



Frequently Asked Questions 101 for New and Existing Chemical Substances Registration

新化學物質及既有化學物質資料登錄
- 常見問答集 101

Taiwan Chemical Registration Center

Translated by Chemlinked

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資料登錄-常見問答集 101

**Frequently Asked Questions 101 for New and
Existing Chemical Substances Registration
(Draft)**

Prepared by Chemical Substances Registration Center

Table of Contents

- I. Toxic Chemical Substances Control Act - Legal Basis
- II. Regulation of New and Existing Chemical Substances Registration
 - 1. Provisions of registrant
 - 2. Determination of registration
 - 3. New chemical substances registration
 - 4. Existing chemical substances registration
 - 5. EPA's Nomination program (Deadline: March 31, 2015)
 - 6. Data supplementation/correction and rejection
 - 7. Information publicity and confidentiality
- III. Toxic Chemical Substances Handling Application and Chemical Substances Registration Fee Standards
- IV. Information Dissemination and Confidentiality
- V. Chemical Substances Registration Platform and Registration System
- VI. Fees and Penalties
- VII. Others

Remarks:

- 1. Toxic Chemical Substances Control Act (hereinafter referred to as "Act")
- 2. Regulation of New and Existing Chemical Substances Registration (hereinafter referred to as "Regulation")
- 3. Toxic Chemical Substances Handling Application and Chemical Substances Registration Fee Standards (hereinafter referred to as "Fee Standards")

I. Toxic Chemical Substances Control Act - Legal Basis

Q1-1: Is it necessary to register for selling of a chemical substance which is purchased in Taiwan? [\$7-1]

Pursuant to Paragraph 1, Article 7-1 of the Act, for the purpose of compiling necessary information of chemical substances for national sound chemical management, those that manufacture or import existing chemical substances with quantities reaching specific amount each year shall apply to the central competent authority for chemical substances information registration by the designated deadlines; those manufacturing or importing new chemical substances shall apply to the central competent authority for chemical substances information registration 90 days prior to commencement of manufacturing or import. Manufacturing or import of said existing and new chemical substances shall only be allowed when the registration is approved.

The Regulation only focuses on source management on manufacture or import of chemical substances, i.e. manufacturer or importer of chemical substances should apply to the central competent authority for registration. For other activities, e.g. sale, export, operation, storage or discarding, do not fall in the scope of the Regulation, so chemical registration is unnecessary.

Q1-2: As a foreign company, I want to export the chemical substances to Taiwan. Is it an essential prerequisite to establish a company or branch in Taiwan before export? Is there any other method? [\$7-1]

1. A person who manufactures or imports chemical substances in Taiwan should apply to the central competent authority for chemical registration pursuant to Paragraph 1, Article 7-1 of the Act.
2. The registrant should be a natural person, a juristic person, an unincorporated body having a representative or manager, an administrative authority, or a person who may be the subject of rights and obligations under other laws pursuant to Paragraph 1, Article 2 of the Regulation.
3. The domestic importer can register as a registrant, or he can appoint a representative to apply for the chemical registration pursuant to Paragraph 2, Article 2 of the Regulation.

Q1-3: Who should do the registration if a company entrusts another company to produce after importing the raw materials, the contract manufacturer or the entrusting company? [\$7-1]

A person who manufactures or imports chemical substances in Taiwan should apply to the central competent authority for chemical registration pursuant to Paragraph 1, Article 7-1 of the Act.

Although the contract manufacturer does not have the ownership of chemical substances, he is the one

Q5-8: Is it necessary to make registration when a Taiwanese company purchased a chemical substance from a Taiwanese manufacturer and exported it overseas while the chemical substance has been returned back for some reasons?

If this chemical substance has been registered when it is manufactured or imported, then it is not necessary to make registration when it is returned back. However, if the chemical substance has not been registered when it is manufactured or imported, then it requires registration when it is turned back.

Q5-9: Is it possible to modify the registration information protection range after registration has been approved if there is no protection application made during the new chemical substance registration application or the protection range needs to be modified?

After checking with the Ministry of Law, according to Article 122 of the Administrative Procedure Law, if the certificate has become non-conferred interest relation with the certificate holder, the holder should make a statement asking the original authority to revoke the certificate according to Article 130 of the Administrative Procedure Law and the competent authority should decide whether to revoke the certificate or not.

By this way, the registers can re-apply for the registration of this substance and make information protection application for its business confidentiality.

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