CHAPTER
673
PUBLIC LAW

#### STATE OF MAINE

4

#### IN THE YEAR OF OUR LORD

#### TWO THOUSAND TWENTY-TWO

#### H.P. 1501 - L.D. 2019

# An Act To Require the Registration of Adjuvants in the State and To Regulate the Distribution of Pesticides with Perfluoroalkyl and Polyfluoroalkyl Substances

Be it enacted by the People of the State of Maine as follows:

- Sec. 1. 7 MRSA §604, sub-§22-A is enacted to read:
- <u>22-A. Perfluoroalkyl and polyfluoroalkyl substances or PFAS.</u> "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" has the same meaning as in Title 32, section 1732, subsection 5-A.
- Sec. 2. 7 MRSA §604, sub-§25, as amended by PL 2005, c. 620, §3, is repealed and the following enacted in its place:
  - **25. Pesticide.** "Pesticide" means:
  - A. Any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pests;
  - B. Any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant; and
- <u>C.</u> Any substance or mixture of substances intended to be used as a spray adjuvant. "Pesticide" includes a highly toxic pesticide.
  - Sec. 3. 7 MRSA §604, sub-§31-A is enacted to read:
- 31-A. Spray adjuvant. "Spray adjuvant" means any wetting agent, spreading agent, sticker, deposit builder, adhesive, emulsifying agent, deflocculating agent, water modifier or similar agent that is intended to be used with any other pesticide as an aid to the application or the effect of it and that is in a package or container separate from that of the other pesticide.
- **Sec. 4. 7 MRSA §606, sub-§1,** as amended by PL 2021, c. 105, §§1 to 3, is further amended to read:
- **1.** Unlawful distribution. A person may not distribute in the State any of the following:

- A. A pesticide that has not been registered pursuant to the provisions of this subchapter;
- B. A pesticide if any of the claims made for it or any of the directions for its use or other labeling differs from the representations made in connection with its registration, or if the composition of a pesticide differs from its composition as represented in connection with its registration; a change in the labeling or formulation of a pesticide may be made within a registration period without requiring reregistration of the product if the registration is amended to reflect that change and if that change will not violate any provision of FIFRA or this subchapter;
- C. A pesticide unless it is in the registrant's or the manufacturer's unbroken immediate container and there is affixed to the container, and to the outside container or wrapper of the retail package, if there is one, through which the required information on the immediate container cannot be clearly read, a label bearing the information required in this subchapter and rules adopted under this subchapter;
- D. A pesticide that has not been colored or discolored pursuant to section 610, subsection 1, paragraph D;
- E. A pesticide that is adulterated or misbranded or any device that is misbranded;
- F. A pesticide in containers that are unsafe due to damage; or
- G. Beginning January 1, 2022, a pesticide containing chlorpyrifos as an active ingredient-:
- H. A pesticide that has been contaminated by perfluoroalkyl and polyfluoroalkyl substances; or
- I. Beginning January 1, 2030, a pesticide that contains intentionally added PFAS that may not be sold or distributed pursuant to Title 38, section 1614, subsection 5, paragraph D.
- Sec. 5. 7 MRSA §606, sub-§2, as amended by PL 2005, c. 620, §5, is further amended to read:
- 2. Unlawful alteration, misuse, divulging of formulas, transportation, disposal and noncompliance. A person may not:
  - A. Detach, alter, deface or destroy, wholly or in part, any label or labeling provided for in this subchapter or rules adopted under this subchapter;
  - A-1. Add any substance to or take any substance from a pesticide in a manner that may defeat the purpose of this subchapter or rules adopted under this subchapter;
  - B. Use or cause to be used any pesticide in a manner inconsistent with its labeling or with rules of the board, if those rules further restrict the uses provided on the labeling;
  - C. Use for that person's own advantage or reveal, other than to the board or proper officials or employees of the state or federal executive agencies, to the courts of this State or of the United States in response to a subpoena, to physicians, or in emergencies to pharmacists and other qualified persons for use in the preparation of antidotes, any information relative to formulas of products acquired by authority of section 607 or any information judged by the board to contain or relate to trade secrets or commercial

- or financial information obtained by authority of this subchapter and marked as privileged or confidential by the registrant;
- D. Handle, transport, store, display or distribute pesticides in such a manner as to endanger human beings or their environment or to endanger food, feed or any other products that may be transported, stored, displayed or distributed with such pesticides;
- E. Dispose of, discard or store any pesticides or pesticide containers in such a manner as may cause injury to humans, vegetation, crops, livestock, wildlife or beneficial insects or pollute any water supply or waterway;
- F. Refuse or otherwise fail to comply with the provisions of this subchapter, the rules adopted under this subchapter, or any lawful order of the board; or
- G. Apply pesticides in a manner inconsistent with rules for pesticide application adopted by the board-; or
- H. Use or cause to be used any pesticide container inconsistent with rules for pesticide containers adopted by the board.
- **Sec. 6. Board of Pesticides Control; rules.** The Department of Agriculture, Conservation and Forestry, Board of Pesticides Control shall adopt rules regulating pesticide containers as authorized in the Maine Revised Statutes, Title 7, section 606, subsection 2, paragraph H no later than January 1, 2023. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.
- **Sec. 7. Appropriations and allocations.** The following appropriations and allocations are made.

# AGRICULTURE, CONSERVATION AND FORESTRY, DEPARTMENT OF Office of the Commissioner 0401

Initiative: Provides allocations for position technology and STA-CAP costs.

OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
All Other	\$0	\$11,502
OTHER SPECIAL REVENUE FUNDS TOTAL	\$0	\$11,502

#### Pesticides Control - Board of 0287

Initiative: Provides allocations for one Environmental Specialist III position, one part-time Environmental Specialist II position, one part-time Office Associate II position and associated All Other costs.

OTHER SPECIAL REVENUE FUNDS	2021-22	2022-23
POSITIONS - LEGISLATIVE COUNT	0.000	1.000
POSITIONS - FTE COUNT	0.000	1.000
Personal Services	\$0	\$168,311
All Other	\$0	\$10,500
OTHER SPECIAL REVENUE FUNDS TOTAL	\$0	\$178,811

# AGRICULTURE, CONSERVATION AND FORESTRY, DEPARTMENT OF DEPARTMENT TOTALS OTHER SPECIAL REVENUE FUNDS \$0 \$190,313 DEPARTMENT TOTAL - ALL FUNDS \$0 \$190,313

#### **Federal Pesticide Container Regulations**

On the June 17, 2022 Board meeting, Board members indicated that they would like a summary of all federal and state pesticide container laws. The pesticide container regulations establish standards for pesticide containers and repackaging as well as label instructions to ensure the safe use, reuse, disposal and adequate cleaning of the containers. Below are the specific regulations that discuss pesticide containers (49 CFR §165); however these regulations cite multiple 49 CFR sections, which will be provided in a separate document (49 CFR 107 – 180; Page 19 – 1007 Vol. 2; Page 1 – 383 Vol. 3) See the Board Meetings page for a link to these documents.

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# PART 165 - PESTICIDE MANAGEMENT AND DISPOSAL

Authority: 7 U.S.C. 136 through 136y.

Source: 71 FR 47422, Aug. 16, 2006, unless otherwise noted.

## **Subpart A - General**

#### § 165.1 Scope.

The part 165 regulations establish standards and requirements for pesticide containers, repackaging pesticides, and pesticide containment structures.

#### § 165.3 Definitions.

Terms used in this part have the same meaning as in the Act and <u>part 152 of this chapter</u>. In addition, as used in this part, the following terms shall have the meanings set forth below.

Act means the Federal Insecticide, Fungicide, and Rodenticide Act.

Agricultural pesticide means any pesticide product labeled for use in or on a farm, forest, nursery, or greenhouse.

Appurtenance means any equipment or device which is used for the purpose of transferring a pesticide from a stationary pesticide container or to any refillable container, including but not limited to, hoses, fittings, plumbing, valves, gauges, pumps and metering devices.

Capacity means, as applied to containers, the rated capacity of the container.

Container means any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding any application tanks) used to enclose a pesticide. Containers that are used to sell or distribute a pesticide product and that also function in applying the product (such as spray bottles, aerosol cans and containers that become part of a direct injection system) are considered to be containers for the purposes of this part.

Containment pad means any structure that is designed and constructed to intercept and contain pesticides, rinsates, and equipment wash water at a pesticide dispensing area.

Containment structure means either a secondary containment unit or a containment pad.

Custom blending means the service of mixing pesticides to a customer's specifications, usually a pesticide(s)-fertilizer(s), pesticide-pesticide, or a pesticide-animal feed mixture, when:

- (1) The blend is prepared to the order of the customer and is not held in inventory by the blender:
- (2) The blend is to be used on the customer's property (including leased or rented property);
- (3) The pesticide(s) used in the blend bears end-use labeling directions which do not prohibit use of the product in such a blend;
- (4) The blend is prepared from registered pesticides; and
- (5) The blend is delivered to the end-user along with a copy of the end-use labeling of each pesticide used in the blend and a statement specifying the composition of the mixture.

*Dilutable* means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use.

*Dry pesticide* means any pesticide that is in solid form and that has not been combined with liquids; this includes formulations such as dusts, wettable powders, dry flowables, water-soluble powders, granules, and dry baits.

*Establishment* means any site where a pesticidal product, active ingredient, or device is produced, regardless of whether such site is independently owned or operated, and regardless of whether such site is domestic and producing a pesticidal product for export only, or whether the site is foreign and producing any pesticidal product for import into the United States.

Facility means all buildings, equipment, structures, and other stationary items which are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person who controls, who is controlled by, or who is under common control with such person).

*Nonrefillable container* means a container that is not a refillable container and that is designed and constructed for one-time use and is not intended to be filled again with a pesticide for sale or distribution. Reconditioned containers are considered to be nonrefillable containers.

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

*Operator* means any person in control of, or having responsibility for, the daily operation of a facility at which a containment structure is located.

Owner means any person who owns a facility at which a containment structure is required.

Pesticide compatible as applied to containers means that the container construction materials will not chemically react with the formulation. A container is not compatible with the formulation if, for example, the formulation:

- (1) Is corrosive to the container;
- (2) Causes softening, premature aging, or embrittlement of the container;
- (3) Otherwise causes the container to weaken or to create the risk of discharge;
- (4) Reacts in a significant chemical, electrolytic, or galvanic manner with the container, or
- (5) Interacts in a way, such as the active ingredient permeating the container wall, that would cause the formulation to differ from its composition as described in the statement required in connection with its registration under FIFRA section 3.

Pesticide compatible as applied to containment means that the containment construction materials are able to withstand anticipated exposure to stored or transferred substances without losing the capability to provide the required containment of the same or other substances within the containment area.

*Pesticide dispensing area* means an area in which pesticide is transferred out of or into a container.

*Portable pesticide container* means a refillable container that is not a stationary pesticide container.

*Produce* means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to section 5 of the Act, and any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

*Producer* means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

*Refillable container* means a container that is intended to be filled with pesticide more than once for sale or distribution.

*Refiller* means a person who engages in the activity of repackaging pesticide product into refillable containers. This could include a registrant or a person operating under contract to a registrant.

*Refilling establishment* means an establishment where the activity of repackaging pesticide product into refillable containers occurs.

*Repackage* means, for the purposes of this part, to transfer a pesticide formulation from one container to another without a change in the composition of the formulation, the labeling content, or the product's EPA registration number, for sale or distribution.

*Rinsate* means the liquid resulting from the rinsing of the interior of any equipment or container that has come in direct contact with any pesticide.

Runoff means surface water leaving the target site.

Secondary containment unit means any structure, including rigid diking, that is designed and constructed to intercept and contain pesticide spills and leaks and to prevent runoff and leaching from stationary pesticide containers.

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

Suspension concentrate means a stable suspension of solid particulate active ingredients in a liquid intended for dilution with water before use.

*Tamper-evident device* means a device which can be visually inspected to determine if a container has been opened.

