

Expert Focus: China's evolving chemical regulatory regime – implications for businesses

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Throughout 2019, China has been working to update its chemical regulatory regime, proposing far-reaching changes that would make China's regime resemble EU-REACH and TSCA in the US.

In January, China's Ministry of Ecology and Environment (MEE) published a Draft Regulation on the Environmental Risk Assessment and Control of Chemical Substances (Draft Regulation), a broad chemical regulatory proposal that has been dubbed 'China-REACH' by some [commenters](#). Then in July, MEE proposed significant (some say [dramatic](#)) revisions to the current chemical regulation, the Measures for Environmental Administration of New Chemical Substances (MEP Order 7).

Although neither of these proposals has yet been finalised, they indicate the Chinese government's intent to more strictly regulate chemicals, especially those that pose the most significant environmental and health risks. US chemical companies that do business in China should

continue to keep close track of these regulations, as they will have significant implications once finalised.

Proposed amendments to MEP Order 7 – the new chemical substances regime

MEP Order 7 is a ministerial order that was issued in January 2010. Although it too has been called China-REACH, it is significantly different from EU-REACH. Most importantly, [MEP Order 7](#) only regulates new substances and does not regulate existing chemicals. To comply with MEP Order 7, companies must submit new substance notifications to the Solid Waste and Chemicals Management Centre (which is part of MEE) if they wish to manufacture, import or process chemical substances that are not on the Inventory of Existing Chemical Substances in China (IECSC), or wish to use an existing chemical for a new use. (The remainder of this article refers only to "manufacturing" for ease of reading but includes all of the covered activities.)

MEE released a significant amendment proposal to MEP Order 7 on 9 July, with comments due 16 August. The proposal's revisions, which MEE has been working on since late 2018, closely align with the new chemical substance (NCS) provisions of January's Draft Regulation.

This alignment indicates that MEE prepared the revisions with the Draft Regulation in mind, and that the Chinese authorities are moving forward with the comprehensive reform envisioned in the Draft Regulation.

Registration process

The MEP Order 7 amendments would start the transition of the NCS regime, while streamlining the NCS notification and registration process. For example, proposed changes to the registration process would:

- Consolidate the various registration requirements for substances manufactured at a rate of over 10 tons per year (“tpy”) into a single “regular registration” process, while providing a “simplified” registration process for substances between 1 tpy and 10 tpy;
- Require only a “record” notification for substances under 1 tpy, as well as certain polymers; and
- Exempt R&D chemicals in volumes up to 100 kg from the regulation entirely, contrary to previous rules which required record-keeping.

These changes broadly correspond to Articles 24, 27 and 43 of the Draft Regulation, which provide for a low-volume record notification and R&D exemption. The Draft Regulation does not provide for a simplified registration process. However, to ensure consistency with the MEP Order 7 amendments, the State Council may include such a process in the final version.

Environmental provisions

MEE’s proposed amendments to MEP Order 7 focus on environmental risks from substances that are persistent, bio-accumulative or toxic (PBT), or very persistent and very bio-accumulative (vPvB). Regardless of the type of registration required, companies will have to submit information on whether a new substance is PBT or vPvB. If the chemical is PBT/vPvB, only the regular registration process can be used, and the submitter must include a socioeconomic analysis to demonstrate the necessity of allowing the chemical’s manufacture.

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Approval will depend on whether any risks found can be adequately controlled. Approval may be limited to specific uses, and registration can be denied if the substance poses uncontrollable, unreasonable risks. These proposed changes are in line with the Draft Regulation, which strongly focuses on determining and regulating the environmental and health risks of chemicals. For example, Article 25 of the Draft Regulation would allow authorities

to impose strict risk-control measures on new substances, similar to the proposed MEP Order 7 amendments.

Reporting and administrative provisions

MEE’s proposed amendments to MEP Order 7 would make some changes to current reporting and administrative provisions. For example, substances would be added to the IECSC five years after their first registration, rather than five years after they are first manufactured. This proposed change corresponds to Article 26 of the Draft Regulation.

Moreover, annual reports would no longer be required after a first activity report was filed, unless the Chinese government specifically requested such reports for a substance. Article 13 of the Draft Regulation, by contrast, provides for annual reporting for existing substances. Thus, the proposed amendments may reflect a potential change in approach, including a recognition of the significant burden that annual reporting would impose, as business comments on the Draft Regulation had noted. Additionally, the proposed amendments may signal an intent to reduce burdens on manufacturers of low-risk chemicals.

Confidential business information provisions

Finally, as will be discussed further below, MEE significantly weakened MEP Order 7’s confidential business information (CBI) provisions. Companies would be required to substantiate the need for CBI protection by providing relevant documentation, and the period of protection would be limited to five years—a short period compared to regimes like TSCA or EU-REACH, which provide longer protection as well as the potential for extension. Moreover, no protection would be provided for health and safety data. Article 28 of the Draft Regulation similarly requires CBI substantiation, although it does not provide a specific duration.

Many of the proposed changes to the NCS are analogous to aspects of the US and EU regimes. For example, proposed use restrictions for new chemicals under the NCS are similar to significant new use rules (Snurs) under TSCA. Although certain features of the proposed regime will be familiar to businesses, some significant differences remain (eg, on CBI), and thus businesses registering new chemicals in China will need to keep a close eye on these changes.

