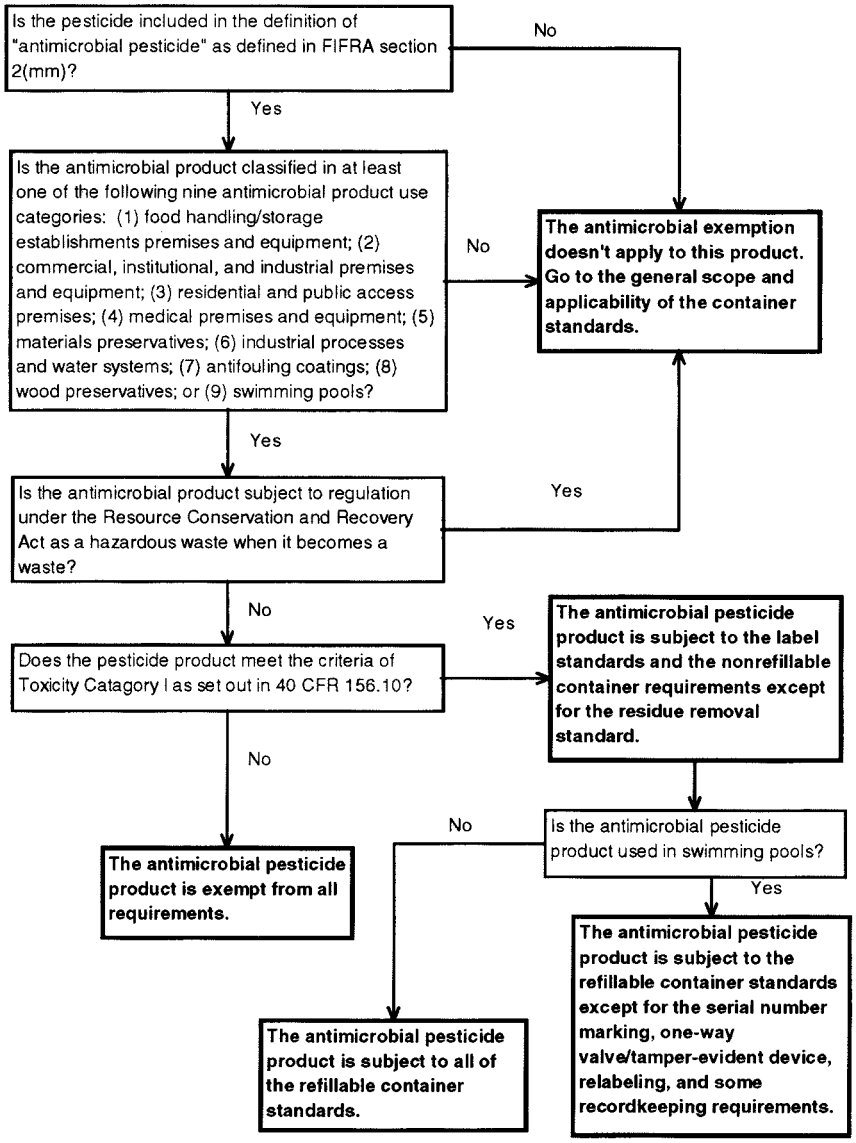

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EPA is interpreting the antimicrobial pesticide exemption to be an exemption from the container design and residue removal standards in proposed subpart F for nonrefillable containers and proposed subpart G for refillable containers. On the other hand, EPA does not intend to exempt eligible antimicrobials from the proposed container-related labeling requirements. EPA believes that container cleaning and disposal instructions should be included on the labels of all pesticides. As described in Unit III.C.4 of this document, it is necessary for pesticide containers to be properly emptied and cleaned prior to being recycled to protect workers who handle the recyclable material and to prevent releases of pesticides to the environment. Because containers from all segments of the pesticide industry, including eligible antimicrobial products, are currently being recycled, container cleaning and disposal instructions are needed on the labels of all pesticides. EPA believes that section 3 of FIFRA provides the Agency with the authority to require cleaning and disposal instructions on the labels of eligible antimicrobial pesticides. Cleaning and disposal instructions were required on the labels of eligible antimicrobial products as part of the directions for use before FIFRA section 19(a) was added in 1988.

Decisions on the label requirements to be included in the final rule will be made separately from the issues discussed in this document. When making these decisions, EPA will consider all the comments received during the initial public comment period, including suggestions for alternative label instructions for household and institutional pesticides. EPA is not soliciting further comments on the specific label statements and standards proposed in 1994.

4. *Request for comments.* EPA requests comments on the approach under consideration for determining that an eligible antimicrobial product must be subject to the container standards to prevent an unreasonable adverse effect on the environment, specifically, setting classification in Toxicity Category 1 as a general criterion and requiring these eligible antimicrobial pesticides to comply with a subset of the container standards, as well as the other possible approaches. EPA also solicits comments on the following specific questions.

i. Should EPA establish general criteria for making this determination (such as classification in Toxicity Category I) or should such a

determination be made only on a case-by-case basis?

ii. If general criteria should be included, is the criterion being considered appropriate or should EPA establish alternative or additional general criteria, such as classification in Toxicity Category II, a provision that accounts for environmental risk, and/or a container size limit?

iii. Should EPA establish a detailed procedure for making a case-by-case determination if there is a serious hazard problem related to the containers of a specific antimicrobial product or group of products? Are the examples of situations where EPA might make such a determination, as discussed in Unit IV.C.2.i of this document, reasonable? What other situations or criteria should EPA use in making a decision to require a specific product to comply with the container regulations?

iv. Is it appropriate to subject eligible antimicrobial products to only a subset of the container requirements as set out in option 3?

v. Is it appropriate for EPA to divide eligible antimicrobial products in Toxicity Category I into subcategories? If so, what would be reasonable criteria for making such a distinction?

vi. Should eligible antimicrobial pesticides in Toxicity Categories II, III, and IV be exempt from the container-related standards only, i.e., should they be required to comply with the label standards? If eligible antimicrobial pesticides in Toxicity Categories II, III, and IV should be exempt from the label standards, please explain why these containers do not need to be properly cleaned prior to being disposed of or recycled.

D. Summary of Scope Modifications and the Antimicrobial Exemption

As described in Unit IV.C.3 of this document, EPA is considering different criteria for antimicrobial pesticides than for all other pesticides in terms of determining whether they would be subject to the container standards. For antimicrobials that are ''eligible'' for exemption, i.e., household, industrial, and institutional antimicrobial pesticides that are not subject to RCRA, EPA is considering requiring those that are classified in Toxicity Category I to comply with most of the container standards. EPA has determined that eligible antimicrobial pesticides that are classified in Toxicity Category I must be subject to the container standards (other than the nonrefillable residue removal standard and, for antimicrobial products used in swimming pools, some of the refillable container standards) to prevent an unreasonable adverse effect on the environment.

For all pesticides other than eligible antimicrobials, EPA is considering applying the full set of container standards to those that meet at least one of the following criteria: Toxicity Category I classification, Toxicity Category II classification, container size greater than or equal to 5.0 liters for liquids or 5.0 kilograms for solids, or outdoor use pesticides that have one of the specified environmental hazard statements on their label. EPA has determined that pesticides that meet one of these criteria are higher-risk from a container-release point of view and should be subject to the container standards.

Because of the overlap in criteria being considered to delineate the antimicrobial exemption and to define the general scope of the container standards, it is useful to consider how these approaches would mesh in the final rule. The following table 5 sets out which pesticides would be included in the container regulations (for both nonrefillable and refillable containers) and which would be exempt, considering both the possible modifications to the scope and the exemption for certain antimicrobial pesticides. Potential alternative regulatory text that is being considered for the final rule is provided in Unit VII of this document.

