

China Publishes Draft Regulation on the Environmental Risk Assessment and Control of Chemical Substances – The Real “China REACH”?

On 8 January 2019, the Ministry of Ecology and Environment (MEE), formerly the Ministry of Environmental Protection (MEP) of the People’s Republic of China (PRC”) published the draft new *Regulation on the Environmental Risk Assessment and Control of Chemical Substances (Consultative Draft)* (the draft “New Regulation”) for public comments until 20 February 2019 (http://www.mee.gov.cn/xxgk2018/xxgk/xxgk06/201901/t20190111_689258.html).

The draft New Regulation intends to govern the environmental risk assessment and control of any chemical substance. It is the very first piece of chemical control legislation proposed by the MEE which covers both existing and new chemical substances, after more than a decade during the course of which the chemical control within the ambit of the MEE focused on the new substances. In addition, the draft New Regulation reveals the key changes which might be brought into the PRC new substances management regime. Any company that is manufacturing, processing and using, importing and exporting chemicals in and from the PRC will be affected by the draft New Regulation, and should therefore closely monitor the development of this legislation and take the necessary actions as early as possible.

Background

Currently, a single chemical may be regulated by various pieces of PRC legislation and government authorities in China, depending on its legal status as a new chemical, existing chemical, or hazardous chemical, etc..

On the new chemicals regulation front, the MEE has promulgated the famous *Measures for the Environmental Management of New Chemical*

Substances (the “MEP Order No.7”), which is currently under revision. This legislation introduced into China requirements similar to the European Union’s Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation for registering new chemical substances. However, it could hardly be considered as the equivalence of the EU REACH, due to the various differences between these two pieces of legislation, including the scope of application (i.e., the EU REACH covers both existing and new chemical substances).

Since 2016, the MEE has also been paving the way for the regulation of existing chemical substances by, among others, drafting the technical guidelines for screening chemicals subject to prioritized assessment and issuing a *Catalogue of Chemicals subject to Prioritized Control (1st Batch)*. This demonstrates that the MEE does not intend to regulate all types of existing substances but would rather focus on the “prioritized” existing substances.

Furthermore, we have also learned at various occasions that the MEE has been drafting a new piece of legislation to cover both existing and new substances. Now, this mysterious legislation is revealed and the draft New Regulation is expected to become the overarching legislation governing both existing and new chemical substances, but with a focus on the control of “environmental risk” (as defined below). Since the New Regulation should be promulgated by the State Council pursuant to the *Legislative Law of the PRC*, its legal effect will be superior to the relevant departmental rules promulgated by the relevant ministries (including the revised MEP Order No.7) which will then serve as the implementation rules of the New Regulation. This also reflects the MEE’s intention to escalate the importance of the regulation of chemicals in the PRC.

Key features

1) SCOPE OF APPLICATION

The draft New Regulation applies to the “environmental risk assessment” and “environmental risk control” of “chemical substances”. It follows that this legislation governs both existing and new substances.

The new substances are the chemical substances that are not included in the Inventory of Chemical Substances of China (the “ICSC”). The term “ICSC”, newly introduced by the draft New Regulation, will be created and updated from time to time by the MEE; and, according to the draft New Regulation, would probably be based on the current Inventory of Existing Chemical Substances of China (the “IECSC”). However, it remains unclear as to whether the ICSC would include all the existing substances that have already been included in the IECSC.

The term “environmental risk” is defined to mean “the degree and probability that a chemical substance with environmental or health hazard properties will enter into the environment and cause harmful effects on the ecological environment and human health”.

2) EXEMPTIONS

The draft New Regulation does not apply to substances that are “used for laboratory scale research or as reference standards, except for the new chemical substances that are manufactured or imported in quantities at or above 100 kg/year”. This follows that a new substance is not subject to this draft legislation, only if it is “used for laboratory scale research or as reference standards” and is manufactured or imported in quantities below 100 kg/year. However, the draft New Regulation does not provide any specification on the phrase “used for laboratory scale research or as reference standards”. This might be specified in the implementation rules or official guidelines issued by the MEE.

3) ENVIRONMENTAL RISK ASSESSMENT AND CONTROL OF CHEMICAL SUBSTANCES

The provisions on environmental risk assessment and control constitute the highlight of the draft New Regulation. These provisions would apply to any “chemical substance” which do not distinguish between existing substances and new substances.

In a nutshell, the draft New Regulation requires the

MEE to organise the environmental risk assessment of “chemical substances subject to prioritized assessment”, on the basis of the information acquired through the relevant reporting by the industry and the specified activities carried out by the MEE, including the “environmental risk screening”.

More specifically, in order to support such risk assessment, any company manufacturing, processing and using, and importing a chemical substance would need to submit to the MEE an annual report of the “basic information” of that substance (including the name, quantities, uses, etc.). As part of the “environmental risk screening”, the MEE would establish a “Plan for the Risk Assessment of Chemical Substances Subject to Prioritized Assessment”. Any company manufacturing, processing and using, and importing a substance that is included in this Plan would have to submit to the MEE the required information (including data on emissions, physico-chemical properties, toxicology, eco-toxicology, etc.).

