

# Recent Developments in Global Regulatory Framework in the Chemical Industry

Stephen Van Heerden

With the European Union's next deadline for REACH registration due in 2013, various chemical manufacturers are scrambling to ensure that compliance measures are taken. Meanwhile, other countries have recently introduced REACH like chemical regulations, making it necessary for chemical manufacturers exporting globally to now comply with not only REACH but also various other regulations around the world. Most of the guidance and regulatory documents are difficult to understand due to language issues, and impede planning of necessary compliance measures. This article gives a brief overview of the recent REACH-type chemical regulations adopted and implemented in China, Turkey, Japan, and Korea.

## EU REACH

Since its inception, the European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) regulation has taken centre stage for companies exporting products to Europe. As per statistics from European Chemical Agency (ECHA), the first registration deadline (30 Nov 2010) for exported substances > 1000 tpa (tonnage per annum) resulted in submission of 25,000+ registrations for approximately 4,300 substances to agency. Registrations with intermediate use comprised approximately 25% and of the total registrations, 19% were submitted by "only representatives". Majority of the registrations (94%+) for the 2010 deadline were done as joint submission, where a company takes the role of lead registrant and submits all data required as per tonnage band with the rest of the companies becoming member registrants who submit the dossiers referring to this data by paying data cost (Letter of access, LoA) except company specific information. Besides the registration, companies submitted more than two million CLP notifications to the agency.

With the successful completion of two deadlines, the present focus of companies is to meet the registration deadline due next year for tonnage band 100-1000 tpa. ECHA has released tentative timelines (Figure 1) for 2013 registrations which show that the lead registrant has to submit the dossier at least three months before the deadline. User information

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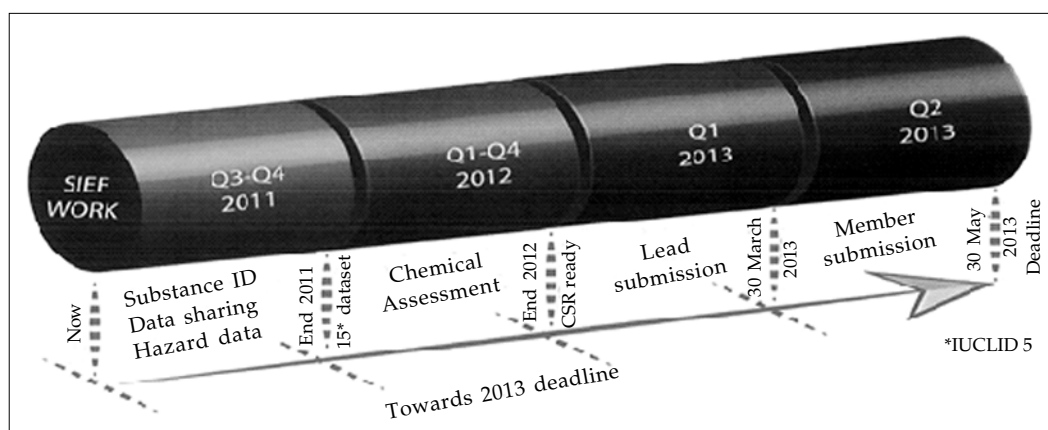


Fig 1: Timelines released by ECHA.

is an important part of the dossier and companies should inform their downstream users and collect uses before 30 May, 2012.

## Global Chemical Regulations

The REACH regulation has played an inspirational catalytic role in the drafting and implementation of chemical regulations across the globe. Countries such as China, Turkey, Japan, and Taiwan have recently adopted regulations on a similar pattern and in some countries such as South Korea, Malaysia, USA, and India the regulations are in draft stages. Chemical regulations of few countries are discussed below.

stances not listed on the Inventory of Existing Chemical Substances in China (IECSC). The inventory has 45,602 substances of which 3,166 substances have been claimed confidential and 8,175 substances are without CAS number. Figure 2 briefly describes the notification process if a substance is not listed in IECSC.

