



# Knowing your Compliance Obligations in Taiwan





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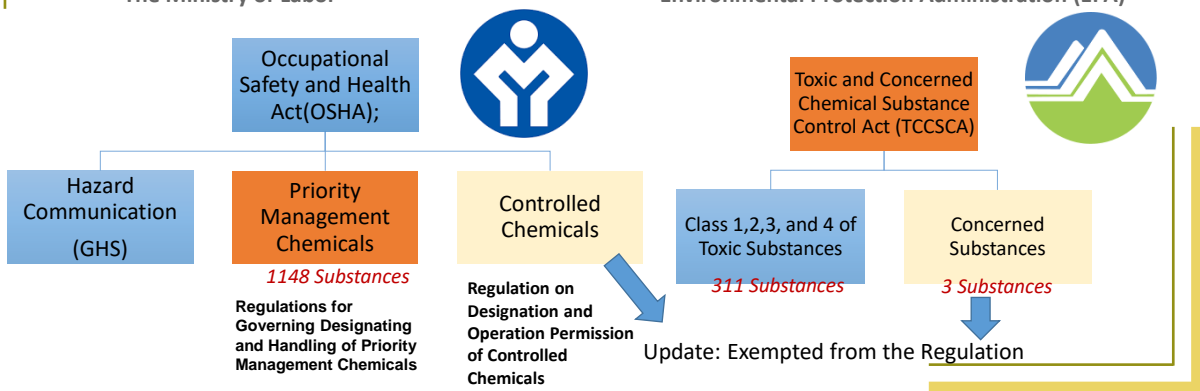
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## Chemical Management in Taiwan

**Chemicals at Workplace:**  
The Ministry of Labor

**Industrial Chemicals:**  
Environmental Protection Administration (EPA)



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## Exemptions

- Substances which occur in nature.
- Chemical substances in machines or equipment for test run purposes.
- Inseparable intermediates from chemical reactions in the reaction vessel or production process.
- Chemical substances for national security or national defense purposes.
- Chemical substances under customs supervision.
- Chemical wastes produced or released from industrial process.
- By-products or impurities that are of no commercial application.
- **Mixtures**; but individual constituents of mixtures shall not be applied to the Article.
- Articles
- **Polymers that the 2% Rule is Applicable** and listed on the inventory of existing chemical substances.
- Agro-pesticides, as defined by the Agro-pesticides Management Act.
- Feeds and feed additives, as defined by the Feed Control Act.
- Fertilizers, as defined by the Fertilizer Management Act.
- Veterinary drugs, as defined by the Veterinary Drugs Control Act
- Medicaments, as defined by the Pharmaceutical Affairs Act.
- Controlled drugs, as defined by the Controlled Drugs Act.
- Cosmetic(s), as defined by the Statute for Control of Cosmetic Hygiene.
- Foods, food additives, food utensils, food containers or packaging, and food cleansers, as defined by the Act Governing Food Safety and Sanitation.
- Tobacco products, as defined by the Tobacco Hazards Prevention Act
- Tobacco and alcohol, as defined by the Tobacco and Alcohol Administration Act.
- Radioactive materials, as defined by the Atomic Energy Act and the Ionizing Radiation Protection Act.
- Industrial use explosive materials, as defined by the Industrial Explosives Administrative Act.
- Chemicals regulated by the Montreal Protocol under the Air Pollution Control Act.
- Environmental agents, as defined by the Environmental Agents Control Act.
- Toxic chemical substances, as defined by the Act.

## Legal Basis and the Authority

### Toxic and Concerned Chemical Substance Control Act (TCCSCA)

- enacted on 16 January 2019
- amended, and renamed from Toxic Chemical Substance Control Act (TCSCA)
- Regulation on New and Existing Chemical Substances (March 2019)
- enforced since 1 January 2020

The competent Authority is Toxic and Chemical Substance Bureau (TCSB)



## Regulations for Governing Designating and Handling of Priority Management Chemicals

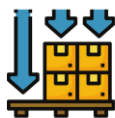
- On March 21, the Occupational Safety and Health Administration of Taiwan's Ministry of Labor released an updated edition of the priority management chemical notification manual
- From April 1, 2022, companies importing, using or supplying any of Taiwan's **1,148** designated priority management chemicals (PMCs) will need to know the category that their substances and notification.