TABLE 5.—SUMMARY OF THE SCOPE MODIFICATIONS AND THE ANTIMICROBIAL EXEMPTION

General Category	Conditions for Inclusion or Exemption [1]	Included or Exempt? [2]
Manufacturing use products	Any manufacturing use product is exempt from the regulations.	Exempt
Antimicrobial products that are eligible for exemption and that are end use products.	A product is included in the regulations if it satisfies all of the following conditions: • It is an end use product. • It is a household, industrial, or institutional antimicrobial product that is not a hazardous waste when disposed.. • It is in Toxicity Category I. [Note: Although these products are included in the regulations, they are exempt from certain specific requirements, such as the residue removal standard for nonrefillable containers. Also, swimming pool pesticides in this category are exempt from some of the refillable container standards.].	Included
	A product is exempt from the regulations if it satisfies all of the following conditions: • It is an end use product. • It is a household, industrial, or institutional antimicrobial product that is not a hazardous waste when disposed.. • It is in Toxicity Category II, III, or IV.	Exempt
All other end use products, which includes the following three categories: (1) products that are not antimicrobial products; (2) antimicrobial products that are not eligible for exemption because they are hazardous wastes when disposed; and (3) antimicrobial products that are not eligible for exemption because they are not household, industrial, or institutional antimicrobial products.	A product is included in the regulations if it satisfies both of the following conditions: • It is in the ''all other end use products'' general category. • It is in Toxicity Category I or II.	Included

TABLE 5.—SUMMARY OF THE SCOPE MODIFICATIONS AND THE ANTIMICROBIAL EXEMPTION—Continued

General Category	Conditions for Inclusion or Exemption [1]	Included or Exempt? [2]
	A product is included in the regulations if it satisfies all of the following conditions: • It is in the ''all other end use products'' general category. ..... • It is in Toxicity Category III or IV. ..... • It is in a container whose capacity is equal to or greater than 5 liters (1.3 gallons) or 5 kilograms (11 pounds)..	Included
	A product is included in the regulations if it satisfies all of the following conditions: • It is in the ''all other end use products'' general category. ..... • It is in Toxicity Category III or IV. ..... • It is in a container whose capacity is less than 5 liters or 5 kilograms. • It has a label with at least one of the environmental hazard statements.. • It has a label that permits outdoor use.	Included
	A product is exempt from the regulations if it satisfies all of the following conditions: • It is in the ''all other end use products'' general category. ..... • It is in Toxicity Category III or IV. ..... • It is in a container whose capacity is less than 5 liters or 5 kilograms. • It has a label with at least one of the environmental hazard statements.. • It has a label that does not permit outdoor use.	Exempt
	A product is exempt from the regulations if it satisfies all of the following conditions: • It is in the ''all other end use products'' general category. ..... • It is in Toxicity Category III or IV. ..... • It is in a container whose capacity is less than 5 liters or 5 kilograms. • It has a label without any of the environmental hazard statements.	Exempt

[1] This column lists the conditions that determine whether a product is included in the regulations or is exempt from the regulations.
[2] This column provides a quick indication of whether the products described in the previous column are included in the regulations or are exempt from the regulations.

E. Request for Comments

EPA requests comments on the overall approach being considered for implementing the antimicrobial exemption and for modifying the scope of the container standards. EPA solicits comments on the complexity, clarity, and appropriateness of the approach and on potential alternatives. Also, EPA requests input on the potential impacts of the approach being considered, i.e., how many pesticides would be excluded and how many would be included.

V. Department of Transportation (DOT) Packaging Standards

A. Background on 1994 Proposal

The third issue being opened for comment in this document is a regulatory approach being considered by EPA to adopt and refer to the relevant portions of the DOT Hazardous Materials Regulations (HMR).

During the public comment period, EPA received many comments that urged EPA to be consistent with the DOT regulations. Over 20 respondents, including individual companies and trade groups from the pesticide registrant and container manufacturing industries, provided commentary on the DOT HMR and the United Nations (U.N.) Recommendations on the Transport of Dangerous Goods. All of the commenters agreed that EPA should be consistent with the DOT HMR and the U.N. standards in terms of definitions, requirements, and testing. Respondents argued that such consistency would: (1) Facilitate compliance because the industry is already familiar with the DOT and U.N. standards; (2) eliminate the potential burden of complying with two different, overlapping regulatory schemes; and (3) not establish additional trade barriers. Most of the commenters on the DOT issue specifically favored the use of DOT's packing group III criteria as the minimum standard for pesticide products not regulated by DOT as hazardous materials. (Ref. 2)

EPA is considering incorporating this suggestion to change the container regulations by adopting and referring to the DOT packing group III criteria. While EPA discussed the DOT standards in some detail in the preamble of the 1994 proposal, EPA did not specifically discuss the approach of adopting and referring to the DOT HMR in the final rule. Therefore, EPA is describing the approach under consideration and soliciting comments in this document.

B. Regulatory Option Under Consideration

Pesticides that are classified as DOT hazardous materials would continue to be packaged in accordance with the DOT HMR. Under the regulatory approach being considered for the final rule, EPA would cross-reference the HMR, so EPA could enforce these standards. Pesticides that are not classified as DOT hazardous materials would be required to be packaged in accordance with the specified packaging design, construction, and marking standards that would apply to a DOT packing group III material. All pesticides, regardless of DOT hazardous material classification, would have to comply with additional requirements for pesticides (''pesticide-specific requirements'') that have no equivalents in the DOT HMR, e.g., a standard for minimizing dripping. In addition, EPA

is considering incorporating a provision to provide exceptions for pesticides not classified as DOT hazardous materials that would be similar to the limited quantity exceptions in the DOT HMR.

Potential regulatory language that is being considered for the approach of referring to and adopting the DOT standards is provided in Unit VII of this document.

C. Discussion

1. *Adoption of the DOT standards.* The HMR are based on the authority in the Federal hazardous materials transportation law, the Hazardous Materials Transportation Act, and are found in 49 CFR Parts 171 through 180. The HMR establish standards governing a wide range of the safety aspects of transportation, including requirements for classification of materials, packaging (including manufacture, continuing qualification, and maintenance), hazard communication (i.e., package marking, labeling, placarding, and shipping documentation), transportation and handling, and incident reporting. For the purposes of applying DOT standards to pesticides that are not classified as DOT hazardous materials, EPA has focused on the DOT requirements for package design (and manufacture, continuing qualification, and maintenance) and package marking, because these are the areas that overlap with the proposed pesticide container standards. EPA is not considering incorporating the HMR standards for labeling, placarding, shipping documentation, transportation and handling, and incident reporting for pesticides that are not classified as DOT hazardous materials. In general, these standards are outside the scope of the original proposed rule for pesticide containers and containment. In other words, EPA is considering referring to and adopting only a subset of the DOT HMR for pesticides that are not classified as DOT hazardous materials.

The DOT HMR include general packaging requirements that address areas such as compatibility, closures, venting, and filling limits. The HMR also set out performance standards for packaging, including drop, leakproofness, hydrostatic pressure, stacking, and vibration tests. The stringency of these tests varies according to the packing group (PG) of the material being transported. The packing group represents a measure of the relative hazards, where PG I includes materials that pose a relatively great hazard and PG III includes materials that pose a relatively minor hazard.

Under the revisions to the pesticide container rule being considered, pesticides that are classified as DOT hazardous materials would continue to be packaged in accordance with the DOT HMR. Most pesticides that are classified as DOT hazardous materials are in Packing Group III, although some are in PG II and a few are in Packing Group I. (Ref. 8) Nothing in the pesticide container rule would change any of the incorporated DOT requirements -- if a pesticide is categorized as a PG II material, it would continue to have to meet the PG II standards and likewise for pesticides in PG I or PG III.

Under the regulatory approach being considered, pesticides that are not classified as DOT hazardous materials would be required to be packaged in accordance with the specified packaging design, construction, and marking standards that would apply to a DOT PG III material. Such pesticides would not have to meet the DOT standards for labeling, placarding, or shipping papers which, as discussed above, are outside the scope of the original proposed container regulations. Specifically, pesticides that are not classified as DOT hazardous materials would have to comply with the packaging standards in 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.203, 173.213, 173.240, and 173.241, the packaging standards and testing requirements in 49 CFR part 178; and the continuing qualification and maintenance requirements in 49 CFR part 180. EPA would retain its independent authority to enforce compliance with these regulations as with any other regulations promulgated under FIFRA.

2. *Include pesticide-specific standards.* One issue involved with the regulatory approach under consideration is whether the DOT package design and marking standards should be the only requirements for pesticide containers or whether EPA should promulgate additional standards that apply only to pesticide containers. Some of the commenters on the proposed rule implied that the only standards necessary are the DOT standards and that EPA should not add any additional requirements. EPA disagrees with this assessment and believes that it is appropriate to promulgate additional pesticide-specific requirements because the purposes of the two sets of regulations are different.

The Hazardous Materials Transportation Act provides DOT with the authority to ''issue regulations for the safe transportation of hazardous materials in intrastate, interstate, and foreign commerce ... [that] shall govern any aspect of hazardous materials transportation safety which the Secretary of Transportation deems necessary or appropriate.'' An overall goal of this law is ''to improve the regulatory and enforcement authority of the Secretary of transportation to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce.''

Section 19 of FIFRA gives EPA a much broader mandate for addressing pesticide containers. Section 19(e) requires EPA to promulgate ''regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.'' This section further specifies that the regulations ensure that containers accommodate procedures used for the removal of pesticides and facilitate the safe use, safe disposal, safe refill, and safe reuse of the containers. In addition, section 19(f) requires EPA to ''promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.''