*Transport vehicle* means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

*Washwater* means the liquid resulting from the rinsing of the exterior of any equipment or containers that have or may have come in direct contact with any pesticide or system maintenance compound, such as oil or antifreeze.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64224</u>, Oct. 29, 2008]

## **§§ 165.4-165.19 [Reserved]**

# <u>Subpart B - Nonrefillable Container Standards: Container</u> Design and Residue Removal

#### § 165.20 General provisions.

- (a) What is the purpose of the regulations in this subpart? The regulations in this subpart establish design and construction requirements for nonrefillable containers used for the distribution or sale of some pesticide products.
- (b) *Do I have to comply with the regulations in this subpart?* You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in nonrefillable containers. If your pesticide product is subject to the regulations in this subpart as set out in § 165.23, your pesticide product must be distributed or sold in a nonrefillable container that meets the standards of these regulations.
- (c) When do I have to comply? Any pesticide product packaged in a nonrefillable container and released for shipment by you after August 16, 2009 must be packaged in a nonrefillable container that complies with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

## § 165.23 Scope of pesticide products included.

- (a) Are manufacturing use products subject to the regulations in this subpart? No, the regulations in this subpart do not apply to manufacturing use products, as defined in  $\S$  158.153(h) of this chapter.
- (b) *Are plant-incorporated protectants subject to the regulations in this subpart?* No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.
- (c) Which antimicrobial pesticide products are not subject to the regulations in this subpart? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:
  - (1) The pesticide product meets one of the following two criteria:
    - (i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or
    - (ii) The pesticide product:
      - (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems,

- surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and
- (B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.
- (2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.
- (3) The pesticide product is not a hazardous waste as set out in <u>part 261 of this chapter</u> when the pesticide product is intended to be disposed.
- (4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (d) of this section.
- (d) How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?
  - (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by <u>paragraph (c)</u> of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:
    - (i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.
    - (ii) The information, data or other evidence is reliable and factual.
    - (iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.
    - (iv) Complying with the container regulations could reasonably be expected to eliminate the problem.
  - (2) If EPA determines that an antimicrobial pesticide product otherwise exempted by <u>paragraph (c)</u> of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant

a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the nonrefillable container regulations within the time frames established by EPA in the rule or in its notification.

#### (e) What other pesticide products are subject to the regulations in this subpart?

- (1) Except for manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt under <u>paragraph (c)</u> of this section, all of the regulations in this subpart apply to a pesticide product if it satisfies at least one of the following criteria:
  - (i) The pesticide product meets the criteria of Toxicity Category I as set out in § 156.62 of this chapter.
  - (ii) The pesticide product meets the criteria of Toxicity Category II as set out in § 156.62 of this chapter.
  - (iii) The pesticide product is classified for restricted use as set out in §§ 152.160 152.175 of this chapter.
- (2) Except for manufacturing use products, plant-incorporated protectants, antimicrobial products that are exempt under (c) of this section, and other pesticide products that are regulated under paragraph (e)(1) of this section, a pesticide product must be packaged in compliance with 49 CFR 173.24. If the pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the Department of Transportation requires it to be packaged according to 49 CFR parts 171-180.
- (f) What does "pesticide product" or "pesticide" mean in the rest of this subpart? In §§ 165.25 through 165.27, the term "pesticide product" or "pesticide" refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (e) of this section.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

#### § 165.25 Nonrefillable container standards.

(a) What Department of Transportation (DOT) standards do my nonrefillable containers have to meet under this part if my pesticide product is not a DOT hazardous material? A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material, or, if subject to a

special permit, according to the applicable requirements of <u>49 CFR part 107 subpart B</u>. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

- (b) What DOT standards do my nonrefillable containers have to meet under this part if my pesticide product is a DOT hazardous material?
  - (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.
  - (2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.
- (c) What will EPA do if DOT proposes to change any of the cross-referenced regulations? If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the Federal Register. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.
- (d) What standards for closures do my nonrefillable containers have to meet? If your nonrefillable container is a rigid container with a capacity equal to or greater than 3.0 liters (0.79 gallons), if the container is not an aerosol container or a pressurized container, and if the container is used to distribute or sell a liquid agricultural pesticide, each nonrefillable container must have at least one of the following standard closures:
  - (1) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5 threads per inch, National Pipe Straight (NPS) standard.
  - (2) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 5 threads per inch, buttress threads.
  - (3) Screw cap, 63 millimeters, at least one thread revolution at 6 threads per inch.
  - (4) Screw cap, 38 millimeters, at least one thread revolution at 6 threads per inch. The cap may fit on a separate rigid spout or on a flexible pull-out plastic spout.
- (e) What standards for dispensing do my nonrefillable containers have to meet? If your nonrefillable container has a capacity of 5 gallons (18.9 liters) or less, if the container is not an

aerosol container, a pressurized container, or a spray bottle, and if the container holds a liquid pesticide, your nonrefillable container must do both of the following:

- (1) Allow the contents of the nonrefillable container to pour in a continuous, coherent stream.
- (2) Allow the contents of the nonrefillable container to be poured with a minimum amount of dripping down the outside of the container.
- (f) What standards for residue removal do my nonrefillable containers have to meet? Each nonrefillable container and pesticide formulation combination must meet the applicable residue removal standard of this section.
  - (1) If the nonrefillable container is rigid and has a capacity less than or equal to 5 gallons (18.9 liters) for liquid formulations or 50 pounds (22.7 kilograms) for solid formulations and if the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application (that is, if the pesticide is dilutable), each container/formulation combination must be capable of attaining at least 99.99 percent removal of each active ingredient when tested using the EPA test procedure "Rinsing Procedures for Dilutable Pesticide Products in Rigid Containers."
  - (2) The test must be conducted only if the pesticide product is a suspension concentrate or if EPA specifically requests the records on a case by case basis.
  - (3) For the rigid container/dilutable product standard in <u>paragraph (f)(1)</u> of this section, percent removal represents the percent of the original concentration of the active ingredient in the pesticide product when compared to the concentration of that active ingredient in the fourth rinse. Percent removal is calculated by the formula:

percent removal =  $[1.0 - RR] \times 100.0$ , where

RR = rinsate ratio = Active ingredient concentration in fourth rinsate/Original concentration of active ingredient in the product

- (g) Can I obtain a waiver from or a modification to any of the nonrefillable container standards? Yes, it is possible for you to obtain a waiver from or a modification to the nonrefillable container standards, as follows:
  - (1) EPA may waive or modify the requirements of <u>paragraph (a)</u> of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of <u>paragraph (a)</u> of this section.
  - (2) EPA may waive or modify the requirements of <u>paragraph (b)</u> of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves

- a level of safety that is at least equal to that specified in the requirements of <u>paragraph (b)</u> of this section. EPA will modify or waive the requirements of <u>paragraph (b)</u> of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.
- (3) EPA may approve a non-standard closure (that is, a closure not listed in <u>paragraph (d)</u> of this section) if EPA determines that both of the following conditions are satisfied:
  - (i) The non-standard closure is necessary for the proper mixing, loading, or application of the pesticide product.
  - (ii) The non-standard closure offers exposure protection to handlers during mixing and loading that is the same or greater than that provided by the standard closures.
- (4) EPA may waive or modify the container dispensing capability standards in <u>paragraph (e)</u> of this section if EPA determines that at least one of the following conditions is satisfied:
  - (i) The product is typically removed from the container by a method other than pouring.
  - (ii) Compliance with the container dispensing capability standards would increase exposure to the pesticide container handler.
- (5) EPA may waive or modify the requirements of <u>paragraph (f)</u> of this section regarding the residue removal standard if EPA determines that both of the following conditions are satisfied:
  - (i) The residue remaining in the container would not cause an unreasonable adverse effect on the environment; and
  - (ii) The product offers significant benefits and cannot be economically reformulated or repackaged.
- (h) *How do I obtain a waiver from or a modification to any of the nonrefillable container standards?* To obtain a waiver from or a modification to any of the nonrefillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a nonrefillable container that does not comply with all of the nonrefillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:
  - (1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.

- (2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.
- (3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.
- (4) A description of the nonrefillable container or containers for which the waiver or modification is requested.
- (5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in paragraph (g) of this section are satisfied.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64225</u>, Oct. 29, 2008]

#### § 165.27 Reporting and recordkeeping.

- (a) What information must I report about my nonrefillable containers? You are not required to report to EPA with information about your nonrefillable containers under the regulations in this subpart. You should refer to the reporting standards in part 159 of this chapter to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).
- (b) What recordkeeping do I have to do for my nonrefillable containers? For each pesticide product that is subject to §§ 165.25 through 165.27 and is distributed or sold in nonrefillable containers, you must maintain the records listed in this section for as long as a nonrefillable container is used to distribute or sell the pesticide product and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe. You must keep the following records:
  - (1) The name and EPA registration number of the pesticide product.
  - (2) A description of the nonrefillable container(s) in which the pesticide product is distributed or sold.
  - (3) At least one of the following records to document compliance with the requirement for closures in § 165.25(d) for each nonrefillable container used to distribute or sell the pesticide product that must comply with § 165.25(d):
    - (i) A letter or document from the container supplier that describes the closure.
    - (ii) A specification about the closure in the contract between the registrant or applicant and the container supplier.
    - (iii) A copy of EPA's approval of any non-standard closure.

- (4) At least one of the following records pertaining to the container dispensing capability requirements in § 165.25(e) for each nonrefillable container used to distribute or sell the pesticide product that must comply with § 165.25(e):
  - (i) Test data or documentation demonstrating that the nonrefillable container meets the standards in § 165.25(e) when it contains the pesticide product.
  - (ii) Test data or documentation demonstrating that a different nonrefillable container meets the standards in § 165.25(e) when it contains the pesticide product or even a different pesticide product and a written explanation of why such data or documentation demonstrates that the container meets the standards in § 165.25(e) for the pesticide product.
  - (iii) A copy of EPA's approval of a request for a waiver from the container dispensing requirement.
- (5) At least one of the following records pertaining to the nonrefillable container residue removal requirement in § 165.25(f) if the pesticide product is a suspension concentrate or if EPA specifically requests the records on a case-by-case basis:
  - (i) Test data showing that the nonrefillable container and pesticide formulation meet the standard in § 165.25(f).
  - (ii) Test data showing that a different nonrefillable container with the same or a different pesticide formulation meets the standard in § 165.25(f), together with a written explanation of why such data demonstrate that the nonrefillable container and pesticide formulation meet the standard in § 165.25(f).
  - (iii) A copy of EPA's approval of a request for a waiver from the residue removal standard requirement.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

#### §§ 165.28-165.39 [Reserved]

# <u>Subpart C - Refillable Container Standards: Container Design</u>

## § 165.40 General provisions.

- (a) What is the purpose of the regulations in this subpart? The regulations in this subpart establish design and construction requirements for refillable containers used for the distribution or sale of some pesticide products.
- (b) Do I have to comply with the regulations in this subpart?

- (1) You must comply with all of the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers. If your pesticide product is subject to the regulations in this subpart as set out in § 165.43, your pesticide product must be distributed or sold in a refillable container that meets the standards of these regulations. This includes your pesticide products that are repackaged according to subpart D of this part.
- (2) You must comply with the regulations in § 165.45(f) for stationary pesticide containers if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. If the pesticide product is subject to the regulations in this subpart as set out in § 165.43, the stationary pesticide containers used to distribute or sell the product must meet the standards of § 165.45(f).
- (3) If you are a refiller of a pesticide product and you are not a registrant of the pesticide product,  $\S 165.45(a)(2)$  provides an exemption from some of the requirements in  $\S 165.45(a)(1)$ .
- (c) When do I have to comply? Any pesticide product packaged in a refillable container and released for shipment by you after August 16, 2011 must be packaged in a refillable container that complies with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64226</u>, Oct. 29, 2008]

#### § 165.43 Scope of pesticide products included.

- (a) Are manufacturing use products subject to the regulations in this subpart? No, the regulations in this subpart do not apply to manufacturing use products, as defined in  $\S$  158.153(h) of this chapter.
- (b) *Are plant-incorporated protectants subject to the regulations in this subpart?* No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.
- (c) Which antimicrobial pesticide products are not subject to the regulations in this subpart? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:
  - (1) The pesticide product meets one of the following two criteria:
    - (i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or
    - (ii) The pesticide product:
      - (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems,

- surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and
- (B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.
- (2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.
- (3) The pesticide product is not a hazardous waste as set out in <u>part 261 of this chapter</u> when the pesticide product is intended to be disposed.
- (4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of <u>paragraph</u> (e) of this section.
- (d) Which requirements must an antimicrobial swimming pool product comply with if it is not exempt from these regulations? An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except § 165.45(d) regarding marking and § 165.45(e) regarding openings. For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:
  - (1) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.
  - (2) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.
- (e) How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?
  - (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by <u>paragraph (c)</u> of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:
    - (i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

- (ii) The information, data or other evidence is reliable and factual.
- (iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.
- (iv) Complying with the container regulations could reasonably be expected to eliminate the problem.
- (2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the refillable container regulations within the time frames established by EPA in the rule or in its notification.
- (f) What other pesticide products are subject to the regulations in this subpart? The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt by paragraph (c) of this section. Antimicrobial products covered under paragraph (d) of this section are subject to the regulations indicated in paragraph (d) of this section.
- (g) What does "pesticide product" or "pesticide" mean in the rest of this subpart? In §  $\underline{165.43}$ (h) through §  $\underline{165.47}$ , the term "pesticide product" or "pesticide" refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in  $\underline{paragraphs}$  (a) through (f) of this section.

