

# **Regulatory Alert**

## **Global Chemical, Environmental, Social, and Governance Regulations, Policies, and Standards**

**Alert 7.2**



## MEE Order 12 Provisions for the Environmental Management of New Chemical Substances Region: China

### WHY IS THIS ALERT IMPORTANT?

The Ministry of Ecology and Environment (MEE) Order 12 Provisions for the Environmental Management of New Chemical Substances (hereinafter China REACH) has a well-established system to manage chemicals on the Chinese market. China REACH has its unique features with data requirements, and its assessment follows a balanced approach with consideration of both hazard and risk of the substance. Due to the difference between China REACH with the European Union (EU) REACH, international chemical suppliers often need careful consideration of their marketing strategy for the Chinese market (especially timeline, annual volume, and supply chain roles). This Alert summarizes the key features and obligations under China REACH and includes the most recent China REACH updates. Non-compliance to the China REACH can incur fines.

### INTENDED AUDIENCE

This updated Alert is intended for those who trade in chemicals (i.e., import, produce, or sell chemicals and articles) in China. MEE Order 12 may impact the aerospace and defense industry, or their supply chain, with operations in China, especially those who changed their product formulations or changed their supply chains, after 2021.

### EXECUTIVE SUMMARY

This Alert aims to inform companies that manufacture, import, or sell chemical substances and polymers in China on their obligations under China REACH. With its unique features, China REACH plays a key role in business decisions and marketing strategy for international chemical manufacturers and traders. Understanding the difference between China REACH and other REACH-like regulations, especially the data requirements, is essential in fulfilling China REACH requirements. Under China REACH (effective January 2021), all new substances not listed in the Inventory of Existing Chemical Substances (IECSC) must undergo registration or notification before being placed on the market. The regulation also applies to new uses of existing substances under restricted use categories. Foreign companies can appoint a China-based agent to fulfil regulatory obligations on their behalf. The regulation introduces a tiered system based on tonnage and hazard of the substance, with simplified requirements for low-risk polymers (PLCs) or substances with low tonnages.

### BACKGROUND ON REGULATION

Initially an amendment to MEP (former Ministry of Environmental Protection) Order 7, MEE Order 12 of 2020 became its own legal text, known as Provisions for the Environmental Management of New Chemical Substances, on 29 April 2020. MEE Order 12 came into effect on 1 January 2021 and replaced MEP Order 7. The main regulatory

requirement under MEE Order 12 is registration/notification of new substances and registration of the new uses of substances. Under MEE Order 12, the number of registration/notification types was streamlined to three: 1) regular registration, 2) simplified registration, and 3) record notification. The regulatory framework and important features of MEE Order 12 are summarized below:

Only new substances are subjected to registration & notification:

- » The Order applies to any new substances being used, sold, manufactured, or imported in China. Any substances that are not in the IECSC are regarded as new substances and will be managed by MEE Order 12.
- » The following substances are designated by the MEE to be substances under new use management:
  - high risk substances: persistent, bio-accumulative, and toxic (i.e., PBT) or very persistent and very bio-accumulative (i.e., vPvB) substances
  - persistent and toxic (i.e., PT) substances
  - persistent and bio-accumulative (i.e., PB) substances
  - bio-accumulative and toxic (i.e., BT) substances
- » Substances completing the regular registration will be added into the IECSC after five years from the day of the approval.
- » If the substances' CAS number or substance name is not listed on the IECSC, the substance is a "new substance" under China REACH.
- » New substances are subjected to Registration if the manufacturer's import tonnage is greater than one tonne per year (T/Y).
- » New substances are subjected to notification if the manufacture import tonnage is less than one T/Y.
- » The following final products are excluded or exempt from registration: medicines; pesticides; veterinary drugs; cosmetics; food, feed and their additives; fertilizers; radioactive substances; and imported goods intended for export without further processing. Exemptions only apply as long as such substances are not being used for general industrial purposes. Raw ingredients and intermediates for the above-mentioned final products are regulated by MEE Order 12.
- » Before a new substance can be manufactured or imported, an application dossier must be submitted, and a registration certificate must be obtained from the MEE's Solid Waste and Chemical Management Centre.
- » When a substance is registered, it may be subject to annual reporting. A substance registration is subject to annual reporting if it is a "substance under new use management." The annual reporting must contain the following information: tonnage information; status of implemented risk management measures; environmental exposure and release information. The annual reporting must be submitted before 30 April of each year.
- » When a registration is complete, a first activity report must be submitted within 60 days of the first commencement of import or manufacture.
- » Registrations must be kept up to date. Re-registration or registration amendment is mandatory under the conditions stipulated in Article 29 and Article 30 of MEE Order 12.
- » Records must be kept of the following: time, quantity and use of the new substance. For regular and simplified registration, these records must be kept for at least ten years; for record notifications they must be kept for three years.
- » The following information must be passed downstream: the registration certificate number or receipt number; the registered use of the chemical substance; the environmental and health hazard

characteristics of new chemical substances and environmental risk control measures; and environmental management requirements for new chemical substances. In addition, if an entity routinely registers new substances, it must make its environmental risk control measures and environmental management requirements available on its website or other easily accessible medium.