EPA believes the broader mandate in FIFRA justifies the approach of requiring that pesticides meet certain pesticide-specific requirements in addition to the DOT standards. In the regulatory option under consideration, EPA would not include in the final regulations a proposed FIFRA-specific container standard if there was an equivalent DOT standard (e.g., the drop test for minibulks). EPA would merely incorporate the equivalent DOT standard. However, EPA would retain other proposed standards (e.g., the container dispensing standards to minimize dripping and to require pouring in a continuous, coherent stream) that did not have equivalent DOT standards.

Therefore, all pesticides that would be subject to the pesticide container regulations -- regardless of whether or not they are classified as DOT hazardous materials -- would have to comply with both the DOT HMR requirements incorporated into EPA's regulations and the pesticide-specific requirements in the final pesticide container rule.

Table 6 categorizes the proposed pesticide container ''design'' and marking requirements according to whether or not the DOT HMR have an equivalent standard. The table is included only to provide a general idea of the proposed requirements that EPA may replace in the final rule with DOT standards and those proposed standards that EPA would retain as pesticide-specific requirements. EPA is not soliciting further comments on the

proposed pesticide container standards listed in the table, except regarding the extent to which DOT standards are appropriate equivalents to such standards. EPA has considered the comments previously submitted on these proposed requirements and will continue to do so as the final rule is developed.

TABLE 6.— COMPARISON OF THE PROPOSED CONTAINER STANDARDS WITH THE DOT REQUIREMENTS

Proposed Pesticide Container Requirement	Proposed 40 CFR Cite	Equivalent 49 CFR Cite
Proposed Pesticide Container Standards with DOT Equivalents		
Nonrefillables: Container integrity/compatibility	165.102(b)	173.24(b) 173.24(e)
Nonrefillables: Marking - container material	165.102(c)(2)	178.3(a) 178.503(a)
Nonrefillables: Dispensing - reclose securely	165.102(d)(3)	173.24(f)
Nonrefillables: Certification[1]	165.111	178.2(a)(2)
Nonrefillables: Recordkeeping[1]	165.114	178.601(l)
Refillables: Marking other than serial number and EPA statement	165.124(b)	178.3(a) 178.503(a) 178.703
Refillables: Minibulk container integrity	165.124(c)	173.24(b) 173.24(e) 178.704
Refillables: Drop test for minibulk containers	165.124(d)	178.603 178.803 178.810
Refillables: Drop test methodology	165.125	178.602 178.603
Refillables: Certification[1]	165.126	178.2(a)(2)
Refillables: Recordkeeping[1]	165.128	178.601(l) 178.801(l)
Refillables: Inspection prior to refill	165.134(e)	173.28 180.352
Refillables: Age of plastic liquid minibulk	165.134(f)	no time limit
Proposed Pesticide Container Standards without DOT Equivalents		
Nonrefillables: Marking - EPA registration no.	165.102(c)(1)	none
Nonrefillables: Dispensing - minimize glugging	165.102(d)(1)	none
Nonrefillables: Dispensing - no dripping	165.102(d)(2)	none
Nonrefillables: Standardized closures	165.102(e)	none
Nonrefillables: Residue removal standard	165.104	none
Refillables: Marking - serial number and EPA statement	165.124(b)	none
Refillables: Apertures	165.125(e)	none
Refillables: Bulk container standards	165.124(f)	none

[1] The DOT HMR include provisions for certification and recordkeeping for the standards in the HMR. However, EPA may choose to retain the proposed certification and recordkeeping requirements for the pesticide-specific requirements.

The proposed ''procedural'' requirements for registrants and refillers in proposed 40 CFR 165.130, 165.132, 165.134, and 165.136 are not included in the table because they are not container design or marking requirements. These four sections would establish requirements for registrants to develop and provide certain documents to refillers, for refillers to obtain these documents and follow specified container handling procedures, and for both registrants and refillers to maintain records. Under the approach being considered for the final rule, EPA would generally retain these procedural standards in the final rule. However, some of the requirements, such as the registrants providing refillers a list of acceptable containers which would be identified by the container manufacturer and model number, may need to be modified to mesh with the revisions.

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

In the HMR, the size of packages that are eligible for limited quantity exceptions varies according to the

hazard class (e.g., Class 8), hazard division (e.g., Division 6.1), and, in some cases, the packing group of the material. The DOT limited quantity exceptions generally provide regulatory relief from the HMR, although they do add some requirements. First, the exceptions only apply to combination packaging (e.g., four plastic jugs in a cardboard box). Second, the packaging must comply with the general packaging standards in 49 CFR 173.24. Third, the package cannot exceed 30 kilograms (66 pounds) gross weight.

Pesticides already regulated under DOT's hazardous materials regulations as Packing Group I, II or III materials shall be subject, under EPA's FIFRA regulations, to the same limited quantity exception to which they are subject under DOT's regulations. For pesticides not already regulated under DOT's regulations, EPA is considering incorporating the relevant parts of the limited quantity exception in 49 CFR 173.155 for Class 9 hazardous materials (miscellaneous hazardous materials) into the final pesticide container rule. Based on amendments made by DOT in 1996, the package sizes eligible for the Class 9 limited quantity exceptions are those that are less than 5.0 liters (1.3 gallons) for liquids and less than 5.0 kilograms (11 pounds) for solids. The purposes of incorporating a DOT limited quantity exception are to maintain consistency with the HMR and to provide regulatory relief for relatively small quantities of pesticides.

EPA is considering using the Class 9 limited quantity exception for pesticides not previously covered by DOT regulations for several reasons. First, Class 9 includes miscellaneous hazardous materials, which are defined in 49 CFR 173.140 to be materials that pose a hazard during transportation but don't meet the definition of any other hazard class. Pesticides that have not previously been covered by DOT's hazardous materials regulations (i.e., that are not classified as DOT hazardous materials) logically fit into such a grouping. Second, DOT has generally placed hazardous materials that are defined as DOT hazardous materials as a result of EPA regulation (e.g. hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act and hazardous wastes under RCRA) into Class 9. Therefore, EPA would be following DOT precedent by regulating these pesticides consistently with many other Class 9 hazardous materials.

Under the regulatory approach being considered, EPA would be applying only the DOT packaging and marking standards to pesticide containers -- not the DOT labeling, placarding, and shipping paper requirements. Therefore, only the ''relevant parts'' of the limited quantity exception would need to be incorporated -- not the provisions that relate to DOT labeling, placarding, and shipping paper standards. Also, EPA believes it is unnecessary to incorporate the consumer commodity exception (as opposed to the limited quantity exception) because the only additional relief provided by a consumer commodity exception is from the shipping paper requirements.

4. *EPA modification*. The regulatory text under consideration (in Unit VII of this document) includes a provision that would allow EPA to modify or waive the requirements of the regulatory section that refers to and adopts the DOT requirements if a person provides an application for exemption to the Director of the Office Pesticide Programs that contains data showing that the alternative, i.e., the partial or modified, set of standards achieves a level of safety that is at least equal to that specified in the requirements of this section. This provision is included to provide flexibility in cases where, for some reason, a container could not meet all of the DOT packing group III standards, but would still function safely and adequately during the use, handling, cleaning, and disposal of the pesticide container.

The DOT standards provide the regulated industry with a similar opportunity to obtain administrative relief from the Hazardous Materials Regulations through an exemption process described in 49 CFR part 107. DOT receives applications for exemptions and grants exceptions if the situations meet the criterion of equivalent levels of safety or levels of safety consistent with the public interest and the policy of the Hazardous Materials Transportation Act. For example, in a **Federal Register** notice (Ref. 9), DOT announced the actions taken on exemptions from July 1997 through December 1997, which included granting 32 modification exemptions, 48 new exemptions and 39 emergency exemptions, denying seven exemption applications, and having seven exemption applications withdrawn.

It is essential for EPA to incorporate a modification process into its regulations to prevent EPA regulations from being less flexible than the DOT requirements, which would happen if DOT granted an exemption for a pesticide and EPA did not have a mechanism to provide the same relief. EPA anticipates that the modification process would be used predominantly to maintain consistency with exemptions granted by DOT that affect pesticides, although EPA would maintain its authority to deny an exemption, even where DOT has granted an exemption, if EPA could not find that an exemption was appropriate under FIFRA and its regulations. On the other hand, EPA could choose to implement the modification provision for technical reasons, if a registrant can show that the modified or more limited set of standards achieves a level of safety that is at least equal to the full set of incorporated DOT requirements.

EPA believes the draft modification provision is sufficient because of the interaction between the Agency and pesticide registrants, despite the fact it is significantly less detailed than the DOT exemption process. However, EPA is considering the option of adopting a more detailed exclusion process in the final rule if the Agency concludes that a general provision would not be adequate, based on comments or information received during the comment period.

