

# Permit Registration and Approval Regulations for Toxic Chemical Substances

Twenty-three articles promulgated by Environmental Protection Administration order Huan-Shu-Tu-Tzu No. 0960095333 on December 17, 2007

## Article 1

These Regulations are determined pursuant to Article 13, Paragraph 5 of the Toxic Chemical Substances Control Act (herein referred to as the Act).

## Article 2

Toxic chemical substance handlers shall apply for permits, registration documents and approval documents for toxic chemical substances for the sites listed with the local special municipality, county or city competent authority:

- I. Manufacturing permit, approval documents: manufacturing site
- II. Import and sales permit, approval documents: business site
- III. Usage registration documents, approval documents: usage site
- IV. Storage registration documents, approval documents: storage site

## Article 3

Except for manufacturing and export permits which are reviewed by the special municipality, county or city competent authority and then issued by the central competent authority, permit registration documents and approval documents of the previous article are issued by the special municipality, county or city competent authority.

## Article 4

If the toxic chemical substance selling, usage or storage site is the same as the manufacturing site, then the applicant for toxic chemical substance manufacturing permit need not additionally apply for selling permit or usage and storage registration documents.

If the toxic chemical substances are imported as raw materials for self-use, applicants for toxic chemical substance manufacturing permits may submit these together with the manufacturing permit application and are not required to submit an application for an import permit.

If the toxic chemical substance selling or storage site is the same as the manufacturing site, then the applicant for toxic chemical substance import permit need not additionally apply for a selling permit or storage registration documents.

If the toxic chemical substance storage site and business address for selling are the same, then the applicant for toxic chemical substance selling permit need not additionally apply for storage registration documents.

Review fees for combined applications of the above four paragraphs: Only a manufacturing review fee is charged for application reviews of the first and second paragraphs above, and only an import or selling permit review fee is collected for application reviews for the third and fourth paragraphs.

## Article 5

Applicants for toxic chemical substance permits must submit an application form and Attachment 1.

If the applicant of the previous paragraph also has a toxic chemical substances storage site, and that storage site and the location of the operating site of the permit application are located in different special

municipalities, counties or cities, then the applicant must first obtain the storage site registration documents before beginning to apply for a permit.

#### **Article 6**

Applicants for toxic chemical substance registration documents must submit an application form and Attachment 2.

#### **Article 7**

Applicants for toxic chemical substance handling authorization documents must submit an application form and Attachment 3.

#### **Article 8**

Applications for extensions, modifications, replacement or renewal of permits, registration documents and approval documents require submission of an application form Attachment 4 and documents to the original application authority.

Applicants changing a handler's basic information according to the previous paragraph must submit factory registration documents, company registration documents and a business license or corporate registration documents within thirty days of their issuance by the relevant industry competent authority.

#### **Article 9**

The central competent authority will designate and officially announce the network submission system designated by the central competent authority to be used when toxic chemical substances handlers process applications, extensions or modifications of permits, registration documents or approval documents.

#### **Article 10**

The competent authority receiving permits, registration documents or approval documents for review will refuse applications for any of the following violations:

- I. Those who do not pay the toxic chemical substances handling standard application fees
- II. Those failing to comply with Articles 5 through 8 stipulating the relevant application documents and who following the period allowed for amendments do not provide corrections
- III. Applying as a handler through the central competent authority in accordance with Article 7 of the Act announcing toxic chemical substances prohibited from handling or applications not restricted by the announcement without obtaining central competent authority approval to lift restrictions or prohibitions

#### **Article 11**

The competent authority will not approve permits, registration documents or approval documents under any of the following circumstances:

- I. The competent authority has, within the last two years, in accordance with the provisions of this Act revoked or repealed the same listed controlled toxic chemical substance permit, registration documents or approval documents or has been ordered to terminate operations.
- II. Has deployed toxic chemical substances professional technical management personnel without conforming to the provisions of the Act

#### **Article 12**

The competent authority will not agree to extensions of permits, registration documents or approval documents under any of the following circumstances:

- I. Violation of the regulations of Article 16, Paragraph 3 or Article 24 of the Act within the last year or violation of the same article two or more times

- II. Toxic chemical substances handling records for the last three years report that operating volume have been continuously zero

### **Article 13**

In addition to the central competent authority's announcement pursuant to Article 11 of the Act, applications for storage of toxic chemical substances of category 1 through category 3 shall comply with the following provisions:

- I. Storage sites storing large amounts at their base of operations may not be located in residential or commercial areas of urban plans.
- II. Those storing in the storage facilities of commercial storage operators shall supply copies of said storage facility's toxic chemical substances storage registration documents to avoid application for storage registration documents.
- III. Except for the preceding subparagraph, storing at other toxic chemical substance handlers storage sites which are self-managed requires verification of consent to use the storage site and the manager entrusted with management of the storage site must provide documents attesting the commissioned storage. The entrusted manager shall process modification of the storage registration documents, noting the sources and information of the toxic chemical substances entrusted for management.
- IV. Storage sites serving as warehouses for loading and unloading unspecified toxic chemical substances as maritime or air cargo must submit the relevant industry competent authority warehouse deployment documents, however customs warehouse operators are not subject to this restriction.

