Content

Title：	Environmental Agent Factory Establishment Standards Ch
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Legislative：	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
Content：	**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 posses 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.

Attachments： 環境用藥工廠設廠標準.pdf

Data Source：Ministry of Environment Laws and Regulations Retrieving System