Working Standards for Environmental Agent Permit Application and Issuance

2018.3.7

Article 1 These Standards are determined pursuant to Article 10, Paragraph 1 of the Environmental Agents Control Act (herein referred to as this Act).

Article 2 Applications for environmental agent licenses, including manufacture, process, and importation should be made to the central competent authority and should include application forms and supporting documentation for Attachment 1 and materials for the application of environmental agent permit (hereinafter referred to as "the permit").

Article 3 The permit should be able to be completed through online application. This restriction shall not apply, however, if the central competent authority agrees to allow written applications.

Article 4 If the documentation referred to in the foregoing paragraph Article 2, Article 16 and Article 17 is in a language other than Chinese, the complete Chinese translation of said documentation must be attached; applications shall be filled out in Chinese, and information about the original manufacturer attached.

Article 5 Applications for permit handled by the central competent authority shall perform checks according to the following rules:

I. When the submitted verifying documents or information is incomplete or does not comply with regulations, if the applicant has failed to properly submit or correct the materials by the deadline after being notified to do so, or if the applicant has performed more than three rounds of correction, the application shall be rejected. Each correction period shall be limited to 90 days.

II. The application shall be summarily rejected when the review fee has not been paid in accordance with regulations.

Article 6 Environmental agents that meet any of the following criteria shall be considered special environmental agents:

I. Agents requiring specialized safety precautions for their use.

II. Agents that require sprayer, fumigators, foggers, sterilizers, ultra-low volume (ULV) sprayers, or other application equipment for their use.

III. Environmental germicides with active ingredient concentrations exceeding the limits listed in Attachment 2.

IV. Application types of germicides used for environmental sanitation not listed in Attachment 2 and that have active ingredient concentrations above 5%.

Article 7 Environmental agents with special qualities may be limited with respect to category, product type, name, volume of content, type of application, components and component content, performance, scope, and method of use.

General use rodenticides shall use a bitterant additive. However, specialized rodenticides are not subject to this restriction.

Article 8 The first time an active component of an environmental agent or microbial preparation used as an environmental agent is registered as an environmental agent in Taiwan, licensing or registration materials from the competent authority of any developed country shall be provided. Chemical agents developed in Taiwan are not subject to this restriction.

Article 9 Applicants seeking to import environmental agents shall submit signed documentation from the Republic of China representative authority stationed overseas:

I. Proof of permission to manufacture and sell said environmental agent from the competent authority in the country of origin.

II. Authorization to act as a sales agent.

If the competent authority in the country of origin has issued manufacture documents for export only in Subparagraph 1 of the foregoing paragraph, production registration or permit issued by any developed country shall be provided. If there is no system for such permits in the country of origin as required, the proof of permission to manufacture may be used instead as proof that said environmental agent is not listed for control by the competent authority in the country of origin

When there is no system for such permits in the country of origin nor any verification documents provided by the relevant competent authority, applicants shall provide verification documents for the manufacture and sale of said environmental agent from the relevant product management agency or institution, or verification documents that the product is already being sold and used as a commercial environmental agent in the country of origin or in countries outside the country of origin. Said documents need not be submitted to Republic of China overseas representative offices for signed verification.

Article 10 The following documents from Mainland China region should first be notarized by Mainland China notary authorities, and then authenticated by the organization or civic group established or designated by the Mainland Affairs Council, Executive Yuan:

I. Proof of permission to manufacture and sell said environmental agent from the competent authority in the Mainland China region

II. Authorization to act as a sales agent

III. Photocopy of formal registration document issued by Mainland China region competent authority

IV. Toxicity testing report

V. Efficacy (potency) testing report

VI. For environmental agents not regulated in the Mainland China region, verification documents from the relevant product management agency or institution, or verification documents that the product is already being sold and

used as a commercial environmental agent in the Mainland China region or in other countries.

Article 11 Permit documents shall include the following items:

I. Permit document number

II. Name, address and statutory responsible person of company

III. Name and address of factory of manufacturer

IV. Types and categories of environmental agents

V. Product names

VI. Product validity period

VII. Performance data

VIII. Application amount and package volume

IX. Composition and contents

X. Date of permit issuance and validity period

XI. Other items designated by the central competent authority

Article 12 A permit is not required for the following substances used as environmental agents:

I. Single component solutions of hypochlorous acid and its salts, sodium chlorite with concentrations of less than 6%.

II. Bleaching agents with chlorine concentrations of 40% or less.

III. Technical grade agents of hypochlorous acid and its salts, Sodium chlorite, chlorine dioxide, sodium borate (boric acid) raw materials.