Toxic chemical substances of the fourth subparagraph of the preceding paragraph, which have not completed the customs clearance procedure but have already been approved for temporary storage in the warehouse or container terminal by customs according to Customs Act regulations, are not required to apply for storage registration documents.

### **Article 14**

The competent authority administering permits, registration documents and approval documents for review, may convene relevant competent authorities, academics and experts to conduct on-site inspections.

### **Article 15**

Permits, registration documents and approval documents are issued for individual toxic chemical substances, operations sites or handlers. But any toxic chemical substances under the same regulatory control number may be combined.

### **Article 16**

Permits, registration documents and approval documents must record the following items:

- I. Basic information
  - A. Handlers name, address and control number
  - B. The full name and identification number of the statutory responsible person
  - C. Handling site name, address and control number
- II. Handling:
  - A. Toxic chemical substances trade name, toxic chemical substance name, regulatory control number, serial number and concentration.
  - B. Handler activities, applications and permitted handling items
- III. Issuance data and period of validity

IV. Those without storage registration documents must be duly noted at the toxic chemical storage site.

#### **Article 17**

The relevant industry competent authority must cancel the permits, registration documents or approval documents of handlers who obtained a permit, registration document or approval document according to these regulations whose business license, factory registration or other permit documents was canceled or revoked.

Toxic chemical substance storage sites which change their location to residential or commercial urban planning districts after obtaining their storage registration documents will have their registration documents annulled and the permits of sites which were not required registration documents according to Article 4 of these regulations will also be annulled.

#### **Article 18**

If the location of an operators site's manufacturing permit, usage or storage registration documents is changed or the import or selling permit or authorization documents location is changed to a area outside the jurisdiction of the competent authority with which the application was originally made then the operator must reapply.

#### **Article 19**

Disposers of toxic chemical substances of category 1 through category 3 must submit a toxic chemical substance disposal declaration for each batch before disposal to apply for registration with the local special municipality, county or city competent authority where the toxic chemical substances are located. Disposal may begin after registration approval.

Toxic chemical substance disposal must be processed in accordance with relevant waste disposal laws and regulations.

#### **Article 20**

Exporters of toxic chemical substances of category 1 through category 3 must fill out a delivery manifest for each batch of toxic chemical substances and provide the documents listed below to the special municipality, county or city competent authority of the originating location for application registration and may begin exporting after stamping approval of the toxic chemical substances delivery manifest.

- I. Toxic chemical substances handler permit, registration documents and approval documents
- II. Export purpose document, orders from overseas buyers, copy of letter of credit or other export purpose verification documents

#### **Article 21**

For management purposes the competent authority may proactively inform the toxic chemical substances operator to renew their permit, registration documents or approval documents to avoid collecting certificate fees.

When they apply for or cancel their storage registration documents, those expanding or reducing their chemical substances storage site must process renewal of relevant permits, registration document or approval documents within six months to not be subject to certificate fees.

When applying for an extension or modification within the time limits of Article 39 of this Act, reference documents and approval documents legally obtained before the promulgation of this Act may be combined with renewal of registration documents or approval documents to avoid certificate fees.

#### **Article 22**

The review period for Article 3 permits, registration document and approval document applications, extensions and modifications all levels of the competent authority, aside from the 30 day period for selling permits, will be 20 days.

When necessary the reviewing competent authority must notify the applicant that the reviewing period of the previous paragraph has been doubled.

**Article 23**

These Regulations shall take effect on the date of promulgation.

# Attachment 1

## **Documents and information to be included by toxic chemical substances permit applicants**

1. Photocopies of factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents
2. Photocopy of the personal identification document of the statutory responsible person
3. Photocopies of professional technical management personnel setup approval documents (not required for non-manufacturing permit applications)
4. Material Safety Data Sheet
5. Product manufacturing process and explanation (not required for non-manufacturing permit applications)
6. Management method statement explaining transport, use, storage and disposal methods
7. Copy of the storage registration document approved by the competent authority
8. Photocopies of the installation, operations planning documents for emergency, detection and alarm equipment approved by the competent authority
9. Photocopies of the hazard prevention and response plans approved by the competent authority
10. Complete and internal manufacturing and storage operations site facilities configuration diagrams
11. Other relevant documents or information designated by the competent authority.