Upon completion of the risk assessment, the MEE, together with other ministries, would promulgate the relevant risk control measures, which would result in the establishment of:

- a Catalogue of Chemical Substances Subject to Prioritized Control (the “Prioritized Control Catalogue” or “PCC”), which contains the substances that would, among others, be subject to the specific regulatory measures provided by the other PRC laws such as the *Prevention of Atmospheric Pollution Law*, the *Prevention of Water Pollution Law* and the *Prevention of Soil Pollution Law*;
- a Catalogue of Restricted Chemical Substances (the “Restriction Catalogue”), which contains the substances selected from the PCC that would be subject to restrictions on uses and relevant licensing for their import and export;
- a Catalogue of Prohibited Chemical Substances (the “Prohibition Catalogue”), which contains the substances selected from the PCC that would be strictly prohibited from being manufactured, processed and used, imported and exported in and from China;
- an “Information Publication Platform for Chemical Substances Subject to Prioritized Control”, on which the relevant companies would need to disclose the required information on an annual basis.

4) NEW SUBSTANCES

While the MEP Order No.7 is still under revision, the draft New Regulation reveals the following key changes that would probably be brought to the new substance management regime in China:

- New substances would be subject to either registration or filing. The current requirement of “simplified registration” provided by the MEP Order No.7 appears to be replaced by the filing process;
- Registration would apply to the new substances that are manufactured or imported at or above one ton/year;
- Filing would apply to the new substances below one ton/year (except for the new substances which are “used for laboratory scale research or as reference standards” and are below 100 kg/year) and the other specified substances (e.g. low-concern polymers);
- The application for the registration of PBTs and “the substances possessing the same hazards” would be rejected, and such substances would be included in the Prohibition Catalogue;
- The registration would be subject to a fee payable to the MEE.

Furthermore, the draft New Regulation maintains the current statutory timeframe for the inclusion of a registered new substance into the ICSC, which is five years after completion of the registration. In addition, the draft New Regulation empowers the MEE to provide in the ICSC the restrictive conditions on the uses of certain substances where necessary.

The real “China REACH”?

When the text of the draft New Regulation was revealed, some voices in China referred to this legislation as the real “China REACH”.

Indeed, we do see certain “REACH-like” elements in this draft New Regulation. Same as the EU REACH, the draft New Regulation governs both existing and new substances. In addition, the environmental risk assessment process appears to be similar to the substance evaluation under the EU REACH, as the MEE plays a dominant role and the industry would be required to submit additional data at the request of the MEE. Furthermore, the process for including a substance into the Restriction Catalogue appears to have certain similarities with the restriction process

under the EU REACH. For example, both processes are risk-based and are initiated by the authorities.

However, various features of the draft New Regulation have made it different from the EU REACH; for example:

- While the draft New Regulation covers only the environmental risk, the EU REACH covers all types of risks, including the risks caused by the physical and health hazards of a chemical substance.
- While the draft New Regulation requires the registration or filing of new substances only and irrespective of the tonnage, the EU REACH requires the registration of both existing and new substances at or above one ton/year.
- The draft New Regulation does not provide an authorisation process, although it introduces the process of including a substance into the Prohibition Catalogue. In other words, inclusion in such a Catalogue would mean a ban on its manufacturing, use, import and export in and from China; while, under the EU REACH, even if an Substance of Very High Concern is included in Annex XIV to REACH (and despite the “black list” effect of such listing), the industry may still apply for an authorisation so as to continue its use(s) in the EU.
- While the borderline between the processes of including a substance into the Restriction Catalogue or the Prohibition Catalogue appears to be clear under the draft New Regulation, there exists interplay between the restriction and authorisation processes under the EU REACH, which may result in the parallel implementation of these two processes for the same substance.

Therefore, we do not consider that the draft New Regulation is the “China REACH” as it stands today, although it possesses certain “REACH-like” elements. The differences between this legislation and the EU REACH, as well as its relationship with the other PRC laws as mentioned above, reflect the uniqueness of the PRC legal and administrative systems, which is always one of the most important aspects that the PRC legislators would take into consideration when drafting a new piece of legislation.

Impact on the industry and going forward

The draft New Regulation will affect any company that is manufacturing, processing and using, and importing and exporting chemicals in and from China. Importantly, the draft New Regulation has introduced relatively severe penalties for the acts violating this legislation. For example, a company failing to complete the required new substance registration may, among others, face an administrative fine of up to RMB 2,000,000 (approx. USD 295,000 or EUR 260,000) (versus a current fine of up to RMB 30,000, which is approx. USD 4,400 or EUR 3,880 under the MEP Order No.7), and, in a severe circumstance may be ordered to cease business. The affected companies are therefore encouraged to submit their comments before the deadline of the public consultation.

Given the current legislative priority of the PRC, as well as the need to align the interests of the different ministries affected by this legislation before the State Council could take the legislative action, we would not expect a rapid promulgation of this legislation. Along its legislative procedure leading to its promulgation, the draft New Regulation might be revised again and subject to additional consultations. The affected companies should therefore constantly monitor this and take the relevant actions proactively as early as possible; for example, by submitting comments already from now on, if they wish to propose any change or introduce additional provisions to the draft New Regulation.

Furthermore, it is vital to monitor proactively the enactment of the implementation rules of the draft New Regulation. While the draft New Regulation has introduced the general requirements, many detailed requirements would need to be specified by the relevant departmental rules and official guidelines to be promulgated by the MEE and the other relevant ministries. These would include, for example, the definition of the technical terms (such as “PBTs” and “substances possessing the same hazards”), the detailed procedure of the environmental risk assessment and control (especially as to whether the industry would be provided with the opportunities to defend their products), the protection of CBI, and the detailed requirements on the new substance management to be provided in the revised MEP Order No.7 and the associated official guidelines.

Finally, the affected companies are encouraged to assess the impact of the draft New Regulation on their products, supply chain organization, global compliance strategy, etc. from a legal and regulatory standpoint as early as possible, with the necessary internal or external legal and regulatory support.

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