

Product Stewardship - China REACH - (updated)

New Chemical Substance Registration (China REACH)

On April 29, 2020, the Ministry of Ecology & Environment issued the newly revised "Provisions on Environmental Administration of New Chemical Substances" (MEE Order No.12), which was officially implemented on January 1, 2021. The MEP Order No. 7 issued on January 19, 2010 was repealed simultaneously.

The "Guideline on New Chemical Substance Registration", which is a significant supportive document of the MEE Order No. 12, was also released on 17 November 2020, specifying the details of registration implementation.

According to MEE Order No. 12, companies shall submit new chemical substance registrations for substances not listed in Inventory of Existing Chemical Substances in China (IECSC). The registration not only applies to new substances, substances in a mixture or substances contained in articles which are intended to be released, but also applies to new substances used as raw materials or intermediates for pharmaceuticals, pesticides, veterinary drugs, cosmetics, food additives, feed, feed supplements, etc.

For existing substances which are listed in IECSC but are subject to new use management, new use registration shall also be submitted if the substances are to be used for purposes other than listed uses.

Inventory of Existing Chemical Substances in China (IECSC)

IECSC contains around 47,000 existing substances, which consists of two parts, the public part and confidential part, about 3500 substances are in the confidential part.

IECSC status for a substance can be searched in the website of MEE. Follow the guidance [here](#) to conduct a search.

If a substance is not listed in the public portion, you may submit a formal enquiry in order to check whether a substance is listed in the confidential part of IECSC. The authority China Solid Waste and Chemicals Management (SCC) then issues a letter of confirmation (usually within 2 weeks) and a 3,000 RMB fee will be charged by SCC for the enquiry.

Who Shall Register

- Manufacturers of new substances in China;
- Importers of new substances in China;
- Companies who intend to apply for new uses registration or to change the registered uses of the preparations managed by other laws and regulations to other industrial uses;
- Foreign companies introducing new substances to China;

Registration Types

There are three types of registrations under China REACH: regular registration, simplified registration and filing:

- *Filing:*

New chemical substances with tonnage no more than 1 ton per year;

Monomers of new substances, polymers containing less than 2%w/w new substances;

Polymers of low concern;

- *Simplified Registration:*

New chemical substances to be manufactured or imported above the annual volume of 1 ton, yet no more than 10 ton.

- *Regular Registration:*

New chemical substances to be manufactured or imported above the annual volume of 10 ton.

Chemical Risk Assessment Report

A chemical risk assessment report must be submitted for regular registration.

Post-Registration Obligations

After registration is complete, different post-registration obligations need to be fulfilled depending on the management category of the substance, including:

- Information transferred throughout the supply chain
- First-time activity report required for both simplified and regular registration

Last development



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Workflow of China...regist

Flow Chart of Registration
under China MEE Order 12

- Annual report due April 30th annually required on regular registration, which will be specified on the certificate
- Disclosure of implementation of environmental risk control measures and environmental management requirements
- Communication with the authority in case of any new hazards or risk exposure
- Keep the record of registration for years

References:

- [MEE Order No. 12 Provisions on Environmental Administration of New Chemical Substances](#)
- [Guideline on New Chemical Substance Registration](#)



Guidance for onl...rch of IE

[Guidance for IECSC Online Search](#)



Contact

More questions? contact [GPRC-Shelly Li](#).