

Keeping up with Global Regulatory Changes – Asia Perspective

Overview of new chemical registration
requirements in the Region's key
markets

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Overview

Through the promulgation of “household name” legislation such as REACH, CLP, and BPR over the past decade, chemical regulation has become highly developed in markets such as the European Union (EU) and is expanding rapidly to new markets in the rest of the world. Multinational companies must be updated with changing regulatory requirements in order to sustain a healthy new product pipeline. Among the multitude of today’s chemical management requirements, new chemical registration is one of the most time- and resource consuming obligations when it comes to product stewardship. Registering new chemicals must be done effectively, with appropriate attention to confidential business information (CBI) and, often, on a relatively short timetable in order to bring compliant products to new markets and deliver a return on investment for business.

Within Asia, only Japan, China, Korea, and Taiwan have established a national existing chemical inventory and defined requirements for new chemical registration (see Figure 1). Thailand is now collecting hazardous chemical information within the country and will establish a similar national inventory, although schedule details and actual requirements for new chemical registration have yet to be outlined. In addition, Vietnam has disclosed a draft national inventory, upon which new chemical registration requirements will be based after official publication. ERM is monitoring these developments and others that are emerging in markets around the world.

In this paper, we provide an overview of key chemical registration requirements in North Asia and emerging developments in Southeast Asia, followed by insights into successful registration strategies particularly relevant to companies making products that are formulations or mixtures.

Figure 1: Geographical Expansion of New Chemical Registration in Asia



Chemical Control in Japan

The earliest of the chemical control regulations in Asia Pacific (APAC) was introduced in Japan through its Chemical Substances Control Law (CSCL) in 1973, establishing the requirement for new chemical registration in advance of both manufacture and importation. Similarly, the Industrial Safety and Health Law (ISHL) enacted in 1972, which regulates chemicals used in the workplace, also requires new chemicals to be registered.

Although some parts of the existing chemical inventory are shared by these two laws, each law requires observation of its own inventory.

CSCL has two volume exemptions for new chemical registration: the Small Volume Exemption (SVE) of 1 ton per year (t/y) and the Low Volume Exemption

(LVE) of 10 t/y. An SVE does not require any physical/toxicity data, and an LVE requires less test data than general notification. The volume ceiling of 1 t/y per applicant for the SVE is shared among all the manufactures and importers. Minor amendments regarding calculation bases and methodology for SVEs as defined by the CSCL are expected to be issued shortly.

The ISHL also allows for SVE for new chemical registration, with an annual threshold of 100 kilograms per year. If the volume of manufacture/importation exceeds this threshold, test data for mutagenicity or carcinogenicity is required for registration.



REACH-like Regulations in Asia

For many years, Japan was the only major market in Asia with strong regulations in place for controlling chemicals; however, a new wave of regulations was introduced in North Asia from 2000s onwards. Many of these newly issued regulations have been branded as being “REACH-like”. However, it is important to understand how these local requirements differ from the original EU REACH regulation, which demands registration of all chemicals exceeding 1 t/y, regardless of being qualified as new or existing substance. Examples of these regulations are described below for China and Korea.

China REACH or Order No. 7

The Measures on Environmental Administration on New Chemical Substances (2010 Revised) (MEP Order No.7) issued on 19 January 2010 and effective on 15 October 2010 represented a step-change in regulatory requirements in China. The Order No.7 regulation stipulates that manufacturers and importers must register new chemical substances and obtain the New Chemicals Substances Registration Certificate before manufacturing or importing new chemical substances. New chemical substances refers to the chemicals not already listed in the Inventory of Existing Chemicals Substances in China (IECSC), which has a public/published version and a confidential version (hence it is not enough to only check the public version to judge if the chemical is actually new).

New chemical registration in China comprises three types of notification based on the manufactured amount and purpose: scientific research

documentation notification, simplified notification (special type and basic type), and general notification. Careful attention to the tonnage and use of a new chemical, the substance identity, and the very specific testing requirements are crucial to bringing new products to market in a timely manner in China.

K-REACH or AREC

Korea enacted the Act on the Registration and Evaluation of Chemicals (AREC or K-REACH) on 01 January 2015. K-REACH is designed to protect public health and the environment by providing information on chemical substances and products containing chemical substances. Requirements under the K-REACH regulation include:

- Registration of new chemicals (without tonnage threshold) and priority existing chemicals (PECs) as listed by the Ministry of Environment (MoE), which are manufactured or imported as raw material with more than 1 tpa (PECs only);
- Notification of products containing over 0.1% of hazard chemical substances that are produced or imported with more than 1 t/y for consumer uses;
- Report of chemical information including chemical name, CAS No., chemical use, chemical volume, for new substances (no tonnage threshold) as well as existing substances (PECs and non-PECs) that are manufactured, imported, or sold as raw material with more than 1 tpa by 30 June every year; and
- Supply chain communication between manufacturers/importers and downstream users on chemical information including use, exposure, quantity used and/or sold, and instructions for safe use.

New chemicals are defined under K-REACH as those not listed in the Korea Existing Chemicals Inventory (KECI) or on the first PEC list of 510 substances as announced by the MoE in July 2015. A consortium is required for each chemical in the PEC list. K-REACH offers a multitude of exemptions from registration and reporting obligations, which need to be reviewed very carefully. In addition, new chemicals should also be registered under the Korean Occupational Health and Safety Act (KOSHA), requiring a different registration scope and effort. Coordination of these various requirements and strategic attention to data sharing are the key to remaining in compliance to support business objectives.

