



ASIA

REGULATORY BRIEFING

Taiwan

Chemical Regulatory Framework — Compliance Reference

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Taiwan

1 Chemical Inventory

Taiwan's chemical regulatory framework is primarily governed by the Toxic and Concerned Chemical Substances Control Act (TCCSCA) and the Occupational Safety and Health Act (OSHA). Under this framework, chemical substances are managed through registration, classification, control measures, and inventory systems aimed at protecting human health, workplace safety, and the environment.

1.1 Taiwan Chemical Substance Inventory

The **Taiwan Chemical Substance Inventory (TCSI)**, established by the Environmental Protection Administration (EPA) in 2014 and officially published in 2015, serves as the definitive list of existing chemical substances in Taiwan. It includes 108,000 substances that were manufactured, imported, or used domestically before December 31, 2014 [141].

- Substances listed in the TCSI are classified as **existing substances** under the TCCSCA and may be subject to additional requirements depending on their classification or risk level.
- Substances not listed in the TCSI are regarded as **new substances** and must undergo the **New Chemical Substance Registration (NCSR) process** before manufacture or import is allowed.

While the TCSI has not undergone major revisions since its publication, companies may apply to include substances after completing the required standard registration under EPA review [142].

1.2 Toxic and Concerned Chemical Substances Lists

In addition to the TCSI, Taiwan maintains several regulatory lists under the TCCSCA:

- **Toxic Chemical Substances List:** Substances are categorized into four hazard classes based on toxicity, persistence, and potential risk. Class 1 substances pose the highest concern, while Class 4 substances are monitored due to public concern. Entities handling these chemicals must obtain permits and comply with strict labeling, storage, accident prevention, and reporting requirements. As of the latest update, this list includes over 480 substances [143].
- **Concerned Chemical Substances List:** This list includes substances that may not be acutely toxic but raise concern due to chronic health or environmental effects, such as endocrine disruption or carcinogenicity. Depending on their classification and volume of use, companies may need to submit usage reports, comply with restrictions, or publicly disclose relevant information. Currently, the list includes 18 designated substances [144].

1.3 Occupational Chemical Inventories under OSHA

Under OSHA, the Ministry of Labor maintains two separate chemical inventories to manage workplace exposure risks: the Priority Management Chemicals List and the Controlled Chemicals List. These inventories focus on workplace exposure risks and require employers to conduct risk assessments, label hazardous substances properly, and ensure the availability of Safety Data Sheets (SDS). Chemical suppliers and users must comply with hazard communication standards to protect worker health and safety.

2 Status of GHS

As of April 25, 2025, Taiwan has fully implemented the **eighth revised edition of the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS 8)**. The national GHS framework is based on the Chinese National Standards (CNS) 15030 series, developed under the coordination of the Bureau of Standards, Metrology and Inspection (BSMI) of the Ministry of Economic Affairs (MOEA), in collaboration with the Environmental Protection Administration (EPA) and the Ministry of Labour (MoL).

The GHS 8-aligned standards were adopted in three phases:

- October 24, 2024: Ten standards on physical hazards (e.g. flammable gases, aerosols).
- February 24, 2025: Ten standards on health hazards, including desensitized explosives
- April 25, 2025: Two standards on environmental hazards and the revised CNS 15030 General Rules.

These updates bring Taiwan's GHS framework fully in line with GHS Revision 8. Notable technical changes include:

- Subdivision of flammable gases into Categories 1A and 1B.
- Introduction of aerosols and chemicals under pressure as distinct hazard classes.
- Revised criteria for acute toxicity, skin corrosion/irritation, and serious eye damage/eye irritation in alignment with OECD methods.
- Inclusion of a new hazard class for desensitized explosives.

Taiwan previously implemented GHS 4, which entered into force on December 1, 2014, via MoL Notice No. 10302007861 and EPA Notice No. 1030094561. Prior to that, a GHS based regulation was issued in 2007, with implementation starting on December 31, 2008 [145].

2.1 GHS Classification Standards

Taiwan's classification framework is based on the CNS 15030 series, each part of which corresponds to a specific GHS hazard class. Table 48 below lists the full set of applicable standards.