Article 13 Natural substance products used as environmental pest repellants, rodent repellants or attracting purposes, and not as pesticides, provided with certification of biological effects and components. The applicant should check the documents and data of Attachment 3 for examination and approval by the central competent authority and be exempted from applying for a permit. However, natural substances with natural pyrethrum extracts require application for a permit according to Article 2.

Article 14 Pursuant to Article 10, Paragraph 1 of this Act regarding environmental agent permit applications, a permit shall not be issued when any one of the following circumstances applies:

I. The toxicity of the environmental agent is categorized as highly toxic or extremely toxic according to the WHO Pesticide Oral and Dermal Toxicity Classification (Attachment 4). However, rodenticides and pollution control agents are not subject to this restriction.

II. The applicant already has a permit covering the same components and said components are sourced from the same manufacturer.

III. The environmental agent includes two or more components with the same efficacy. However, germicides and components that are proven to add functionality are not subject to this restriction.

IV. The environmental agent product name already exists or the Chinese name of the active component in the environmental agent is the product name. However, those manufacturing or importing technical grade agents using the Chinese name of the active ingredient as the product name are not subject to this restriction.

V. The competent authority has determined that there is cause for concern that an environmental agent may be hazardous to humans or to the environment.

Article 15 The period of validity of a permit is five years, and each extension cannot exceed five years. If it is necessary to continue manufacturing, processing or importing after the expiry of the period, the extension shall be applied for from the central competent authority within three months to six months prior to the expiration date.

When applying for extension according to the provisions of the preceding paragraph, if the renewal is delayed beyond the license expiry date due to the review process by the Central Competent Authority, the original license shall remain temporarily in effect.

If the application for extension is not applied for during the period specified in the first item, and the central competent authority has not yet made a decision, the original permit will lose its effect from the date of expiry of the term.

Article 16 If a permit extension is granted, the application documents, the supporting documents, and data in Attachment 5 shall be examined and submitted to the central competent authority.

Article 17 Any person who alters, reissues, or renews a permit shall complete the application, the supporting documents and materials listed in Attachment 6, and then apply to the central competent authority.

Any change of company name, company address, domestic manufacturer's name, or address occupant for the above permit shall be made within 90 days after the relevant certification authority receives the final supporting documents from the target business agency.

Article 18 The application method for the extension or change of the permit shall be handled according to the provisions of Article 3.

The procedures for reviewing the extension or change of permit shall be handled in accordance with the provisions of Article 5.

Article 19 The physical and chemical properties of environmental agent testing in the foregoing article shall be conducted by the following testing organizations (institutions):

I. The permit for the Environmental Testing and analysis organizations are authorized under Article 36 of this Law by the central competent authority.

II. Testing and analysis organizations designated by the central competent authority testing and analysis organizations, or public or private academic and

research institutions.

III. An inspection and test organization that conforms to principles of Good Laboratory Practices (GLP) of the OECD, and related documents of proof shall be provided. The composition analysis and testing of environmental agents should be performed as prescribed in the first subparagraph and the second subparagraph of the foregoing paragraph.

The environmental agent efficacy (effectiveness) test shall be handled in accordance with the subparagraph 2 of Paragraph 1. However, those who conduct tests abroad are not subject to this restriction.

Article 20 An environmental agent toxicity testing organization must be a professional toxicological testing organization, and must comply with superior laboratory operating regulations or testing regulations of Taiwan, the United States, European Union, Japan, or the Organization for Economic Cooperation and Development (OECD).

Article 21 Environmental agent toxicity testing items are as follows:

I. For first-time applications to register an active component as an environmental agent, see Attachment 7.

II. For technical grade environmental agents and general and special environmental agents, see Attachment 8.

III. For microbial preparations used as environmental agents and pollution control agents, see Attachment 9.

IV. The toxicity test of human chemical repellents, see Attachment 10 and Attachment 11.

For the general and special environmental agents in the foregoing second item, synergists representing less than 1% of the total volume shall not be deemed active components.

Article 22 Testing methodologies adopted for the environmental agent efficacy (potency) testing, active component content analysis or physical and chemical properties reports shall be conducted in accordance with Chinese National Standards or central competent authority testing methodologies; if standard testing methodologies for certain items have not been officially announced, then the applicant shall provide the testing methodology.

