Working Standards for Environmental Agent Permit Application and Issuance

Twenty articles promulgated by Environmental Protection Administration Order Huan-Shu-Tu-Tze No. 0950057292 on July 21, 2006, effective as of November 10, 2006.

Revisions to Articles 4, 6, 11, 12, 18, 20, revisions to Attached Table 6 in Article 14 and Attached Table 7 in Article 15, and deletion of Article 19 promulgated in Environmental Protection Administration Order Huan-Shu-Tu-Tze No. 0980109222A on December 4, 2009.

Twenty articles promulgated by Environmental Protection Administration Order Huan-Shu-Tu-Tze No. 1020048402 E on June 13, 2013.

Article1 These Standards are determined pursuant to Article 10, Paragraph 1 of the Environmental Agents Control Act (herein referred to as this Act).

Article2 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 1). 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.

VI. Information on documents or application forms are false or misleading.

The permit will not be extended in the case of Paragraph 5 or Paragraph 6 of the aforesaid.

Article3 An environmental agent permit is not required for the following environmental agents:

I. Single component solutions of hypochlorous acid and its salts, sodium chlorite with concentrations of less than 6%; or solutions of greater than 6% concentration when not for use as germicides.

II. Bleaching agents with chlorine concentrations of 40% or less; or concentrations of 40% or greater when not for use as germicides.

III. Hypochlorous acid and its salts, chlorine dioxide, sodium borate (boric acid) raw materials. However, general or special environmental agents using sodium borate (boric acid) or chlorine dioxide as a component are not subject to this restriction.

IV. Natural substances used as pest repellants and not as pesticides, provided with certification of

biological effects and components. However, natural substances with natural pyrethrum extracts are not subject to this restriction.

In Subparagraph 3 of the foregoing paragraph, general or restricted-use environmental sanitation agents containing chlorine dioxide as an active component are regulated to apply for Environmental Agents Permit and will take effect on July 1, 2014.

Efficacy and components of natural materials shall be provided and are regulated in Subparagraph 4 of Paragraph 1 and will take effect on January 1, 2014.

Article4 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%.

Article5 Environmental agents with special qualitites may be limited with respect to category, product type, name, volume of content, type of application, components and component content, performance, and scope and method of use,

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

Article6 Applications for environmental agent licenses, including extensions, modifications, replacements, and renewals should be made to the central competent authority and should include application forms and supporting documentation and materials (Attachment 3). Such applications should be made online as prescribed by the central competent authority. This restriction shall not apply, however, if the central competent authority agrees to permit written applications. This restriction shall not apply, however, when the central competent authority has granted its consent.

If the documentation referred to in the foregoing paragraph 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.

Article7 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.

Article8 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.

~~Article10~~Article9 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.

~~Article11~~Article10 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.

Regulations on standard tests adopted by test reports of physical and chemical properties of environmental agents in Paragraph 1 will be in effect on July 1, 2014.

~~Article12~~Article11 The environmental agent testing in the foregoing article shall be conducted by the following testing organizations:

I. Testing and analysis organizations by the central competent authority or certified testing and analysis organizations.

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 Practice (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 of the foregoing paragraph.

Subparagraph 2 of Paragraph 1 will take effect on January 1, 2014.

~~Article13~~Article12 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).

~~Article14~~Article13 Environmental agent toxicity testing items are as follows:

I. For first-time applications to register an active component as an environmental agent, see Attachment 4.

II. For technical grade environmental agents and general and special environmental agents, see Attachment 5.

III. For microbial preparations used as environmental agents and pollution control agents, see Attachment 6.

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.

~~Article15~~Article14 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 7.

II. Control performance data included in the registration application must include an efficacy (potency) testing report; however, for agents that control centipedes, millipedes, and spiders, 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.

~~Article16~~Article15 The performance data of environmental agents in Article 9, Paragraph 1 of this Act shall be determined pursuant to efficacy testing results standards (Attachment 8).

~~Article17~~Article16 Applications for approval or modification of general and special environmental agents 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 manufacture.

Applications for approval or modification of technical grade environmental agents with validity periods of more than three years shall submit products with the same manufacture date and batch number, along with active component analysis reports conducted at the time of manufacturing and when conducted three years or more following manufacture.

The validity period for environmental agents shall be no longer than a maximum of five years.

~~Article18~~Article17 Environmental agent 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

~~Article19~~Article18 Applications for environmental agent permits 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 60 days.
II. The application shall be summarily rejected when the review fee has not been paid in accordance with regulations.

~~Article20~~Article19 The central competent authority has the right to revoke 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.

~~Article21~~Article20 The standards shall take effect from the date of promulgation unless an enforcements

date is specified.