Table 48 Taiwan CNS 15030 Standards for GHS classifications

Standard	Current edition	GHS hazard class
CNS 15030	2025-04	Classification and labelling of chemicals—General rules
CNS 15030-1	2024-10	Explosives
CNS 15030-2	2024-10	Flammable gases
CNS 15030-3	2024-10	Aerosols and chemicals under pressure
CNS 15030-4	2024-10	Oxidizing gases
CNS 15030-5	2024-10	Gases under pressure
CNS 15030-6	2015-01	Flammable liquids
CNS 15030-7	2024-10	Flammable solids
CNS 15030-8	2008-12	Self-reactive substances and mixtures
CNS 15030-9	2008-12	Pyrophoric liquids
CNS 15030-10	2008-12	Pyrophoric solids
CNS 15030-11	2015-01	Self-heating substances and mixtures
CNS 15030-12	2024-10	Substances and mixtures which, in contact with water, emit flammable gases
CNS 15030-13	2008-12	Oxidizing liquids
CNS 15030-14	2024-10	Oxidizing solids
CNS 15030-15	2024-10	Organic peroxides
CNS 15030-16	2024-10	Corrosive to metals
CNS 15030-17	2025-02	Acute toxicity
CNS 15030-18	2025-02	Skin corrosion/irritation
CNS 15030-19	2025-02	Serious eye damage/eye irritation

Standard	Current edition	GHS hazard class
CNS 15030-20	2025-02	Respiratory or skin sensitization
CNS 15030-21	2025-02	Germ cell mutagenicity
CNS 15030-22	2025-02	Carcinogenicity
CNS 15030-23	2025-02	Reproductive toxicity
CNS 15030-24	2025-02	Specific target organ toxicity–Single exposure
CNS 15030-25	2025-02	Specific target organ toxicity–Repeated exposure
CNS 15030-26	2025-02	Aspiration hazard
CNS 15030-27	2025-04	Hazardous to the aquatic environment
CNS 15030-28	2025-04	Hazardous to the ozone layer
CNS 15030-29	2025-02	Desensitized explosives

2.2 Local Adaptation of GHS

With the adoption of GHS 8, Taiwan’s classification framework now includes all relevant hazard classes. The latest updates introduced additional building blocks such as:

- Flammable gases - Categories 1A and 1B, including pyrophoric gas - Category 1A and chemically unstable gases - Category A and B
- Aerosols - Category 3
- Chemicals under pressure - all categories
- Desensitized explosives - all categories

No building blocks from GHS 8 have been excluded in the current CNS 15030 standards.

2.3 GHS Labeling Requirements

In Taiwan, GHS labeling must comply with the CNS 15030 standards and the requirements of the Environmental Protection Administration (EPA). Labels must include:

- Pictograms: a red diamond on a white background (45° orientation) with a black symbol.
- Product name.
- Hazardous ingredients (with CAS numbers and Chinese/English names when above threshold limits).
- Signal words (“Danger” or “Warning”).
- Hazard and precautionary statements.
- Name, address, and telephone number of the manufacturer, importer, or supplier.

Label language must be in traditional Chinese, though English names and CAS numbers may also appear. For containers with a capacity below 100 ml, only the product name, hazard pictograms, and signal words are required. The minimum label dimensions depend on the container volume and are listed in Table 49.

Table 49 Minimum dimension of labels under TCCSCA

Volume of container (l)	Minimum label size (mm)
Volume ≤ 3	≥ 52 × 74
3 < Volume < 50	≥ 74 × 105
50 < Volume < 500	≥ 105 × 148
Volume > 500	≥ 148 × 210

2.4 Safety Data Sheets

In Taiwan, Safety Data Sheets (SDS) are required for all hazardous chemicals in accordance with the CNS 15030 standards. SDSs must follow the standard 16-section format and be written in traditional Chinese.

Companies responsible for the chemical (manufacturers, importers, or suppliers) are required to prepare and update the SDS. SDSs must be reviewed and revised at least once every three years or sooner if new hazard information becomes available.

Employers are required to ensure that SDSs are accessible to all workers who may be exposed to hazardous chemicals during their work activities.

2.5 GHS in Transport

In Taiwan, the principles of the Globally Harmonized System (GHS) are also applied to the transportation of hazardous chemicals. Transport labels must comply with both GHS labeling elements and the international rules from the **United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG)**.

Chemicals being transported must display appropriate hazard symbols, shipping names, UN numbers, and packaging requirements. These labeling requirements ensure that risks such as flammability, toxicity, and environmental hazards are clearly communicated during shipping.

3 Chemical Regulation

The chemical regulatory framework in Taiwan is primarily governed by the **Toxic and Concerned Chemical Substances Control Act (TCCSCA)**, which entered into force on March 11, 2019 [142]. The TCCSCA replaced the former Toxic Chemical Substances Control Act, expanding the scope to include substances of environmental or health concern in addition to toxic substances [146]. It sets requirements for classification, registration, handling, and control of chemical substances to protect human health and the environment.