5. *Providing notice to the public*. The regulatory text under consideration (in Unit VII of this document) also includes a provision that says EPA will provide notice to the public in the **Federal Register** if DOT proposes to change any of the regulations that are incorporated in EPA's pesticide container regulations. The intent of this provision is to ensure that the pesticide-related regulated community is notified of regulatory modifications being considered by DOT, since the pesticide industry may not regularly monitor DOT's regulatory activity.

6. *Alternative approach*. Under the regulatory approach being considered for the final rule, EPA would refer to and adopt the full HMR for pesticides that are classified as DOT hazardous materials. Specifically, § 165.102(b)(1) of the potential alternative regulatory language includes the following statement: ''Pesticide products that meet the definition of a hazardous material in 49 CFR 171.8 shall be packaged as required by 49 CFR parts 171-180.'' EPA believes this approach is advantageous because EPA could enforce the DOT standards for pesticides that are DOT hazardous materials.

However, EPA is considering not explicitly stating in its regulations that pesticides that are DOT hazardous materials must comply with the DOT HMR. EPA requests comments on whether the Agency should simply include a reference to the DOT HMR, such as ''Pesticide products that meet the definition of a hazardous material in 49 CFR 171.8 are subject to the

requirements of 49 CFR parts 171–180.'' Another alternative would be to cite only the portions of the HMR that pesticides that are not classified as DOT hazardous materials would have to comply with.

Under the regulatory approach being considered for the final rule, pesticides that are not classified as DOT hazardous materials would be required to be packaged in accordance with the specified packaging design, construction, and marking standards that would apply to a DOT packing group III material. EPA believes this approach would be the most straightforward in terms of compliance by the regulated industry and enforcement by the appropriate governmental agencies. The pesticide registrants and enforcement officials could rely on the marking indicating compliance with the packing group III standards.

EPA considered but rejected an alternative approach specifying that pesticides that are not classified as DOT hazardous materials would be required to be packaged in containers that are capable of meeting the specified packaging design, construction, and some of the marking standards that would apply to a DOT packing group III material. Under this approach, the containers would not actually have to be marked to indicate compliance with the PG III standards. This would eliminate the need to comply with some of the continued maintenance and production testing. However, to make this approach work logistically, EPA would have to specify some recordkeeping so the Agency could determine that the containers were capable of meeting the PG III standards and require some marking, such as ''Meets EPA standards for refillable containers'' to provide an indicator of compliance to enforcement officials. Standards similar to these two provisions were included in the proposal and were strongly criticized by commenters, who opposed standards that would create a different framework and set of packaging standards for accomplishing the same goals as the existing DOT standards.

D. Request for Comments

EPA requests comments on the regulatory approach discussed above for revising the pesticide container regulations to refer to and adopt the DOT HMR packaging and marking standards. In addition to general comments, EPA solicits comments on the following questions and issues:

(1) Is it clear which portions of the DOT HMR would be referred to and adopted?

(2) Does the sample regulatory text in Unit VII of this document accomplish EPA's intent?

(3) Is the approach of incorporating the Class 9 limited quantity exception appropriate?

(4) The regulatory option under consideration would expand the number of tests containers are required to meet. Under the original 1994 proposal, nonrefillable containers weren't subject to any of the DOT performance tests and minibulks were subject to a drop test only. Despite the large increase in potentially applicable testing requirements, EPA believes referring to and adopting the DOT HMR PG III standards would not greatly increase the economic burden of the regulations because: (i) Many pesticide products, including an estimated one-third of all agricultural products, are classified as DOT hazardous materials (Ref. 8); (ii) many other pesticides are packaged in containers that meet the DOT PG III standards, even though it isn't required; and (iii) the container and pesticide manufacturing industries are familiar with the DOT regulations. Is EPA's assessment that there would only be a relatively minor cost increase attributed to the regulatory approach being considered accurate? EPA also requests specific information about the potential economic impacts of referring to and adopting the DOT PG III standards, such as the costs of conducting the leakproofness, hydrostatic pressure, stacking, and drop testing.

(5) In general, the proposed regulations would apply to all types of packaging, including but not limited to rigid (plastic and steel) containers, paper and plastic bags, and water-soluble packaging, although specific requirements would apply to appropriate subsets of these container types. Under the regulatory approach discussed in this document, EPA would require all types of pesticide containers to meet the DOT PG III standards. EPA believes that it may be easier for some kinds of packaging, e.g., rigid plastic or steel containers, to comply with the DOT PG III standards than for other types of containers, e.g., bags or water-soluble film. EPA requests comments about whether the ease of complying with the DOT PG III standards varies according to the container type and whether certain kinds of packaging may be disproportionately impacted.

(6) Is the provision that would allow EPA to modify or waive the requirements referring to and adopting the DOT requirements sufficient or should EPA include a more detailed exemption provision?

(7) Should EPA adopt any of the alternative approaches discussed in Unit V.C.6 of this document instead of the preferred approach discussed in Units V.B and V.C.1 - V.C.5 of this document?

VI. Proposed Definition of Small Business Used in Impact Analysis

As discussed in Unit II.A. of this document, section 601(3) of the RFA establishes as the default definition of small business the SBA size standards, which are primarily intended to define whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101). Section 601(3) of the RFA also allows an agency to establish an alternate definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment.

In the regulatory impact analyses (RIA) and the initial regulatory flexibility analyses for the 1994 proposed rule (Ref. 10 and 11), EPA used alternate definitions of small business for identifying the potentially affected small entities. The alternate definitions were presented in these analyses, but EPA did not specifically solicit comment on these alternate definitions in conjunction with the 1994 proposed rule. EPA is, therefore, specifically seeking comment on the establishment of these alternate definitions for use in identifying small pesticide formulators, small agrichemical dealers, and small independent custom (aerial and ground) applicators for analytical purposes related to this rulemaking. These alternate definitions are only used for analytical purposes and do not in any way affect the scope or any other provision of the proposed rule.

The following discussion provides additional information about the alternate definitions that EPA used in the regulatory flexibility analysis for the 1994 proposed rule.

A. Overview of the Alternate Definitions for Use in the Analysis

As described in Unit I.A. of this document, the three major industry sectors that would be affected by the pesticide container and containment rule are pesticide formulators, agrichemical dealers, and independent custom (aerial and ground) applicators. The SBA, at 13 CFR part 121, defines a small business as having:

- 500 or fewer employees for pesticide formulators (SIC 2879)
- 100 or fewer employees for agrichemical dealers (SIC 5191)

• Maximum revenues of $5.0 million for independent applicators (SIC 0721)

In analyzing the potential impacts of the 1994 proposed rule, EPA determined that it was appropriate to use alternate definitions to assess the potential impacts on small pesticide formulators, small agrichemical dealers, and small independent custom (aerial and ground) applicators. EPA's alternative definitions of small businesses for pesticide formulators, agrichemical dealers, and independent commercial pesticide applicators are given in the following table 7. SBA's definitions are also provided in the table for the purposes of comparison.

TABLE 7.—COMPARISON OF THE DEFINITIONS OF SMALL BUSINESSES TO USE IN ANALYZING IMPACTS

Industry Sector	Definition of Small Business	
	SBA definition (13 CFR part 121)	Proposed EPA definition
Pesticide formulators.	500 or fewer employees.	1 to 19 employees
Agrichemical dealers.	100 or fewer employees.	1 to 9 employees
Independent commercial applicators[1].	Maximum revenues of $5.0 million.	One plane and $93,750 in sales

[1] Profiles of small, medium, and large facilities were developed for aerial applicators but not for ground applicators, because not enough information was available to profile ground applicators.

B. Discussion

After careful consideration of the SBA small business definitions for the three industry sectors, EPA determined that it was appropriate to use alternate definitions of small business. As indicated previously, the SBA size standards are primarily intended to define whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101), with the objective ''to ensure that a concern that meets a specific size standard is not dominant in its field of operation.'' (13 CFR 121.102(b)). See section 632(a)(1) of the Small Business Act. Under SBA's definitions, all agrichemical dealers, all independent commercial applicators, and *nearly all* pesticide formulators would be considered small businesses. When assessing the potential impacts on small entities, however, EPA believes that it is important to ensure that the definition of small business is not as broad. EPA is concerned that using an overly broad definition of small business in the analysis may cause potentially significant economic impacts on smaller facilities to be camouflaged when combined with information about potential impacts on those facilities that meet the SBA size standard for small business, but which are not typical of a small business in that industrial sector. For example, a small pesticide formulator with 1 to 19 employees is going to have significantly different sales and profits than a formulating facility with over 100 employees. To account for such differences, facilities in the pesticide formulating, agrichemical dealer, and independent applicator industries were profiled as small, medium or large, as summarized in the following table 8.

TABLE 8.— PROFILE OF SMALL, MEDIUM, AND LARGE BUSINESS CATEGORIES USED IN THE IMPACT ANALYSIS

Industry sector/size	Definition of category	Number of facilities	Percent of facilities
Pesticide formulators			
Small	1 to 19 employees	172	62
Medium	20 to 99 employees	81	29
Large	100 to 2,499 employees	24	9
Agrichemical dealers			
Small	1 to 9 employees	12,991	77
Medium	10 to 49 employees	3,623	22
Large	50 to 99 employees	181	1
Independent applicators[1]			
Small	1 plane and $93,750 in sales	780	39
Medium	2 to 4 planes and $375,000 in sales	1,120	56
Large	5 or more planes and $750,000 in sales	100	5

[1] Profiles of small, medium, and large facilities were developed for aerial applicators but not for ground applicators, because not enough information was available to profile ground applicators.

In considering the analysis of the 1994 proposed rule on pesticide formulators, the RIA defined a number of ''representative'' facilities, with different financial characteristics (e.g., sales, net profit before tax, and tax rate) and varying operating characteristics (number of employees, filling lines, and formulations). The RIA then evaluated the impacts of three different regulatory options on a small and medium-sized representative facility in each of the four different pesticide markets (agricultural, industrial, institutional, and household) and on four different kinds of large representative facilities in the agricultural market. For each regulatory option, the RIA also considered two different implementation scenarios for the nonrefilable residue removal standard. Based on the regulatory flexibility analysis prepared for the 1994 proposed rule, Table 9 provides a summary illustration of the representative facilities that might be significantly impacted under the different regulatory options and implementation scenarios presented in the 1994 proposed rule.

Table 9 below shows that, for the options/scenarios identified in the analysis with a potential for significant impacts, the small representative facilities are more likely to have these

impacts than the medium or large facilities. If EPA had evaluated the impact of the proposed regulations on only medium or large facilities (based on an ''average'' small business under SBA's definition), the potential impacts on these small companies might not have been identified as clearly in the analysis.

The initial regulatory flexibility analysis identified residue removal testing as the most critical variable affecting EPA's small formulators. The proposed regulations addressed this issue in several ways. First, the proposal made allowances for using residue removal test data from similar products and containers as documentation that another container/formulation combination meets the residue removal standard (i.e., implementation scenario 1). Second, the regulations include a provision for obtaining a waiver from the residue removal standard. The regulatory flexibility analysis also describes an alternative to increase the compliance period for residue removal testing, although this alternative was not included in the proposed rule.

TABLE 9.—REPRESENTATIVE FACILITIES THAT WOULD BE SIGNIFICANTLY IMPACTED BY THE PROPOSED PESTICIDE CONTAINER REGULATIONS[1]

Representative Facility by Market and Size	[2] Option 1		[2] Option 2		[2] Option 3	
	[3] Scenario 1	[3] Scenario 2	[3] Scenario 1	[3] Scenario 2	[3] Scenario 1	[3] Scenario 2
Small agricultural facility				x	x	x
Small industrial facility				x	x	x
Small institutional facility				x	x	x
Small household facility				x		x
Medium agricultural facility						x
Medium industrial facility				x	x	x
Medium institutional facility					x	x
Medium household facility						
Large agricultural facility 1						
Large agricultural facility 2						
Large agricultural facility 3				x		x
Large agricultural facility 4						

[1] In the analysis, a representative facility was determined to be significantly impacted if the ratio of its annualized cost of compliance (ARR) over its sales was greater than one percent and the ratio of its ARR over its profits before tax was greater than 20%.
[2] EPA considered three regulatory options. Option 1 included the least stringent standards, option 2 was the EPA proposed rule, and option 3 included the most stringent requirements.
[3] For each regulatory option, EPA considered two implementation scenarios for the nonrefillable residue removal requirement. Under scenario 1, 50% of container/formulation combinations would have to be tested to determine compliance with the residue removal standard. Under scenario 2, all container/formulation combinations would have to be tested.

This example of the economic impact analysis and regulatory flexibility analysis for pesticide formulators supports the use of EPA's alternative definitions for small businesses, by showing that EPA's alternative definitions:

- Are more reflective of the small facilities in the relevant industry sectors
- Provide a more meaningful analysis of the facilities likely to have the most significant economic impact
- Distinguish facilities that have the stronger technical expertise and larger revenue sources (and, therefore, can more easily comply with the regulations) from those that do not.

C. Consultation with the SBA Office of Advocacy

EPA recently contacted the SBA Office of Advocacy for the purpose of consulting on the use and establishment of the alternate definitions of small business for analytical purposes related to this rulemaking. (Ref. 12) After a discussion of the potential changes presented in this action, the regulatory flexibility analysis prepared for the 1994 proposed rule, and the alternate definitions EPA used in that analysis, the SBA suggested that EPA consider combining the small and medium categories for the purpose of analyzing the potential impacts on small entities. SBA indicated that it generally

recommends using a broader definition of small business to ensure a broader assessment of the potential impacts on small entities. Additional information is available in the public version of the official record described in Unit I.B.3 of this document.

D. Request for Comments

EPA solicits comments on the alternate definitions used in the impact analyses to identify small pesticide formulators, small agrichemical dealers, and small independent commercial applicators. EPA will consider SBA's recommendations, along with any public comments received, when preparing the final rule. Comments regarding the alternate definitions should be submitted to EPA according to the process established in Unit I.C. of this document.

VII. Potential Alternative Regulatory Text

If the changes discussed in this document are adopted, the potential alternative regulatory text in this section, or a variation of it, may be incorporated into the final rule. However, EPA may choose to retain the regulatory text from the original 1994 proposal or incorporate language implementing one of the alternative approaches discussed in this section.

EPA is considering the following two modifications to the regulatory text for the final rule for Subpart F ''Nonrefillable Container Standards: Container Design and Residue Removal.'' First, EPA is considering replacing the proposed regulatory text for 40 CFR 165.100 with the following.

§ 165.100 *Applicability and scope.*

(a) *Scope.* This subpart establishes design and construction standards and requirements for nonrefillable containers used for the sale or distribution of pesticide products. This subpart applies to pesticide registrants.

(b) *Manufacturing use products.* This subpart does not apply to containers that contain manufacturing use products, as defined in § 158.153(h) of this chapter.

(c) *Antimicrobial pesticide products.* (1) Except as provided in paragraph (c)(2) of this section, this subpart does not apply to containers that contain a pesticide product that meets all of the following criteria:

(i) The pesticide product meets the definition of ''antimicrobial pesticide'' in FIFRA section 2(mm).

(ii) The label of the pesticide product includes directions for use on sites in at least one of the following antimicrobial product use categories:

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

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

(C) Residential and public access premises.

(D) Medical premises and equipment.

(E) Materials preservatives.

(F) Industrial processes and water systems.

(G) Antifouling coatings.

(H) Wood preservatives.

(I) Swimming pools.

(iii) The pesticide product does not meet the criteria for hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(2) A pesticide product that meets the criteria in paragraphs (c)(1)(i) through (1)(iii) of this section is subject to the following requirements if the pesticide meets the criteria of Toxicity Category I as set out in § 156.10(h)(1) of this chapter:

(i) 40 CFR 165.102(b) regarding DOT standards for nonrefillable containers.

(ii) 40 CFR 165.102(c) regarding permanent marking for nonrefillable containers.

(iii) 40 CFR 165.102(d) regarding container dispensing for nonrefillable containers.

(iv) 40 CFR 165.111 regarding certification for nonrefillable containers.

(v) 40 CFR 165.114 regarding recordkeeping and inspections for nonrefillable containers.

(vi) 40 CFR 165.117 regarding compliance dates for nonrefillable containers.

(d) *General applicability.* Except for pesticide products that are excluded by paragraph (b) of this section or addressed by paragraph (c) of this section, a pesticide product distributed or sold in a nonrefillable container shall meet all of the standards of this subpart if at least one of the conditions in paragraphs (d)(1) through (4) of this section is met:

(1) The product meets the criteria of Toxicity Category I as set out in § 156.10(h)(1) of this chapter.

(2) The product meets the criteria of Toxicity Category II as set out in § 156.10(h)(1) of this chapter.

(3) The container size is equal to or larger than 5.0 liters (1.3 gallons) for liquid formulations or 5.0 kilograms (11.0 pounds) for solid formulations.

(4) The product label meets the standards in paragraphs (d)(4)(i) and (ii) of this section.

(i) The product label includes at least one of the following environmental hazard statements:

(A) This pesticide is toxic (or extremely toxic) to wildlife.

(B) This pesticide is toxic (or extremely toxic) to fish.

(C) This pesticide is toxic (or extremely toxic) to birds.

(D) This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

(E) This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

(F) Any environmental hazard statement pertaining to wildlife, fish, birds, or groundwater.

(ii) The product label permits outdoor use.