#### (h) Are there any other exceptions?

- (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.
- (2) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64226, Oct. 29, 2008]

#### § 165.45 Refillable container standards.

- (a) What Department of Transportation (DOT) standards do my refillable containers have to meet under this part if my pesticide product is not a DOT hazardous material?
  - (1) A pesticide product that does not meet the definition of a hazardous material in <u>49 CFR 171.8</u> must be packaged in a refillable container that, if portable, is designed, constructed, and marked to comply with the requirements of <u>49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of <u>49 CFR part 107 subpart B</u>. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.</u>
  - (2) A refiller is not required to comply with 49 CFR 173.28(b)(2) for pesticide products that are not DOT hazardous materials if the refillable container to be reused complies with the refillable container regulations in this subpart and the refilling is done in compliance with the repackaging regulations in subpart D of this part.
- (b) What DOT standards do my refillable containers have to meet under this part if my pesticide product is a DOT hazardous material?
  - (1) If your pesticide product meets the definition of a hazardous material in <u>49 CFR 171.8</u>, the DOT requires your pesticide product to be packaged according to <u>49 CFR parts 171-180</u> or, if subject to a special permit, according to the applicable requirements of <u>49 CFR part 107 subpart B</u>.
  - (2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.
- (c) What will EPA do if DOT proposes to change any of the cross-referenced regulations? If the DOT proposes to change any of the regulations that are incorporated in <u>paragraphs (a)</u> and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the Federal Register. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.
- (d) What standards for marking do my refillable containers have to meet? Each refillable container must be marked in a durable and clearly visible manner with a serial number or other identifying code that will distinguish the individual container from all other containers. Durable marking includes, but is not limited to, etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, and marking with durable ink. The serial number or other identifying code must be located on the outside part of the container except on

a closure. Placement on the label or labeling is not sufficient unless the label is an integral, permanent part of or permanently stamped on the container.

- (e) What standards for openings do my refillable containers have to meet? If your refillable container is a portable pesticide container that is designed to hold liquid pesticide formulations and is not a cylinder that complies with the DOT Hazardous Materials Regulations in 49 CFR parts 171-180, each opening of the container other than a vent must have a one-way valve, a tamper-evident device or both. A one-way valve may be located in a device or system separate from the container if the device or system is the only reasonably foreseeable way to withdraw pesticide from the container. A vent must be designed to minimize the amount of material that could be introduced into the container through it.
- (f) What standards do my stationary pesticide containers have to meet? If a stationary pesticide container designed to hold undivided quantities of pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide is located at the refilling establishment of a refiller operating under written contract to you, the stationary pesticide container must meet the following standards:
  - (1) Except during a civil emergency or any unanticipated grave natural disaster or other natural phenomenon of an exceptional, inevitable and irresistible character, the effects of which could not have been prevented or avoided by the exercise of due care or foresight, each stationary pesticide container (for liquid and dry pesticides) and its appurtenances must meet both of the following standards:
    - (i) Each stationary pesticide container and its appurtenances must be resistant to extreme changes in temperature and constructed of materials that are adequately thick to not fail and that are resistant to corrosion, puncture, or cracking.
    - (ii) Each stationary pesticide container must be capable of withstanding all operating stresses, taking into account static heat, pressure buildup from pumps and compressors, and any other foreseeable mechanical stresses to which the container may be subjected in the course of operations.
  - (2) Each stationary container of liquid pesticides must meet all of the following standards:
    - (i) Each stationary container of liquid pesticides must be equipped with a vent or other device designed to relieve excess pressure, prevent losses by evaporation, and exclude precipitation.
    - (ii) External sight gauges, which are pesticide-containing hoses or tubes that run vertically along the exterior of the container from the top to the bottom, are prohibited on stationary containers of liquid pesticides.
    - (iii) Each connection on a stationary container of liquid pesticides that is below the normal liquid level must be equipped with a shutoff valve which is capable of being locked closed.

A shutoff valve must be located within a secondary containment unit if one is required by subpart E of this part.

- (g) Can I obtain a waiver from or a modification to any of the refillable container standards? Yes, it is possible for you to obtain a waiver from or a modification to some of the refillable container standards, as follows:
  - (1) EPA may waive or modify the requirements of <u>paragraph (a)</u> of this section regarding the DOT standards for pesticide products that are not DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of paragraph (a) of this section.
  - (2) EPA may waive or modify the requirements of <u>paragraph (b)</u> of this section regarding the DOT standards for pesticide products that are DOT hazardous materials if EPA determines that an alternative (partial or modified) set of standards or pre-existing requirements achieves a level of safety that is at least equal to that specified in the requirements of <u>paragraph (b)</u> of this section only after consulting with DOT to ensure consistency with DOT regulations and exemptions.
- (h) *How do I obtain a waiver from or a modification to any of the refillable container standards?* To obtain a waiver from or a modification to any of the refillable container standards, you must submit a written request for a waiver or a modification to the EPA to the following address: Office of Pesticide Programs (7504P); U.S. Environmental Protection Agency; Ariel Rios Building; 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. You cannot distribute or sell the pesticide product in a refillable container that does not comply with all of the refillable container standards unless and until EPA approves the request for the waiver or modification in writing. You must include two copies of the following information (which may be part of an application for registration or amended registration) with your written request:
  - (1) The name and address of the registrant; the date; and the name, title, signature, and phone number of the company official making the request.
  - (2) The name and EPA registration number of the pesticide product for which the waiver or modification is requested.
  - (3) A statement specifying the requirement or requirements from which you are requesting a waiver or a modification.
  - (4) A description of the refillable container or containers for which the waiver or modification is requested.
  - (5) Documentation or justification to demonstrate that the applicable waiver or modification criteria in <u>paragraph (g)</u> of this section are satisfied.

# § 165.47 What information must I report about my refillable containers?

You are not required to report to EPA with information about your refillable containers under the regulations in this subpart. You should refer to the reporting standards in <u>part 159 of this chapter</u> to determine if information on container failures or other incidents involving pesticide containers must be reported to EPA under FIFRA section 6(a)(2) (7 U.S.C. 136d(a)(2)).

#### §§ 165.48-165.59 [Reserved]

## <u>Subpart D - Standards for Repackaging Pesticide Products</u> <u>into Refillable Containers</u>

#### § 165.60 General provisions.

- (a) What is the purpose of the regulations in this subpart? The regulations in this subpart establish requirements for repackaging some pesticide products into refillable containers for distribution or sale.
- (b) *Do I have to comply with the regulations in this subpart?* You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers, if you are a registrant who distributes or sells pesticide products to a refiller (that is not part of your company) for repackaging into refillable containers, or if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. Each pesticide product that is subject to the regulations in this subpart as set out in § 165.63 and that is distributed or sold in a refillable container must be distributed or sold in compliance with the standards of these regulations.
- (c) When do I have to comply? Any pesticide product repackaged into a refillable container and released for shipment by you after August 16, 2011 must be repackaged in compliance with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64227</u>, Oct. 29, 2008]

## § 165.63 Scope of pesticide products included.

(a) Are manufacturing use products subject to the regulations in this subpart? No, the regulations in this subpart do not apply to manufacturing use products, as defined in  $\S$  158.153(h) of this chapter.

- (b) Are plant-incorporated protectants subject to the regulations in this subpart? No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in § 174.3 of this chapter.
- (c) Which antimicrobial pesticide products are not subject to the regulations in this subpart? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:
  - (1) The pesticide product meets one of the following two criteria:
    - (i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or
    - (ii) The pesticide product:
      - (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and
      - (B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.
  - (2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.
  - (3) The pesticide product is not a hazardous waste as set out in <u>part 261 of this chapter</u> when the pesticide product is intended to be disposed.
  - (4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of <u>paragraph</u> (e) of this section.
- (d) Which requirements must an antimicrobial swimming pool product comply with if it is not exempt from these regulations?
  - (1) An antimicrobial swimming pool product that is not exempt by <u>paragraph (a)</u>, <u>(b)</u>, or <u>(c)</u> of this section must comply with all of the regulations in this subpart except for the following requirements:

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

- (2) For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:
  - (i) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.
  - (ii) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.
- (e) How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?
  - (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:
    - (i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.
    - (ii) The information, data or other evidence is reliable and factual.
    - (iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

- (iv) Complying with the container regulations could reasonably be expected to eliminate the problem.
- (2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the repackaging regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be repackaged in compliance with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be repackaged in compliance with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the repackaging regulations within the time frames established by EPA in the rule or in its notification.
- (f) What other pesticide products are subject to the regulations in this subpart? The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt <u>paragraph</u> (c) of this section. Antimicrobial products covered under <u>paragraph</u> (d) of this section are subject to the regulations indicated in that section.
- (g) What does "pesticide product" or "pesticide" mean in the rest of this subpart? In §§ 165.63(h) through 165.70, the term "pesticide product" or "pesticide" refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (f) of this section.

#### (h) Are there any other exceptions?

- (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.
- (2) Custom blending is not subject to the regulations in this subpart.
- (3) The regulations in this subpart do not apply to containers that hold pesticides that are gaseous at atmospheric temperature and pressure.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

# § 165.65 Registrants who distribute or sell pesticide products in refillable containers.

(a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products in refillable

containers. This means that you conduct all of the repackaging for a pesticide product and that you do not distribute or sell the pesticide product to a refiller that is not part of your company for repackaging into refillable containers. If you are a registrant that repackages a product directly into refillable containers for sale or distribution and you also sell or distribute other quantities of that product to an independent refiller for repackaging, then you must meet the requirements in this section for those quantities you distribute or sell directly and the requirements in § 165.67 for those quantities that you distribute or sell to an independent refiller.

- (b) *Am I responsible for product integrity?* Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.
- (c) *What information must I develop?* For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.
  - (1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.
    - (i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.
    - (ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under "Directions for Use," or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.
  - (2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.
    - (i) An acceptable container is one that you have determined meets the standards in <u>subpart</u> <u>C of this part</u> and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.
    - (ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in <u>subpart C of this part</u>.
- (d) What requirements must my individual establishments follow regarding repackaging a pesticide product into refillable containers? A refiller at your individual establishment that

repackages a pesticide product into refillable containers for distribution or sale must comply with all of the following provisions.

- (1) The establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.
- (2) The refiller must not change the pesticide formulation unless the refiller has a registration for the new formulation.
- (3) The refiller must repackage a pesticide product only into a refillable container that is identified on your description of acceptable containers for that pesticide product.
- (4) The refiller may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that the refiller can use.
- (5) The refiller must have all of the following items at the establishment before repackaging a pesticide product into any refillable container for distribution or sale:
  - (i) The pesticide product's label and labeling.
  - (ii) The written refilling residue removal procedure for the pesticide product.
  - (iii) The written description of acceptable containers for the pesticide product.
- (6) Before repackaging a pesticide product into any refillable container for distribution or sale, the refiller must identify the pesticide product previously contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with <u>paragraph</u> (f) of this section. The refiller may identify the previous pesticide product by referring to the label or labeling.
- (7) The refiller must inspect each refillable container according to <u>paragraph (e)</u> of this section.
- (8) The refiller must clean each refillable container according to <u>paragraph</u> (f) or (g) of this section, if required by either paragraph.
- (9) The refiller must ensure that each refillable container is properly labeled according to paragraph (h) of this section.
- (10) The establishment must maintain records in accordance with <u>paragraph (i)</u> of this section.
- (11) The establishment must maintain records as required by part 169 of this chapter.
- (12) The establishment must report as required by <u>part 167 of this chapter</u>.

- (e) *How must my individual establishments inspect refillable containers?* Before repackaging a pesticide product into any refillable container, a refiller at your establishment must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and openings. If the condition in <u>paragraph (e)(1)</u> of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in <u>paragraph (e)(2)</u> or <u>(e)(3)</u> of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in <u>subpart C of this part</u>. The conditions are:
  - (1) The integrity of the container is compromised in at least one of the following ways:
    - (i) The container shows signs of rupture or other damage which reduces its structural integrity.
    - (ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.
    - (iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.
    - (iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.
  - (2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.
  - (3) The container does not have an intact and functioning one-way valve or tamper-evident device on each opening other than a vent, if required.
- (f) *How must my individual establishments clean refillable containers?* A refiller at your establishment must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in paragraph(f)(1) of this section and either paragraph(f)(2) or paragraph(f)(3) of this section are satisfied:
  - (1) If required, each tamper-evident device and one-way valve is intact.
  - (2) The refillable container is being refilled with the same pesticide product.
  - (3) Both of the following conditions are satisfied:
    - (i) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.

