International Chemical Control Laws: Outside the United States and European Union

A great deal has been written about the European Union (EU) REACH initiative, controlling the placement of chemicals on the EU market as well as US TSCA and Canadian CEPA requirements. What is going on in other parts of the world? Do other countries have chemical control laws? Are they similar to REACH? The answers are ‘definitely YES’ and ‘yes, to a degree’. While there are similarities between chemical control laws, one will not find the consistency of GHS. Exemptions (such as for foods or medicinals, or polymers) exist, but vary. Some on the higher profile countries:

AUSTRALIA

The Australian Inventory of Chemical Substances (AICS), containing over 38,000 chemicals identifies existing chemicals under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). It consists of non-confidential and confidential sections. Chemicals on AICS can be imported or manufactured in Australia without first being notified to NICNAS as new chemicals, although some may require secondary notification: these are flagged. Any chemical not included in AICS is regarded as a new and must be notified and assessed before being manufactured or imported into Australia. New chemicals will be notified in one of several categories based on substance characteristics. All importers and/or manufacturers of industrial chemicals for commercial purposes must register with NICNAS regardless of the amount of industrial chemicals imported and/or manufactured in that registration year.

CHINA

There are approximately 45,000 substances on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). For chemicals not listed companies must submit new chemical substance notifications to the Chemical Registration Centre (CRC), irrespective of annual tonnage. The notification applies to new substance as such, in preparation or in articles, and also to new substances used as ingredients or intermediates for pharmaceuticals, pesticides, veterinary drugs, cosmetics, food additives and feed additives. Foreign companies selling into China must engage a local representative. In January, 2010, the Ministry of Environmental Protection (MEP) of China released the revised version of the Measures on Environmental Administration of New Chemical Substances, replacing the 2003 version and coming into force in October, 2010. Similar to EU REACH this is also known as "China REACH".

There are multiple types of notifications in the Chinese scheme:

• Typical, in four tonnage bands, with data requirements similar to EU REACH
• Simplified for new chemicals < 1 tpa
• Simplified w/specific conditions; export only, certain research applications
• Scientific Research: < 0.1 tpa
Polymers listed on the IECSC are exempted, however polymers not listed on IECSC must be regarded as a new chemical, even if all monomers are listed on IECSC.

INDIA
Currently 15 acts and 19 rules govern chemicals as directed by six Ministries. Regulations have been framed for:
• Import and Export
• Transportation of chemicals
• Consumer use of chemicals
• Protection of human health and environment
India’s Ministry of Chemical and Fertilizers has proposed a national policy that would create a REACH-like law to govern use of chemicals under a single agency. This would consolidate the various acts and rules governing the sector.

JAPAN
The Chemical Substances Control Law (CSCL) covers general industrial chemical products, including both new and existing chemicals.
The following categories are regulated:
• New Chemicals;
• General Chemicals;
• Priority Assessment Chemicals (~1,000 substances);
• Monitoring Chemicals (~36 substances);
• Class II Specified Chemicals (23 substances);
• Class I Specified Chemicals (16 substances)
Existing chemical substances and notified substances are given MITI numbers. There is no standard existing chemical inventory. A combined list of existing and notified chemical substances is referred to as the Japanese Existing and New Chemical Substances (ENCS).

The CSCL was amended effective April 2011 with similarities to REACH. However, the mechanism of the risk evaluation is different: the government gradually evaluates the risk and requests appropriate management by manufacturers and importers according to the risk in CSCL. The new system covers all industrial chemicals.

Three government bodies responsible for the implementation of CSCL are the Ministry of Economy, Trade and Industry (METI), Labor and Welfare (MHLW), and the Ministry of the Environment (MOE). Manufacturers and importers must submit new chemical notification to these authorities to obtain approval prior to the manufacture or import. Foreign manufacturers may also submit new chemical notifications.
Manufacturers and importers of the chemical substances below are required to report their quantities, shipment and usage category annually between 1 April and 30 June:

- General Chemicals
- Priority Assessment Chemical Substances (PACs)
- Monitoring Chemical Substances
- Class II Specified Chemical Substances

General industrial chemical products might also be subject to the requirements of the Industrial Safety and Health Law (ISHL) and other acts. Polymers are regulated under CSCL and ISHL with annual usage reporting. New polymers, not listed on ENCS are to be notified with certain exceptions.