Attachment 1

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 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

I. Documents and Information to Be Submitted with Environmental Agent Permit Applications

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 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of factory registration (Note 1) 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 (Note 4)	1.Photocopy of document verifying company registration (not required in the case of non-companies) 2. Photocopy of document verifying commercial registration 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 (Note 2) 6. Signed original copy of foreign enterprise authorization document (Note 3) 7. Information on overseas product commercialization (labels) 8. Photocopy of environmental agent licensing application sample approval document (Note 4)
Materials	
1. Physical and chemical properties data for technical grade and finished product agents (microbial preparations must submit biological properties data) (Note 5 and Note 6) 2. Methodology of physical, chemical, and biological analyses 3. Active component content analysis report (Note 4,Note 7,Note 9andNote 13.1) 4. Toxicity texting report (Note 4,Note 9, Note 10 and Note 11) 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 (Note 4,Note 7 and Note 9) 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) (Note 5 and Note 6) 2. Methodology of physical, chemical, and biological analyses 3. Active component content analysis report (Note 4,Note 7,Note 9andNote 13.1,) 4. Toxicity texting report (Note 4,Note 8, Note 9, Note 10 and Note 11) 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 (Note 7 and Note 9) 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 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 (Note 1) 6. Photocopy of manufacturing and sales permits from regulatory authorities in country of origin (Note 2 (1)~(4)) 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

Note 1: If the photocopy of document verifying factory registration does not list the dosage form of the environmental agent for which the application has been made, the applicant must submit a photocopy of the letter of approval stating the chief product from the competent authority in charge of factory registration.

Note 2: Verification documents of manufacturing and sales permits from the competent authority in the country of origin shall include:

A. Date of issuance and date of signing

B. Permit number

C. Name of environmental agent

D. Type of active component and contained amount

E. Company name and address

F. Manufacturer name and address

G. Seal of competent authority or signature of responsible person in country of origin

The content of documents shall be sufficient to judge whether the authorization documents are for the same environmental agent. When such content is not clearly indicated, explanations and documents with such content must be submitted and authenticated. If manufacturing and sales verification documents are from different competent authorities in the country of origin, then verification documents from each competent authority in the country of origin shall be submitted

Note 3: Foreign manufacturers authorization and verification documents shall include

A. Company name and address

B. Manufacturer name and address
C. Name of authorized domestic agent or distributor
D. Product name
E. Manufacturer name and address
F. Name of authorized domestic agent or distributor
G. Product name

If foreign companies have licensed domestic manufacturers to manufacture the environmental agent, then proof of authorization to manufacture shall be attached.

Note 4: When manufacturing or importing samples needed for testing, an application must be made to the central competent authority for approval pursuant to Article 23, Paragraph 1 of this Act, and samples must be provided to relevant units for testing within one year after receipt of approval.

Note 5: Test reports shall be submitted with physical and chemical information. When applying for a environmental agent new dosage form or new use method (where no domestic registration has been made to manufacture the environmental agent with that dosage form or use method), technical data for the technical grade manufacturing plant and relevant explanation should be provided. When a new dosage form or new use method has been developed domestically, a comparative table showing the doses of relevant current dosage forms (powder, liquid, gas) used must be provided.

Note 6: When applying for a technical grade environmental agent permit, five component analysis reports shall be provided and all impurities accounting for more than 0.1% of the technical grade environmental agent must be listed and related toxicity information must be supplied by the manufacturer of said technical grade environmental agent. If technical grade agents are isomers, then cis-trans isomer ratio analysis data shall be submitted along with related explanations. The central competent authority will determine the method for isomer or impurity testing to be used by the applicant. Apart from food-grade substances, materials safety data sheets for other secondary components added to general or special environmental agents must be attached.

Note 7: Environmental agent manufacturing permit applications must submit efficacy (potency) testing results for all batches manufactured on the same date as the testing sample. If applicants for import permits are conducting testing in Taiwan, samples for environmental agent testing must be taken from the same batch and same manufacturing date as the active component samples. When a synergist is added to a finished product, an analytical report concerning the synergist's active components must be provided regardless of whether the synergist content exceeds 1%, and synergist test values must be included. When importing an environmental agent whose active component is p-dichlorobenzene or manufacturing technical grade environmental agent p-dichlorobenzene, test must also be performed to determine whether the substance contains o-dichlorobenzene, which is prohibited in environmental agents. The composition test report should list the test method numbers.

Note 8: Toxicity testing and efficacy (potency) testing for environmental agent import permit applications must submit testing reports from the original manufacturer of the product. Efficacy testing may not be conducted by the original manufacturer. However, the independent institutions established

pursuant to relevant laws are not subject to this restriction. Efficacy (potency) testing must be done by testing institutions authorized by the central competent authority.