- (ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.
- (g) How must my individual establishments clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve? As required in paragraph (f) of this section, a refiller at your establishment must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.
- (h) *How must my individual establishments label refillable containers?* Before distributing or selling a pesticide product in a refillable container, a refiller at your establishment must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of <u>part 156 of this chapter</u>. In particular, the refiller at your establishment must ensure that the net contents statement and EPA establishment number appear on the label.
- (i) What recordkeeping must my individual establishments do? Each of your individual establishments that repackages a pesticide product into refillable containers for distribution or sale must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. The establishment must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.
  - (1) For each pesticide product distributed or sold in refillable containers, both of the following records must be maintained for the current operating year and for 3 years after that:
    - (i) The written refilling residue removal procedure for the pesticide product.
    - (ii) The written description of acceptable containers for the pesticide product.
  - (2) Each time a refiller at your establishment repackages a pesticide product into a refillable container and distributes or sells the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:
    - (i) The EPA registration number of the pesticide product distributed or sold in the refillable container.
    - (ii) The date of the repackaging.

(iii) The serial number or other identifying code of the refillable container.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64227</u>, Oct. 29, 2008]

# § 165.67 Registrants who distribute or sell pesticide products to refillers for repackaging.

- (a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products to a refiller that is not part of your company for repackaging into refillable containers.
- (b) *Under what conditions can I allow a refiller to repackage my pesticide product into refillable containers?* You may allow a refiller to repackage your pesticide product into refillable containers and to distribute or sell such repackaged product under your existing registration if all of the following conditions are satisfied:
  - (1) The repackaging results in no change to the pesticide formulation.
  - (2) One of the following conditions regarding a registered refilling establishment is satisfied:
    - (i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.
    - (ii) The pesticide product is repackaged by a refilling establishment registered with EPA as required by § 167.20 of this chapter at the site of a user who intends to use or apply the product.
  - (3) You have entered into a written contract with the refiller to repackage the pesticide product and to use the label of your pesticide product.
  - (4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.
  - (5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refiller's EPA establishment number.
- (c) What violations are applicable to illegal repackaging? Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the refiller that is repackaging your pesticide product under written contract with you may be liable for violations pertaining to the repackaged product.
- (d) When must I provide the written contract to the refiller? If you allow a refiller to repackage your product as specified in <u>paragraph (b)</u> of this section you must provide the

written contract referred to in <u>paragraph (b)(3)</u> of this section to the refiller before you distribute or sell the pesticide product to the refiller.

- (e) *Am I responsible for product integrity?* Yes, for a product that you distribute or sell to a refiller that is not part of your company for repackaging into refillable containers, you are responsible for the pesticide product not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.
- (f) *What information must I develop?* For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.
  - (1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.
    - (i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.
    - (ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under "Directions for Use," or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.
  - (2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.
    - (i) An acceptable container is one that you have determined meets the standards in <u>subpart</u> C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.
    - (ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in <u>subpart C of this part</u>.
- (g) When must I provide the information to the refiller? You must provide the refiller with all of the following information and documentation before or at the time of distribution or sale of your pesticide product to the refiller:
  - (1) Your written refilling residue removal procedure for the pesticide product.
  - (2) Your written description of acceptable containers for the pesticide product.
  - (3) The pesticide product's label and labeling.

- (h) What recordkeeping must I do? You must maintain all of the records listed in this section for the current operating year and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:
  - (1) Each written contract entered into with a refiller for repackaging your pesticide product into refillable containers.
  - (2) Your written refilling residue removal procedure for the pesticide product.
  - (3) Your written description of acceptable containers for the pesticide product.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

#### § 165.70 Refillers who are not registrants.

- (a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a refiller of a pesticide product and you are not the registrant of the pesticide product.
- (b) *Under what conditions can I repackage a registrant's pesticide product into refillable containers?* A registrant may allow you to repackage the registrant's pesticide product into refillable containers and to distribute or sell such repackaged product under the registrant's existing registration if all of the following conditions are satisfied:
  - (1) The repackaging results in no change to the pesticide formulation.
  - (2) One of the following conditions regarding a registered refilling establishment is satisfied:
    - (i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.
    - (ii) The pesticide product is repackaged by a refilling establishment registered with EPA as required by § 167.20 of this chapter at the site of a user who intends to use or apply the product.
  - (3) The registrant has entered into a written contract with you to repackage the pesticide product and to use the label of the registrant's pesticide product.
  - (4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.
  - (5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refillers EPA establishment number.

- (c) What violations are applicable to illegal repackaging? Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in <u>paragraph (b)</u> of this section is a violation of section 12 of the Act. Both you and the pesticide product's registrant may be liable for violations pertaining to the repackaged product.
- (d) *Am I responsible for product integrity?* Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.
- (e) What requirements must I follow regarding repackaging a pesticide product into refillable containers? You must comply with all of the following provisions.
  - (1) Your establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.
  - (2) You must not change the pesticide formulation unless you have a registration for the new formulation.
  - (3) You must repackage a pesticide product only into a refillable container that is identified on the description of acceptable containers for that pesticide product provided by the registrant.
  - (4) You may repackage any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that you can use.
  - (5) You must have all of the following items at your establishment before repackaging a pesticide product into any refillable container for distribution or sale:
    - (i) The written contract referred to in <u>paragraph (b)(3)</u> of this section from the pesticide product's registrant.
    - (ii) The pesticide product's label and labeling.
    - (iii) The registrant's written refilling residue removal procedure for the pesticide product.
    - (iv) The registrant's written description of acceptable containers for the pesticide product.
  - (6) Before repackaging a pesticide product into any refillable container for distribution or sale, you must identify the pesticide product previously contained in the refillable container to determine whether a residue removal procedure must be conducted in accordance with paragraph (g) of this section. You may identify the previous pesticide product by referring to the label or labeling.
  - (7) You must inspect each refillable container according to <u>paragraph (f)</u> of this section.

- (8) You must clean each refillable container according to <u>paragraph (g)</u> or <u>(h)</u> of this section, if required by either paragraph.
- (9) You must ensure that each refillable container is properly labeled according to <u>paragraph</u> (i) of this section.
- (10) You must maintain records in accordance with <u>paragraph (j)</u> of this section.
- (11) You must maintain records as required by part 169 of this chapter.
- (12) You must report as required by part 167 of this chapter.
- (13) The stationary pesticide containers at your establishment must meet the standards in  $\S$  165.45(f).
- (14) You may be required to comply with the containment standards in <u>subpart E of this part</u>.
- (f) *How must I inspect refillable containers?* Before repackaging a pesticide product into any refillable container, you must visually inspect the exterior and (if possible) the interior of the container and the exterior of appurtenances. The purpose of the inspection is to determine whether the container meets the necessary criteria with respect to continued container integrity, required markings, and openings. If the condition in paragraph(f)(1) of this section exists, the container fails the inspection and must not be refilled unless the container is repaired, reconditioned, or remanufactured in compliance with the relevant DOT requirement. If the condition in paragraph(f)(2) or paragraph(f)(3) of this section exists (or both), the container fails the inspection and must not be refilled until the container meets the standards specified in paragraph(f)(2) or paragraph(f)(3) of this part. The conditions are:
  - (1) The integrity of the container is compromised in at least one of the following ways:
    - (i) The container shows signs of rupture or other damage which reduces its structural integrity.
    - (ii) The container has visible pitting, significant reduction in material thickness, metal fatigue, damaged threads or closures, or other significant defects.
    - (iii) The container has cracks, warpage, corrosion or any other damage which might render it unsafe for transportation.
    - (iv) There is damage to the fittings, valves, tamper-evident devices or other appurtenances that may cause failure of the container.
  - (2) The container does not bear the markings required by § 165.45(a), (b) and (d), or such markings are not legible.

- (3) The container does not have an intact and functioning one-way valve or tamper-evident device on each opening other than a vent, if required.
- (g) *How must I clean refillable containers?* You must clean each refillable container by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container, unless the conditions in <u>paragraph (g)(1)</u> of this section and either paragraph (g)(2) or (g)(3) of this section are satisfied:
  - (1) If required, each tamper-evident device and one-way valve is intact.
  - (2) The refillable container is being refilled with the same pesticide product.
  - (3) Both of the following conditions are satisfied.
    - (i) The container previously held a pesticide product with a single active ingredient and is being used to repackage a pesticide product with the same single active ingredient.
    - (ii) There is no change that would cause the composition of the product being repackaged to differ from the composition described in its confidential statement of formula that is required under FIFRA section 3. Examples of unallowable changes include the active ingredient concentration increasing or decreasing beyond the limits established by the confidential statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.
- (h) How must I clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve? As required in paragraph (g) of this section, you must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.
- (i) *How must I label refillable containers?* Before distributing or selling a pesticide product in a refillable container, you must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of <u>part 156 of this chapter</u>. In particular, you must ensure that the net contents statement and EPA establishment number appear on the label.
- (j) What recordkeeping must I do? You must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.
  - (1) For each pesticide product distributed or sold in refillable containers, all of the following records must be maintained for the current operating year and for 3 years after that:

- (i) The written contract from the pesticide product's registrant for the pesticide product.
- (ii) The written refilling residue removal procedure for the pesticide product.
- (iii) The written description of acceptable containers for the pesticide product.
- (2) Each time you repackage a pesticide product into a refillable container and distribute or sell the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:
  - (i) The EPA registration number of the pesticide product distributed or sold in the refillable container.
  - (ii) The date of the repackaging.
  - (iii) The serial number or other identifying code of the refillable container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

### §§ 165.71-165.79 [Reserved]

### **Subpart E - Standards for Pesticide Containment Structures**

### § 165.80 General provisions.

- (a) What is the purpose of the regulations in this subpart? The purpose of the containment regulations in this subpart is to protect human health and the environment from exposure to agricultural pesticides which may spill or leak from stationary pesticide containers. This protection is achieved by the construction of secondary containment units or pads at certain facilities handling agricultural pesticides. These regulations will also reduce waste generation associated with:
  - (1) Storage and handling of large quantities of pesticide products.
  - (2) Pesticide dispensing and container-refilling operations.
- (b) **Do I have to comply with the regulations in this subpart?** You must comply with the regulations in this subpart if you are an owner or operator of one of the following businesses and if you also have a stationary pesticide container or a pesticide dispensing (including container refilling) area:
  - (1) Refilling establishments who repackage agricultural pesticides and whose principal business is retail sale (*i.e.*, more than 50% of total annual revenue comes from retail operations).

- (2) Custom blenders of agricultural pesticides.
- (3) Businesses which apply an agricultural pesticide for compensation (other than trading of personal services between agricultural producers).
- (c) When do I have to comply? You must comply with all applicable containment regulations for new and existing structures as of August 17, 2009.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64227</u>, Oct. 29, 2008]

### § 165.81 Scope of stationary pesticide containers included.

- (a) What is a stationary pesticide container? A stationary pesticide container is a refillable container that is fixed at a single facility or establishment, or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.
- (b) What stationary pesticide containers are subject to the regulations in this subpart? Stationary pesticide containers designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide are subject to the regulations in this subpart and must have a secondary containment unit that complies with the provisions of this subpart unless any of the following conditions exists:
  - (1) The container is empty, that is, all pesticide that can be removed by methods such as draining, pumping or aspirating has been removed (whether or not the container has been rinsed or washed).
  - (2) The container holds only pesticide rinsates or wash waters, and is labeled accordingly.
  - (3) The container holds only pesticides which would be gaseous when released at atmospheric temperature and pressure.
  - (4) The container is dedicated to non-pesticide use, and is labeled accordingly.

### § 165.82 Scope of pesticide dispensing areas included.

- (a) What pesticide dispensing areas are subject to the regulations in this subpart? A pesticide dispensing area is subject to the containment regulations in this subpart and must have a containment pad that complies with the requirements of this subpart if any of the following activities occur:
  - (1) Refillable containers of agricultural pesticide are emptied, cleaned or rinsed.

- (2) Agricultural pesticides are dispensed from a stationary pesticide container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide for any purpose, including refilling or emptying for cleaning. This applies when pesticide is dispensed from the container into any vessel, including, but not limited to:
  - (i) Refillable containers;
  - (ii) Service containers;
  - (iii) Transport vehicles;
  - (iv) Application equipment.
- (3) Agricultural pesticides are dispensed from a transport vehicle for purposes of filling a refillable container.
- (4) Agricultural pesticides are dispensed from any other container for the purpose of refilling a refillable container for sale or distribution. Containment requirements do not apply if the agricultural pesticide is dispensed from such a container for use, application or purposes other than refilling for sale or distribution.
- (b) What pesticide dispensing areas are exempt from the regulations in this subpart? A pesticide dispensing area is exempt from the regulations in this subpart if any of the following conditions exist:
  - (1) The only pesticides in the dispensing area would be gaseous when released at atmospheric temperature and pressure.
  - (2) The only pesticide containers refilled or emptied within the dispensing area are stationary pesticide containers which are already protected by a secondary containment unit that complies with the provisions of this subpart.
  - (3) The pesticide dispensing area is used solely for dispensing pesticide from a rail car which does not remain at a facility long enough to meet the definition of a stationary pesticide container; that is, 30 days.

