

## Attachment 9

### Testing Items for Microbial Preparations Used as Environmental Agents and Pollution Control Agents

#### I. Toxicity (Pathogenicity) Testing for Microbial Preparations Used as environmental Agents:

Test Items		Mandatory	Optional
1. Biological toxicity testing	(1) Acute oral toxicity (pathogenicity testing)	○	
	(2) Acute dermal toxicity	○	
	(3) Acute pulmonary or inhalation toxicity (pathogenicity testing)	○	
	(4) Eye irritation (contagion testing)	○	△1
	(5) Dermal sensitization	△	
	(6) Intravenous injection acute toxicity (pathogenicity testing)	△	
	(7) Cell culture testing	△	△2
	(8) Other	△	
2. Ecological Toxicity Data △3	(1) Aquatic organism acute toxicity	○	△4
	(2) Avian acute toxicity	△	△4
	(3) Non-target plant pathogeny	△	
	(4) Non-target insect pathogeny	△	△4
	(5) Honey bee pathogeny/acute toxicity	△	

#### II. Toxicity (Pathogenicity) Testing of Pollution Control Agents and Pollution Control Microbial Preparations:

Test Items		Mandatory	Optional
1. Biological toxicity testing	(1) Acute oral toxicity (pathogeny test)	○	
	(2) Acute dermal toxicity test	△	
	(3) Acute lung or inhalation toxicity (pathogeny test)	△	
	(4) Eye irritation (infection test)	△	
	(5) Allergic reaction	△	
2. Ecological Toxicity Data △3	(1) Residue in the environment from microbial preparation production	△	
	(2) Impact on nutrient cycling	△	△5
	(3) Acute aquatic organism toxicity	○(aquatic)	△5
	(4) Aquatic organism acute toxicity	○(soil)	
	(5) Other	△	

#### Explanation:

I. ○: Mandatory

II. △: Further testing dependant on results.

III. △1: For opportunistic pathogens, injection pathology test results (intravenous, intracerebral, or intraperitoneal) shall be submitted.

IV. △2: This data must be submitted for viral environmental agent microbial preparations.

V. △3: For pollution control agents and environmental agent microbial preparations consisting of microbes for which no literature or reports exist for whether they are pathogenic to the human body or other beneficial biological life, if used in physical or chemical isolation processing equipment, or if the quantity of microbes from the preparation occurring in the discharge from this processing (total microbes per milliliter) is lower than the quantity of the same microbe in the carrier substance (water or soil), data on residue in the environment from microbial preparation production may be submitted, and the data listed in the sub-items of this main testing item do not need to be submitted. However, projects involving genetic engineering absolutely must perform this testing item.

VI. △4: Not required if agent is to be used indoors.

△5: Mandatory for genetically engineered microbial preparations; other importers or local operators shall be required to conduct such testing as deemed necessary.