How the proposed amendments may impact the Draft Regulation

The alignment of MEP Order 7’s proposed amendments with provisions of the Draft Regulation indicates that China is moving ahead in updating its chemical regulatory

regime as proposed in January. Although the MEP Order 7 changes are significant, the Draft Regulation will have a far greater reach because it covers existing chemicals in addition to new ones. The potential impact of the proposed chemical regulatory regime has been widely analysed this year, including on Chemical Watch and by Latham & Watkins, which has worked extensively with US businesses to comment on the Draft Regulation.

For existing chemicals, similar to MEP Order 7's proposed amendments, the Draft Regulation focuses on the control of environmental and health risks of substances of concern such as PBT/vPvB substances. The proposed risk-evaluation and risk-control mechanisms have similar features to those of EU-REACH and TSCA, with which businesses are already familiar. The Draft Regulation (Articles 12-16) envisions a system of nationwide information gathering and risk assessments for existing substances, which would have a major impact on chemical companies operating in China.

Chinese regulators would collect information and data to create a priority list of chemicals that are PBT, vPvB, or otherwise pose a significant risk to human health or the environment. There is no REACH-like registration requirement obligating companies to create a dossier of studies and data, but Chinese regulators would appear to have the authority to require businesses to submit such data. This process looks akin to the US EPA's efforts under TSCA, such as the 2014 TSCA Work Plan and the prioritisation process required by the 2016 TSCA amendments.

For chemicals on the priority list, the Chinese regulators would monitor the substance in the environment and create risk assessments. Once a substance is prioritised, companies would be required to submit available data, including physical chemistry, health studies, and ecological toxicology, which the Chinese regulators would use in the risk assessment.

Following the risk assessment, the Chinese regulators would take measures to reduce any risks that are found through the risk-assessment process. Such measures can be taken under other laws—eg, China's air and water pollution control laws—but the Draft Regulation would also allow for the restriction or prohibition of chemicals following their inclusion on restricted/prohibited substance lists (Articles 17-22).

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The information gathering, evaluation, and restriction aspect of the Draft Regulation will likely look familiar to US and EU companies. For example, TSCA's prioritisation process and REACH's community rolling action plan (Corap) process already prioritise chemicals of concern for potential restrictions. Risk-management measures under the Draft Regulation are also similar to those found under TSCA (eg, Section 5 rules) and REACH (eg, the authorisation listing process). Thus, China likely will look to existing efforts by the EPA and Echa to help inform its efforts following the anticipated changes to its chemical regulatory programme.

Business implications for foreign chemical companies MEE's proposed amendments to MEP Order 7, especially when compared with the Draft Regulation, signals that the China intends to continue to move in the same general direction as the TSCA and REACH regimes. The NCS likely will become relatively settled following adoption of the MEP Order 7 amendments. Assuming finalisation of the Draft Regulation, the entire Chinese chemical regime will be significantly changed.

Chemical companies doing business in China can use familiar strategies to anticipate and adapt to these changes once they occur. Given that prioritisation processes have already been taking place for years in the US (eg, the 2014 TSCA Work Plan) and the EU (eg, SVHC listings started in 2008), using the outcomes of processes such as TSCA prioritisation, CoRAP evaluations, and SVHC listings as a crystal ball may help predict which substances Chinese authorities may prioritise. REACH registration dossiers likely already contain information that companies may be required to submit in China for prioritised existing chemicals. Companies may be able to form REACH-like consortia to share compliance costs and to coordinate data access and compensation, should that become necessary.

MEP Order 7: Weakening of CBI

The proposed Chinese chemical regulatory regime presents certain notable concerns. A significant issue is that CBI protection under the MEP Order 7 proposal would be significantly weakened. Although the proposal shares some features with other regimes—for example, the amended TSCA also does not protect health and safety studies from disclosure, and requires substantiation of CBI claims—the proposed five-year time limit for CBI is comparatively very short.

Even under the TSCA amendments, which significantly curtailed CBI protection and continue to cause [controversy](#) over CBI, protection lasts for ten years and can be renewed. In contrast, MEE's proposed amendments to MEP Order 7 do not contain a renewal provision. To emphasize the importance of providing sufficient protection of sensitive information, companies may want to engage on the proposed amendments.

Draft Regulation: Expansive liability provisions

The Draft Regulation includes broad liability provisions for companies. In addition to penalties for violations (such as importing a prohibited substance or failure to provide required information), the proposed law has a broad "public interest litigation" provision that allows any agency or organisation to file a lawsuit if the production or import of a chemical substance "injures social public interest".

The inclusion of specific authorisation for public interest litigation is consistent with many recent Chinese environmental statutes (eg, the Environmental Protection Law and the Soil Pollution Law). Moreover, the Draft Regulation explicitly imposes tort liability on "responsible parties" for any environmental pollution caused by the production, processing, use, import, or export of chemicals. Depending on how aggressively these provisions are implemented, companies may face

significant liability, including liability for the manifestation of risks that were not known at the time of production of the chemical.

Businesses can, and should, stay engaged

Although the Draft Regulation and the MEP Order 7 proposed amendments set forth general rules, the relevant Chinese agencies will have authority to create implementing regulations. Depending on how the Chinese regulators decide to implement these laws, compliance could become significantly more complicated and expensive.

Companies likely will have the opportunity to provide comments and engage with Chinese authorities. One potential forum through which businesses can engage is the China International Business Dialogue on Environmental Governance (CIBDEG), which has been active in China's chemical regulatory reform.

Meanwhile, businesses should continue to closely review the draft chemical regulations that are likely forthcoming over the next few years as China continues to develop its chemical regulatory regime.

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