### § 165.83 Definition of new and existing structures.

- (a) What is a new containment structure? A new containment structure is one whose installation began after November 16, 2006. Installation is considered to have begun if:
  - (1) You, as the owner or operator, have obtained all Federal, State, and local approvals or permits necessary to begin physical construction of the containment structure; AND

- (2) You have either begun a continuous on-site physical construction or installation program OR you have entered into contractual obligations. The contract must be such that it cannot be canceled or modified without substantial loss, and must be for the physical construction or installation of the containment structure within a specific and reasonable time frame.
- (b) What is an existing containment structure? An existing containment structure is defined as one whose installation began on or before November 16, 2006.

# § 165.85 Design and capacity requirements for new structures.

- (a) For all new containment structures, what construction materials must I use? These are the material specifications for a new containment structure:
  - (1) The containment structure must be constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The structure must be liquid-tight with cracks, seams and joints appropriately sealed.
  - (2) The structure must not be constructed of natural earthen material, unfired clay, or asphalt.
  - (3) The containment structure must be made of materials compatible with the pesticides stored. In this case, compatible means able to withstand anticipated exposure to stored or transferred substances and still provide containment of those same or other substances within the containment area.
- (b) For all new containment structures, what are the general design requirements? These are the general design requirements for new containment structures:
  - (1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to, supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.
  - (2) Appurtenances, discharge outlets or gravity drains must not be configured through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart. Appurtenances must be configured in such a way that spills or leaks are easy to see.
  - (3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.
  - (4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.

- (c) For new secondary containment units for stationary containers of liquid pesticides and new containment pads in pesticide dispensing areas, what are the capacity requirements? These are the capacity requirements:
  - (1) New secondary containment units for stationary containers of liquid pesticides, if protected from precipitation, must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.
  - (2) New secondary containment units for stationary containers of liquid pesticides, if exposed to or unprotected from precipitation, must have a capacity of at least 110 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.
  - (3) New containment pads in pesticide dispensing areas which have a pesticide container or pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons.
  - (4) New containment pads in pesticide dispensing areas which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.
- (d) For new secondary containment units for stationary containers of liquid pesticides, what are the specific design requirements? You must either anchor or elevate each stationary container of liquid pesticides protected by a new secondary containment unit to prevent flotation in the event that the secondary containment unit fills with liquid.
- (e) For new containment pads in pesticide dispensing areas, what are the specific design requirements? Each new containment pad in a pesticide dispensing area must:
  - (1) Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.
  - (2) Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary pesticide container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.
  - (3) Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.

- (4) Have its surface sloped toward an area where liquids can be collected for removal, such as a liquid-tight sump or a depression, in the case of a single-pour concrete pad.
- (f) For new secondary containment units for stationary containers of dry pesticides, what are the specific design requirements? These are the specific design requirements for new secondary containment units for stationary containers of dry pesticides:
  - (1) The stationary containers of dry pesticides within the containment unit must be protected from wind and precipitation.
  - (2) Stationary containers of dry pesticides must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.
  - (3) The storage area for stationary containers of dry pesticides must include a floor that extends completely beneath the pallets or raised concrete platforms on which the stationary containers of dry pesticides must be stored.
  - (4) The storage area for stationary containers of dry pesticides must be enclosed by a curb a minimum of 6 inches high that extends at least 2 feet beyond the perimeter of the container.

[71 FR 47422, Aug. 16, 2006, as amended at <u>73 FR 64227</u>, Oct. 29, 2008]

# § 165.87 Design and capacity requirements for existing structures.

- (a) For all existing containment structures, what construction materials must I use? These are the material specifications for an existing containment structure:
  - (1) The containment structure must be constructed of steel, reinforced concrete or other rigid material capable of withstanding the full hydrostatic head, load and impact of any pesticides, precipitation, other substances, equipment and appurtenances placed within the structure. The structure must be liquid-tight with cracks, seams and joints appropriately sealed.
  - (2) The structure must not be constructed of natural earthen material, unfired clay, or asphalt.
  - (3) The containment structure must be made of materials compatible with the pesticides stored. In this case, compatible means able to withstand anticipated exposure to stored or transferred substances and still provide containment of those same or other substances within the containment area.
- (b) For all existing containment structures, what are the general design requirements? These are the general design requirements for existing containment structures:
  - (1) You must protect appurtenances and pesticide containers against damage from operating personnel and moving equipment. Means of protection include, but are not limited to,

supports to prevent sagging, flexible connections, the use of guard rails, barriers, and protective cages.

- (2) You must seal all appurtenances, discharge outlets and gravity drains through the base or wall of the containment structure, except for direct interconnections between adjacent containment structures which meet the requirements of this subpart.
- (3) The containment structure must be constructed with sufficient freeboard to contain precipitation and prevent water and other liquids from seeping into or flowing onto it from adjacent land or structures.
- (4) Multiple stationary pesticide containers may be protected within a single secondary containment unit.
- (c) For existing secondary containment units for stationary containers of liquid pesticides and existing containment pads in pesticide dispensing areas, what are the capacity requirements? These are the capacity requirements:
  - (1) Existing secondary containment units for stationary containers of liquid pesticides must have a capacity of at least 100 percent of the volume of the largest stationary pesticide container plus the volume displaced by other containers and appurtenances within the unit.
  - (2) Existing containment pads in pesticide dispensing areas which have a pesticide container or pesticide-holding equipment with a volume of 750 gallons or greater must have a holding capacity of at least 750 gallons.
  - (3) Existing containment pads in pesticide dispensing areas which do not have a pesticide container or pesticide-holding equipment with a volume of at least 750 gallons must have a holding capacity of at least 100 percent of the volume of the largest pesticide container or pesticide-holding equipment used on the pad.
- (d) For existing secondary containment units for stationary containers of liquid pesticides, what are the specific design requirements? You must either anchor or elevate each stationary container of liquid pesticides protected by an existing secondary containment unit to prevent flotation in the event that the secondary containment unit fills with liquid.
- (e) For existing containment pads in pesticide dispensing areas, what are the specific design requirements? Each existing containment pad in a pesticide dispensing area must:
  - (1) Be designed and constructed to intercept leaks and spills of pesticides which may occur in the pesticide dispensing area.
  - (2) Have enough surface area to extend completely beneath any container on it, with the exception of transport vehicles dispensing pesticide for sale or distribution to a stationary pesticide container. For such vehicles, the surface area of the containment pad must accommodate at least the portion of the vehicle where the delivery hose or device couples to

the vehicle. This exception does not apply to transport vehicles that are used for prolonged storage or repeated on-site dispensing of pesticides.

- (3) Allow, in conjunction with its sump, for removal and recovery of spilled, leaked, or discharged material and rainfall, such as by a manually activated pump. Automatically-activated pumps which lack automatic overflow cutoff switches for the receiving container are prohibited.
- (f) For existing secondary containment units for stationary containers of dry pesticides, what are the specific design requirements? These are the specific design requirements for existing secondary containment units for stationary containers of dry pesticides:
  - (1) The stationary containers of dry pesticides within the containment unit must be protected from wind and precipitation.
  - (2) Stationary containers of dry pesticides must be placed on pallets or a raised concrete platform to prevent the accumulation of water in or under the pesticide.
  - (3) The storage area for stationary containers of dry pesticides must include a floor that extends completely beneath the pallets or raised concrete platforms on which the stationary containers of dry pesticides must be stored.
  - (4) The storage area for stationary containers of dry pesticides must be enclosed by a curb a minimum of 6 inches high that extends at least 2 feet beyond the perimeter of the container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64228, Oct. 29, 2008]

# § 165.90 Operational, inspection and maintenance requirements for all new and existing containment structures.

- (a) What are the operating procedures required for all new and existing containment structures? As the owner or operator of a new or existing pesticide containment structure, you must:
  - (1) Manage the structure in a manner that prevents pesticides or materials containing pesticides from escaping from the containment structure (including, but not limited to, pesticide residues washed off the containment structure by rainfall or cleaning liquids used within the structure.)
  - (2) Ensure that pesticide spills and leaks on or in any containment structure are collected and recovered in a manner that ensures protection of human health and the environment (including surface water and groundwater) and maximum practicable recovery of the pesticide spilled or leaked. Cleanup must occur no later than the end of the day on which pesticides have been spilled or leaked except in circumstances where a reasonable delay

would significantly reduce the likelihood or severity of adverse effects to human health or the environment.

- (3) Ensure that all materials resulting from spills and leaks and any materials containing pesticide residue are managed according to label instructions and applicable Federal, State and local laws and regulations.
- (4) Ensure that transfers of pesticides between containers, or between containers and transport vehicles are attended at all times.
- (5) Ensure that each lockable valve on a stationary pesticide container, if it is required by § 165.45(f), is closed and locked, or that the facility is locked, whenever the facility is unattended.
- (b) What are the inspection and maintenance requirements for all new and existing containment structures? As owner or operator of a new or existing pesticide containment structure, you must:
  - (1) Inspect each stationary pesticide container and its appurtenances and each containment structure at least monthly during periods when pesticides are being stored or dispensed on the containment structure. Your inspection must look for visible signs of wetting, discoloration, blistering, bulging, corrosion, cracks or other signs of damage or leakage.
  - (2) Initiate repair to any areas showing visible signs of damage and seal any cracks and gaps in the containment structure or appurtenances with material compatible with the pesticide being stored or dispensed no later than the end of the day on which damage is noticed and complete repairs within a time frame that is reasonable, taking into account factors such as the weather, and the availability of cleanup materials, trained staff, and equipment.
  - (3) Not store any additional pesticide on a containment structure if the structure fails to meet the requirements of this subpart until suitable repairs have been made.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64228, Oct. 29, 2008]

# § 165.92 What if I need both a containment pad and a secondary containment unit?

You may combine containment pads and secondary containment units as an integrated system provided the requirements set out in this subpart for containment pads and secondary containment units in  $\S\S 165.85(a)$  and  $\S 165.85(a)$  are satisfied separately.

# § 165.95 What recordkeeping do I have to do as a facility owner or operator?

As a facility owner or operator subject to the requirements of this subpart, you must maintain the following records, and you must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

- (a) Records of inspection and maintenance for each containment structure and for each stationary pesticide container and its appurtenances must be kept for 3 years and must include the following information:
  - (1) Name of the person conducting the inspection or maintenance;
  - (2) Date the inspection or maintenance was conducted;
  - (3) Conditions noted;
  - (4) Specific maintenance performed.
- (b) Records for any non-stationary pesticide container designed to hold undivided quantities of agricultural pesticides equal to or greater than 500 gallons (1,890 liters) of liquid pesticide or equal to or greater than 4,000 pounds (1,818 kilograms) of dry pesticide that holds pesticide but is not protected by a secondary containment unit meeting these regulations must be kept for 3 years. Records on these non-stationary pesticide containers must include the time period that the container remains at the same location.
- (c) Records of the construction date of the containment structure must be kept for as long as the pesticide containment structure is in use, and for 3 years afterwards.

### § 165.97 States with existing containment programs.

- (a) What options are available to States that already have containment regulations? States that have promulgated containment regulations effective prior to August 16, 2006, and which also have primary enforcement responsibility and/or certification programs, have the option of continuing to implement their own programs in lieu of these Federal regulations.
- (b) *How may a State request authority to continue implementing its State containment regulations?* A State with pesticide containment regulations may request the authority to continue implementing State containment regulations by August 16, 2007 in the following manner:
  - (1) The State must submit a letter and any supporting documentation to EPA. Supporting documentation must demonstrate that the State's program is providing environmental protection equivalent to or more protective than that expected to be provided by the Federal regulations in this subpart.
  - (2) The State must identify any significant changes to State regulations which would be necessary in order to provide environmental protection equivalent to the EPA regulations,

and develop an estimated timetable to effect these changes. The letter must be signed by the designated State Lead Agency.