Second, EPA is considering deleting proposed §§ 165.102(a)(3) and 165.102(b) and incorporating the following regulatory text as § 165.102(b). Proposed §§ 165.102(a)(1) and 165.102(a)(2) would not be changed under the regulatory approaches being considered in this document. The proposed standard for container integrity in proposed § 165.102(b) could be deleted because there is an equivalent standard in the incorporated DOT standards.

§ 165.102(b) *DOT standards.* (1) Pesticide products that meet the definition of a hazardous material in 49 CFR 171.8 shall be packaged as required by 49 CFR parts 171–180. In addition, such pesticide products shall comply with the requirements of this subpart.

(2) Pesticide products that do not meet the definition of a hazardous material in 49 CFR 171.8 shall be packaged in containers that are designed, constructed, and marked to comply with the requirements of 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.203, 173.213, 173.240, 173.241, Part 178, and Part 180 as applicable to a Packing Group III material, liquid or solid, as appropriate. In addition, such pesticide products shall comply with the requirements of this subpart.

(3) Limited quantities of pesticide products that do not meet the definition of a hazardous material in 49 CFR 171.8 are excepted from the requirements set out in paragraph (b)(2) of this section when packaged in combination packagings according to this paragraph. Each package shall conform to the general requirements for packagings and packages in 49 CFR 173.24 and may not exceed 30 kilograms (66 pounds) gross weight. The following combination packagings are authorized:

(i) For liquids, inner packagings not over 5.0 liters (1.3 gallons) net capacity each, packed in strong outer packagings.

(ii) For solids, inner packagings not over 5.0 kilograms (11.0 pounds) net capacity each, packed in strong outer packagings.

(4) The Agency may modify or waive the requirements of this section if a person provides an application for exemption to the Director of the Office of Pesticide Programs that contains data showing that the alternative (partial or modified) set of standards achieves a level of safety that is at least equal to that specified in the requirements of this section.

(5) If the Department of Transportation proposes to change any of the regulations that are incorporated in paragraph (b)(1), (b)(2), or (b)(3) of this section, the Agency will provide notice to the public in the **Federal Register**.

EPA is considering the following two modifications to the regulatory text for the final rule for Subpart G ''Refillable Container Standards: Container Design and Residue Removal.'' First, EPA is considering replacing the proposed regulatory text for 40 CFR 165.120 with the following potential alternative regulatory text. [This language is very

similar to the above regulatory text for nonrefillable containers. The main differences are the lists of regulatory sections that eligible antimicrobial products in Toxicity Category I would have to comply with.]

§ 165.120 *Applicability and scope.*

(a) *Scope.* This subpart establishes design and construction standards and requirements for refillable containers used for the sale or distribution of pesticide products. This subpart also establishes the standards and requirements for repackaging pesticide products into refillable containers.

(b) Manufacturing use products. This subpart does not apply to containers that contain manufacturing use products, as defined in § 158.153(h) of this chapter.

(c) *Antimicrobial pesticide products.* (1) Except as provided in paragraphs (c)(2) and (3) of this section, this subpart does not apply to containers that contain a pesticide product that meets all of the following criteria:

(i) The pesticide product meets the definition of ''antimicrobial pesticide'' in FIFRA section 2(mm).

(ii) The label of the pesticide product includes directions for use on sites in at least one of the following antimicrobial product use categories:

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

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

(C) Residential and public access premises.

(D) Medical premises and equipment.

(E) Materials preservatives.

(F) Industrial processes and water systems.

(G) Antifouling coatings.

(H) Wood preservatives.

(I) Swimming pools.

(iii) The pesticide product does not meet the criteria for hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(2) A pesticide product that meets the criteria in paragraphs (c)(1)(i), (c)(1)(ii)(A) through (ii)(H), and (c)(1)(iii) of this section is subject to the following requirements if the pesticide meets the criteria of Toxicity Category I as set out in 40 CFR 156.10(h)(1):

(i) 40 CFR 165.124(a) regarding DOT standards for refillable containers.

(ii) 40 CFR 165.124(b) regarding permanent marking for refillable containers.

(iii) 40 CFR 165.124(e) regarding apertures for refillable containers.

(iv) 40 CFR 165.124(f) regarding standards for bulk refillable containers.

(v) 40 CFR 165.126 regarding certification for refillable containers.

(vi) 40 CFR 165.128 regarding recordkeeping and inspection for refillable containers.

(vii) 40 CFR 165.129 – 165.136 regarding procedural standards for registrants and refillers who repackage pesticide into refillable containers.

(viii) 40 CFR 165.139 regarding compliance date for refillable containers.

(3) A pesticide product that meets the criteria in paragraphs (c)(1)(i), (c)(1)(ii)(I), and (c)(1)(iii) of this section is subject to the following standards if the pesticide meets the criteria of Toxicity Category I as set out in § 156.10(h)(1) of this chapter:

(i) 40 CFR 165.124(a) regarding DOT standards for refillable containers;

(ii) 40 CFR 165.124(f) regarding standards for bulk refillable containers;

(iii) 40 CFR 165.126 regarding certification for refillable containers;

(iv) 40 CFR 165.128 regarding recordkeeping and inspection for refillable containers;

(v) 40 CFR 165.129 regarding the transfer of registered pesticide products into refillable containers;

(vi) 40 CFR 165.130 – 165.132 regarding procedural standards for registrants who repackage pesticide into refillable containers;

(vii) 40 CFR 165.134(a) – 165.134(h) regarding procedural standards for refillers who repackage pesticide into refillable containers;

(viii) 40 CFR 165.136(a) regarding recordkeeping for each pesticide product that is repackaged by a refiller; and

(ix) 40 CFR 165.139 regarding compliance date for refillable containers.

(d) *General applicability.* Except for pesticide products that are excluded by paragraph (b) of this section or addressed by paragraph (c) of this section, a pesticide product distributed or sold in a nonrefillable container shall meet all of the standards of this subpart if at least one of the conditions in paragraphs (d)(1) through (4) below is met:

(1) The product meets the criteria of Toxicity Category I as set out in § 156.10(h)(1) of this chapter.

(2) The product meets the criteria of Toxicity Category II as set out in § 156.10(h)(1) of this chapter.

(3) The container size is equal to or larger than 5.0 liters (1.3 gallons) for liquid formulations or 5.0 kilograms (11.0 pounds) for solid formulations.

(4) The product label meets the standards in paragraphs (d)(4)(i) and (ii) of this section:

(i) The product label includes at least one of the following environmental hazard statements:

(A) This pesticide is toxic (or extremely toxic) to wildlife.

(B) This pesticide is toxic (or extremely toxic) to fish.

(C) This pesticide is toxic (or extremely toxic) to birds.

(D) This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

(E) This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

(F) Any environmental hazard statement pertaining to wildlife, fish, birds, or groundwater.

(ii) The product label permits outdoor use.

Second, EPA is considering deleting proposed §§ 165.124(a)(3) and 165.124(c) and incorporating the following regulatory text as § 165.124(c). Proposed §§ 165.124(a)(1) and 165.124(a)(2) would not be changed under the regulatory approaches being considered in this document. The proposed standard for minibulk container integrity in proposed § 165.124(c) could be deleted because there is an equivalent standard in the incorporated DOT standards.

§ 165.124(c) *DOT standards.* (1) Pesticide products that meet the definition of a hazardous material in 49 CFR 171.8 shall be packaged as required by 49 CFR parts 171–180. In addition, such pesticide products shall comply with the requirements of this subpart.

(2) Pesticide products that do not meet the definition of a hazardous material in 49 CFR 171.8 shall be packaged in containers that are designed, constructed, and marked to comply with the requirements of 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.203, 173.213, 173.240, 173.241, Part 178, and Part 180 as applicable to a Packing Group III material, liquid or solid, as appropriate. In addition, such pesticide products shall comply with the requirements of this subpart.

(3) Limited quantities of pesticide products that do not meet the definition of a hazardous material in 49 CFR 171.8 are excepted from the requirements set out in paragraph (b)(2) of this section when packaged in combination packagings according to this paragraph. Each package shall conform to the general requirements for packagings and packages in 49 CFR 173.24 and may not exceed 30 kilograms (66 pounds) gross weight. The following combination packagings are authorized:

(i) For liquids, inner packagings not over 5.0 liters (1.3 gallons) net capacity each, packed in strong outer packagings.

(ii) For solids, inner packagings not over 5.0 kilograms (11.0 pounds) net capacity each, packed in strong outer packagings.

(4) The Agency may modify or waive the requirements of this section if a person provides an application for exemption to the Director of the Office of Pesticide Programs that contains data showing that the alternative (partial or modified) set of standards achieves a level of safety that is at least equal to that specified in the requirements of this section.

(5) If the Department of Transportation proposes to change any of the regulations that are incorporated in section (b)(1), (b)(2), or (b)(3) of this section, the Agency will provide notice to the public in the **Federal Register**.