Under the TCCSCA, Taiwan's Chemical Registration and Assessment Regulations establish the procedures for registering both new and certain existing chemical substances. Managed by the Environmental Protection Administration (EPA), these regulations require companies to register substances exceeding specified annual tonnage thresholds before manufacture or import. The registration process is divided into three types: **Phase 1 Registration** for designated existing substances, **Standard Registration** based on volume, and **Simplified Registration** for low-volume or low-risk substances. Registrants must submit data on substance identity, usage, and risk assessments, and are obligated to update dossiers if new risk information becomes available. This system mirrors key elements of the EU REACH Regulation, promoting transparency, hazard evaluation, and responsible chemical management.

In parallel, Taiwan's **Occupational Safety and Health Act (OSHA)** regulates workplace safety, focusing on protecting workers from chemical-related hazards. Enacted in 1974 and updated regularly, OSHA mandates employers to provide safety training, proper equipment, hazard communication, and emergency response measures. It also sets exposure limits for hazardous chemicals and establishes accident reporting requirements. The Ministry of Labor (MoL) is responsible for OSHA enforcement, ensuring companies maintain safe and healthy working environments.

Together, TCCSCA and OSHA form a comprehensive chemical management system addressing both environmental and occupational health risks.

3.1 Authority

In Taiwan, the **Environmental Protection Administration (EPA)**, through its **Toxic and Chemical Substances Bureau**, is the main authority responsible for chemical regulation. EPA manages the national chemical inventory, reviews chemical registrations, classifies toxic and concerned substances, and sets control measures.

The **Ministry of Labor (MoL)** enforces the **Occupational Safety and Health Act (OSHA)** to protect worker health and safety. It ensures companies provide safety training, equipment, and proper instructions when handling hazardous substances, as well as compliance with exposure limits, accident reporting, and emergency planning. The **Ministry of Economic Affairs (MOEA)** is also involved in industrial operations management. These authorities coordinate efforts to ensure chemicals are managed safely across both environmental and occupational settings [147].

3.2 Concerned Bodies

Under Taiwan's chemical regulations, the responsibility for submitting chemical registrations or notifications lies primarily with local manufacturers and importers. Companies based in Taiwan must complete the registration process with the Environmental Protection Administration (EPA) for both new and existing substances.

For foreign companies, Taiwan allows the appointment of a **Third-Party Representative (TPR)** to act on their behalf. This system, similar to the **"Only Representative"** mechanism under EU REACH, enables non-Taiwanese suppliers to manage compliance obligations while protecting confidential business information. The TPR must be legally established in Taiwan and is responsible for submitting registration dossiers, handling communication with the EPA, and ensuring compliance with local requirements.

3.3 Similarities to EU REACH

Taiwan's chemical regulation under the Toxic and Concerned Chemical Substances Control Act (TCCSCA) shares several similarities with the European Union's REACH Regulation. Both frameworks require the registration of chemical substances prior to manufacture or import, with obligations determined by annual tonnage thresholds. The systems emphasize substance identification, hazard assessment, and risk management to ensure safe handling and use of chemicals.

Like REACH, Taiwan's regulatory framework offers standard and simplified registration pathways and includes exemptions for research and development activities. Both systems aim to enhance transparency, assign primary responsibility for chemical safety to industry, and promote responsible chemical management practices.

4 Compliance Procedure Global Product Compliance

4.1 Pre-registration/Notification

Under Taiwan's Toxic and Concerned Chemical Substances Control Act (TCCSCA), companies intending to manufacture or import a new chemical substance must submit a **New Chemical Substance Registration (NCSR)** to the Environmental Protection Administration (EPA) **at least 90 days before** the planned activity. This pre-registration is mandatory and serves as the initial step in the regulatory process for new substances not listed in the Taiwan Chemical Substance Inventory (TCSI).

The NCSR application must include detailed information such as:

- Substance identity and structure.
- Physical-chemical properties.
- Toxicological and ecotoxicological data.
- Exposure scenarios.
- Proposed risk management measures.

EPA reviews this information to assess potential risks to human health and the environment. Only after receiving official approval can the company proceed with manufacturing or importing the substance. This system ensures that new chemicals are evaluated for safety before entering the market.

4.2 Tonnage Band Requirements

The type of registration required under Taiwan's Chemical Registration and Assessment Regulations depends on the annual tonnage of the chemical substance. The regulations define thresholds that determine the level of information required. Substances manufactured or imported in larger volumes are subject to more comprehensive data requirements, while lower-volume substances may follow simplified procedures. The registration types and corresponding tonnage thresholds are outlined in Table 50 below.

