

## Regulatory Alert

### Taiwan Toxic and Concerned Chemical Substances Control Act (TCCSCA)

**Country:** Taiwan

*Please see the Disclaimer at the end of the alert*

#### INTENDED AUDIENCE

This Alert is intended for A&D companies and their suppliers who have facilities and/or operations that require the manufacture, import, export, use, sales, transport and/or disposal of chemical substances in Taiwan.

#### EXECUTIVE SUMMARY

##### **Background on Regulation:**

The Toxic and Concerned Chemical Substance Control Act (TCCSCA) was promulgated on 16 January 2019 by Presidential Order. The revision renames the legislation, which was previously known as the Toxic Chemical Substances Control Act (TCSCA).

Previously, TCSCA regulated 'toxic chemical substances' (substances that are intentionally produced by human activity or unintentionally derived from production processes, and that have been officially announced by the central competent authority as being toxic). TCCSCA increased the scope of TCSCA to include 'substances of concern' - a new group of regulated chemicals. These are substances that may not be directly toxic, but may carry health and safety risks. Substances of concern cover a broader range of chemicals such as explosive precursors, food safety risk chemicals and hazardous chemicals (e.g. explosive, corrosive). Other changes introduced under TCCSCA include:

- Compulsory GHS safety data sheets and labels for Class 1 to Class 4 toxic chemical substances;
- A requirement for handlers to appropriately mark toxicity information for Class 1 to Class 4 substances on chemical substance containers, packaging, handling sites and facilities, and keep safety data sheets for the corresponding toxic chemical substances
- Extended chemical accident prevention measures;
- Creation of a national chemicals management board.

TCCSCA requires enterprises manufacturing or importing new and existing chemical substances above certain quantities to register those substances with the Taiwanese Environmental Protection Agency (EPA). A new substance is defined as a substance not listed on the Taiwan Chemical Substance Inventory (TCSI). TCSCA had required pre-registration of all existing chemicals manufactured or imported in Taiwan (known as Phase 1 registration). Under TCCSCA, there are further registration requirements for manufacturers and importers of certain 'Priority Existing Chemicals' (PECs) - this is known as Phase 2 registration.

Taiwan's EPA lists toxic chemical substances under the Toxic Chemical Substances List (TCSL). Handlers (companies that manufacture, import, export, sell, transport, use, store or discard) toxic chemical substances are required to:

- Apply for registration documents or approval documents when handling the substances;
- Apply for a permit when the registration/ approval documents have been obtained;
- Report the annual tonnage per year (t/y) and handling record annually to the local authorities.
- Comply with any relevant management measures (prepare fire alarms, insurances, expertise, etc.).

- Implement emergency measures: Report any unexpected leakage in 30 minutes and ensure professional personnel arrive at the site within 2 hours.

## APPLICABILITY

- Manufacturers or importers of the following substances need to complete the corresponding registrations:
  - New chemicals substances: New substance registration;
  - Existing substances manufactured or imported in quantities above 0.1 t/y: Late phase 1 registration;
  - Priority Existing Chemicals (PECs) manufactured or imported above 1 t/y: PEC registration.

Note: See the 'Regulatory Obligations' section to this document

The following are exempt from the requirements of substance registration under the TCCSCA [Note: the below list includes only those categories of interest/applicability to A&D industry]. Please note that importers or manufacturers of raw material for the following chemical products are NOT exempted:

1. Pesticides referred to in the Pesticide Management Law.
  2. The radioactive materials referred to in the atomic energy law and the free radiation protection law.
  3. Explosives for business purposes referred to in the Regulations on Explosives for Business Use.
  4. The Montreal Protocol as listed in the Air Pollution Control Law lists chemical substances.
  5. Toxic chemical substances referred to in this Law.
- Those who manufacture, import, export, sell, use or dispose of toxic or concerned chemical substances are subject to the regulatory obligations discussed under the 'Regulatory Obligations' section to this document.