VIII. Statutory Review Requirements

As required by FIFRA 25(a), this document was submitted to the U.S. Department of Agriculture (USDA) for review and comment. USDA elected not to comment officially on it. This document was submitted to the Committee on Agriculture of the U.S. House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the U.S. Senate. EPA did not receive comments on this document. The FIFRA Scientific Advisory Panel

(SAP) waived its review of this document.

IX. References

1. U.S. EPA, ''Proposed Rule: Standards for Pesticide Containers and Containment'' 59 FR 6712 (February 11, 1994).
2. U.S. EPA, ''Summary of Comments on the Proposed Rule on Standards for Pesticide Containers and Containment,'' (October 28, 1996).
3. U.S. EPA, ''Appendix of Antimicrobial Product Use Sites and Categories,'' (January 14, 1997).
4. Rogers, William H. ''Environmental Law: Hazardous Wastes and Substances,'' West Publishing, St. Paul, Minnesota, pp. 40–59, (1992).
5. U.S. EPA, ''Characterization of Antimicrobial Pesticides,'' (July 16, 1998).
6. U.S. EPA, ''Pesticide Industry Sales and Usage: 1994 and 1995 Market Estimates,'' number 733–R–002, (August 1997).
7. U.S. EPA, ''Pesticide Regulation (PR) Notice 96–8: Toxicologically Significant Levels of Pesticide Active Ingredients,'' (October 31, 1996).
8. U.S. EPA, ''Characterization of Pesticides as Department of Transportation Hazardous Materials,'' (July 15, 1998).
9. U.S. DOT, ''Notice of Actions on Exemption Applications,'' 63 FR 14990 (March 27, 1998).
10. U.S. EPA, ''Regulatory Impact Analysis: Proposed Container Design and Residue Removal Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act as Amended, 1988,'' (1993).
11. U.S. EPA, ''Regulatory Impact Analysis: Standards for Pesticide Containment Structures Under the Federal Insecticide, Fungicide, and Rodenticide Act as Amended, 1988,'' (1993).
12. U.S. EPA, ''Use of an Alternate Definition for 'Small Business' in the Small Entity Economic Impact Analysis Conducted for the 1994 Proposed Standards for Pesticide Container and Containment [RIN 2070–AB95],'' (1999).
13. U.S. EPA, ''Economic Analysis for the Potential Changes Discussed in the Supplemental **Federal Register** Notice,'' (July 28, 1998).
14. U.S. EPA, ''Supporting Statement for SF–83; Container Design and Residue Removal Regulations (40 CFR part 165),'' prepared for EPA by Mitchell Systems Corporation (1993).

X. Regulatory Assessment Requirements

The regulatory assessment requirements applicable to the original proposed rule are discussed in the preamble for that proposal. (See 59 FR 6774, February 11, 1994) The following discussion is intended to supplement that original discussion by describing the regulatory assessment requirements applicable to this action.

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), it has been determined that this action is not a ''significant regulatory action'' subject to review by the Office of Management and Budget (OMB). The Agency's estimated impacts of the proposed rule are contained in a document entitled ''Regulatory Impact Analysis: Proposed Container Design and Residue Removal Regulations under the Federal Insecticide, Fungicide, and Rodenticide Act as Amended, 1988'' (Ref. 10) The Agency's estimates with regard to the potential changes discussed in this document are contained in a document entitled ''Economic Analysis for the Potential Changes Discussed in the Supplemental **Federal Register** Notice'' (Ref. 13). Both of these documents are available as a part of the public version of the official record for this rulemaking (see Unit I.B.3 of this document). The impacts related to the potential changes discussed in this document are briefly summarized here.

1. *Summary of potential economic impacts.* EPA estimates that the potential changes presented in this document would decrease the overall estimated cost of the rule by 13 to 27%.

As set out in the Regulatory Impact Analysis (RIA) of the 1994 proposed rule (Ref. 10), the annualized cost of the proposed rule was estimated to be between $38.7 million and $49.9 million, which would be split between the pesticide formulating industry (about $20 million to $27.2 million), the pesticide refilling industry ($11.2 million), independent (for-hire) pesticide applicators ($1.6 million) and pesticide end users ($6 million to nearly $10 million).

The potential regulatory changes discussed in this document would primarily affect the pesticide formulating industry. The proposed regulations that would apply to the pesticide refilling industry (i.e., mainly the ''procedural'' container-related standards and the containment regulations), independent pesticide applicators (the containment standards), and pesticide end users (the label requirements) would not be modified significantly by the changes discussed in this document.

EPA estimates that the potential changes discussed in this document would decrease the overall cost of the rule by 13 to 27%. The regulatory options discussed in Units III and IV of this document would lower the costs by decreasing the number of pesticide products and containers that would be subject to the pesticide container standards and by excluding certain antimicrobial products from the nonrefillable residue removal standard. (See Ref. 13 for a more detailed discussion of the economic analysis.)

2. *Antimicrobial exemption.* EPA estimates that about 25% of the 20,000 currently registered pesticide products are eligible antimicrobial pesticides. As discussed in Unit IV.C.3 of this document, an estimated 70% of eligible antimicrobial pesticides are classified in Toxicity Category I and, therefore, would be subjected to the container standards. Also, the nonrefillable residue removal standard accounts for about 50% of the annualized cost for the pesticide formulating industry, as estimated in the economic analysis of the proposed rule.

If EPA implemented the exemption for certain antimicrobial products as discussed in this document, 30% of the eligible antimicrobial products would be exempt from the rule and the remaining products would not have to comply with the nonrefillable residue removal standard. In this scenario, the cost to the pesticide formulating industry for eligible antimicrobials to comply with the rule would be $1.8 million to $2.4 million (compared to a range of $5.0 million to $6.8 million for the same products to comply with the proposed rule).

3. *Modifications to the scope.* For the purpose of analyzing how many products, other than eligible antimicrobials, would be included by the scope modifications under consideration, EPA estimates that 50 to 90% of pesticides other than eligible antimicrobial pesticides would meet one of the scope criteria, as shown in the following table 10.

TABLE 10.—ANALYSIS OF THE SCOPE CRITERIA UNDER CONSIDERATION

Criterion	Percentage of products included in criterion (%)
Toxicity Category I	10 – 25
Toxicity Category II	15 – 20
Environmental Hazard Statement	10 – 20
Container Size	15 – 25
Total	**50 – 90**

According to this estimate, 10 to 50% of products other than eligible antimicrobials would be categorized as ''lower-risk'' and would be exempt from the container standards. If EPA implemented the modifications to the scope as discussed in this document, the cost to the formulating industry for products other than eligible antimicrobials to comply with the rule would be $7.5 million to $18.4 million

(compared to a range of $15.0 million to $20.4 million for the proposed rule).

4. *Combined cost decrease.* Therefore, the estimated annual cost to the pesticide formulating industry of the container standards (considering the antimicrobial exemption and the modifications to the scope) would be $9.3 million to $20.8 million. The following table 11 compares the costs of the container standards estimated for the proposed rule and the changes being considered in this document. EPA estimates that the changes considered in this document would lead to a $6.4 million to $10.6 million cost decrease compared to the proposed rule -- a 13 to 27% decrease.

TABLE 11.—COMPARISON OF COST ESTIMATES

Industry Segment	Annualized Cost (millions of $)		Percent Decrease (%)
	1994 Proposal (59 FR 6712)	Changes in this Document	
Pesticide formulating industry	19.9 – 27.2	9.3 – 20.8	31 – 53
Pesticide refilling industry	11.2	11.2	0
Independent (for-hire) pesticide applicators	1.6	1.6	0
Pesticide end users	6.0 – 9.9	6.0 – 9.9	0
Total	**38.7 – 49.9**	**28.1 – 43.5**	**13 –27**

5. *DOT packaging standards.* The third major regulatory change considered in this document would require all pesticide containers (that are subject to the container regulations) to comply with at least the DOT packing group III standards in addition to pesticide-specific requirements which were previously proposed. Unlike the other two issues that have already been discussed, the change to refer to and adopt the DOT PG III standards would increase the costs to the pesticide formulating industry.

However, EPA believes that the magnitude of the cost increase from referring to and adopting the DOT PG III standards will be relatively minor, particularly compared to the $6.4 million to $10.6 million decrease from the other changes. As discussed in Unit V.D of this document, despite the increase in potentially applicable testing requirements, EPA believes referring to and adopting the DOT standards would not greatly increase the economic burden of the regulations because: (i) Many pesticide products are classified as DOT hazardous materials; (ii) many other pesticides are voluntarily packaged in containers that meet the DOT standards; and (iii) the container and pesticide manufacturing industries are familiar with the DOT regulations.