For the foregoing paragraph standard tests or methods that are not promulgated in Taiwan, test standards approved by the Organization for Economic Cooperation and Development (OECD) and organizations validated by it or the competent authority of any country such as the U.S. or Japan shall be adopted or the applicant shall provide the test method.

Article 23 Environmental agent efficacy (potency) testing reports shall comply with the following rules:

I. For the biological species and conditions to be used in environmental agent

efficacy testing, see Attachment 12.

II. Control performance data included in the registration application must include an efficacy (potency) testing report; however, for agents that control centipedes, millipedes, spiders, and chiggers, the examiner may indicate recommended application amount and method of application based on documentation, which can then be submitted by the applicant.

III. Efficacy (potency) testing reports for special environmental agents and microbial preparations used as environmental agents shall include the dilution factor of its control performance (including the highest dilution factor to achieve control results that meet efficacy auditing standards).

IV. Applications related to mosquito repellent incense, electrically-activated mosquito repellent incense, and electrically-activated liquid mosquito repellent incense indicating usage period of over 8 hours must submit a time-correlated testing and analysis evidence report.

V. For dichlorobenzenes, naphthalene, or synthetic camphor products with the same active component as the technical grade agent, the enterprise shall carry out efficacy testing on either the technical grade agent or the product.

Article 24 The performance data of environmental agents in Article 9, Paragraph 1 of this Act shall be determined pursuant to efficacy testing results standards (Attachment 13).

Article 25 Applications for approval or modification of general and special environmental agents or environmental medicine microbiological preparations with validity periods of more than two years shall submit products with the same manufacture date and batch number, along with efficacy (potency) testing reports and active component analysis reports conducted at the time of manufacturing and when conducted two years or more following manufacturing. However, the effective period of environmental agent products is up to five years.

The effective period of the product for technical grade environmental agent is up to five years.

Article 26 The central competent authority has the right to revoke and repeal the Environmental Agents Permit in any of the following cases:

I. False contents of documents or information.

II. False items that are recorded on the record form for environmental agents on the basis of the obligation recorded in Paragraph 1, Article 24 of the Act

If environmental technical grade agents import permit acquired for the manufacture and processing of environmental agents for export is not used on the manufacture and processing of the abovementioned agents, the central competent authority shall withdraw the import permit.

Article 27 The standards shall take effect from the date of promulgation.

Attachment 1

I. Documents of Proof and Information for Application required for applying for permits

Manufacture Permit	Import Permit
Documentation	
1. Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of factory registration 5. Photocopy of verification letter of professional technician at site 6. Photocopy of technical grade environmental agents transfer approval or technical grade environmental agent permit use authorization 7. Photocopy of environmental agent licensing application sample approval document	1.Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of environmental agent sales vendor permit 5. Signed original copy of manufacturing and sales permits from regulatory authorities in country of origin 6. Signed original copy of foreign enterprise authorization document 7. Information on overseas product commercialization (labels) 8. Photocopy of environmental agent licensing application sample approval document
Materials	
1. Physical and chemical properties data for technical grade and finished product agents (microbial preparations must submit biological properties data) 2. Methodology of physical, chemical, and biological analyses 3. Active component content analysis report 4. Toxicity texting report 5. Efficacy testing (for environmental agents and microbial preparations used for environmental sanitation) or potency testing (for microbial preparations used for pollution control and pollution control agents) 6. Overview of production method (explanation of production process) 7. Product safety and quality testing, usage and storage description 8. Pollution control manual 9. Labels	1. Physical and chemical properties data for technical grade and finished product agents (and attach data concerning original manufacturing plant; attach biological data in the case of microbial preparations) 2. Methodology of physical, chemical, and biological analyses 3. Active component content analysis report 4. Toxicity texting report 5. Efficacy testing (for environmental agents and microbial preparations used for environmental sanitation) or effectiveness testing (for microbial preparations used for pollution control and pollution control agents) 6. Overview of production method (explanation of production process, and attach data concerning original manufacturing plant) 7. Product safety and quality testing, usage and storage description 8. Labels

II. Documents of Proof and Information for Application for Import Permit of Technical Grade Agents Required by Export of General or Restricted-Use Environmental Agents