Description	Number of Sub.
Carcinogen, mutagen or reproductive toxicant(Appendix 1)	
Chemicals With Properties Hazardous to Female Workers Under the Age of 18, Pregnant or Less Than One Year After Childbirth; and mixtures containing more than one percent of these chemicals by weight	96
<b>CMR Category 1</b>	
Chemicals that fall under the 186 substances on the designation list and have a concentration of one percent or more ( <b>notification is required regardless of the amount</b> )	186
<b>Other than CMR Category 1</b>	
Chemicals that fall under the 703 substances on the designation list and <b>have a concentration of one percent or more and whose total annual use is one ton or more</b> in any operation involving these chemicals	703
The 163 chemicals on the designation list	163

## Who can register?



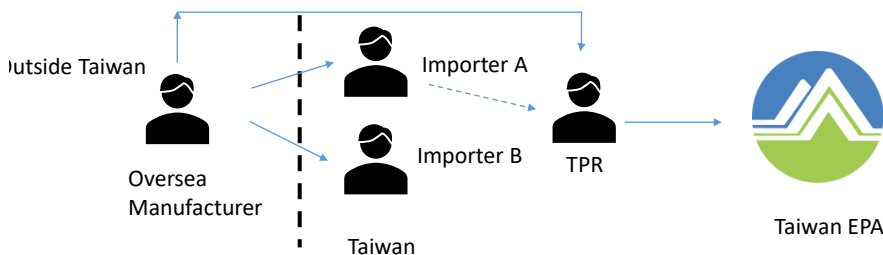
Manufacturer



Importer



Third Party Representative (TPR) with legal entity in Taiwan



It is not compulsory to do "Joint Registration".

Difficult to find Lead Registrants

## Substance Registration of Existing Chemicals

### Phase One Registration

Manufacturers / Importers, who manufacture/import existing chemical substances in an annual amount of **100 kilograms** or more, should apply for the **Phase One Registration** within 6 months from the date of manufacture/import.

### Standard Registration

Taiwan's EPA announced the first batch of Priority Existing Chemical (PEC) in which contains 106 substances. Companies manufacturing/importing PECs with a quantity above 1 TPA need to submit Standard Registration:

- Before **December 31, 2024** (if the Phase One Registration Number received before January 1, 2020)
- Before **December 31, 2025** (if the Phase One registration Number received after January 1, 2020).

*December 2021, Taiwan's EPA extended the deadline for Standard Registration of Priority Existing Chemical (PEC) substance to 2024 and 2025 (irrespective of their tonnage)*

Taiwan Chemical Substances Inventory (TCSI) contains 100,000+ substances that were manufactured in or imported in Taiwan between 1993 and 2014

Substances will be listed to the inventory later.

## Existing Chemical: Phase One Registration



Information required:

1. Name of substance, CAS No.
2. Tonnage band in a calendar year (estimated)
3. Information on use
4. Use information of this chemical (Product type)

## Existing Chemical: Standard Registration (PECs)

First Batch of PECs: 106 Substances

\* The highest number of data required for submission

Section	Level 1 (1-10 tons)	Level 2 (10-100 tons)	Level 3 (100-1000 tons)	Level 4 (1000+ tons)
1 Information of the registrant and basic identification of the substance	v	v	v	v
2 Information on manufacture, use and exposure of the substance	v	v	v	v
3 Hazards classification and labelling	v	v	v	v
4 Safe use information	v	v	v	v
5 Physical and chemical properties	v(13)*	v(13)	v(15)	v(15)
6 Toxicological information	v(5)	v(8)	v(8)	v(9)
7 Ecotoxicological information	v(3)	v(7)	v(9)	v(16)
8 Hazard assessment		v	v	v
9 Exposure assessment		v	v	v

Guidance for Existing Chemical Substances Standard Registration (Version 1) – June 2020