## Attachment 2:

### **Documents and information to be included by toxic chemical substances registration document applicants**

1. Photocopies of factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents
2. A photocopy of the personal identification document of the statutory responsible person
3. Photocopies of professional technical management personnel setup approval documents
4. Material Safety Data Sheet
5. Usage methods and application explanations (not required for storage registration document applications)
6. Documents related to the storage site(According to Article 13 of the Act)
7. Photocopies of the installation, operations planning documents for emergency, detection and alarm equipment approved by the competent authority
8. Photocopies of the hazard prevention and response plans approved by the competent authority
9. Complete and internal usage and storage operations site facilities configuration diagrams
10. Other relevant documents or information designated by the competent authority.

# Attachment 3:

## **Documents and information to be included by toxic chemical substances handling permit applicants**

1. Photocopies of factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents
2. Photocopy of the personal identification document of the statutory responsible person
3. Documents related to the storage site(According to Article 13 of the Act)
4. Material Safety Data Sheet
5. Toxic Chemical Substance Hazard Prevention Data Sheet
6. Other relevant documents or information designated by the competent authority.

# Attachment 4

## Additional verification documents and information for application for extension of permit, registration documents or approval documents for toxic chemical substances

Permits	Registration documents	Approval documents
<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Photocopies of factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> <li>4. Material Safety Data Sheet</li> </ol>	<ol style="list-style-type: none"> <li>1. Registration documents</li> <li>2. Photocopies of factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> <li>4. Material Safety Data Sheet</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. Photocopies of factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> <li>4. Material Safety Data Sheet</li> </ol>

## Additional required verification documents, information and registration items for application for modification of permit, registration documents or approval documents for toxic chemical substances

Changed items	Permits	Registration documents	Approval documents
<b>Handlers name ( Note 1 ) , address, and statutory responsible person</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Photocopies of company registration documents and a business license or corporate registration documents (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. Photocopies of company registration documents and a business license or corporate registration documents (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. Photocopies of company registration documents and a business license or corporate registration documents (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> </ol>

<b>Changed items</b>	<b>Permits</b>	<b>Registration documents</b>	<b>Approval documents</b>
<b>Name of storage site</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Copy of the storage registration document approved by the competent authority</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. in accordance with Article 13 of the Act.</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. in accordance with Article 13 of the Act.</li> </ol>
<b>Address of storage site</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Copy of the storage registration document approved by the competent authority</li> <li>3. Complete and internal storage operations site facilities configuration diagrams</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. in accordance with Article 13 of the Act.</li> <li>3. Photocopies of the hazard prevention and response plans approved by the competent authority</li> <li>4. Complete and internal operations site facilities configuration diagrams</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. in accordance with Article 13 of the Act.</li> <li>3. Toxic Chemical Substance Hazard Prevention Data Sheet</li> </ol>
<b>Entrusted manager of storage site</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Copy of the storage registration document approved by the competent authority</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. in accordance with Article 13 of the Act.</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. in accordance with Article 13 of the Act.</li> </ol>
<b>Additional storage sites</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Copy of the storage registration document approved by the competent authority</li> <li>3. Complete and internal storage operations site facilities configuration diagrams</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. in accordance with Article 13 of the Act.</li> <li>3. Reapply if different from the original jurisdiction</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. in accordance with Article 13 of the Act.</li> <li>3. Toxic Chemical Substance Hazard Prevention Data Sheet</li> <li>4. Reapply if different from the original jurisdiction</li> </ol>
<b>Constituent amounts</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Material Safety Data Sheet</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. Material Safety Data Sheet</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. Material Safety Data Sheet</li> </ol>
<b>Additional constituent amounts</b>	<ol style="list-style-type: none"> <li>1. Original Permit</li> <li>2. Material Safety Data Sheet</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents</li> <li>2. Material Safety Data Sheet</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents</li> <li>2. Material Safety Data Sheet</li> </ol>
<b>Other</b>	Relevant documents and data	Relevant documents and data	Relevant documents and data

Note 1: Change of handlers name is limited to corporate reorganizations in which case the operations continues and only the name changes.

**Additional verification documents and information for replacement or renewal of permit, registration documents or approval documents for toxic chemical substances**

<b>Permits</b>	<b>Registration documents</b>	<b>Approval documents</b>
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<b>Permits</b>	<b>Registration documents</b>	<b>Approval documents</b>
<ol style="list-style-type: none"> <li>1. Original permit ( Note 2 )</li> <li>2. Factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> </ol>	<ol style="list-style-type: none"> <li>1. Original registration documents ( Note 2 )</li> <li>2. Factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> </ol>	<ol style="list-style-type: none"> <li>1. Original approval documents ( Note 2 )</li> <li>2. Factory registration or factory establishment permits (not required for non-factory applicants), company registration documents or business license (not required for non-corporate applications), business registration certificate or other legal certification documents</li> <li>3. Photocopy of the personal identification document of the statutory responsible person</li> </ol>

Note 2: Photocopies of the replacement applicant's permit (registration document or approval document)