

SAFEGUARDS

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TAIWAN REACH REGULATION OF NEW AND EXISTING CHEMICAL SUBSTANCES REGISTRATION

On 4 December 2014, the Taiwan Environmental Protection Administration (EPA) published the Regulation of New and Existing Chemical Substances Registration (Taiwan REACH)¹. The Regulation is stipulated according to the Toxic Chemical Substances Control Act (TCSCA) and became effective on 11 December 2014.

The newly published regulation will require Taiwan manufacturers or importers of chemicals to submit applications for registration to the EPA. The information required includes identification of the registrant and substances, substances manufactured or imported and their uses, hazards classification and labelling, physical and chemical properties, toxicological and eco-toxicological information as well as hazard and exposure assessments. A measure similar to the Only Representative (OR) under REACH in the European Union (EU) was created to assist non-Taiwan exporters to carry out their registration responsibilities.

SCOPE

According to Taiwan REACH, the scope applies to a chemical substance on its own, and in a mixture. The regulation does not apply to the following substances:

1. Substances which occur in nature
2. Chemical substances in machines or equipment for test - run purposes
3. Inseparable intermediates from chemical reactions in the reaction vessel or production process
4. Chemical substances for national defense purposes
5. Chemical substances under customs supervision
6. Waste
7. By-product or impurity that is of no commercial application
8. Mixtures. Exemption is not applicable to the individual chemical constituents of the mixtures
9. Articles
10. A polymer for which the 2% rule is applicable and listed on the inventory of existing chemical substances, or that is a new chemical substance meeting the 2% rule
11. Products governed by specific laws such as cosmetics and food



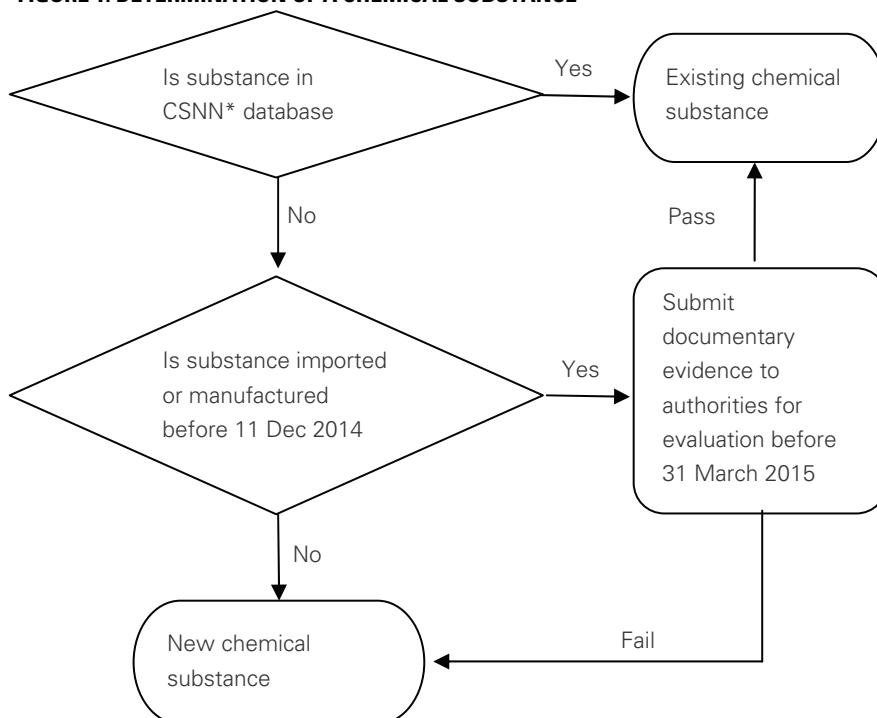
¹ [Taiwan EPA](#)

The regulated chemical substances on their own or in mixtures are separated into 2 groups:

- Existing chemical substances or
- New chemical substances

These 2 groups of substances can be differentiated in Figure 1.

FIGURE 1. DETERMINATION OF A CHEMICAL SUBSTANCE



* CSNN = Chemical Substance Nomination and Notification

FIGURE 2. REGISTRATION REQUIREMENTS FOR NEW CHEMICAL SUBSTANCES

Chemical sort	100 kg/year	1 ton/year	10 ton/year	100 ton/year	1000 ton/year
CMR					
New Chemical substance					
Intermediate					
Polymer					
PPORD ²					
SRD ³					
PLC ⁴					

² Product and Process Orientated Research and Development (PPORD) refers to any scientific development related to product development or the further development of a substance, in the course of which pilot plant or production trials are used to develop.

³ Scientific Research and Development refers to any scientific experimentation, education, analysis, or chemical research carried out under strictly controlled conditions.

⁴ Polymer of Low Concern (PLC).

Phase 1 registration—existing chemical substances

In accordance with Article 18, phase 1 registration shall be an obligation for an importer or manufacturer from 1 September 2015 to 31 March 2016 when an existing chemical substance is manufactured or imported in a quantity of 100 kg or more per year in the last 3 years, or with an annual quantity of 100 kg or above in any 1 of the last 3 years. After 1 April 2016, phase 1 registration applies to an existing chemical substance that is manufactured or imported in a quantity of 100 kg or more per year for the first time.

New Chemical Registration

The registration of a new chemical substance became effective on 11 December 2014. There are 4 types of registration and these are dependent on the type of chemical and the annual quantity, Figure 2.

	Registration types	Information need to be submitted
	Small quantity registration	Appendix 3
	Simplified registration	Appendix 2
	Standard registration	Appendix 1
	Standard registration	Appendix 1+additional information

Information dissemination and business secret protection

The chemical substance information granted under registration, unless intended to be kept confidential, shall be made public.

Penalty

A manufacturer or importer selling or transferring an existing chemical substance or a new chemical substance shall take the initiative to present registration number, registration document or other identifiable labels as granted under registration.

According to Article 7(1) of Toxic Chemical Substances Control Act, a civil penalty will be imposed to manufacturers or importers of chemical substances without a grant. Those who do not make corrections by the deadline may be fined per violation, and be ordered to suspend manufacturing or importing.

CHEMICAL SUBSTANCES	FINE (NTD)
New chemical substance	0.2 to 2 million
Existing chemical substance	0.03 to 0.3 million

Others

There are many provisions that are similar to REACH in the EU, including joint registration and an IT tool system.

SGS is committed to keeping you up to date on the latest regulations and policies concerning the use of hazardous substances in consumer products. Furthermore, through its global expertise and network of chemical labs, SGS can support you in ensuring your products comply with relevant hazardous substances requirements on all relevant markets around the world. Whether you are in need of hazardous substances testing or other third party verification, certification or inspection services, SGS is ideally positioned to satisfy all your business's needs. www.sgs.com/cgnr



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