## IECSC:

- » There is an [ongoing update of the IECSC](#) and currently the inventory includes more than 45,000 substances.
- » It includes “General Existing Substance” and “Existing Substance Subjected to New Use Management”.
  - Most existing substances on the IECSC are General Existing Substances with no use restrictions. There is one obligation under MEE Order 12.
  - “Existing Substance Subjected to New Use Management” is listed on the IECSC with its “approved uses”. Due to the hazard of those substances (e.g. PBT), any intended uses out of the scope of the approved uses of that specific substance are subjected to “new use registration.”

## New polymer registration and reduced requirements for polymers of low concern:

- » China REACH requires polymer registration (rather than monomer registration).
- » All new polymers with annual quantity of less than one tonne are subjected to “new substance notification” without data requirement.
- » All polymers that meet the Polymers of No Concern (PLC) criteria are subjected to “polymer notification” with Gel Permeation Chromatography (i.e., GPC) requirements.
- » Other new polymers that do not meet the reduced data requirements are subject to “new substance registration” if the annual tonnage is  $\geq 1$  tonne.

Confidential Business Information (CBI): Confidentiality can be requested for five years, provided there is a necessity and risks are not concealed.

China Agent: Foreign companies can appoint a China-based company as Agent (equivalent to EU REACH “Only Representative”) for registrations. MEE Order 12 obligations can also be fulfilled by China-based importers or manufacturers.

Data Quality: China is not an Organization for Economic Co-operation and Development (OECD) member country, but China has its own Good Laboratory Practice (i.e., GLP) standards. Some general rules for preparing data for China REACH registration are the following:

- » Physical chemistry: Can be an in-house lab or any laboratory.
- » Toxicology: Can be an OECD laboratory following OECD guidelines or other internationally recognized testing guidelines.
- » Ecotoxicity data: Some endpoints must be commissioned through China-based laboratories due to the requirements on local species.
- » New Approach Methodologies (NAMs; e.g., new approaches, non-testing, read-across, etc.) cannot be used unless experimental studies are not technically feasible. To use NAMs, applicants must request a lab to issue a non-viable statute to show the test is not viable and illustrate the technical reason.

## APPLICABILITY

The China REACH applies to entities that import, produce, or sell chemicals and articles in China. Registration and notification requirements apply for new substances (those not listed in IECSC) that are:

- » in products or formulations with specific functions: e.g. surfactants, plasticizers, preservatives, dispersants, and retardants
- » intentionally released from articles
- » UVCB (i.e., Unknown or Variable composition, is a Complex reaction product, or is a Biological material) substance
- » polymers
- » new isolated intermediates
- » raw ingredients of medicines, pesticides, veterinary drugs, cosmetics, food, food additives, feed, feed additives, fertilizers

Existing Substance Subjected to New Use Management, which are any intended uses out of the scope of the approved uses of that specific substance, are subjected to “New use registration.”

## RELEVANT DATES

- » MEE Order 12 effective: 1 January 2021
- » Registration or notification must be completed before placing the products on the market
- » CBI application: submit together with the registration

## REGULATORY OBLIGATIONS

The table below summarizes the key obligations under MEE Order 12 and its update.

Substance type	Annual Tonnage & Condition	Obligation	Data Requirement Overview
New Substance	<1T	Notification	No
New Substance	1-10T	Simplified registration	Physical, chemical, and toxicological data
New Substance	≥10T	Regular registration	Physical, chemical, toxicological, and eco-toxic data and risk assessment
New Polymer	<1T	Notification	No
New Polymer	≥1T Polymer of Low Concern (PLC)	Polymer notification	PLC proof data requirements: Molecular weight distribution report, composition table, residual monomer analysis, SDS, etc.
New Polymer	1-10T, polymers that do not meet the reduced data requirements	Simplified registration	Physical, chemical, and toxicological data
New Polymer	≥10T polymers that do not meet the reduced data requirements.	Regular registration	Physical, chemical, toxicological and eco-toxic data and risk assessment
Existing Substance Subjected to New Use Management	Any intended uses out of the scope of the approved uses, regardless of the tonnage.	New Use Registration	Physical, chemical, toxicological, eco-toxic data risk assessment and Social-Economic Benefit Report, etc.

## RISKS TO AEROSPACE AND DEFENSE

Violations of the regulations, such as failing to obtain registration, importing new chemical substances without approval or failing to report first-use or annual data, can incur administrative fines of up to ¥30,000 (approximate \$4,500) and administrative “dishonesty” sanctions (such as suspension of future registrations for up to three years), but no criminal imprisonment is prescribed under these provisions. Non-compliance is given as the following: violation of MEE Order 12 by means of fraud, bribery or improper means; failure to report; activity without registration and uses other than those on the registration; failure to keep records, update registrations and fulfil supply chain obligations; and failure to implement the environmental management requirements.

## USEFUL LINK

- » [MEE Update of IECSC](#)
- » [Example of Existing Substance Subjected to New Use Management](#)
- » [MEE Homepage](#)
- » [MEE Order 12](#)

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