Expert Focus: What changes has China's revised law on new chemical substances introduced?

20 May 2020

China's MEE Order 12 sets up a more comprehensive legal system for new substances regulation, says Heng Li, senior associate, Mayer Brown

On 7 May China's Ministry of Ecology and Environment (MEE) published its long-awaited revised law on new chemical substances: the Measures for the Environmental Management Registration of New Chemical Substances (MEE Order 12).

MEE Order 12 is the revised version of the Measures for the Environmental Management of New Chemical Substances (MEP Order 7). It will take effect and replace the latter on 1 January 2021.

This update focuses on the major changes that MEE Order 12 has introduced, and their implications for industry from a legal standpoint.

Scope of application

Like MEP Order 7, MEE Order 12 regulates new chemical substances – in other words those substances falling outside the Inventory of Existing Chemical Substances (IECSC).

Generally speaking, the exemptions provided by the new law are similar to those of MEP Order 7. They include certain specified substances and mixtures that are already governed by other legislation (pharmaceuticals, cosmetics, food, food additives, fertilisers, radioactive substances, etc) and therefore fall outside the scope of its application.

However, the low volume exemption (LVE) for new substances manufactured or imported below 100kg per year for research purposes, still in the draft revision of MEP Order 7, has been removed.

The draft Environmental Risk Assessment and Control Regulation for Chemical Substances (Erac), published in 2019, includes a similar LVE so it would be available throught this measure, if retained in the final version.

It remains unclear whether additional exemptions will be included in the revised MEE guidelines, as was the case for MEP Order 7.

Type of registration

Three types of registration remain under MEE Order 12, but the tonnage thresholds triggering them are changed as follows:

- **standard registration** – new substances at or above 10 tons a year;
- **simplified registration** – new substances of 1 to 10 tons a year; and
- **filing** – new substances below 1 ton a year and certain specified polymers (for example, low concern polymers) irrespective of volume.

This appears to have reduced the burden on industry by lifting the threshold for standard registration from 1 ton to 10 tons a year, and shifting many conditions for simplified registration (under MEP Order 7) to the filing process. However, further analysis of the data requirements is required to ascertain to what extent this is lessened.

Data requirements

MEE Order 12 provides general data requirements. These will be further outlined in the revised MEE guidelines.

Some information, such as safety data sheets (SDSs), required under MEP Order 7 will no longer be so. But there are also new requirements. For example, a "socio-economic benefit analysis" for "highly hazardous substances" (HHS) such as persistent, bioaccumulative and toxic (PBT) substances, very persistent and very bioaccumulative substances (vPvB), or "substances possessing the equivalent environmental or health hazards". Also required in this case would be a "letter of commitment" on the "implementation or communication of environmental risk control measures and environmental management requirements".

Another important change is a requirement to submit "other information on the environmental and health hazards and environmental risks" that a registrant "holds", in addition to the data that is expressly listed in MEE Order 12.

The current MEP Order 7 technical guidance includes a similar requirement. However, its addition in MEE Order 12 means it will be a statutory obligation for companies to submit all such information, for example that which they have acquired for the purpose of registration in other jurisdictions, under EU REACH, K-REACH, Turkish KKDIK, etc.

It is unclear whether the term 'hold' refers to data that a company owns, that which it only has the right to refer to, or any that the company is aware of. The MEE guidelines may clarify this. If not, many companies may find it difficult to comply if they do not have the right to use data they 'hold' for other purposes in China.

Who can register?

The following general principle is unchanged: China-based manufacturers and importers are required to register their substances. A few exceptions, heavily debated during the revision process, are confirmed under MEE Order 12.

For imported substances, foreign manufacturers, or trading companies located outside China, can apply for registration but need to appoint a China-based agent and comply with registration and post-registration obligations together with their agent.

In addition to manufacturers and importers, "processors and/or users" can apply for registration, if:

- an exempted product is intended to be used for other than exempted uses; or
- a substance subject to the "new use management" (see below) is intended to be used for other than the approved uses.

The addition of foreign manufacturers and "processors and/or users" as registrants has provided industry with flexibility regarding its registration strategy under the specified circumstances. The following practical issues may need to be considered when deciding who should register, and be reflected in contractual arrangements where necessary:

- control of the registration process;
- protection of data ownership and rights; and
- who benefits from the registration.

Registration process

The registration process remains largely the same. The decision-making process for standard and simplified registration is now mainly risk-based. For example, a registration certificate will be issued for a standard registration if no "unreasonable environmental risk" is identified.

Notably, the Solid Waste and Chemical Management Centre (SCC) has expanded responsibilities. The SCC will undertake the "technical review" of standard registrations together with the expert committee and be solely responsible for checking simplified registrations.

Post-registration requirements

Some post-registration requirements are eased (such as annual reporting, which will only apply to substances designated by the MEE), but MEE Order 12 has also introduced new obligations.

These will affect not only manufacturers and importers, but also "processors and users" and "researchers". For example, any of these registrants of a new substance must notify the MEE if they discover a "new environmental or health hazard property" or a "new environmental risk". In turn, the ministry may request additional information and withdraw a registration certificate.

Another important change is linked to 'new use management' – a requirement now applying to HHS and persistent and bioaccumulative (PB), persistent and toxic (PT) and bioaccumulative and toxic (BT) substances that are subject to standard registration and listed in the IECSC with permitted uses. Any other proposed use will require MEE approval. The approval process is the same as for standard registration. Interestingly, new use management appears to have certain similarities with EU REACH authorisation which is also use specific and partially company specific.

Inclusion on the IECSC

As with the previous regime, under MEE Order 12 only substances registered for standard registration can be included in the IECSC five years from the date of the first registration.

For HHS and PB, PT and BT substances, the IECSC will also include various "environmental management requirements" such as permitted use(s), emissions limits.

The law also provides transitional arrangements for substances that have been registered under MEP Order 7 and the old MEP Order 17. For example, substances that have been registered under MEP Order 7 will be included in the IECSC five years after the date of the first manufacture or import, or five years after entry into force of the MEE Order 12 (1 January 2021).

Penalties

Various penalties remain in place, including fines. Under MEE Order 12 this is as before – up to RMB 30,000 (approximately €3,913 or $4,231).

Under "severe circumstances", a violation will also trigger repercussions under China's social credit system and lead to non-acceptance of future registration applications for one or three years. Once in motion, these newly added penalties will have a significant negative impact on companies operating in, and exporting to, China.

Implications for the industry

To sum up, MEE Order 12 has set up a more comprehensive system for the regulation of new substances. Compliance with this law will no longer mean just registering a substance. The bolstered post-registration requirements and newly introduced penalties will affect actors along the supply chain both inside and outside China, directly and indirectly. Where necessary, contractual arrangements should be put in place to ensure compliance of these actors and to compensate for possible losses.

It also puts more emphasis on the regulation of HHS and PB, PT and BT substances. Companies manufacturing, exporting, importing, or using them should expect to bear more regulatory burdens, such as being subject to the 'new use management' requirement. We understand that MEE intends to limit their manufacture, import and use in China.

It is expected that many aspects, including the scope of exemptions, detailed data requirements (including studies required, requirements for risk assessment, compilation of socio-economic benefit analysis, etc) and new use management will be further clarified in MEE's revised or new guidelines. Companies should closely monitor the development of these guidelines and participate in the public consultations if any.

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The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch.