

## Regulatory Alert

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

**Country:** China

#### INTENDED AUDIENCE

This Regulatory Alert is intended for those who trade (import/produce/sell) chemicals (including the selling of articles containing a new chemical substance which is intentionally released during normal use conditions) in the People's Republic of China. It may impact any IAEG member that has operations in or sells chemicals to the People's Republic of China.

#### EXECUTIVE SUMMARY

##### **Background on Regulation:**

Initially an amendment to MEP (former Ministry of Environmental Protection) Order 7, MEE (Ministry of Ecology & Environment) Order 12 of 2020 became its own legal text known as Provisions for the Environmental Management of New Chemical Substances on 29 April 2020. The MEE Order 12 will come into effect on 1 January 2021 and will replace MEP Order 7. The main regulatory requirement under Order 12 is registration/ notification of new substances and registering the new uses of substances.

Under Order 12, the number of registration/ notification types was streamlined to three: Regular Registration; Simplified Registration; Record Notification. Registration and data sharing are encouraged but currently there are no rules regarding this in the Order. Confidentiality can be requested for 5 years provided there is a necessity and risks are not concealed.

In comparison with MEP Order 7, MEE Order 12 reduces the data requirements for certain polymers and low volume (< 10 tonnes per annum) substances; strengthens management of new substances that are persistent, bioaccumulative and toxic (PBTs); implements a notification system for new uses of listed substances; reduces annual reporting requirements.

#### APPLICABILITY

- The Order applies to any new substances being used, sold, manufactured or imported in the People's Republic of China. Any substances that are not in the Inventory of Existing Chemical Substances in China (IECSC) are regarded as new substances and will be managed by Order 12. Substances completing the regular registration will be added into the IECSC after 5 year from the day of the approval.
- The following final products are excluded or exempt from registration: medicines; pesticides; veterinary drugs; cosmetics; food, feed and their additives; fertilisers; 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 Order 12.

- Articles that intentionally release new chemical substances under normal use conditions.

#### RELEVANT DATES

- ❖ **MEP Order 7 repealed:** 1 January 2021
- ❖ **MEE Order 12 effective:** 1 January 2021
- ❖ **MEP Order 7 confidentiality expires:** 31 December 2025

#### REGULATORY OBLIGATIONS

The differences between MEP Order 7 and MEE Order 12 consist of:

- reduced data requirements for certain polymers and low volume (< 1 tonnes per annum) substances;
- strengthened management of new substances that are persistent, bioaccumulative and toxic (PBTs)
- implementation of a registration system for new uses of listed substances (substance under new use management);
- reduced annual reporting requirements.

Table 1 - Comparison between Orders

Registration Type	MEP Order 7		MEE Order 12	
	Nature	Requirements	Nature	Requirements
Record Notification	Scientific purposes < 0.1 TPA.		< 1 TPA	
Simplified Registration	Split into Regular and Special types. Based on the purpose and nature of the substance.	Ecotoxicology testing.	1 - 10 TPA	Physical, chemical and ecotoxicology testing; other information on hazard and risk; letter of commitment to environmental risk management.
Regular Registration	Banded into 4 levels based on TPA.	Risk assessment report.	> 10 TPA	Environmental risk assessment report; other information on hazard and risk; letter of commitment to environmental risk management; analysis of socio-economic benefits.

- The notification types under Order 12 have been streamlined to three: Record Notification; Simplified Registration; Regular Registration. Regular Registrations take approximately 6 months. Simplified Registrations take approximately up to 5 months. These windows can be extended by stopping the regulatory clock in order to obtain more data. Activity may begin once the registration receipt has been returned. For Record Notifications, activity may begin as soon as the notification has been sent.

- 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 (SCC). Confidentiality (CBI) may be requested, but it will expire after 5 years and cannot be used to conceal risk.
- A foreign exporter must appoint a local Chinese representative to submit new substance notifications and registrations, similar to EU REACH 'only representatives'.
- When a substance is registered, it may be subject to annual reporting, though this has been reduced compared to MEP Order 7. 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 Order 12.
- Registration under Order 7 will still be valid under Order 12. Once Order 12 is enacted, substances registered under Order 7 will be subject to the Post-registration obligation of MEE Order 12 registration.
- 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.
- Chapter V details fines of between 10,000 and 30,000 CNY for non-compliance. Other sanctions include an automatic refusal of applications for one year. Non-compliance is given as the following: violation of the Order 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.
- Substances under new use management: One of the new requirements under Order 12 is the "new use registration" for "Substances under new use management." Substances under new use management include those substances with use restriction (Priority Environmental Management and Hazardous Substances) in IECSC (registered under Order 7); and those under new use management registered under MEE Order 12. The following substances are designated by the MEE to be substances under new use management:

- High Risk substances (PBT or vPvB)
- Persistent and Toxic (PT) substances or;
- Persistent and Bioaccumulative (PB) substances or;
- Bioaccumulative and Toxic (BT) substances

If a company intends to use the 'substances under new use management' for an unregistered use, the company needs to apply for new use registration. The applicants can be importers, manufacturers, or other down-stream users.

#### RISKS TO AEROSPACE AND DEFENSE

Low risk. The majority of A&D manufacturers will likely not be placing new chemical substances on the Chinese market. A&D potential supply risk exists if actors involved in the supply of new chemicals to China are not aware of MEE Order 12 requirements.

#### IAEG ACTIONS RELATED TO THIS RISK

Encourage any IAEG members selling chemicals to China to cross check Inventory of Existing Chemical Substances in China (IECSC) and complete notify, register, filing obligations as appropriate.  
Continue to monitor potential changes to MEE Order 12 & advise IAEG members accordingly.

#### USEFUL LINKS – (in Chinese)

**Ministry of Ecological Environment (MEE) Homepage:**  
<http://www.mee.gov.cn/> [click EN for English version]

**MEP Order 7 Notice:**  
[http://www.gov.cn/flfg/2010-02/04/content\\_1528001.htm](http://www.gov.cn/flfg/2010-02/04/content_1528001.htm)

**MEE Order 12 Notice:**  
[http://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202005/t20200507\\_777913.html](http://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202005/t20200507_777913.html)

**MEP Inventory of Existing Chemical Substances (IECSC) Notice:**  
[http://www.mee.gov.cn/gkml/hbb/bgg/201301/t20130131\\_245810.htm](http://www.mee.gov.cn/gkml/hbb/bgg/201301/t20130131_245810.htm)

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