Note 9: Active component analysis testing, toxicity testing and efficacy (potency) testing reports must be signed by tester and statutory responsible person and must display the seal of the testing body or institution. If submitted toxicity report and materials are photocopies, such photocopies shall be signed by the certified toxicity expert, director of the toxicity testing lab, or the original manufacturer related to the testing. If a toxicology test report or data is photocopied, one of the concerned parties must sign the test report; the signer may be a toxicologist who has passed an examination, the statutory responsible person of the original toxicological analysis and testing organization or unit, or the responsible person of the original manufacturing plant.

Note 10: Toxicity testing reports:

A. For active components registered in Taiwan for the first time as environmental sanitation agents, toxicity testing reports for the technical grade agent must be submitted as per items in Attachment 4.

B. For applications for general or special environmental agent import permits, written explanation of the source of the technical grade agent of the finished product and the toxicity testing report of the finished product as per items in Attachment 5 shall be submitted. If the source of the technical grade agents has not been registered domestically, then a toxicity testing report of the technical grade agent shall be submitted as well, as per items in Attachment 5.

C. For applications for general or special environmental agent manufacturing permits, a toxicity testing report for the finished product shall be submitted as per items in Attachment 5. In the case of a general or special environmental agent, if a registered manufacturer's registration of the same components and composition has been authorized, and documents verifying the registered manufacturer's authorized registration file are provided, a toxicity test report is not needed. However, an application for change of components or composition may not be made when a product's registration has been authorized.

D. For applications for me-too component technical grade environmental agent manufacture or import permits, a toxicity testing report shall be submitted as per items in Attachment 5.When, in the case of a technical grade environmental agent, a registered manufacturer has been authorized to use toxicity test data or authorized to manufacture the environmental agent, the applicant must submit composition analysis reports for five lots of the environmental agent produced by the authorized manufacturer and the original manufacturing plant's original composition analysis report for comparison and explanation, and must also provide a detailed explanation of the original manufacturing process from the registered manufacturer and an explanation of the manufacturing process from the company authorized to use toxicity test data or manufacturer authorized to manufacture the environmental agent; if the technical grade environmental agents have the same composition, and documents verifying the registered manufacturer's authorized registration file are provided, a toxicity test report is not needed.

E. For environmental agent microbial preparations and pollution control agents, toxicity testing items shall be submitted per Attachment 6.

Note 11: Applications for active components hypochlorous acid and its salts, chlorine dioxide, sodium chlorite, bleach powder, sodium borate (boric acid), dichlorobenzenes and naphthalene shall submit toxicity data but need only to cover acute oral toxicity and acute dermal toxicity. Hazardous Substances Data Base (HSDB), Registry of Toxic Effects of Chemical Substances (RTECS), or other research documentation regarding toxicity must also be submitted. If in a foreign language, then Chinese summary translation shall be attached translated sections clearly indicated.

Note 12: The registered content quantities on an environmental agent permit are limited to ten. The registered content quantity packaging of general environmental agents in a liquid state is limited to 5 liters.

III. 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 3. Photocopy of the personal identification document of the statutory responsible person 4. Photocopy of factory registration (Note 1) 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 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 (note 3) 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)
Information	
1. Analysis report of the content of active ingredients in the last year (note 7 and note 13.1) 2. Efficacy(potency) test report in the last year (note 7 and note 13) 3. Labels	1. Report of the content of active components analysis conducted domestically in the last year (note 7 and note 13.1) 2. Report of Efficacy(potency) test conducted domestically in the last year (note 7 and note 13) 3. Labels

Note13: For extensions to permits for technical grade environmental agent, p-dichlorobenzene, naphthalene, and synthetic camphor, no efficacy (potency) testing is required.

Note13.1：When new permit and permit renewal applications are made for mosquito incense agents, a test report concerning dioxin content of the mosquito incense agent from within the most recent year must be attached.

