
Chemical Substance Registration in Taiwan

台湾の化学物質登録

Randis ChemWise (Taiwan) Co. Ltd.

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Chemical Substance Registration in Taiwan

► Ruled by 2 regulations in parallel

⦿ The Regulation of New Chemical Substances Registration

- Issued by Ministry of Labor of Taiwan (OSHA-MOL)
- Effective from Jan. 1st of 2015



勞動部職業安全衛生署
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, MINISTRY OF LABOR

⦿ Regulation of New and Existing Chemical Substances Registration

- Issued by EPA of Taiwan
- Effective from Dec. 11th of 2014



行政院環境保護署 Environmental Protection Administration Executive Yuan, R.O.C.(Taiwan)

1) Main Differences of the 2 Regulations

▶ EPA:

- ④ manages both Existing and New Chemical Substances
- ④ Chemicals not in TCSI (Taiwan Chemical Substance Inventory i.e. the Existing chemical substance inventory) can still be supplemented, deadline is March 31st, 2015.
- ④ Requires environmental hazard information for Standard Registration.



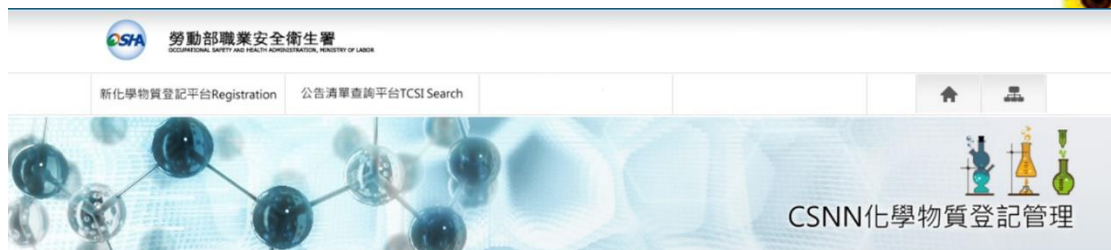
▶ MOL:

- ④ Manages only New Chemical Substances.
- ④ Does not accept TCSI supplement anymore.
- ④ No requirement on environmental hazards for Standard Registration.



2) Same Points of the 2 Regulations

- ▶ Both refers to TCSI issued by MOL.
- ▶ Exemption scope, procedures, data requirements, registration types of both Regulations are closely similar.
- ▶ **Importers and manufacturers inside Taiwan shall make the registration, companies outside Taiwan can not make the registration**
- ▶ For confidential protection, overseas suppliers can provide chemical information to 3rd party Agent (e.g. Randis).
- ▶ Different registrants of same substance may apply for Joint Registration, with summed quantity.



3) New Chemical Substance Registration

- ▶ Transition period: new chemical substances (NCS) to Taiwan in year 2015 can make a one-year-valid registration by providing only basic information of the substance and of the registrant.
- ▶ Afterwards, normal registration requirements should be followed:
 - ◉ Small Quantity Registration
 - ◉ Simplified Registration
 - ◉ Standard Registration

3) New Chemical Substance Registration Types

Ton/y	CMR	Other cases	Product & Process R&D	On-site Isolated Intermediate	Polymer	Scientific Research	Low Concern Polymer
<0.1	Yellow	Blue	Blue	Blue	Blue	Light Grey	Light Grey
<1	Yellow	Light Blue	Blue	Blue	Blue	Light Grey	Light Grey
<10	Yellow	Yellow	Light Blue	Light Blue	Light Blue	Light Blue	Blue
>10	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Blue

Remark: CMR refers to category 1 of Carcinogenicity, Mutagenicity, toxic to Reproduction

	Registration is not needed
	Small Quantity Registrati
	Simplified Registration
	Standard Registration
Low Concern Polymer:	Confirmation application is needed

3) New Chemical Substance Registration – Information needed

- ▶ Small Quantity Registration:
 - ⊙ Registrant's basic information
 - ⊙ Chemical substance's basic information
 - ⊙ Quantity and usage
- ▶ Simplified Registration
 - ⊙ Information for Small quantity Registration, and
 - ⊙ Melting point
 - ⊙ Boiling point
 - ⊙ Density
 - ⊙ Logk_{ow}
 - ⊙ Water solubility

3) New Chemical Substance Registration – Information needed

► Standard Registration:

- ④ 4 levels: 1~10 ton; 10~100 ton; 100~1000 ton; >1000 ton.
- ④ Information needed for Simplified Registration, and
- ④ Further properties on physic-chemical properties, toxicological properties e.g. oral toxicity etc, ecotoxicological properties e.g. toxicity testing on fish
- ④ Hazard assessment
- ④ Exposure assessment

3) New Chemical Substance Registration – Approval and Listing into TCSI

▶ Approval Validity Period

- ④ 5 years for Standard Registration, then the substance is included in TCSI.
- ④ 5 years for Small Quantity Registration of Low Concern Polymer, then the substance is included in TCSI.
- ④ 2 years for Simplified Registration and other Small Quantity Registrations. The substance can not be listed in TCSI.

▶ Advance TCSI Listing

- ④ Registrant can apply for the listing of the substance by Standard Registration and by Small Quantity Registration of Low Concern Polymer.



4) Existing Chemical Substance Registration (EPA)

First Stage:

- ⦿ manufactured/imported in/to Taiwan with quantity >100kg in any year of past 3 years, shall make the registration between Sep. 1st of 2015 ~ Mar. 31st of 2016.
- ⦿ From Apr. 1st of 2016, manufactured/imported in/to Taiwan with quantity > 100kg/year shall make the registration at the time to be announced by government.
- ▶ The registration shall be made by manufacturers/importers inside Taiwan.
- ▶ Again, for confidential protection, overseas suppliers can provide chemical information to 3rd party Agent (e.g. Randis).

4) Existing Chemical Substance Registration (EPA)

2nd stage: Standard Registration

- ▶ EPA may announce Designated List of Existing Chemical Substances Subject to Standard Registration in stages, including quantity threshold and the deadline for registration.
- ▶ Registrants shall make the registration within the deadline announced.

5) Service from Randis ChemWise

- ▶ Randis ChemWise (Taiwan) Co., Ltd. --- subsidiary wholly owned by Randis ChemWise (Shanghai) Co., Ltd. --- can help the whole process of the registrations, including new chemical substances and existing chemical substances.
- ▶ The registrant shall be your affiliate manufacturers in Taiwan or your downstream importers in Taiwan. Randis ChemWise can complete the whole registration process for them.
- ▶ In the meantime, confidential business information is not disclosed to affiliate manufacturers in Taiwan or downstream importers in Taiwan.

Contact Randis

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