- (c) *How will EPA notify the State if its request is granted?* EPA's Office of Pesticide Programs will review the State's correspondence and determine whether the State program is adequate to provide environmental protection equivalent to or more protective than these Federal regulations for new and existing containment structures. EPA's Office of Pesticide Programs will inform the State of its determination through a letter authorizing or declining to authorize the State to continue implementing its containment regulations and will detail any reasons for declining authorization.
- (d) *How must a State inform EPA of revisions to its containment regulations?* Any state that has received authorization to continue implementing its state containment regulations must inform EPA by letter signed by the designated State Lead Agency within 6 months of any revision to the State's containment regulations. EPA will inform the state by letter if it determines that the State's containment regulations are no longer adequate based on the revisions. The State's containment regulations will remain in effect, unless and until EPA sends the state a letter making this determination.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64228, Oct. 29, 2008]

### **State Pesticide Container Regulations**

On the June 17, 2022 Board meeting, the Board indicated that they would like a summary of all federal and state pesticide container laws. In Maine, there are some pesticide container regulations in place, but the majority of regulations are at the federal level. Below are regulations from the Maine Board of Pesticide Control Rules (CMR01-26) and Maine Department of Environmental Protection (CMR06-96) regarding pesticide containers. In Maine, once pesticide containers are triple rinsed, they are then considered universal waste and may be recycled/disposed of according to general waste provisions CMR 06-96 Chapter 858: Universal Waste Rules.

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### CMR01-26 CHAPTER 20: SPECIAL PROVISIONS

### Section 3. Pesticide Storage and Disposal

- A. Unused pesticides, whether in sealed or open containers, must be kept in a secure enclosure and otherwise maintained so as to prevent unauthorized use, mishandling or loss; and so as to prevent contamination of the environment and risk to public health.
- B. Obsolete, expired, illegal, physically or chemically altered or unusable pesticides, except household pesticide products, shall be either:
  - 1. stored in a secure, safe place under conditions that will prevent deterioration of containers or any contamination of the environment or risk to public health, or
  - 2. returned to the manufacturer or formulator for recycling, destruction, or disposal as appropriate, or
  - 3. disposed of in a licensed hazardous waste facility or other approved disposal site that meets or exceeds all current requirements of the Maine Department of Environmental Protection and the U.S. Environmental Protection Agency for facilities receiving such waste.

### CMR01-26 CHAPTER 24: PESTICIDE STORAGE FACILITY STANDARDS/PESTICIDE DISTRIBUTORS

- Section 6. Operational and Emergency Equipment Requirements for All Major and Minor Pesticide Storage Facilities
  - A. All pesticide storage facilities shall be kept securely locked at all times, except when authorized personnel are present.
  - B. Each entrance to the pesticide storage facility shall be prominently posted with the words, "Danger Pesticide Storage Keep Out."
  - C. No smoking shall be allowed in any pesticide storage area. All entrances to the pesticide storage facility shall be posted with signs indicating smoking is not allowed.
  - D. All pesticide containers shall be stored in a manner that prevents damage and allows inspection for rusting, bulging or leaking. All containers held in storage

shall be in good condition and have full labeling intact. Pesticide distributors must conduct periodic inspection of containers for rust and/or leaks.

### E. Emergency Equipment

- I. All pesticide storage facilities shall be equipped with at least one eye wash station capable of flushing eyes for a minimum of fifteen minutes.
- II. All pesticide storage facilities shall be equipped with fire extinguishers that are capable of extinguishing all types of fires that may occur in the pesticide storage facility. These fire extinguishers must be clearly marked as to their fire suppression capabilities. The number and placements of fire extinguishers shall conform with the National Fire Protection Association Standard No. 10.
- III. All pesticide storage facilities shall be equipped with spill response and clean-up equipment, including, but not limited to, absorbents, empty containers, brooms and shovels and personal protective equipment for employees.
  - a. Compatible absorbents for water and oil-based products shall be present in sufficient quantity to clean up two-times the volume of the largest container stored in the facility.
  - b. Proper personal protective clothing and equipment, as well as training to use that equipment, shall be provided to employees and emergency responders.
  - c. Pesticide distributors may coordinate the provision of spill response equipment with other facilities in the locality as will as with appropriate municipal safety agencies.
- F. Pesticides shall not be stored within 10 feet from products intended for human or animal consumption. 01-026 Chapter 24 page 9
- Section 7. Special Requirements for Pesticide Distributor Self-Service Sales Areas
  - A. All pesticides, unless they are exempted products under 22 M.R.S.A. §1471-W(5), shall be displayed in a separate area that is identified by a Board approved sign informing the public where to obtain additional information. The signs must be positioned between four and seven feet above the floor and prominently posted in all areas where non-exempt pesticides are displayed.
  - B. All pesticide containers in the self-service sales area shall be in good condition and have full labeling intact. It is prohibited to have torn, punctured, rusted or leaking pesticide containers in the self-service sales area.
  - C. All pesticide products not exempted under 22 M.R.S.A. §1471-W(5) shall not be displayed within 10 feet of food or animal feed products unless they are stored in

- adjoining aisles separated by a solid barrier. Pesticides shall not be on display above food or animal feed products.
- D. Any outdoor pesticide display area must be securely fenced and must have a roof to protect the material from the elements.
- E. Each retail or wholesale establishment must be equipped with spill cleanup materials sufficient to absorb 2 times the volume of the largest container stored. These cleanup materials must be readily available and easily accessible.

#### Section 8. Local Ordinances

These regulations are minimum standards and are not meant to preempt any local ordinances which may be more stringent.

Section 9. 40 CFR, Part 165, Federal Pesticide Management and Disposal Rule Adopted by Reference

The Federal Pesticide Management and Disposal Rule, 40 CFR, Part 165 (July 1, 2008), is incorporated herein by reference

### CMR01-26 CHAPTER 29: STANDARDS FOR WATER QUALITY PROTECTION

Section 2. Securing Pesticide Product Containers and Mix Tanks on Sprayers, Nurse Vehicles and Other Support Vehicles during Transportation

No person shall transport any pesticide unless it is secured so as to prevent release of pesticides onto the vehicle or from the vehicle. All tanks, liquid containers, cartons and bags must be securely held so they may not shift and become punctured or spilled

### CMR01-26 CHAPTER 21 [REPEALED—Effective: December 23, 2012] Pesticide Container Disposal and Storage

These rules set forth the regulations for the management of emptied pesticide containers for limited and restricted use pesticides. They establish deposit amounts, sticker requirements, triple rinse or equivalent procedures, and refund places and procedures. The rules are organized according to classification of the pesticide as to whether it was purchased in state or out of state.

### CMR06-96 Chapter 102: OPEN BURNING

- 1. Scope
  - **A.** This section shall be applicable in all ambient air quality regions in the State of Maine.
  - **B.** This section shall not interfere with or supersede any local law or ordinance which is more stringent.

- 2. Prohibitions and Permissible Open Burning. Outdoor burning is prohibited in all areas of the State, except as follows:
  - **A. Permissible Open Burning With Permit.** When not prohibited by local ordinances the following types of burning are permissible if a permit has been obtained from the Town Forest Fire Warden, forest ranger, or local fire prevention official having jurisdiction over the location where the fire is to be set, so long as the burning is conducted according to the terms and conditions of such permit and provided no nuisance is created.

NOTE: Any kindling or use of out-of-door fires is regulated by the Department of Conservation, Maine Forest Service. Any requirements or conditions of issuance of a fire permit must be in accordance with Title 12, Chapter 807 - Forest Fire Control, Subchapter IV - Regulation of Open Burning, Article II Out-of-Door Fires, Sections 9321-9324 and Title 25, Chapter 317 - Preventative Measures and Restrictions, sec. 2436-A.

- (1) Recreational campfires kindled when the ground is not covered by snow;
- (2) Fires in conjunction with holiday and festive celebration, pursuant to Section 2(A)(5) of this rule:
- (3) Burning of solid or liquid fuels and structures for the purpose of research or bona fide instruction and training of municipal or volunteer firefighters pursuant to Maine Revised Statutes Title 26, section 2102 and industrial fire fighters in methods of fighting fires when conducted under the direct control and supervision of qualified instructors and with a written objective for the training. For purposes of this section, "qualified instructor" means the fire chief or designee or a fire-fighting instructor. Structures burned for instructional purposes must first be emptied of waste materials that are not part of the training objective.
- (4) Burning for agricultural purposes which include but are not limited to open burning of blueberry fields, potato tops, hayfields and prescribed burning for timberland management.
- (5) Out-of-door burning of wood wastes and painted and unpainted wood from demolition debris in the open, or in an incinerator with a primary chamber volume no greater than 133 cubic feet or 1,000 gallons that is not licensed by the Department of Environmental Protection. For purposes of this chapter, the term "wood wastes" means brush, stumps, lumber, bark, wood chips, shavings, slabs, edgings, slash, sawdust and wood from production rejects that are not mixed with other solid or liquid waste, and "lumber" means material that is entirely made of wood and is free from metal, plastics, coatings and chemical treatments.
- (6) Open burning of leaves, brush, deadwood and tree cuttings accrued from normal property maintenance by the individual landowner or lessee of the land unless expressly prohibited by municipal ordinance.
- (7) Burning on site for the disposal of wood wastes and painted and unpainted wood from construction and demolition debris generated from the clearing of any land or by the erection, modification, maintenance, demolition or construction of any highway, railroad, power line, communication line, pipeline, building or development.

- (8) Burning of vegetative growth for hazardous abatement purposes, such as, but not limited to, the burning of grass fields.
- (9) Burning for the containment or control of spills of gasoline, kerosene, heating oil or similar petroleum product.
- (10) The burning of wood wastes and painted and unpainted wood from construction and demolition debris at solid waste facilities in accordance with a facility license issued pursuant to Maine's Solid Waste Management Rules, 06-096 CMR 400 to 409.
- (11) The burning of empty containers, including fiberboard boxes and paper bags, previously containing explosives and being disposed of in accordance with the provisions of Maine Revised Statutes Title 25, section 2472.
- (12) Explosives being disposed of under the direct supervision and control of the State Fire Marshal

NOTE: Although this rule does not require the separation of painted and unpainted wood from demolition debris, Maine law requires that "A person engaged in any renovation, remodeling, maintenance or repair project involving lead-based paint ...shall take reasonable precautions to prevent the release of lead to the environment, including the cleanup, removal and appropriate disposal of all visible lead-based paint debris generated by the project." (Title 38 MRSA § 1296)

NOTE: Any open burning occurring at a municipal solid waste disposal site must be conducted in accordance with those forest fire prevention measures specified in Title 12, Chapter 807 - Forest Fire Control, Subchapter IV - Regulation of Open Burning, Article I - Dumps, Sections 9301 - 9304.

- **B.** Permissible Open Burning Without Permit. When not prohibited by local ordinances, the following types of burning are permissible without a permit so long as no nuisance is created.
  - (1) Residential use of outdoor grills and fireplaces for recreational purposes such as preparing food.
  - (2) Recreational campfires kindled when the ground is covered with snow or on frozen bodies of water.
  - (3) Use of outdoor grills and fireplaces for recreational purposes such as preparing food at commercial campgrounds in organized towns, as long as the commercial campgrounds are licensed by the health engineering division of the Department of Human Services.
- **C.** No person, firm, corporation, association, municipal or state agency shall engage in any open burning except in conformity with Section 2.

NOTE: Paper or cardboard may be burned as kindling only in amounts necessary to ensure ignition of fires pursuant to Sections 2(A) and 2(B) of this rule.

### CMR06-96 CHAPTER 400: GENERAL PROVISIONS

- 1. Definitions. The following terms, as used in the Maine Solid Waste Laws and in these rules have the following meanings, unless the context indicates otherwise:
  - **D. Agricultural waste**. "Agricultural waste," means wastes that result from agricultural activities (the growing of vegetables, fruits, seeds, nursery crops, poultry, livestock, field crops, cultivated or pasture hay and farmlot wood products, including Christmas trees) that are returned to the soils as fertilizers. It includes waste pesticides when generated by a farmer, provided that the farmer triple rinses each emptied pesticide container in accordance with Departmental rules and disposes of the pesticide residues in a manner consistent with the disposal instructions on the pesticide label. It does not include any material regulated as a residual under 06-096 CMR 419.

### CMR06-96 CHAPTER 850: IDENTIFICATION OF HAZARDOUS WASTES

- C. Identification of hazardous wastes by particular substance, by chemical class or as waste products of specific industrial activities
  - (2) **Hazardous wastes from non-specific sources**. A waste is a hazardous waste if it is listed below:
    - (a) The F-listed wastes listed in the table below:

F020	Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the production or manufacturing use [as a reactant, chemical intermediate or component in a formulating process] of tri- or tetrachlorophenol, or of intermediates used to produce their pesticide derivatives. (This listing does not include wastes from the production of Hexachlorophene from highly	(H)
F020	purified 2,4,5-trichlorophenol.)  Wastes (except wastewater and spent carbon from hydrogen chloride purification) from the production or manufacturing use [as a reactant, chemical intermediate or component in a formulating process] of tri- or tetrachlorophenol, or of intermediates used to produce their pesticide derivatives. (This listing does not include wastes from the production of Hexachlorophene from highly purified 2,4,5-trichlorophenol.)	(H)

- (b) The provisions of 40 C.F.R. § 261.31(b) further define the F037 and F038 listings.
- (c) Polychlorinated biphenyl (PCB) and polychlorinated biphenyls (PCBs), where PCB and PCBs mean any chemical substance that is limited to the biphenyl molecule that has been chlorinated to varying degrees or any combination of substances which contains such substance.