Documentation
1.Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of environmental agent sales vendor permit 5. Photocopy of factory registration 6. Photocopy of manufacturing and sales permits from regulatory authorities in country of origin 7. Signed original copy of foreign enterprise authorization document 8. Information on overseas product commercialization (labels)
Materials
1. Physical and chemical properties data for technical grade agents 2. Methodology of physical, chemical analyses 3. Toxicity texting report summary (Chinese and English summaries) 4. Efficacy testing summary (Chinese and English summaries) 5. Overview of production method (explanation of production process) 6. Product safety and quality testing, usage and storage description 7. Labels

Attachment 2

Concentrations of Germicides for General Environmental Sanitation Use

Active Component Chinese/English Name	Application Type	Concentration
Name of Active ingredient		
Alky1 dimethy1 benzy1 ammonium saccharinate	Liquid, aerosol spray	4.80 %
Benzalkonium chloride	Liquid, aerosol spray	4.80 %
Didecyldimethyl ammonium chloride	Liquid, aerosol spray	1.68 %
Glutaraldehyde	Liquid, aerosol spray	2.68 %
n-Alkyldimethylbenzyl ammonium chloride	Liquid, aerosol spray	4.80 %
Obanol-516	Liquid, aerosol spray	5.00 %
o-Benzyl-p-chlorophenol	Liquid, aerosol spray	5.00 %
o-Phenylphenol	Liquid, aerosol spray	5.00 %
p-Chlorophenol	Liquid, aerosol spray	5.00 %
p-Dichlorobenzene	Liquid, aerosol spray	5.00 %
Polyalkyl polyamino ethylglycine	Liquid, aerosol spray	5.00 %
p-ter-Amylphenol	Liquid, aerosol spray	5.00 %
Calcium hypochlorite, $Ca(ClO)_2$	Pellet, tablet, powder, liquid	90 %
Chlorine dioxide, ClO_2	Liquid, powder, tablet	50 %
Sodium chlorite, $NaClO_2$	Liquid, powder, tablet	50 %
Sodium hypochlorite, NaClO	Powder	50 %
Bleach	Powder	80 %

Attachment 3

Verification Documents and Materials Required for Natural Material Products

Manufacture Permit	Import Permit
Documentation	
1. Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of factory registration 5. Photocopy of verification of origin of natural raw materials	1. Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of factory registration 5. Photocopy of verification of origin of natural raw materials 6. Information on overseas product commercialization
Materials	
1. Active component content analysis report (Contains raw materials and products) 2. Efficacy texting report 3. Explanation of production process of raw material for natural substance 4. Labeling instructions (see Note)	1. Active component content analysis report (Contains raw materials and products) 2. Efficacy texting report 3. Explanation of production process of raw material for natural substance 4. Labeling instructions (see Note)

Note: Labeling instructions for labeling items

I. Approved number.

II. The name of product.

III. The content of product:

(1) Composition and content of natural material

(2) Net weight, capacity, quantity or measurement, etc.; its net weight, capacity or measure shall be marked with statutory weights and measures, and if necessary, other units may be added.

IV. Control performance.

V. The scope of application and use.

VI. Precautions for the use and storage.

VII. Poisoning symptoms, first aid and detoxification methods.

VIII. Recycling and cleaning methods for discarded containers.

IX. Production, name of manufacturer, telephone number, address and place of origin of the product. Any imported product should indicate the name, telephone number and address of importer.

X. Manufacturing date and batch number.

XI. Product expiration date.

Attachment 4

Toxicity Classification for Pesticides by WHO in 2009

	LD_{50} for Rat (mg/kg)	
	Oral	Dermal
Extremely Toxic	<5	<50
Highly Toxic	5-50	50-200
Moderately Toxic	50-2000	200-2000
Lightly Toxic	>2000	>2000
Slightly Toxic	>=5000	

Attachment 5

Documentation and Materials Required for the Extension of Environmental Agent Permits

Manufacture permit	Import permit
Documents of proof	
1. Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of factory registration 5. The original permit 6. Photocopy of document of approval for transfer of technical grade environmental agent or document of authorization of use for technical grade agent	1. Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration (not required if it's a company) 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of environmental agent sales vendor permit 5. The original permit 6. Official copy of document of authorization issued by a foreign firm in the last 2 years 7. Information of proof that the original permits for manufacture and marketing are still effective (such as information from official website or other official documents)
1. Analysis report of the content of active ingredients in the last year 2. Efficacy(potency) test report in the last year 3. Labels	1. Report of the content of active components analysis conducted domestically in the last year 2. Report of Efficacy(potency) test conducted domestically in the last year 3. Labels

Attachment 6

Verification Documents and Materials Required for Permit Modification, Reissue, and Renewal Applications

