What is happening with chemical regulation outside of the European Union?

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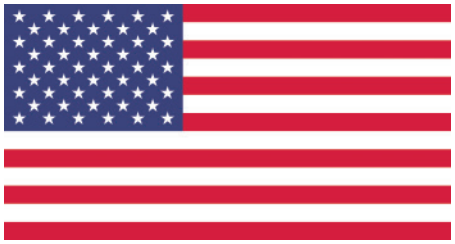
Since the European Union's (EU) Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) legislation came into force in 2008, many companies have understandably focused on EU-centric chemical registration obligations. What about commercial markets outside of the EU? Chemical regulations vary, often significantly. Companies need to navigate global regulatory requirements nimbly and make cost-effective business decisions to market chemical products globally.

We present below a snapshot of key similarities and differences in three regulatory schemes. This analysis emphasizes the need for a strategic approach in placing and managing new and existing substances in the global market.

United States Toxic Substances Control Act (TSCA)



TSCA is a comprehensive chemical management program that includes new (requiring pre-manufacture notice (PMN)) and existing chemicals (requiring no pre-market approval). TSCA does not mandate a prescriptive set of data requirements. Data are not required to be generated prior to initial submission, but data in the possession of the manufacturer must be submitted to the U.S. Environmental Protection Agency (EPA). Existing chemical substances may be subject to various types of assessments to determine hazard profile and safe use, but by and large are not regulated beyond reporting obligations such as the Chemical Data Reporting (CDR) Rule.

EPA has initiated several programmes intended to identify chemical substances that may present greater exposure risks, and thus warrant more immediate review. EPA's Work Plan Chemicals program, as well as its review and approach to nanoscale chemical substances are examples.

It is well recognized that the almost 40-year old TSCA is badly in need of reform. Legislation is pending to achieve that goal. The most recent version of TSCA Reform legislation was passed by the U.S. House of Representatives on June 23, 2015. The U.S. Senate is likely to consider TSCA reform legislation in September, or later this year. Whether legislation will be enacted is unclear.

The People's Republic of China's Ministry of Environmental Protection (MEP) Environmental Management of New Chemical Substances in China (Decree No. 7) and Regulation on Safe Management of Chemicals in China (Decree No. 591)

Chemical regulation in China is addressed under Decree No. 7 and Decree No. 591. The Decrees and guidance documents are published in Chinese with no "official" English translation. With significant variations between written and verbal Chinese, it is important to understand the intent behind published documentation. The Decrees are broad on principle and short on details with additional information located in the guidance documents. Notification must be conducted in Chinese, by a Chinese entity (Chinese Agents are allowed similar to a REACH "Only Representative"). Data requirements are based on volume thresholds, and some studies must be conducted in a Chinese laboratory. Factors influencing costs and timing relate to data collection and generation. The more complex the substance and/or approach to an endpoint, the longer the review period by the Expert Review Committee.

China does not have an existing chemicals notification/assessment programme, but manages hazardous substances under Decree No. 591. This is the foundation on which other regulations are built as part of China's Chemical Management Programme.

South Korea's Act on the Registration and Evaluation, etc. of Chemical Substance (K-REACH) and the

Chemical Control Act (CCA)

K-REACH and the CCA came into force on January 1, 2015. Korea's implementation of its chemical management program is different from EU REACH. CCA activities focus principally on the control of hazardous substances. A separate notification to the Ministry of Employment and Labor (MoEL), as part of the Occupational Safety and Health Act (OSHA), is required for new substances exceeding 100 kg. The official regulation is only available in Korean, with translations available via third parties. While guidance documents are being drafted in Korean, it is not certain that official English versions will be provided. Guidance documents are viewed as instrumental to understand the nuances of the law and

manage expectations. Guidance is often unclear, and companies must seek clarity from the Korean Chemicals Management Association (KCMA) and MoEL.

Notifications are submitted in Korean. As in the EU and China, a South Korean entity can serve as an Only Representative for non-resident participants. Notification is required prior to exceeding the next volume threshold. Although new substance notification activities have been in place since January 1, 2015, the framework to support existing substance notifications is not yet available. Priority existing substances have been nominated.

Conclusion

Placing a new chemical or managing an existing chemical product in the global market involves strategic thinking. A company looking outside its local jurisdiction and expanding its chemical portfolio into a new market needs to work with experts to guide the process. A thorough understanding of each country's chemical regulations/notification schemes is essential to ensuring successful placement in the market, protecting the product formulation from disclosure, and growing the business' bottom line to ensure commercial sustainability.

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More information on global notification management can be found on The Acta Group's (Acta®) website here: http://www.actagroup.com/practices/global-chemical-notification-programs.

Points to remember:

- Elements are similar, but the devil is in the details
- Identify potential markets early
- Check language constraints and find reliable translation services
- Generally, the higher the volume, the greater the data requirements
- Pool data/testing requirements to reduce global burden
- Consider appointing competent representatives to manage regulatory burdens and leverage scarce internal resources