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## 106 PECs

No.	CAS No.	English Name	Chinese Name
	11979-10-07	Acrylic acid	丙烯酸
	210043-01-3	Aluminium sulfate	硫酸鋁
	7664-41-7		
3		Ammonia, anhydrous	氨·無水
41336-21-6		Ammonium hydroxide	氫氧化銨
5123-77-3		1,1'-Azobis(formamide)	1,1'-偶氮雙(甲酰胺)
6100-52-7		Benzaldehyde	苯甲醛
7552-30-7		Benzene-1,2,4-tricarboxylic acid 1,2-anhydride	苯-1,2,4-三甲酸 1,2-酐
8119-61-9		Benzophenone	二苯基酮
925973-55-1		2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol	2-(2H-苯并三唑-2-基)-4,6-二叔戊基苯酚
1090-43-7		2-Biphenylo	2-二苯基酚
11103-23-1		Bis(2-ethylhexyl) adipate	己二酸雙(2-乙基己基)酯
12106-94-5		1-Bromopropan	1-溴丙烷
13111-76-2		2-Butoxyethanol	2-丁氧基乙醇
1425013-16-5		Butylated hydroxyanisole	丁基化羥苯基甲基醚
15128-37-0		Butylated hydroxytoluene	丁基化羥基甲苯
1657693-14-8		C.I. Acid black 172	C.I. 酸性黑 172
17105-60-2		ε-Caprolactam	ε-己內酰胺
181333-86-4		Carbon black	碳黑
1995-48-7		o-Cresol	鄰甲酚
20108-77-0		Cyanuric chloride	三聚氰化氯
21108-94-1		Cyclohexanone	環己酮
2295-33-0		N-Cyclohexyl-2-benzothiazolesulfenamid	N-環己基-2-苯并噻唑亞磺酰胺
23108-91-8		Cyclohexylamine	環己胺
241309-64-4		Diantimony trioxide	三氧化二銻
251303-86-2		Diboron trioxide	三氧化二硼
2680-43-3		Dicumyl peroxide	過氧化雙異苯丙基
2717173-51-5		Didecylmethylammonium chloride	氯化二癸基二甲基銨

Source: Appendix of TCSCA

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## New Chemical Substance Registration(1)

New Chemical Substances can be registered in three types:

**Standard registration** (above 1 TPA),

**Simplified registration** (between 100 kilograms to 1 TPA)

**Small quantity registration** (less than 100 kilograms).

Application needs to be submitted 90 days before manufacturing and importing.

Identify:

Check inventory, quantity, specific usage, polymer of low concern, CMR

## New Chemical Substance Registration (2)

Item	≤100 kg	100 kg - 1 ton	1 ton -10 tons	10 tons -100 tons	100 tons – 1000 tons	1000 + tons
<b>New Chemical Substance</b>	Small quantity Registration	Simplified registration	Standard Registration (Level 1)	Standard Registration (Level 2)	Standard Registration (Level 3)	Standard Registration (Level 4)
Scientific Research and Development			Simplified registration		Standard Registration (Level 1)	
Process oriented Research and Development (PRORD) On-site isolated intermediates Polymer	Small quantity Registration		Simplified registration		Standard Registration (Level 1)	
Polymer of Low <sup>1</sup> Concern			Small quantity Registration			
CMR Substance	Standard Registration (Level 1)		Standard Registration (Level 2)	Standard Registration (Level 3)	Standard Registration (Level 4)	

## New Chemical Substance Registration (3)

	Section	Small quantity Registration	Simplified Registration	Standard Registration
1	Information of the registrant and basic identification of the substance	v	v	v (Level 1)
2	Information on manufacture, use and exposure of the substance	v	v	v (Level 1)
3	Hazards classification and labelling		v	v (Level 1)
4	Safe use information		v	v (Level 1)
5	Physical and chemical properties		v	v (Level 1)
6	Toxicological information			v (Level 1)
7	Ecotoxicological information			v (Level 1)
8	Hazard assessment			v (Level 2-4)
9	Exposure assessment			v (Level 2-4)

## Annual Reporting

Annual Reporting for Registered Chemical Substances took place during April 1<sup>st</sup> to September 30<sup>th</sup> every year. Manufacturers, importers and authorized TPR with valid Registration Number are eligible for Annual Reporting Information to be included in Annual Reporting:

- Substance name
- CAS Number
- Registration number for each substance
- Volume in the previous year
- Information on importer or manufacturer



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## Take Home Message

Identify your substances that are exporting to Taiwan

Check your compliance obligations: Existing/New Sub.

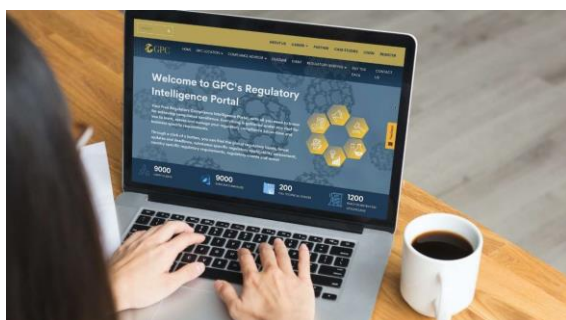
If the substance is considered a PEC and the quantity is above 1 TPA, prepare a plan for Standard Registration – Dossier Data preparation and Maintenance

New Deadline: Dec. 31, 2024/2025

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