Permit document / Required / Modification	Manufacture permit	Import permit
Company name	1. Photocopy of company license or document of proof for company registration (not required if it's not a company) 2. Photocopy of business registration certificate (not required if a company) 3. Photocopy of factory registration 4. The original permit 5. Labels 6. Photocopy of certificate for employment of professional technicians	1. Photocopy of company license or document of proof for company registration (not required if it's not a company) 2. Photocopy of business registration certificate (not required if a company) 3. Photocopy of environmental agent vendors permission license 4. Official copy of verified document of proof for approval of manufacture and marketing by the last 2 years competent authority of country of origin 5. Statement for legal liability of the product (required for permit holders for change of information) 6. The original permit 7. Labels
Company address	1. Photocopy of company license or document of proof for company registration (not required if not a company) 2. Photocopy of business registration certificate (not required if a company) 3. Photocopy of factory registration 4. The original permit 5. Labels	1. Photocopy of environmental agents vendors permission license 2. The original permit 3. Labels
Responsible person	1. Photocopy of company license or document of proof for company registration (not required if not a company) 2. Photocopy of business registration certificate (not required if a company) 3. Photocopy of factory registration 4. Photocopy of person identification	1. Photocopy of environmental agent vendors permission license 2. Photocopy of person identification 3. The original permit

	5 The original permit	
Manufacturer name	1. Photocopy of company license or document of proof for company registration (not required if not a company) 2. Photocopy of business registration certificate (not required if a company) 3. Photocopy of factory registration 4. The original permit 5. Labels	1. Official copy of verified document of proof for approval of manufacture and marketing by the competent authority of country of origin in the last 2 years 2. Official copy of document of authorization issued by a foreign firm in the last 2 years 3. The original permit 4. Labels
Manufacturer address	1. Photocopy of company license or document of proof for company registration (not required if not a company) 2. Photocopy of business registration certificate (not required if a company) 3. Photocopy of factory registration 4. The original permit 5. Labels	1. Official copy of verified document of proof for approval of manufacture and marketing by the competent authority of country of origin in the last 2 years 2. The original permit 3. Labels
Product name	1. The original permit 2. The last date of manufacture, lot number and quantity of environmental agent 3. Labels 4. Document of proof issued by a firm of exported country	1. Official copy of verified document of proof for approval of manufacture and marketing by the competent authority of country of origin in the last 2 years 2. The original permit 3. The last date of manufacture, lot number and quantity of environmental agent 4. Labels 5. Document of proof issued by a firm of exported country
Packing	The original permit	1. Document of approval issued by the original foreign manufacturer 2. The original permit
Performance	1. Report of the content of active ingredients analysis conducted domestically in the last year 2. Report of efficacy(potency) test conduct domestically in the last year 3. The original permit 4. Labels	1. Mill certificate issued by the manufacturer 2. Report of the content of active components analysis conducted domestically in the last year 3. Performance (effectiveness) test report in the last year 4. The original permit 5. Labels
Accessory constituent	1. Information about physical and chemical properties 2. Material Safety Data Sheet(MSDS)	1. Mill certificate issued by the manufacturer 2. Information about physical and chemical properties

	3. The original permit	3. Material Safety Data Sheet(MSDS) 4. The original permit
Shelf life active of product	1. Report for measurement of active ingredient content decay (the active ingredient content analysis reports before and after the expiration date) 2. Test report for the performance (effectiveness) test of the said agent from the same manufacture date and lot number of the agent containing the identical active components (cross-reference; the chemical agents prior to cross-reference shall be the environmental agents produced within six months before sampling) 3. The original permit 4. Labels	1. Mill certificate issued by the manufacturer 2. Report for measurement of active component content decay (the active component content analysis reports before and after the expiration date) 3. Test report for the performance (effectiveness) test of the said agent from the same manufacture date and lot number of the agent containing the identical active components （cross-reference）; test reports not required for technical grade products 4. The original permit 5. Labels
Others	Relevant documents or information	Relevant documents or information

Attachment 7

Toxicity Testing Items for Registering Environmental Agent Active Components in Taiwan for the first Time