A significant update of K-REACH was proposed by MoE at the end of 2016 and provided for public comment until early February 2017. This update is expected to expand the scope of chemical substances subject to registration to all existing chemicals manufactured or imported in volumes greater than 1 metric ton per year. The registration process will follow a similar scheme to that applied under EU REACH where a tiered grace period is provided depending on yearly volumes manufactured/imported with pre-registration as a prerequisite. The update is subject to confirmation, which is anticipated to be provided by the end of 2017.

Chemical Registration in Taiwan

Not all Asia chemical control regulation is modelled

on REACH. In particular, Taiwan introduced its new chemical registration system in 2015. Similar to Japan, two separate laws govern the new chemical registration process. These laws are the Toxic Chemical Substance Control Act (TCSCA) and the Occupational Safety and Health Act (OSHA). The two laws require that a manufacturer or importer of new chemical substances must register those substances before beginning to manufacture or import them. Manufacturing or importing (i.e., market authorization) new chemical substances will only be allowed when the registration is approved by the Environmental Protection Administration (Taiwan EPA) and the Ministry Of Labour. New chemical substances are defined as chemical substances not listed in the Taiwan Chemical Substance Inventory (TCSI).

There are three types of registrations for new chemical substances in Taiwan, depending on the uses and quantity: small-quantity registration, simplified registration, and standard registration.

Currently, the Taiwan EPA acts as the single registration window to avoid the duplication of registration requirements based on TCSCA and OSHA laws. Additionally, only a local legal entity can act as importer or manufacturer to conduct chemical registration. For overseas manufacturers who wish to export chemical substances into Taiwan and register new substances, domestic importers or third-party representatives (like ERM Taiwan) must be identified to conduct the chemical registration.

Asia Expansion

In addition to above mentioned requirements, several more countries in Asia are preparing or planning to introduce requirements for new chemical registration and general chemical management. Consider the following developments in Southeast Asia focussing on Thailand, Vietnam, and Indonesia.

Thailand

The main chemical regulation in Thailand is the Hazardous Substances Control Act (HSCA), which was first enacted 25 years ago in 1992. On 19 February 2015, the Notification on the List of Hazardous Substances (No. 2) B.E. 2558 (2015) was announced. This new notification lists 10 specific hazard properties, and stipulates that chemicals with these properties and exceeding a 1 tpa threshold for manufacturing and import must be notified. Any chemicals that were notified by the end of 2016 were included in the national chemical inventory. It is understood that notified hazardous chemicals and chemicals already listed under HSCA will be included in the national chemical inventory. Detailed requirement on the process and methodology for new chemical substances in Thailand are still to be determined and will be watched with interest by ERM and our clients.

Vietnam

In Vietnam, the Chemical Law (06/2007/QH12) is the main law governing chemical management, manufacturing, and import of chemicals in the country and has been in place since 2007. A new regulation, known as Article 44, establishes a set of registration requirements for new chemical substances; however, Article 44 has not been implemented as yet due to lack of an existing

chemical inventory. In late 2016, a draft existing chemical inventory was published and interested parties were invited to provide comments. At this stage, it is not clear when the existing chemical inventory will be finalized and the Article 44 chemical registration implemented. Companies manufacturing or importing chemicals into Vietnam are awaiting the next steps for Article 44.

Indonesia

The main chemical management regulation No. 74/2001, also called B3 (Bahan Berbahaya dan Beracun) is currently under revision in Indonesia. This revision to existing regulation may require chemicals newly introduced to the market to be reported to the regulators. At this stage, it is not clear what the revised regulation will require.

Keys to Success in APAC Chemical Registration

In addition to the insights on registration of complex products detailed in this paper, ERM has found that whether registering a single chemical or chemicals in a mixture, some of the common themes of successful chemical registration in the Asia Pacific region include:

- Following a coherent strategy for managing OBI
- Using an established, in-country legal entity with appropriate business license, when required
- Clear substance identity
- Careful attention to country-specific testing requirements
- Realistic sales projections to support registration at the right tonnage
- Careful attention to evolving requirements, as well as, requirements to coordinate between different laws and ministries within a single country
- Providing updated regulatory news to suppliers

Prepare for Success with Complex Products

Preparation for the variety of requirements of new chemical registration can pose a particular challenge for mixtures, mainly due to communication with suppliers of the component ingredients that make up the mixtures. In cases where 100% of the ingredient information is obtained from the supplier, compliance with registration requirements and proceedings can be relatively simple. Unfortunately, this is often not the standard. Additionally, certain ingredients are subject to confidential business information (CBI) and will not be disclosed by the supplier.

In some cases, ERM clients have had to change the supply chain or even cease business due to lack of information from the suppliers of the ingredients for mixtures. On occasions, ERM has served as a third-party representative, allowing the supplier to deposit confidential information directly to ERM;

enabling ERM to prepare the registration without disclosing the confidential information to the client. This solution addresses the CBI restrictions and can lead to a successful chemical registration.

Even after the supplier provides an appropriate response, experience shows that confirmation that all the ingredients are listed in the inventory takes considerable time. For example, the Japanese CSCL inventory lists some polymers with a general description, which can require time to assess proper interpretation to decide whether it is a “new chemical”. In such instances, consultation with the relevant authorities may be required. The greatest challenge is to avoid a supplier identifying a new chemical in their product and/or refusing to provide the necessary CBI at the 11th hour in a registration process or right before the enactment of a new registration requirement.



Conclusion

Compliance with new and emerging chemical registration and management regulations is essential to doing business in APAC and requires companies to stay current with regulatory updates and communicate with suppliers in the early stages. For affected industries within Asia, being well prepared for these new requirements can help avoid a lengthy registration process that delays the return on investment in creating a new product or opening up a new market. Not all of the challenges of registration can be avoided entirely; however, proactive communication with suppliers and the use of other tools such as third-party representatives provide solutions to achieve successful registration. Proactive product stewardship can support business success.

How to Learn More

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About ERM

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