

Environmental Agent Factory Establishment Standards

12 articles jointly promulgated by Environmental Protection Administration, Ministry of Economic Affairs and Taiwan Provincial Government orders on August 12, 1998

12 articles revised and promulgated by Environmental Protection Administration and Ministry of Economic Affairs orders on October 24, 2001

Article 1 revised and promulgated by Environmental Protection Administration and Ministry of Economic Affairs orders on July 10, 2006

Article 1

These Standards are determined pursuant to Article 13 of the Environmental Agents Control Act (herein referred to as “this Act”).

Article 2

The establishment of an environmental agent factory must comply with the following regulations.

- I. Those environmental agent factories manufacturing internal pressure aerosols shall have a surrounding wall or natural barrier, and may not obstruct environmental sanitation and safety.
- II. The manufacturing and storage areas of those factories engaged in the synthesis of highly flammable, highly explosive, or highly toxic technical grade environmental agents shall be a distance of at least 8 meters from the factory's outer wall. Necessary facilities shall be employed to separate manufacturing and storage areas from each other and from other working areas.
- III. Plant and warehouse structures shall be sturdy and clean. Walls and floors shall be made of concrete, terrazzo, or other easily washable materials.
- IV. Operating areas shall possess good ventilation and may not generate dust. Dustproof equipment shall be required in operating areas containing dust agents.
- V. The floors of those factories engaged in the synthesis of technical grade environmental agents and of operating areas where emulsions, liquid, suspensions, oils, and ultra-low capacity agents are manufactured (or processed) shall be made of impermeable material, may not allow puddling to occur, and shall be equipped with channels and pipes specifically for collecting wastewater and conveying it to a wastewater treatment facility.
- VI. Manufacturing and administrative areas within a factory shall be clearly delineated. All operating areas shall be clearly distinguished, and separation facilities shall be employed to prevent mutual contamination.
- VII. Environmental agent storage areas shall be clearly marked. Those factories storing technical grade environmental agents shall establish special storage areas subject to locking control and separated from other materials. Those environmental agent finished products and semi-finished products in storage must be clearly segregated from other materials.

Article 3

Those factories manufacturing microbial preparations used as environmental agents shall possess the following equipment.

- I. Microbial fermentation, culture, or preparation equipment
- II. Packaging equipment
- III. Storage equipment

IV. Sterilization and disinfection equipment

Structural equipment in operating areas containing microbial preparations used as environmental agents, including indoor ceilings, walls, doors and windows, and floors, etc., shall be convenient to wash and disinfect; areas where such agents are manufactured or processed shall be equipped with independent air conditioning systems.

Article 4

Areas where emulsions, liquid, suspensions, oils, and ultra-low capacity environmental sanitation agents are manufactured or processed shall possess the following equipment.

- I. Blending containers
- II. Mixing machines
- III. Storage tanks
- IV. Filling equipment
- V. Packaging equipment

Those factories manufacturing internal pressure aerosols shall possess pressurized filling equipment and leak testing and inspection equipment.

Article 5

Those factories manufacturing and processing dust environmental sanitation agents shall possess the following equipment.

- I. Grinding machines or sifting equipment
- II. Mixing or smelting equipment
- III. Packaging equipment

Article 6

Those factories manufacturing and processing environmental sanitation agents in the form of granules, tablets, chunks, flakes, or gels shall possess the following equipment.

- I. Mixing or smelting equipment
- II. Molding, shaping, or filling equipment
- III. Packaging equipment

Article 7

Equipment used for the production of rodenticide environmental agents may not be used interchangeably with equipment used to produce other environmental sanitation agents.

Article 8

Except in the case of rodenticides and microbial preparations, the manufacturing, processing, and packaging equipment of those environmental sanitation agent manufacturing enterprises that concurrently produce pesticides must be used exclusively for specific purposes.

Article 9

Environmental agent factories shall possess testing equipment or testing laboratories to test the quality of environmental agent finished products. However, if the environmental agent finished products at a factory are entirely identical with technical grade environmental agents in composition and contents, that

factory shall not be subject to this restriction.

Article 10

Those environmental agent manufacturing enterprises that wish to apply for an environmental agent manufacturing permit shall first obtain a factory registration certificate in accordance with the law.

When an environmental agent factory wishes to apply for an environmental agent manufacturing permit, the dosage form equipment of the agent in question shall comply with these Standards.

Article 11

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Article 12

These Standards shall take effect on the date of promulgation.