Table 50 Registration types and data requirements under the TCCSCA

Annual tonnage	Registration type	Data requirements
≥ 1 tonne	Standard Registration	Full chemical safety report including hazard, exposure, and risk assessments
≥ 100 kg	Simplified Registration	Basic substance identity and use information
< 100 kg	Small Quantity Registration	Minimal data, primarily for research and development purposes

4.3 Priority Existing Chemicals

Under the TCCSCA, a list of Priority Existing Chemicals (PECs) has been established for substances that are produced or imported in large volumes and pose potential hazards to human health or the environment. The PECs are subject to more stringent registration requirements compared to general existing substances.

The first batch of 106 PECs was announced in March 2019. Manufacturers and importers handling these substances in quantities of 1 tonne or more per year must complete **Standard Registration** with the Environmental Protection Administration (EPA). The registration process requires detailed information, including substance identity, hazard properties, exposure scenarios, and risk management measures.

Taiwan has implemented a phased registration timeline based on annual tonnage:

- Substances manufactured or imported at **≥ 100 tonnes per annum (TPA)** were required to complete registration by **December 31, 2021**.
- Substances manufactured or imported at **1–100 TPA** had a deadline of **December 31, 2022**.
- Companies that completed Phase 1 registration before the end of 2019 were required to submit their Standard Registration by **December 31, 2024**.

To facilitate the process, EPA issued guidelines in June 2020, allowing the use of alternative data sources, such as QSAR models, read-across techniques, and publicly available data. Phased submissions were also permitted for complex dossiers.

4.4 Annual Report

Under the TCCSCA, companies that have completed the registration of new or existing chemical substances are required to submit an annual report to EPA. This obligation applies to all registrants, including local manufacturers, importers, and appointed Third-Party Representatives (TPRs) acting on behalf of foreign suppliers.

The annual report must be submitted through EPA's online reporting system between **April 1 and September 30** of each year and must cover the activities of the previous calendar year. The report should include the following information:

- Registrant details (company name, registration number).
- Substance-specific information (CAS number, chemical name).
- Total volume manufactured or imported during the reporting period.

Even if a registered substance was not manufactured or imported during the reporting year, companies are still required to submit a report indicating zero volume, unless the registration has been formally cancelled.

Reports can be submitted directly by registrants or by their authorized TPRs using a government-issued IC card. Companies that fail to submit the annual report within the specified timeframe may apply for an extension of up to 30 working days to complete or correct their submission.

4.5 Fees

Under Taiwan's TCCSCA, registration fees are determined based on the type of submission, annual tonnage, and whether alternative (non-animal) testing methods are used. EPA adjusted the fee structure in April 2021 to promote the use of non-animal test data and streamline confidentiality claims. The current fee structure is shown in Table 51. The fees are payable upon dossier submission.

Table 51 Registration fees under TCCSCA

Type of submission	Fee		Notes
	TWD	USD	
Standard registration (PECs or new substances > 1 TPA)	50,000	1,565	Per submission
	37,000	1,150	Reduced fee when using non-animal test data (QSAR, read-across, etc.)
Simplified registration (new substances 0.1-1 TPA)	20,000	620	Per submission
Small quantity registration (new substances < 0.1 TPA)	2,000	60	Per submission
Confidential Business Information (CBI) claim	12,500	390	Per item (to protect confidential information in the registration dossier)
Extension of CBI protection	10,000 - 12,000	310-390	Depending on registration type

4.6 Penalties for Non-Compliance

Under the TCCSCA, companies that fail to meet registration, notification, reporting, or other regulatory obligations may be subject to administrative penalties and enforcement actions by EPA. The severity of penalties is determined based on the nature and frequency of the violation.

Key penalties include:

- **Failure to register new chemical substances before manufacture or import:**
 - Fine of TWD 200,000 to TWD 2,000,000 (approximately USD 6,260-62,600).
- **Failure to register designated existing substances (including PECs):**
 - Fine of TWD 30,000 to TWD 300,000 (approximately USD 940-9,400)
- **Repeat violations of registration obligations:**
 - May result in suspension of business operations, orders to re-export the substances, or export restrictions.
- **Serious infractions (e.g. handling prohibited chemicals without permits or failing to implement environmental safeguards):**
 - Fine of TWD 1,000,000 to TWD 5,000,000 (approximately USD 31,300-156,500), along with possible suspension of operations or revocation of permits (TCCSCA Article 55).
- **Confiscation of illegal gains:**
 - Authorities are empowered to confiscate profits obtained through non-compliant activities.

In addition, companies that fail to submit their annual report within the specified timeframe (April 1 to September 30) may request an extension of up to **30 working days** to complete or correct their submission. Failure to comply after the extension period can result in administrative fines.