**KOREA**
The Toxic Chemicals Control Act (TCCA) was implemented by the Ministry of Environment (MOE) and last revised in 2008. The National Institute of Environmental Research (NIER) is responsible for new chemical notification.

Existing chemicals are categorized as toxic, observational, and restricted or banned with various requirements. New chemicals, above 0.1 ton per year, are to be evaluated and notified before manufacture and/or import. Existing polymers are not regulated by TCCA if they are not toxic. They are exempt from new chemical notification if they meet certain criteria.

Korea will implement a new chemicals control regulation, the Act on the Registration and Evaluation of Chemicals, known as Korea REACH; expected in 2013. Korea REACH requires manufacturers and importers of chemicals to notify substances to the MOE, which will then designate certain existing chemicals as “chemicals subject to assessment” for registration.

Under Korea REACH, existing substances (including polymers) designated as “chemicals subject to assessment” will be given a transitional period up to 8 years to register if they are pre-registered. Foreign exporters can submit pre-registration or registration through the appointment of only representatives. New chemical substances are to be registered prior to the manufacture or importation in tonnage bands of >100t/y and <100t/y.

**PHILIPPINES**
The Department of Environment and Natural Resources (DENR), through its Environmental Management Bureau (EMB) regulates chemicals via the “Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990”. This requires compiling and maintaining an inventory of all chemicals and chemical substances in use throughout the country. The Philippine Inventory of Chemicals and Chemical Substances (PICCS) contains approximately 24,000 chemicals and chemical substances nominated in
1993 by manufacturers, importers, distributors and users. It is updated every five years. Sites subject to updating must maintain an Annual Chemical Inventory.

Substances already included in the PICCS require no clearance from the DENR, provided they are not listed in the Philippine Priority Chemicals List (PCL), and are not subject to Chemical Control Order (CCO). Chemicals and chemical substances not included in the PICCS cannot be manufactured, imported, distributed, or used unless they have undergone the Pre-Manufacture and Pre-Importation Notification (PMPIN) process.

SWITZERLAND

Switzerland moved toward Reach implementation with the partial revision of the Swiss Chemicals Ordinance (ChemO) on February 1, 2009. It adopts Reach-like registration requirements for new substances placed on the Swiss market in quantities over 1 tpa.

TAIWAN

Existing Chemical Substance Nomination (ECN) and New Chemical Notification (NCN) programs in Taiwan are being implemented by the Council of Labour Affairs (CLA) assisted by the Safety and Health Technology Center (SAHTECH). A nomination process, completed in 2010, has been re-opened from June 1 to August 31, 2012. The Inventory of Existing Chemical Substance (IECS) will then be finalized. Substances not nominated or otherwise exempted, will be subject to New Chemical Notification procedures. Offshore manufactures must appoint a Taiwan Agent for their ECN nominations.

New Chemical Substances (NCS) are defined as those not listed on the IECS. Manufacturers or importers should file a prior notification with CLA together with a risk assessment report to obtain specific permission unless the substance is categorically excluded from the obligation.

There are three types of new substance notifications:
Informing: 10 – 100 kg/a
Simplified: substances / polymers at 0.1 – 1 tpa or listed on at least two other inventories.
Full: substances or polymers > 1 tpa and new substances between 0.1 – 1 tpa classified as CMR or aquatic chronic toxic Class 1.

TURKEY

All substances produced or imported into Turkey as such or in preparations over 1 tpa, with certain exceptions, are required to be registered. The current law updates 1983 and 2003 laws and came into effect in 2011. Two tonnage bands define the required data to be
submitted: 1-1000 tpa and > 1000 tpa. There are similarities to the EU REACH regulation. There is no data sharing, but group submission is allowed.

This discussion considers some of the many countries with Chemical Control Laws. Other countries with official lists of approved chemicals or defined processes which should be considered prior to placing products onto those markets include Argentina, Hong Kong, Israel, Indonesia, Malaysia, Serbia and Thailand. One can see it is necessary to study the specific requirements of each country and inquire as to the requirements of local chemical control laws prior to movement to a new geography.

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