## RELEVANT DATES

- ❖ **TCCSCA promulgated:** 16 January 2019
- ❖ **TCCSCA in force:** 16 January 2020
- ❖ **TCCSCA annual reporting for registrants:** 1 April - 30 September from 1 January 2020
- ❖ **Phase 2 next registration deadline:** 31 December 2021

## REGULATORY OBLIGATIONS

### New Chemical Substance Registration:

Manufacturers and importers of new chemical substances in Taiwan are required to register such substances. A new chemical substance is any substance not already listed on the TCSI, unless it meets the exemption criteria discussed in the 'Applicability' section to this document. Manufacturers and importers of new chemical substances must submit a Registration at least 90 days before manufacture/import. There is no tonnage threshold for new chemical substances. However, based on both the intended use and the tonnage band at which the substance is manufactured or imported, there are three types of registration: low-volume registration, simplified registration and standard registration. Standard registrations are subject to differing data requirements based on

their level (1-4). See Table 1 for an overview of new substance registration requirements. TCCSCA also harmonizes the new substance registration requirements with that under the Occupational Health and Safety Act (OSHA).

**Table 1 - Types of New Chemical Registration**

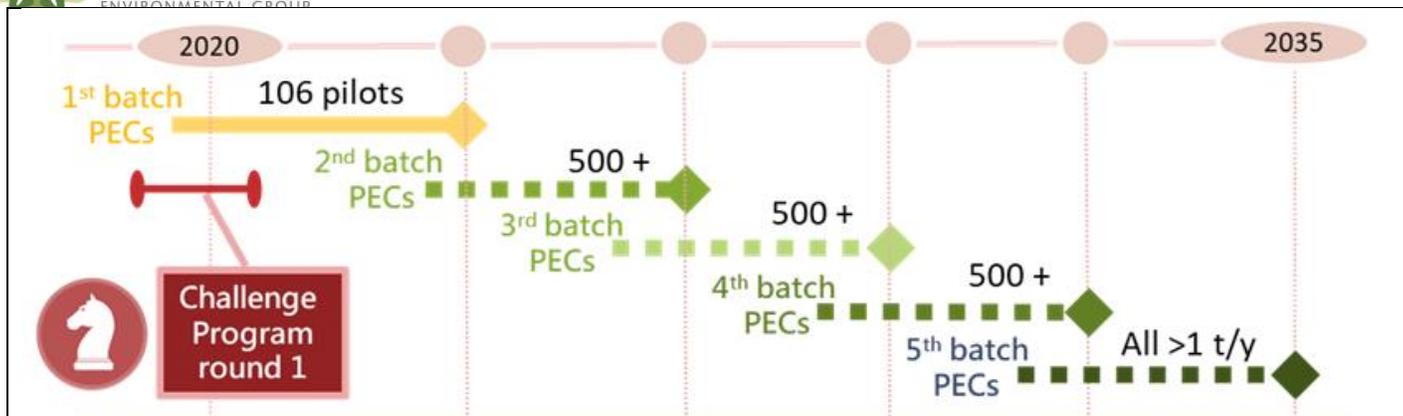
Tonnage band (t/y)	R&D	PPORD	CMR Cat 1	General substances	OSII	General Polymer	PLC
<0.1	Exempt	Low-volume Registration	Standard Registration Level 1	Low-volume Registration	Low-volume Registration	Low-volume Registration	Exempt (PLC confirmation required)
0.1-1				Low-volume Registration			
1-10	Simplified Registration	Simplified Registration	Standard Registration Level 2	Standard Registration Level 1	Simplified Registration	Simplified Registration	Low-volume Registration
10-100	Standard Registration Level 1	Standard Registration Level 1	Standard Registration Level 3	Standard Registration Level 2	Standard Registration Level 1	Standard Registration Level 1	
100-1000			Standard Registration Level 4	Standard Registration Level 3			
≥1000			Standard Registration Level 4				

R&D = Research & Development; PPORD = Product and Process Oriented Research and Development; OSII = On-site Isolated Intermediate; PLC = Polymer of Low Concern.

#### Existing Chemical Substances:

**Phase 1 Registration.** Existing substances are subject to Phase 1 Registration if they are manufactured or imported at >0.1 t/y (unless exemption conditions are met, see the 'Applicability' section to this document). Phase 1 Registration involves submission of basic company information, substance identification, uses information and quantities manufactured/ imported. A manufacturer/ importer of a newly imported substance must submit the Registration within 6 months after exceeding 0.1 t/y.

**Phase 2 Registration** was introduced by TCCSCA and requires manufacturers and importers of 'Priority Existing Chemicals' (PECs) to submit a standard registration if such substances are manufactured or imported at or above 1 t/y. The revised "Regulations of New and Existing Chemical Substances Registration" were published under TCCSCA on 11 March 2019, and introduced the first batch of 106 PECs. A further four stages of PECs are due to be released over the next 15 years; each stage will have a grace period of 2-3 years. Taiwan's Information, Safety and Technology Center (SAHTECH) issued the following expected timeline under their challenge program (which aimed to gather information from industry on the uses and hazards of proposed PECs):



Phase 2 registration deadlines will be based on the volume when applying for Phase 1 registration (pre-registration/late pre-registration) and the date on which the Phase 1 registration number is obtained:

- If a Phase 1 registration number is obtained before 31 December 2019, the following registration deadlines apply: For substances M/I (Manufactured/ Imported) in quantities  $\geq 1$  t/y but  $< 100$  t/y the registration deadline is 31 December 2022; for substances M/I in quantities  $\geq 100$  t/y the registration deadline is 31 December 2021.

- If a Phase 1 registration number is obtained after 1 January 2020, the following registration deadlines apply: Substances M/I in quantities  $\geq 1$  t/y but  $< 100$  t/y must be registered within 3 years of the 1 January of the next year after a Phase 1 registration number is obtained; Substances M/I in quantities  $\geq 100$  t/y must be registered within 2 years of the 1 January of the next year after a Phase 1 registration number is obtained.

- If an enterprise is manufacturing or importing the substance in quantities less than 1 t/y when the Phase 1 registration code is obtained for the first time, the following deadlines apply: if the tonnage reaches 1 t/y before 31 December 2019, the standard registration deadline is before 31 December 2022; if the tonnage reaches 1 t/y after 1 January 2020, registration must be completed within 3 years from 1 January the following year.

Further information on toxic substances can be found in the document entitled 'Regulations of New and Existing Chemical Substances Registration' under the 'Useful Links' Section to this document.

#### Annual reporting:

From 1 January 2020, all registrants will need to submit an annual report on the tonnage of substances manufactured or imported in Taiwan, the reporting year takes place for the last year between 1 April and 30 September. A registrant must either report by themselves (if based in Taiwan) or can authorize a third party representative (TPR) based in Taiwan, to do so for them. Registrants can only access the IT system using the MOEACA (Industrial and Commercial Certificate Management Center of the Ministry of Economy) IC (Citizen Digital Identification) card.

#### Toxic and Concerned Chemical Substances:

Toxic Chemical Substances are listed under the Toxic Chemical Substances List (TCSL), there are currently over 300 Toxic substances listed, which fall under one of the four following classes:

- Class 1: substances that do not readily decompose under standard conditions, or those that may pollute the environment or endanger human health due to bioaccumulative or biotransformation properties (i.e. PBT/vPvB)

- Class 2: substances known to cause tumours, infertility, teratogenesis, genetic mutations, or other chronic disease (i.e. CMR/ EDC substances)
- Class 3: substances which may harm humans or biological organisms upon exposure
- Class 4: substances for which there is a concern for pollution of the environment or harm to human health.