Testing Items	Mandatory	Optional
(Acute toxicity testing)		
(Acute oral toxicity)	○	
(Acute dermal toxicity)	○	
(Acute inhalation toxicity)	○	
(Acute eye irritation)	○	
(Acute dermal irritation)	○	
(Dermal sensitization)	○	
(Acute neurotoxicity)		△
(Subchronic toxicity testing)		
(90-day feeding toxicity)	○	
(21-day dermal toxicity)		△
(90-day inhalation toxicity)		△
(90-day neurotoxicity)		△
(Chronic toxicity testing)		
(Long-term Chronic feeding toxicity)	○	
(Oncogenicity)	○	
(Two-Generation Reproduction Toxicity)	○	
(Teratogenicity)	○	
(Mutagenicity testing)		
In vitro mammalian cell chromosome assay	○	
Bacterial reverse gene mutation assay	○	
In vivo mammalian cell chromosome cytogenetics assay	○	
(Metabolism)		
(Metabolism in animal)	○	
(Metabolism in plant)		△
(Environmental fate studies)		
(Hydrolysis)	○	
(Photodegradation)	○	
(Metabolism in soil)	○	
(Metabolism in Aquatic)		△
(Accumulation studies)		△
(Nontarget organism toxicity)		
(Aquatic organism toxicity)	○	
(Avian toxicity)		△
(Honey bee acute contact toxicity)		△

△Selective inspection tool: The toxic test data should be provided if the original manufacturer has it.

Attachment 8

Toxicity Testing Items for Technical Grade Environmental Agents and General and Special Environmental Agents

Classifications \ Types \ Test Items		Active Components	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Primary eye irritation (skin irritation)	Mutagenicity testing (genetic mutation, chromosomal aberration, other)	Dermal Sensitization	Aquatic Organism Toxicity
Technical Grade Environmental Agent	Previously registered component (me-too comp.)	1	○	○	○	○	○		○
General Use Environmental Agents	Pesticides, Miticides (aerosol)	1							△1
		2–3	○	○					△1
		4 or more	○	○	○	○	○	○	△1
	Pesticides, Miticides (mosquito-repellent incense, electrically-activated mosquito repellent incense, liquid electrically-activated mosquito repellent incense, smoke generator, fumigant)	1							△1
		2–3	○	○	△3				△1
		4 or more	○	○	○	○	○	○	△1
	Pesticides, Matricides (bait, powder, granules, flakes, pieces/chunks, liquid, oil, paste)	1							△1
		2–3	○	○		△2			△1
		4 or more	○	○	○	○	○	○	△1
	Rodenticide	1							△1
	Bactericides /Fungicides	1							△1
		2–3	○	○		△2			△1
		4 or more	○	○	○	○	○	○	△1
Special environmental agents	Insecticide (liquid, suspensions, oils, wettable powders, ultra-low capacity agents, hydrates, emulsions, or other preparations), Germicides	1				△2			△1
		2–3	○	○		△2			△1
		4 or more	○	○	○	○	○	○	△1

Explanation:

I. ○: Mandatory

II. △1: Finished products made with technical grade environmental agents that are toxic to aquatic organisms and labeled as being toxic to aquatic organisms are not required to submit aquatic organism toxicity data.

III. △2: Finished products made with technical grade environmental agents that can cause dermal sensitization and that have been labeled as causing dermal sensitization are not required to submit dermal sensitization data.

IV. △3: Agents labeled to indicate that the windows should be temporarily closed when used in an indoor environment and that people and domestic animals should vacate the space are exempt from having to submit acute inhalation toxicity testing data of the finished product, whereas those without such labeling must submit said data.

V. If an active component of an environmental sanitation germicide is being registered for environmental use for the first time, but the same active component has already been registered for agricultural, pharmaceutical, or veterinary use, technical grade environmental agent toxicity testing items shall be submitted.

VI. Mutagenicity testing includes *in vitro* mammalian cell chromosome assay, bacterial reverse gene mutation assay, *in vivo* mammalian cell chromosome cytogenetics.

VII. First time domestic application for pheromones should make certain that the toxicological test item is attached to the same effective ingredient (me-too comp.) that has been registered.

Attachment 9
Testing Items for Microbial Preparations Used ad 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 testingitem.

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.