6. *Request for comments.* EPA is interested in comments on its assessment of the potential impacts associated with the changes presented in this document. EPA is particularly interested in any information or data specific to the number of products and containers that would be excluded by these potential changes, and any information or data related to the costs or cost savings attributable to each of these potential changes.

B. Paperwork Reduction Act

This action does not contain any new information collection requirements that need additional approval or review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq (PRA). In conjunction with the proposed rule that was published in 1994, EPA prepared an Information Collection Request (ICR) document for the paperwork burden imposed by the proposed container and labeling standards (EPA ICR No. 1631.01) (Ref. 14). Although EPA specifically sought comment on the ICR document in the proposed rule, EPA is hereby seeking additional comment on the original estimated burden presented in that ICR document, specifically with regard to the anticipated decrease in the burden resulting from this action. The ICR document is available in the public version of the official record for the proposed rule (Ref. 14), and a copy may be obtained in person from the PIRIB as described in Unit I.B.3. of this document, by mail from Sandy Farmer, OP Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., SW.; Washington, DC 20460, by calling (202) 260–2740, or electronically by sending an e-mail message to ''farmer.sandy@epa.gov.'' An electronic copy of the ICR document has also been posted with this **Federal Register** notice on EPA's home page.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register** as part of the final rule, are maintained in a list at 40 CFR part 9. The information requirements contained in EPA's 1994 proposal, as potentially amended by the changes discussed in this document, are not effective until EPA issues a final rule and has obtained OMB approval for the information collection requirements contained in the final rule.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

EPA anticipates that the changes being considered in this document should decrease the estimated total annual reporting and recordkeeping burden of 573,425 hours by about 13 to 27%. This decrease results mainly from decreasing the number of products and containers subject to the regulations. Not requiring eligible antimicrobial products to comply with the nonrefillable residue removal standard should further decrease the original burden estimates. In addition, referring to and adopting the DOT standards as a minimum should streamline the reporting and recordkeeping process by allowing companies to use the processes and systems they currently have in place for complying with the DOT HMR. Many companies cited this as a significant reason for supporting the

DOT regulatory option. On the other hand, the potential additional step of EPA providing a separate notice in the **Federal Register** whenever DOT issued a **Federal Register** notice that proposes to change any of the incorporated DOT standards may increase the burden on EPA and industry. However, EPA believes that any such increase would be insignificant compared to the decreases described above.

Please note that OMB has not approved the ICR associated with the container and labeling provisions in the 1994 proposed rule. Instead, OMB provided comments about the proposed residue removal standard and the potential burden that the standard may have on registrants of products with active ingredients that have low toxicities or that are present at small concentrations. Specifically, OMB stated that ''EPA should consider less burdensome testing requirements to meet the objective that disposal of containers pose no unreasonable risk to health or the environment.'' As stated in Unit IV.C.3 of this document, EPA is considering changes to the residue removal standard in the context of preparing a final rule, but is not specifically addressing this issue in this document. However, EPA's preferred approach for implementing the FQPA antimicrobial provision -- excluding eligible antimicrobial products in Toxicity Category I from the nonrefillable residue removal standard and exempting all other eligible antimicrobial products from the entire rule -- would greatly decrease the potential burden that would be imposed by the final rule and would address OMB's comment.

EPA is specifically interested in your comments on EPA's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Send comments on the ICR to the EPA at the address provided in Unit I.C of this document. In addition, send a copy of your comments on the ICR to OMB at the following address: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Please remember to include the ICR number in any correspondence. The final rule will respond to comments that EPA receives on the information collection requirements.

C. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), EPA has determined that this regulatory action is not subject to the requirements of sections 202 and 205, because this action does not contain a ''Federal mandate'' that would result in expenditures of $100 million or more for State, local, or Tribal governments, in the aggregate, or for the private sector in any one year. This regulatory action would not impose an enforceable duty on any State, local or Tribal governments or on anyone in the private sector. In addition, this document contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, no action is needed under section 203 of the Unfunded Mandates Reform Act.

D. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing Intergovernmental Partnerships* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's document does not create an unfunded Federal mandate on State, local or tribal governments. This document does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this document.

E. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's document does not significantly or uniquely affect the communities of Indian tribal governments. This document does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this document.

F. Executive Order 12898

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities and has determined that this document will not adversely affect environmental justice.

G. Executive Order 13045

This document is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866 (see Unit X.A above), nor do the environmental health or safety risks addressed by this action have an affect on children.

H. Regulatory Flexibility Act

Pursuant to section 605(b) of the RFA, EPA hereby certifies that this action will not have a significant economic impact on a substantial number of small

entities. The RFA requires an agency to prepare a regulatory flexibility analysis for any rule for which the agency is required to issue a notice of proposed rulemaking under the Administrative Procedures Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This action does not impose any new requirements that would result in any adverse impacts on the potentially affected entities. Instead, the changes considered in this document would decrease the potential impacts of the 1994 proposed rule. EPA prepared an initial regulatory flexibility analysis for the 1994 proposed rule. Although EPA did not specifically certify under section 605(b) of the RFA, EPA stated that the regulatory flexibility analysis showed that there would not be significant impact on potentially affected small facilities and that there would not be a substantial number of small aerial applicators adversely impacted (see 59 FR 6712, at 6776). This action does not affect that conclusion and the potential changes would only decrease the estimated total impact presented in that analysis.

The initial regulatory flexibility analysis that EPA prepared as part of the 1994 proposed rule made the following conclusions. First, whether or not small formulating facilities would be significantly impacted depended on how many container/formulation combinations would need to be tested to confirm compliance with the proposed residue removal standard. Second, representative refillers/refilling establishments would not be adversely affected by compliance with the 1994 proposed regulations. Third, some small for-hire applicators, primarily aerial application businesses, could be adversely affected by the proposed containment requirements.

The potential changes discussed in this document would not affect pesticide refillers and for-hire applicators significantly, so the relevant conclusions presented in the initial regulatory flexibility analysis that EPA prepared as part of the 1994 proposed rule would not change. The rest of this discussion focuses on EPA's assessment of the potential impact of the changes considered in this document on small formulating facilities, including the nonrefillable residue removal standard.

EPA anticipates that the changes being considered in this document would decrease the costs for small formulators. As discussed previously, EPA estimates that the changes in this document would lead to a 13 to 27% lower cost than the cost of the proposed rule. EPA believes that all formulators would experience similar cost decreases, since formulators in each of the size categories -- small, medium, and large -- would have products exempt from the container regulations by either the antimicrobial exemption or the scope criteria.

In addition, EPA believes that the antimicrobial exemption would make it unlikely that small formulating facilities in the household, industrial, and institutional pesticide markets would be significantly impacted. The crucial factor determining the significance of the impact on these facilities was the implementation of the residue removal standard. Under the approach being considered, antimicrobial products that would be subject to the container standards (eligible antimicrobial pesticides in Toxicity Category I) would not have to comply with the nonrefillable residue removal standard. While small household, institutional, and industrial formulators produce pesticides other than antimicrobials, exempting antimicrobial products from the nonrefillable residue removal standard should greatly decrease the potential economic impact on these facilities. Also, it is worth noting that changes to the residue removal standard are being considered separately from this document.

As discussed previously, the change to refer to and adopt the DOT PG III standards would increase the costs to the pesticide formulating industry. However, EPA believes that the magnitude of the cost increase from referring to and adopting the DOT PG III standards will be relatively minor, particularly compared to the significant cost decrease due to the other changes being considered. EPA therefore certifies that the regulatory changes considered in this notice will not have a significant economic impact on a substantial number of small entities.

As discussed in Unit VI. of this document, EPA believes it is appropriate to use alternate definitions of small business for the sole purpose of assessing the potential impacts of the proposed rule on the potentially impacted small businesses. With this document, EPA is providing the public with an opportunity to comment on these definitions and has consulted with the SBA Office of Advocacy as required by section 601(3). Seeking comment on the use of the alternate definitions does not impact EPA's ability to certify that this action, which is likely to decrease the potential burden of the 1994 proposed rule, will not result in a significant impact on a substantial number of small entities. Comments regarding the potential impacts of these changes, including any comments on the definitions, should be submitted to EPA according to the process established in Unit I.C. of this document.

I. National Technology Transfer and Advancement Act

This document does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Section 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. EPA invites public comment on this conclusion.

J. Federalism Review

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132 (64 FR 43255, August 10, 1999), which will go into effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685, October 30, 1987) on federalism still applies. Under this order, this rule will not have a substantial direct effect upon States, upon the relationship between the national government and the States, or upon the distribution of power and responsibilities among the various levels of government. This rule does not apply to States; it applies to pesticide registrants, manufacturers and agricultural chemical dealers.

List of Subjects in 40 CFR Part 165

Environmental protection, Antimicrobial pesticides, Packaging and containers, Pesticides and pests.

Dated: October 12, 1999.

Carol M. Browner,

Administrator.

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