Concerned Chemical Substances will be announced by Taiwan's EPA - these will be subject to quantity and/ or concentration limits which will apply to the handlers of such substances. There are currently no substances identified as concerned chemical substances.

Handlers (those who manufacture, import, use, sell, export or dispose) of toxic and concerned chemicals should obtain storage registration documents or approval documents, then apply to the local authority for a permit. A validity period of 5 years applies to the permit, registration and approval documents. The handling of Class 1, 2 and 3 toxic substances may be restricted or prohibited by the EPA. Handlers may apply for the removal of the restrictions or prohibitions, provided they can prove that prevention and control methods applied to the use and processing of the toxic chemical substance can prevent or avoid pollution of the environment or the endangerment of human health.

The handler of toxic and concerned chemical substances must produce regular reports on how such substances are specifically handled (release quantities are not required for concerned chemical substances). Some concerned chemical substances will also be subject to accident prevention and response provisions, based on their hazards. Handlers of toxic and concerned substances must also label and produce Safety Data Sheets (SDS) in line with "[Administrative measure on the labeling and SDS management of toxic and concerned chemicals](#)".

Handlers who manufacture, use or store toxic chemical substances must submit an annual report of any operations involving toxic chemicals in quantities  $\geq 300$  t/y or  $\geq 10$  tonnes per day. If multiple sites of operation are associated with the same handler, a single report must be submitted that covers different sites as a unit. Reports must be submitted before the 31 January of the operating year. Handlers should keep an operational record detailing the use of toxic chemicals and chemicals of concern, this should include daily checks for changes in volume or concentration of such chemicals. Records must be updated monthly and declared to the competent authority on the tenth of each month. Further information can be found in Chinese under "[Administrative measure on the operation and release records of chemical substances](#)".

Handlers of Class 4 toxic chemical substances are under slightly less stringent measures, but are still required to report toxicity and other relevant information to the competent authorities. Handlers of Class 4 toxic substances should follow the guidance provided in Chinese under "[Management Measures for the Approval of Category 4 Toxic Chemicals](#)".

## RISKS TO AEROSPACE AND DEFENSE

A&D companies with operations in Taiwan should make sure that their suppliers are following appropriate chemical registration and reporting obligations. Otherwise, these suppliers may not be able to provide necessary chemical mixtures and preparations to support A&D activities, potentially disrupting operations.

A&D companies with facilities/operations in Taiwan also have permit acquisition and reporting obligations as handlers (users) of toxic and concerned chemical substances.

## USEFUL LINKS

**Toxic and Concerned Chemical Substances Control Act (TCCSCA):**

<https://law.moj.gov.tw/LawClass/LawAll.aspx?PCode=O0060012>

<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=O0060012> (in English)

**Registration and Approval Management Measures:**

<https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=O0060038>

<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=O0060038> (in English)

**Regulations of New and Existing Chemical Substances Registration:**

<https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=O0060043>

<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=O0060043> (in English)

**Taiwan Existing Substance Inventory:**

[https://csnn.osh.gov.tw/content/home/Substance\\_Query\\_Q.aspx](https://csnn.osh.gov.tw/content/home/Substance_Query_Q.aspx) (in Chinese)

**Toxic Chemical Substances List (TSCL):**

<https://flora2.epa.gov.tw/ToxicC/Query/database.aspx> (in Chinese, though English chemical names can be typed into the second search box, then hit the green button)

**Administrative measure on the labeling and SDS management of toxic and concerned chemicals:**

<https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=O0060037>

<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=O0060037> (in English)

**Administrative measure on the operation and release records of chemical substances:**

<https://oaout.epa.gov.tw/law/LawContent.aspx?id=FL044796> (in Chinese) Management Measures for the

**Approval of Category 4 Toxic Chemicals:**

<https://www.tcsb.gov.tw/cp-23-2114-57e2c-1.html> (in Chinese)

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