Attachment 10

New Effective Components of Chemical Repellents for Humans and Toxicity Testing Products

Testing Items	Mandatory	Optional
(Acute toxicity testing)		
(Acute oral toxicity)	○	
(Acute dermal toxicity)	○	
(Acute inhalation toxicity)	○	
(Acute eye irritation)	○	
(Acute dermal irritation)	○	
(Dermal sensitization)	○	
(Acute neurotoxicity)		△
(Subchronic toxicity testing)		
(90-day feeding toxicity)	○	
(21-day dermal toxicity)		△
(90-day inhalation toxicity)		△
(90-day neurotoxicity)		△
(Chronic toxicity testing)		
(Long-term Chronic feeding toxicity)	○	
(Oncogenicity)	○	
(Two-Generation Reproduction Toxicity)	○	
(Teratogenicity)	○	
(Mutagenicity testing)		
In vitro mammalian cell chromosome assay	○	
Bacterial reverse gene mutation assay	○	
In vivo mammalian cell chromosome cytogenetics assay	○	
(Metabolism)		
(Metabolism in animal)	○	
(Metabolism in plant)		△
(Environmental fate studies)		
(Hydrolysis)	○	
(Photodegradation)	○	
(Metabolism in soil)	○	
(Metabolism in Aquatic)		△
(Accumulation studies)		△
(Nontarget organism toxicity)		
(Aquatic organism toxicity)	○	
(Avian toxicity)		△
(Honey bee acute contact toxicity)		△

△ Selective inspection tool: The toxic test data should be provided if the original manufacturer has it.

Attachment 11

Chemical Repellents for Humans and Toxicity Testing Products for End Products

Test / Types / Items Classifications		Active Components	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Primary eye irritation (skin irritation)	Mutagenicity testing	Dermal Sensitization	Aquatic Organism Toxicity
Technical Grade Environmental Agents	Previously registered component (me-too comp.)	1	○	○	○	○	○	○	△
General Use Environmental Agents	Chemical repellents for human use	1	○	△2	△1	△3		○	
		2–3	○	○	△1	△3		○	
		4 or more	○	○	○	○	○	○	

Explanation:

(1) ○ Indicators must be checked.

(2) △ If original manufacturer has toxic test data, it should be provided.

(3) △1 Spray should be provided.

(4) △2 Oral acute toxicity LD_{50} <2000mg/kg bw, should be provided.

(5) △3 Those who have skin allergies should provide skin irritation and eye irritation.

(6) The mutagenicity test includes: In vitro mammalian cell chromosome assay, bacterial reverse gene mutation, and in vivo mammalian cell chromosome cytogenetics assay.

Attachment 12

Type of Organisms and Conditions for Environmental Agent Performance tests

Test Organisms	Type	Scientific Name	Sex	Strain	No. of Generation	Age	Test Condition
Mosquitoes, adults	*Aedes albopictus*	○	Female	○	<10	3-7 days of eclosion	Have not sucked blood
	or						
	Aedes aegypti	○	Female	○	<10	3-7 days of eclosion	Have not sucked blood
and	*Culex quinquefasciatus*	○	Female	○	<10	3-7 days of eclosion	Have not sucked blood
	or						
	culex pipiens molestus	○	Female	○	<10	3-7 days of eclosion	Have not sucked blood
Mosquitoes, larvae	*Aedes albopictus*	○		○	<10	3-4 days	
	or						
	Aedes aegypti	○		○	<10	3-4 days	
and	*Culex quinquefasciatus*	○		○	<10	L3-L4	
	or						
	culex pipiens molestus	○		○	<10	L3-L4	
Flies, adults	*Musca domestica*	○	Female	○	<10	3-7 days of eclosion	
Flies, larvae	*Musca domestica*	○		○	<10	3-5 days	
Cockroaches	*Periplaneta americana*	○	Female/male	○		Adult △	
	Blattella germanica	○	Female/male	○		Adult △	
Fleas	*Ctenocephalides felis*	○		○		Adult	Have not sucked blood
	or						
	Xenopsylla cheopis	○		○		Adult	Have not sucked blood

Flea larvae	*Ctenocephalides felis*	○		○		2-3 days
	Xenopsylla cheopis	○		○		2-3 days
Termites (indoor)	or *Coptotermes flaviceps*	○		○		Workers△
	or *Odontotermes formosanus*	○		○		Workers△
Ants	*No limit for types or strains*	No limit for types or strains		○		Workers△
Fire ants △	*No limit for strains*	No limit for strains				
Rats	*Rattus norvegicus*	○	○	○	<10	Adult (>200g)
	or *Rattus rattus*	○	○	○	<10	Adult (>100g)
Forcipomyia taiwana	○	○	Female	○		
Forcipomyia taiwana, larvae	○	○		○		
		○				
Dust mites	*Dermatophagoides farina*	○				
and	*Dermatophagoides pteronyssinus*	○				
Drosophilas,	*Drosophila*	○		○	<10	Adult 1-3
Phorid flies	*melanogaster*	○		○	<10	days
	Megaselia scalaris					Adult 1-3 days
Mothflies		○		○		Adult or larva
Bed bugs	*Cimex lectularius*	○	Female/male	○	<10	Adult or
or	*Cimex hemipterus*	○	Female/male	○	<10	Nymph
		○		○		