(i) Any waste chemical substances or combination of waste substances that contain 50 parts per million (on a dry weight basis) or greater of PCBs are hazardous waste.

Substances that are regulated by this Chapter include, but are not limited to, dielectric fluids, contaminated solvents, oils, waste oils, heat transfer fluids, hydraulic fluids, paints, sludges, slurries, dredge spoils, soils, materials contaminated as a result of spills, and other chemical substances or combination of substances, including impurities and byproducts. "PCB Item" as defined in 40 C.F.R. § 761.3 is also subject to this Chapter.

In addition, the use of waste oil that contains any detectable concentration of PCB as a sealant, coating, or dust control agent is prohibited. Prohibited uses include, but are not limited to, road oiling, general dust control, use as a pesticide or herbicide carrier, and use as a rust preventative on pipes.

(3) **Hazardous Wastes from specific sources**. A waste is a hazardous waste if it is listed in the table below:

Pesticides:		(T)
K031	By-product salts generated in the production of MSMA and cacodylic acid.	
K032	Wastewater treatment sludge from the production of chlordane.	(T)
K033	Wastewater and scrub water from the chlorination of cyclopentadiene in the production of chlordane.	(T)
K034	Filter solids from the filtration of hexachloro- cyclopentadiene in the production of chlordane.	(T)
K035	Wastewater treatment sludges generated in the production of creosote.	(T)
K036	Still bottoms from toluene reclamation distillation in the production of disulfoton.	(T)
K037	Wastewater treatment sludges from the production of disulfoton.	(T)
K038	Wastewater from the washing and stripping of phorate production.	(T)
K039	Filter cake from the filtration of diethylphosphoro-dithioic acid in the production of phorate.	(T)

K040	Wastewater treatment sludge from the production of phorate.	(T)
K041	Wastewater treatment sludge from the production of toxaphene.	(T)
K042	Heavy ends or distillation residues from the distillation of tetrachlorobenzene in the production of 2,4,5-T.	(T)
K043	2,6-Dichlorophenol waste from the production of 2,4-D.	(T)
K097	Vacuum stripper discharge from the chlordane chlorinator in the production of chlordane.	(T)
K098	Untreated process wastewater from the production of toxaphene.	(T)
K099	Untreated wastewater from the production of 2,4-D.	(T)
K123	Process wastewater (including supernates, filtrates, and washwaters) from the production of ethylenebisdithiocarbamic acid and its salts.	(T)
K124	Reactor vent scrubber water from the production of ethylenebisdithiocarbamic acid and its salts.	(C,T)
K125	Purification solids (including filtration, evaporation, and centrifugation solids) from the production of ethylenebisdithiocarbamic acid and its salts.	(T)
K126	Baghouse dust and floor sweepings in milling and packaging operations from the production or formulation of ethylenebisdithiocarbamic acid and its salts.	(T)
K131	Wastewater from the reactor and spent sulfuric acid from the acid drier from the production of methyl bromide.	(C,T)
K132	Spent adsorbent and wastewater separator solids from the production of methyl bromide.	(T)

### CMR06-96 CHAPTER 851: STANDARDS FOR GENERATORS OF HAZARDOUS WASTE

### 4. Applicability

**A.** A generator who handles hazardous waste on the site of its generation also shall comply with applicable standards and requirements set forth in 06-096 C.M.R. chs. 850, 852, 854, 855, 856 and 857.

NOTE: Refer to 06-096 C.M.R. ch. 850, § 3(A)(5)(d) for the standards for a Small Quantity Generator or Small Quantity Generator Plus as defined in this Chapter.

- **B.** Any person who imports hazardous waste from a foreign country into the State of Maine or exports hazardous waste to a foreign country shall comply with the standards and requirements applicable to generators established in this Chapter, in 06-096 C.M.R. ch. 857 and in 40 C.F.R. Part 262 Subpart H.
- **C.** A farmer who generates waste pesticide residues which are hazardous waste as a result of farming activity on the farmer's own farm and who complies with all of the requirements of Section 10 of this Chapter is not required to comply with other standards in this Chapter or in 06-096 C.M.R. chs. 852, 854, 855 and 856 with respect to such pesticide residues.

#### 10. Farmers.

A farmer, disposing of waste pesticide residues which are hazardous wastes generated from farming activity on the farmer's own farm, is not required to comply with the standards in this Chapter or other standards in 06-096 C.M.R. chs. 852, 854, 855 or 856 for those waste residues provided the farmer collects wash and rinse water from the cleaning of spray equipment and triple rinses each emptied pesticide container in accordance with 06-096 C.M.R. ch. 850, § 3(C)(4)(c) of the Department's rules and disposes of the pesticide residues on the farmer's own farm in a manner consistent with the use or disposal instructions on the pesticide label. The containers must then be disposed of in accordance with rules administered by the Pesticide Control Board, Maine Department of Agriculture, Conservation and Forestry.

### CMR06-96 CHAPTER 852: LAND DISPOSAL RESTRICTIONS

### 13. Prohibitions on Land Disposal

Generators, owners or operators of treatment facilities, and owners or operators of land disposal facilities shall comply with the prohibitions and effective dates of 40 C.F.R.§§ 268.20 and 268.30 through 268.39, provided however, that references to:

- 40 C.F.R. § 261.31 shall mean 06-096 C.M.R. ch. 850, § 3(C)(2),
- 40 C.F.R. § 261.32 shall mean 06-096 C.M.R. ch. 850, § 3(C)(3),
- 40 C.F.R. § 261.33 shall mean 06-096 C.M.R. ch. 850, § 3(C)(4),
- 40 C.F.R. Part 268 or sections thereof shall mean this Chapter,
- sections or subparts of 40 C.F.R. Part 264 shall mean applicable provisions of Chapter 854,
- sections or subparts of 40 C.F.R. Part 265 shall mean applicable provisions of Chapter 855,
- 40 C.F.R. § 268.5(h)(2) shall mean Section 8(B)(2) of this Chapter,

and the prohibitions in 06-096 C.M.R. ch. 854, § 5(E) and 06-096 C.M.R. ch. 855, § 5(B)(7) continue to apply. Refer to 40 C.F.R. Part 268 Appendix VII for tables of effective dates organized by waste code.

### Appendix III: List of Halogenated Organic Compounds Regulated Under Section 13 of this Chapter

In determining the concentration of HOCs in a hazardous waste for purposes of the land disposal prohibition of Section 13 of this Chapter, the Department has defined the HOCs (see Section 3(B) of

this Chapter) that must be included in the calculation as any compounds having a carbon halogen bond which are listed in this Appendix. Appendix III to Chapter 852 consists of the following compounds:

### **Organochlorine Pesticides**

Aldrin

alpha-BHC

beta-BHC

delta-BHC

gamma-BHC

Chlordane

DDD

DDE

DDT

Dieldrin

Endosulfan I

Endosulfan II

Endrin

Endrin aldehyde

Heptachlor

Heptachlor epoxide

Isodrin

Kepone

Methoxyclor

Toxaphene



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

4

October 31, 1996

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

### PESTICIDE REGULATION (PR) NOTICE 96-8

### NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION:

Persons Responsible for Registration of Pesticide Products

SUBJECT:

Toxicologically Significant Levels of Pesticide Active Ingredients

This notice sets out the Environmental Protection Agency's (EPA's) interpretation of the term"toxicologically significant" as it applies to contaminants in pesticide products that are also pesticide active ingredients (AIs). This notice provides risk-based concentration levels of such contaminants that will generally be considered toxicologically significant. These concentrations are defined according to the type of pesticide that is contaminated and the pesticide category of the contaminant. As provided by regulation, registrants must report to EPA contamination exceeding toxicologically significant levels. This Notice sets out procedures for reporting such contamination.

The following contamination scenarios are excluded from this notice: (1) rodenticides as a contaminant and/or as the contaminated product; (2) microbial and biochemical pesticides that are manufactured in fermentors and that are contaminated by active microbial pesticide ingredients; and (3) plant-pesticides that are contaminated with other active plant-pesticide ingredients. EPA would like to clarify that the Agency's previous position on toxicologically significant levels of impurities that are also AIs would apply to pesticides that are exempt from this notice. In other words, any level of a contaminant in these three exempted categories would be considered potentially toxicologically significant and must be reported to EPA.

#### I. BACKGROUND

EPA requires all impurities of toxicological significance to be reported and accepted as part of product registration (40 CFR 158.167). EPA also requires that registrants propose upper certified limits for toxicologically significant impurities in technical grade active ingredients or products produced by an integrated system (40 CFR 158.175), and may require upper certified limits for other impurities.

At the time EPA promulgated these regulations it did not set quantitative criteria for determining whether an impurity is toxicologically significant. Rather, EPA has taken the

position that any level of an active ingredient that is an impurity or contaminant in another product is potentially toxicologically significant and must be reported to the Agency. Failure to report such an impurity is a violation of FIFRA section 12(a)(1)(C) (composition of the product differs from that registered with the Agency).

The Agency did make clear at the time it promulgated its current reporting regulations that its interpretation of the term "toxicologically significant" could be subject to further refinement to the extent new information on impurities was available to the Agency. Based on the analysis conducted during the development of this notice, the Agency has now determined that for certain pesticides (see section IV below) it can establish generally applicable quantitative criteria for determining the toxicological significance of contaminants that are also active ingredients. For this reason, EPA is today further refining its interpretation of the term "toxicologically significant."

In Section IV of this notice, EPA is setting risk-based levels at which active ingredients that are contaminants will generally be considered "toxicologically significant." For the purposes of this notice, a contaminant is defined as an active ingredient that is not accurately listed on the product's confidential statement of formula or listed in the discussion of impurities. This notice addresses only impurities that are also active ingredients; EPA's position on other impurities has not changed.

Additionally, nothing in this notice changes the conditions outlined in the Bulk Pesticides Enforcement Policy (Bulk Policy) dated July 11, 1977 and amended on March 4, 1991. The Bulk Policy is an important part of applying the 40 CFR Part 158 standards to bulk pesticides at repackaging/refilling establishments (often retail dealers). Specifically, EPA's position that both parties (the registrant and the repackager) are accountable for the integrity of the product as set out in the Bulk Policy remains the same.

#### II. OBJECTIVES

EPA determined that this interpretation on cross contamination should:

- o Recognize that cross contamination is a reality, and that not all cross contamination is problematical;
- o Set a clear standard that can be readily applied by EPA/States and the regulated industry alike;
- o Ensure that allowable cross contamination does not pose unreasonable adverse effects;
- o Minimize the paperwork burden for EPA and registrants;
- o Maintain accountability for the product from the registrant to the end user; and

o Not preclude marketplace/private solutions to correct problems that do arise.

#### III. APPROACH

EPA decided that a risk-based approach would most likely meet these objectives.

EPA considered the risks for several endpoints, including human health, adulterated food, contamination of ground water, and ecological effects to determine which endpoints would be most sensitive to cross contamination and what levels of cross contamination could be tolerated and remain generally protective of human health and the environment. For each endpoint, an analysis was done to evaluate a reasonable worst case scenario or a range of potential scenarios to see if an overall, generally protective contaminant concentration could be determined. EPA grouped contaminants and pesticides into different categories (see the table in section IV) to yield a scheme of toxicologically significant concentrations.

The following end points were considered. In most cases phytotoxicity to the target plants is the most sensitive endpoint and, therefore, the limiting factor in determining toxicological significance.

Human health effects. Because cross contamination caused by a specific AI is most likely an intermittent event, short-term exposure is most likely. Therefore, EPA focused on the potential risks to individuals who would be handling contaminated products. The analyses of these human health risks show that acute risks to humans at the cross contamination levels allowed by this interpretation are negligible. Although intermittent contamination is the most likely scenario for cross contamination, it is possible that the same AI contaminant would be present in a particular pesticide product over a long period of time. EPA analyses indicate that chronic exposure to cross contamination is unlikely to present an unreasonable risk to human health.

EPA also considered contamination in pesticides applied to the human body (e.g., insect repellents) and concluded that the risks from cross contamination at the level set in this notice for these pesticides are negligible.