China also has implemented Regulations on Safe Management of Hazardous Chemicals ("China GHS", 2011) which require companies to update the Safety Data Sheets (SDS). The regulation is in force since December, 2011. In past few months, a Chinese authority in Shanghai has seized shipments of > 1.55 million tonnes of hazardous chemicals worth \$45 million, which were not in compliance with China's regulatory requirements such as faulty labels.

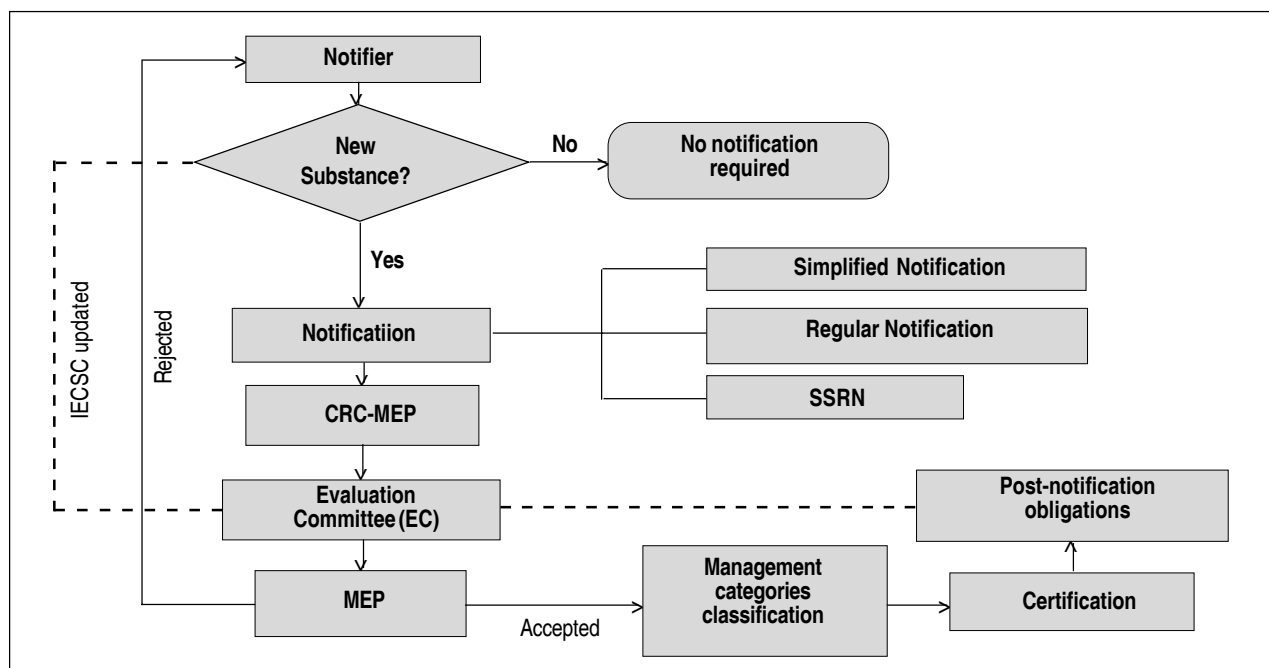


Fig 2: Notification process for China REACH

## Global Regulations

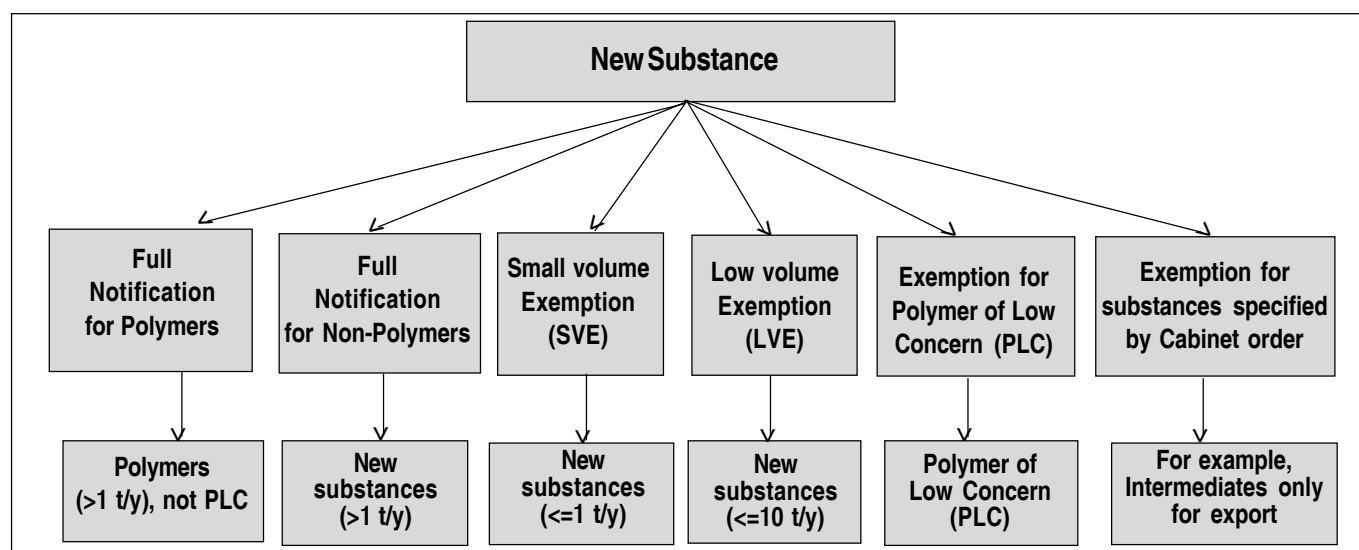


Fig 3: Type of registration depending on the nature of the substance and tonnage in Japan

Table 1: REACH Comparison Part 1: EU, Korea, China, Japan & Turkey					
Details	EU REACH	K-REACH	China REACH	Japan CSCL	T-REACH
<b>In force since</b>	1 June 2007	Draft, expected to enter into force on 1st January 2013	15 October 2010	Fully implemented since 30th June 2011	Fully implemented since 31 March 2011
<b>Main actors</b>	EEA manufacturers, OR, importers and downstream users	Korean manufacturers and importers	Chinese manufacturers and importers	Japanese manufacturers and importers	Turkish manufacturers and importers
<b>OR/representative system</b>	Yes (REACH Article 8)	Yes	Yes (agent / representative)	No but confidential information can be submitted directly to METI by foreign manufacturer	Yes (Article 10.3)
