

China New Chemical Substance Registration

Comprehensive Regulatory and Compliance Support

The “Measures for the Environmental Management of New Chemical Substances”(Order No. 17) was issued by the State Environmental Protection Administration of China (SEPA) in 2003. The updated “Measures for the Environmental Management of New Chemical Substances” (MEP Order No. 7) was revised and issued by the Ministry of Environmental Protection (MEP) of the People’s Republic of China in 2010. Later, MEP Order No. 7 was revised by the Ministry of Ecology and Environment (MEE) of the People’s Republic of China in 2020, followed by the recast regulations “Measures for the Environmental Management Registration of New Chemical Substances” - **MEE Order No. 12** issued on April 29th, 2020, which came into force on January 1st, 2021. Under the provisions of **MEE Order No. 12** ‘new’ chemical substances, which are to be manufactured, imported, used for R&D, processed, or utilized within the customs territory of the People’s Republic of China, are subject to registration prior to their placing on the market in China.

Under **MEE Order No. 12**, all chemical substances not listed in the Inventory of Existing Chemical Substances in China (IECSC) are considered ‘new’ chemical substances subject to registration where used as raw materials, intermediates or in articles with intentional release under normal conditions. **MEE Order No. 12** does not apply to ‘new’ substances for medicine, pesticide, veterinary medicine, cosmetics, food, food additives, fodder, fodder additives and fertilizers, except where they are also to be used for other industrial uses. Additionally, ‘existing’ substances as listed in the IECSC and subject to environmental management of new uses as stipulated in the IECSC or used for industrial purposes other than a permissible use are also subject to **MEE Order No. 12**. Based on the intended annual registered volume of a ‘new’ chemical substance, **MEE Order No. 12** provides for Filing, Simplified Registration and Regular registrations.



Categories of applicant

- Domestic manufacturer of new chemical substances (enterprises or public institutions),
- Domestic importer of new chemical substances (enterprises or public institutions)
- Foreign manufacturer / formulator exporting new chemical substances into China, and
- Foreign trader exporting new chemical substances into China.

A foreign applicant shall appoint a qualified ‘Notifying Agent’ (enterprise or public institution) for new chemical substance registration.

Our services

Intertek provides one-stop solutions and compliance services for ‘new’ chemical substance registration:

- Development of registration strategies and procedures
- IMEE Order No. 12 ‘Notifying Agent’ services (similar but not identical to an EU Only Representative)
- IECSC inventory checks
- Data evaluation and data gap analysis
- Design & facilitation of testing/study programs
- Test/study monitoring
- Provision of expert statements
- Exercise options for protection of proprietary chemical knowledge
- Preparation of chemical safety reports
- Preparation of registration dossiers, submission, and follow-up
- Pre- and post-registration communications with the regulatory authorities
- Post-registration compliance services (annual report, first activity report, etc.) and IECSC inventory listing application
- Safety Data Sheet Authoring
- Training
- Technical consultation

For more information



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Type of Registration

Registration Type	Scope of Application
Filing	Registered volume < 1 ton per annum Polymer with new monomer content less than 2% or polymer of low concern
Simplified Registration	1 ton per annum ≤ registered volume < 10 ton per annum
Regular Registration	Registered volume ≥ 10 ton per annum

Total Quality. Assured.