		○		○		
Silverfish	*Ctenolepisma villosa*	○	Female/male	○	<10	Adult or
or	*Lepisma saccharina*	○	Female/male	○	<10	Nymph
						Adult
Booklice	*Liposcelis entomophila*	○	Female/male	○	<10	Adult
or	*Liposcelis bostrychophila*	○	Female/male	○	<10	Adult
Case-bearing		○	Female/male	○	<10	Larva
clothes moths		○	Female/male	○	<10	Larva (late
Arthropoda						age)
	Crossopriza lyoni	○	Female/male	○	<10	Adult
Spiders	*Lycosidae (Wolf*	○	Female/male	○	<10	Adult
or	*spider)*					
	Longhorn springtail	○	Female/male	○	<10	Adult or
Springtails						Nymph

Explanation:

I. ○: Mandatory

II. △: If uses insect growth regulators (IGR), 3rd instar or older larvae or nymph shall be used.

Attachment 13
Control Efficacy Testing Results Evaluation Standards for Environmental Agent Permit Registrations

Efficacy	Evaluation standards	Required efficacy testing report data
Pesticides efficacy Miticides efficacy Insect repellent effect	For residue control, mortality rate greater than 70 %.	1. 24 hour mortality. 2. For those testing reptiles with residue method and suitable for indoor uses, test report on residue period (2 weeks at least) is required.
	1. Mortality rate greater than 80 %. 2. Those added with knockdown agent shall comply with review criteria: KT_{50} less than 6 minutes for mosquitoes, KT_{50} less than 8 minutes for flies and KT_{50} less than 11 minutes for cockroaches are considered effective for knockdown.	1. 24 hour mortality. 2. The added knockdown agent shall have a 50% knockdown time (KT_{50}).
	For long release formulations (such as baits), mortality greater than 80 %.	There shall be mortality and the number of average days of mortality. Maximum observation period is 14 days.
	Flush-out time: FT_{50} less than or equal to 7 minutes is considered effective for flush-out.	Flush-out agent shall have 50% flush-out time.
Growth inhibition efficacy	Growth retarding rate (or mortality) greater than or equal to 70 % is considered effective for growth retarding.	Growth retarding rate for control of cockroaches, ants, fire ants and other insects.
	Pupal or eclosion retarding rate greater than or equal to 50 % is considered effective for growth regulation.	Those for control of larvae of mosquitoes, flies and fleas shall have pupal rate and eclosion rate.
Knockdown efficacy(mosquito coil, mosquito mat, mosquito liquid)	1. KT_{50} less than 6 minutes for mosquitoes, KT_{50} less than 8 minutes for flies and KT_{50} less than 11 minutes for cockroaches are considered effective for knockdown. 2. Knockdown agent with a mortality of 80% is considered effective for pest control.	1. Knockdown agent shall have 50% knockdown time KT_{50}). 2. The knockdown agent looking for not only knockdown effect but also control effect shall have 24 hour mortality.
Rat mortality	Greater than 80 %	Rodenticides shall have mortality and the number of average days of mortality.
Sterilization effect	Sterilization rate greater than 99.9 %.	Bactericides/fungicides shall be marked with disinfection rate (note 1).
Repelling effect	Repelling rate greater than 75 %.	1. Insect repellents shall have repelling effect of 24 hours. 2. The repellent rate of chemical repellents used by humans.

Note 1: The following bacteria should be included in Environmental Sanitation Germicide testing.

Bacillus cereus	*Bacillus cereus* BCRC 10603
Escherichia coli	*Escherichia coli* BCRC 10675
Pseudomonas aeruginosa	*Pseudomonas aeruginosa* BCRC 10944
Salmonella choleraesuis	*Salmonella choleraesuis* BCRC 10744
Staphlococcus aureus subsp. aureus	*Staphlococcus aureus subsp. aureus* BCRC12657
Aspergillus niger (note 2)	*Aspergillus niger* BCRC 30130

Note 2: For germicidal preparations used as environmental sanitation agents not targeting fungi, *Aspergillus niger* testing is not required.