IV. Verification Documents and Materials Required for Environmental Agent Permit Modification 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 not a company) 2. Photocopy of business registration certificate 3. Photocopy of factory registration 4. The original permit 5. Labels 6. Photocopy of certificate for employment of professional technicians (Note 14)	1. Photocopy of company license or document of proof for company registration (not required if not a company) 2. Photocopy of business registration certificate 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 (note 2) 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 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 3. Photocopy of factory registration 4. Photocopy of person identification 5 The original permit	1. Photocopy of environmental agent vendors permission license 2. Photocopy of person identification 3. The original permit
Manufacturer name	1. Photocopy of company license or document of proof for	1. Official copy of verified document of proof for approval of manufacture

	company registration (not required if not a company) 2. Photocopy of business registration certificate 3. Photocopy of factory registration 4. The original permit 5. Labels （note 15）	and marketing by the competent authority of country of origin in the last 2 years (note 2) 2. Official copy of document of authorization issued by a foreign firm in the last 2 years（note 3） 3. The original permit 4. Labels （ note 15 and note 16）
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 3. Photocopy of factory registration 4. The original permit 5. Labels （note 17）	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（note 2） 2. The original permit 3. Labels （note 16）
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 (note 18-1)	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（note 2） 2. The original permit 3. The last date of manufacture, lot number and quantity of environmental agent 4. Labels （note 18） 5. Document of proof issued by a firm of exported country (note 18-1)
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（note 7） 2. Report of efficacy(potency) test conduct domestically in the last year（note 7） 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（note 7） 3. Performance (effectiveness) test report in the last year（note 7） 4. The original permit 5. Labels
Addictives (note 19)	1. Information about physical and chemical properties 2. Material Safety Data Sheet(MSDS) 3. The original permit	1. Mill certificate issued by the manufacturer 2. Information about physical and chemical properties 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) 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

Note 14: The change of name of the permit-holding manufacturer is limited to that the name of firm is to be changed due to merging or returning to business.

Note 15: The change of name of the manufacture or import permit-holding manufacturer is limited to that the name of firm is to be changed due to merging or returning to business.

Note 16: For the change of manufacturer commissioned by the foreign firm that has the permit for manufacture, a certified document of commission to manufacture shall be provided. New application is required for a manufacturer of a different country.

Note 17: The change of address of manufacturer stated in the manufacture permit is limited to rearrangement of address.

Note 18: For the change of the product name in foreign language on the permit of import, the document of proof for the name of product in foreign language issued by the original foreign firm and the document of proof for the name of product in foreign language issued by the highest competent authority of the country of origin shall be provided.

Note 18-1: The foreign name of an environmental agent is for export and import only. The environmental agent shall be registered with a foreign name according to the request of firms in import countries.

Note 19: the change of addictives is limited to the change of type or packing of addictives providing the same performance.

Note 20: In case of multiple changes in a single permit which require the same documents, the repeated ones can be omitted.

Note 21: Review fees are required for changes of information. However, the change of company address and responsible person or the rearrangement of manufacturer's address shall be subject to this restriction.

Note 22: When applying for the manufacturing and processing of environmental agents for exports for which the technical grade agents are not from the R.O.C., documents and information for the application for import permit of technical grade agents are required as on Attachment 3 (II).

Attachment 4

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	○	
Primary eye irritation	○	
Primary dermal irritation	○	
Dermal sensitization	○	
Acute delayed neurotoxicity		△
Subchronic testing		
90-day feeding studies	○	
21-day dermal studies		△
90-day inhalation		△
90-day neurotoxicity		△
Chronic testing		
Chronic feeding	○	
Oncogenicity study	○	
Reproduction-2 generations at least	○	
Teratogenicity	○	
Mutagenicity		
Chromosomal aberration	○	
Gene mutation	○	
Other genotoxic effects	○	
Metabolism		
Metabolism in animal	○	
Metabolism in plant		△
Environmental fate studies		
Hydrolysis	○	
Photodegradation	○	
Metabolism in soil	○	
Metabolism in Aquatic		△
Accumulation studies		△
Non-target organism toxicity		
Aquatic organism toxicity	○	
Avian toxicity		△
Honey bee acute contact toxicity		△

△Optional items: original manufacturers in possession of toxicity test data shall submit such data.

Attachment 5　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 (skin irritation)	Mutagenicity (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, Miticides（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.

Attachment 6

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.

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

Attachment 7

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	3-4 days	
	or							
		culex pipiens molestus	○		○	<10	3-4 days	
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	
	or	*Xenopsylla cheopis*	○		○		2-3 days	
Termites (indoor)		*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*	○					
Drosophila, adults		*Drosophila albomicans*	○		○	<10	1-3 days	
Mothfly			○		○			

Explanation:

I. ○: Mandatory

II. △: If fire ant testing uses insect growth regulators (IGR, then workers or queens must be used; Cockroach mortality testing or bait efficacy testing employing IGR must use 3rd instar or older larvae.

Attachment 8

Control Efficacy Testing Results Evaluation Standards for Environmental Agent Permit Registrations

Efficacy	Evaluation standards	Required efficacy testing report data
Pesticides efficacy Miticides efficacy	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	Repelling rate greater than 75 %.	Insect repellents shall have repelling effect of 24 hours.

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.