Adulterated food. Theoretically, a contaminant could cause residues in food or feed for which no tolerance has been established or that are in excess of an established tolerance. In this case, that food or feed would be adulterated under the Federal Food, Drug, and Cosmetic Act. EPA's analysis indicates that this is a highly unlikely occurrence. Moreover, because cross contamination with a specific AI occurs intermittently and at low levels, EPA believes that potential exposure to and dietary risk from residues of unreported contaminants under this notice would be negligible.

Ground water. The possibility of the contamination of ground water was raised as a potential concern in locations with sandy soils and shallow aquifers. The Florida Department

of Agriculture and Consumer Services (DACS) conducted a preliminary ground water modeling exercise using a number of conservative assumptions regarding leachability, pesticide half-life, and product application rate. EPA accepts the Florida DACS conclusion that, while contamination of ground water is possible, it is of minimal concern because pesticide AIs as contaminants at the levels allowed by this notice are unlikely to move to ground water in concentrations that would pose significant risk to human health.

Ecological effects/phytotoxicity. Based on a preliminary review of potential ecological effects from cross contamination (e.g., risks to birds, aquatic organisms, and plants), EPA believes that plant toxicity, or phytotoxicity, is the most sensitive endpoint given the relatively low concentrations of contaminants being considered. EPA believes that phytotoxicity damage poses the greatest potential for ecological harm. EPA's phytotoxicity analyses focus on the direct application of the contaminated product to terrestrial plants because this scenario represents a higher level of exposure than other exposure pathways, such as runoff and off-target drift.

EPA conducted several risk analyses based upon phytotoxicity as the end point of concern to determine the appropriate toxicologically significant levels. These analyses are presented in a technical support document. (See section VII on how to obtain more information.)

Rationale for not including certain microbial and biochemical pesticides and plant-pesticides. Many microbial and certain biochemical pesticides are manufactured in fermentors. A likely source of contamination of these pesticide products arises when a fermentor is used also for the production of a different microbial pesticide active ingredient. Quantitative criteria are not appropriate for determining whether active microbial pesticide ingredients are contaminants of 'toxicological significance'. This is because microorganisms can multiply in the environment, and especially in association with target pest hosts. The criteria of from 20 ppm to 1000 ppm as "toxicologically significant levels" (Section IV) when applied to a microbial pesticide active ingredient could allow for the presence of thousands to millions of contaminating microorganisms per gram or milliliter of pesticide product. It cannot be assumed that such levels of contamination are of insignificant toxicity, especially to non-target organisms.

EPA is in the process of developing policy for regulatory oversight of plant-pesticides, including defining the scope of oversight. Therefore, any determination of whether the quantitative criteria for toxicological significance apply to plant pesticides should be made once the plant-pesticide rule is finalized. Where applicants/registrants voluntarily submit plant-pesticides for EPA regulation, the reporting as discussed in Section V of this Notice will remain applicable unless otherwise changed by regulation.

### IV. TOXICOLOGICALLY SIGNIFICANT LEVELS OF CONTAMINATION

The following table defines the levels of contaminants that EPA generally considers to be toxicologically significant. Specifically, the presence of a contaminant at a concentration greater than the concentration specified in the table will generally be considered toxicologically significant. Each contaminant should be considered individually.

The toxicologically significant levels apply to all registered products that are sold or distributed, regardless of whether the container is nonrefillable (i.e., "packaged product") or refillable (i.e., "bulk product.") The toxicologically significant levels do not apply to products that are not sold or distributed, such as tank mixtures in an end user's application equipment.

Toxicologically Significant Levels of Contaminants<sup>1,2</sup>

Category	Type of Contaminant	Type of Pesticide that is  Contaminated	Toxicol. Significant Level <sup>3</sup> (ppm) <sup>4</sup>
1	Insecticide <sup>5</sup> , fungicide, molluscide, or nematicide in	Any insecticide, fungicide, molluscide, nematicide, herbicide, plant growth regulator, defoliant, or desiccant	1000
2	Herbicide, plant growth regulator, defoliant, or desiccant in	Any pesticide <sup>6</sup> where the contaminant is accepted for use on all sites for which the product is labeled	1000
3	Any pesticide <sup>6</sup> other than a low application rate herbicide <sup>7</sup> in	An antimicrobial pesticide	1000
4	Normal rate herbicide <sup>8</sup> , plant growth regulator, defoliant, or desiccant in	Any herbicide, plant growth regulator, defoliant, or desiccant	250
5	Any pesticide <sup>6</sup> in	A pesticide <sup>6</sup> applied to the human body	100
6	Normal rate herbicide, plant growth regulator, defoliant, or desiccant in	Any insecticide, fungicide, molluscide, or nematicide	100
7	Low application rate herbicide in	A low application rate herbicide	Level of quantification <sup>9</sup> or 100 ppm, which eve is higher

8	Low application rate herbicide in	A normal rate herbicide, plant growth regulator, defoliant, or desiccant	Level of quantification <sup>9</sup> or 20 ppm, which ever is higher
9	Low application rate herbicide in	A pesticide <sup>6</sup> other than a herbicide, plant growth regulator, defoliant, or desiccant	Level of quantification <sup>9</sup> or 1 ppm, whichever is higher

#### Notes:

- (1) For the purposes of this notice, a contaminant is defined as an AI that is not on the product's confidential statement of formula or listed in the discussion of impurities.
- (2) The following contamination scenarios are excluded from this notice: (1) rodenticides as a contaminant and/or as the contaminated product; (2) microbial and biochemical pesticides that are manufactured in fermentors and that are contaminated by active microbial pesticide ingredients; and (3) plant-pesticides that are contaminated with other active plant-pesticide ingredients. EPA would like to clarify that the Agency's previous position on toxicologically significant levels of impurities that are also AIs would apply to pesticides that are exempt from this notice. In other words, any level of a contaminant in these three exempted scenarios would be considered potentially toxicologically significant and would have to be reported to EPA.
- (3) This column presents the toxicologically significant level, i.e., the concentration at or above which EPA would consider the contaminant to be toxicologically significant.
- (4) The concentration is determined in ppm based on the ratio of the weight of the contaminant to the weight of the formulated product.
- (5) The FIFRA definition of insect includes mites and other arthropods that are not classified by scientific nomenclature as "insects." See FIFRA section 2(o).
- (6) The phrases "any pesticide" and "a pesticide" do not include the pesticides that are specifically exempt from this notice as described in note #2 above.
- (7) For the purposes of this notice, a low application rate herbicide is defined as a herbicide with a maximum labeled application rate of AI less than or equal to 0.5 pounds AI/acre. This definition is intended to include products with AIs that are amino acid inhibitors or ALS inhibitors, including but not limited to the sulfonylureas, imidazolinones, and triazolopyrimidines. (8) For the purposes of this notice, a normal rate herbicide is defined as a herbicide with a maximum labeled application rate of AI greater than 0.5 pounds AI/acre.
- (9) For purposes of this notice, the level of quantification is the level of quantification achievable by EPA or its designated representative (State Lead Agency) using an analytical method suitable for enforcement purposes at the time the analysis is performed.

For categories 7, 8 and 9, the level of quantification is included in the table because EPA does not currently have analytical methods to detect and quantify these AIs in other products at concentrations as low as 100 ppm for category 7 (or lower for categories 8 and 9). EPA does not want to set a standard it cannot enforce. Conversely, EPA does not want to set a standard that constantly changes over time as analytical methods are continuously refined. Therefore, the standard of category 7 is the level of quantification until the point in time when the quantification limit drops below 100 ppm. The standard would then be 100 ppm, which is the limit based on toxicological significance. For purposes of this notice, the level of quantification is the level of quantification achievable by EPA or its designated representative (State Lead Agency) using an analytical method suitable for enforcement purposes at the time the analysis is performed.

In selecting the levels in the table, EPA attempted to strike a reasonable balance between greater protectiveness and cost/burden considerations. If future experience indicates that these values are not sufficiently protective, the Agency may find it appropriate to modify these levels of toxicological significance.

EPA believes the values in the table are generally protective in most contaminant/product combinations. Because it is impracticable to consider every potential contaminant/product permutation, however, adverse effects could occur when contamination is present below the concentrations in the table.

The Agency recognizes that these standards will not prevent all possible adverse effects from occurring; this is not a zero risk standard. For example, EPA is aware of a situation where a normal rate herbicide contaminated an insecticide at levels below 100 ppm (as set out in Category 6) and plant damage occurred. The Agency will continue to deal with such situations using other regulatory tools including section 6(a)(2) of FIFRA.

Accordingly, this notice does not excuse applicants or registrants from the requirement to submit to EPA factual information regarding unreasonable adverse effects of a pesticide under section 6(a)(2) of FIFRA and EPA regulations at 40 CFR 152.50(f)(3). If an applicant or registrant possesses factual information not previously reported to EPA indicating that a contaminant in a product may pose risk to human health or the environment in concentrations lower than those specified in the above table, that information must be submitted to EPA. Failure to submit such information on a timely basis is a violation of sections 12(a)(2)(B)(ii) and 12(a)(2)(N) of FIFRA. In addition, the distribution or sale of any product containing an unreported contaminant that exceeds the levels identified in this notice is a violation of section 12(a)(1)(C) (composition differs) of FIFRA.

#### V. WHAT REGISTRANTS MUST DO

### A. CONTAMINANT LEVEL EQUAL TO OR GREATER THAN THE TOXICOLOGICALLY SIGNIFICANT LEVEL

If an applicant or registrant knows or has reason to believe that a contaminant that EPA would consider toxicologically significant (i.e., an AI at a concentration equal to or greater than the appropriate level in the table) may be present, s/he must then include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present in accordance with 40 CFR 158.167(c). EPA would then make a regulatory decision on whether to approve the registration or amendment to allow the sale and distribution of the product under FIFRA. Sale or distribution of a pesticide which equals or exceeds the toxicologically significant level prior to EPA approval of the registration amendment would be a violation. Reporting would be required regardless of where the contamination would be expected to occur in the production and distribution processes. As noted in the preamble to the regulations at 40 CFR 158.167, formulators utilizing registered materials are not required

to seek information on the identity or level of impurities in the registered technical products they purchase. The Agency realizes that such information may not be made known to the formulator.

To submit an expanded discussion in accordance with 40 CFR § 158.167(c), an applicant or registrant must provide EPA with (1) the identity of the contaminant and (2) the concentration at which it might be present. The information should be sent to EPA as follows.

For US Postal Service submissions:

Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001.

#### For courier deliveries:

Document Processing Desk
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202.

### B. CONTAMINANT LEVEL LESS THAN THE TOXICOLOGICALLY SIGNIFICANT LEVEL

If an applicant or registrant knows or has reason to believe that a contaminant may be present at a concentration that is less than the toxicologically significant level, s/he is not required to report this information to EPA. Please note that if a product is distributed or sold with levels of contamination that are equal to or exceed the toxicologically significant level, the product is in violation of FIFRA, irrespective of the registrant's knowledge.

However, adverse effects could still occur below the "toxicologically significant" concentrations set out in this notice. Registrants are reminded that they are responsible for reporting any adverse effects under FIFRA section 6(a)(2). Specifically, if an applicant or registrant possesses factual information not previously reported to EPA indicating that a contaminant in a product may pose risk to human health or the environment in concentrations lower than those specified in the above table, that information must be submitted to EPA. Failure to submit such information on a timely basis is a violation of sections 12(a)(2)(B)(ii) and 12(a)(2)(N) of FIFRA.

This notice is not intended to relieve registrants from liability that may exist under State law resulting from damage caused by contaminants.

As noted above, this notice is intended to inform registrants of the interpretation of the term "toxicologically significant" that the Agency intends to apply in implementing the provisions of 40 CFR Part 158. It is not intended, nor can it be relied upon, to create any rights enforceable by any party on litigation with the United States. EPA officials may act at variance with the guidance when circumstances indicate that a contaminant is of toxicological significance at levels different from those set forth in this notice.

EPA will take any regulatory action necessary to ensure that the levels of contamination in a product do not cause unreasonable adverse effects to human health or the environment.

### VI. EFFECTIVE DATE

This notice is effective immediately.

### VII. FURTHER INFORMATION

The public comments received on the proposed interpretation, the comment summary and response document, and the technical support document for this notice are available in the public docket under document number "OPP-00424." The public docket is located at: Public Docket and Freedom of Information Section, Field Operations Division, Office of Pesticide Programs, U.S. Environmental Protection Agency (7506C), Room 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia, 22202.

If you have questions about the implementation of this notice, please contact Jim Jones at (703) 308-8358.

Daniel M. Barolo, Director Office of Pesticide Programs