Notification of new chemicals in China – Certainly not a “REACH-lite”

Last year, while many EU-companies were struggling to meet the first REACH deadline, China introduced a new chemical legislation. Mostly unnoticed by many chemical companies, these “New Measures for the Environmental Management of New Chemical Substances” (Order No.7 (2010) of Ministry of Environmental Protection) entered into force on 15 October, 2010. Referring to the name and the responsible competent authority, the focus seems to be on the potential environmental impact of chemicals. Indeed, this is reflected in some specific requirements.

Manufacturers and importers of new chemical substances are obliged to obtain a registration certificate prior to manufacture/import by notifying toxicological and other relevant data to the Chemical Registration Centre (CRC) of the Ministry of Environmental Protection (MEP). The new Measures significantly increase the burden on industry in terms of data generation and risk management obligations. Not by chance, the article 5 in the Measures says more or less the same as article 5 of the REACH regulation, namely “no data – no market.”

While it is a crucial element within REACH to cover both existing and new chemicals, the Measures are exclusively dedicated to New Chemicals. But this may lead to a perilous misconception, such as “we are not concerned because only new substances are subject to this legislation. All our substances are on EINECS thus we are not dealing with new substances.” In China, all chemical substances not listed in Inventory of Existing Chemical Substances in China (IECSC) are defined as new chemical substances. Of course, the IECSC is not equivalent to EINECS. There are about 103,000 substances on EINECS, and even 146,000 substances have been pre-registered as phase-in substances under REACH. However, only about 45,000 substances are listed on the IECSC. Thus, this discrepancy leaves room for several thousand misconceptions. While most commodities are likely to be listed on IECSC, many other substances may be identified as new substances. This is of particular interest to companies that export innovative chemical substances, or preparations containing such substances, to China or that manufacture them there.

It is not surprising that the new legislation has been dubbed “China REACH” since it takes over many elements of REACH – particularly those concerning risk assessment, risk management and data submission. But there are also some important differences to REACH that must be considered.

For instance, we are all aware of the transition phases...
for phase-in substances under REACH (2010, 2013, and 2018). Only non-phase-in substances have to be registered before starting manufacture or import. A possible misconception due to the naming as “China REACH” may be that companies are by mistake relying on long transition phases also in China. But for the Chinese Measures, you cannot make use of a transition phase but have to submit new substances notification to MEP-CRC before these substances are placed on the market.

Moreover, unlike REACH, a notification (albeit just a “simplified” one) will still need to be made in the case of amounts below 1 t/a. There are also differences in the data requirements. Equal to REACH the data requirements increase with higher tonnage bands. But in toxicology as well as in ecotoxicology the Measures are even more demanding than REACH. In some cases you need specific data already at lower tonnages (e.g., the 28 day test for subchronic toxicity in the first tonnage band, 1-10 t/a).

While under REACH for several endpoints only testing proposals have to be submitted, under the Measures you are obliged to provide the data within your notification dossier. Furthermore, ecotoxicological data has to be generated in Chinese labs using Chinese test species (e.g., Danio rerio for fish test). Thus, if you have a REACH data package, check thoroughly whether it fulfills the criteria defined for the Measures.

Because notifications can only be filed by Chinese-registered legal entities, foreign exporters with no affiliates in China are entitled to appoint a “local agent” in China for these purposes (like an Only Representative under REACH).

The enforcement in China has already started and there are strict penalties imposed for non-compliance. The first companies have already been punished by a fine. Compared to REACH, the level of fines is low (1,000 – 3,000€). But much more deterrent, a company that has a record of being sanctioned for non-compliance is not permitted to make a notification of a new chemical substance for a period of three years. This means, the practical costs of non-compliance can be an inability to produce, import or use a particular product, leading to cancellation of contracts and finally this can kick a company out of the market!

Thus, the Measures are obviously not a “REACH-lite.” Don’t take it too easy.

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We are pleased to announce the launch of a “member logo” that can be included on Gold subscriber company websites and promotional materials.

This initiative was created in response to REACHReady Gold subscribers who asked how to demonstrate to their customers and suppliers that they are on the road to REACH and CLP compliance with the assistance of the REACHReady Helpdesk.

As you know, it’s important that all manufacturers, importers and downstream users of chemicals are prepared and fully aware of the impact that the REACH and CLP legislation has on their business, so why not reward these efforts by identifying these subscribers as proactive, and with our support, informed?

The logo will be provided in .jpg format on request along with terms and conditions for use.

We encourage you to take advantage of this exciting new Gold subscriber benefit today!

Please e-mail enquiries@reachready.co.uk to request a .jpg of the logo, or, if you have any questions about the logo and its use, e-mail or call the Helpdesk on +44 (0)20 7901 1444.