<b>Substances covered</b>	All substances manufactured in or imported into EEA $\geq 1$ t/yr, certain exemptions (esp. REACH Article 2)	Existing and New chemicals	Only new chemicals substances (not in IECSC)	Existing and New chemicals	Existing and New chemicals
<b>System of existing and new chemicals</b>	REACH covers existing and new substances	Yes	Yes, but only new chemicals not listed in IECSC	Yes	Yes
<b>Requirements for Existing chemicals if applicable</b>	Pre-registration for existing ("phase-in") substances to benefit from staggered registration deadlines	- If CSA pre-registration followed by registration - if non-CSA – annual report	None	Notification of volumes, shipment details and use categories	Notification by 31 March 2011
<b>Requirements for new chemicals if applicable</b>	To be registered before they can be manufactured in EEA or imported into EEA	Registration	Notification prior to import	Notification prior to import	Notification after 15 months from first placement on the market

Table 2: REACH Comparison Part 2: EU, Korea, China, Japan &amp; Turkey

Details	EU REACH	K-REACH	China REACH	Japan CSCL	T-REACH
<b>Existing inventories (lists) + website link</b>	<a href="http://echa.europa.eu/web/guest/information-on-chemicals">http://echa.europa.eu/web/guest/information-on-chemicals</a> , <a href="http://esis.jrc.ec.europa.eu/">http://esis.jrc.ec.europa.eu/</a>	KECI <a href="http://ncis.nier.go.kr">http://ncis.nier.go.kr</a>	IECSC (46 603 substances) <a href="http://www.crc-mep.org.cn/iecscweb/IECSC.aspx?La=1">http://www.crc-mep.org.cn/iecscweb/IECSC.aspx?La=1</a>	ENCSh <a href="http://www.safe.nite.go.jp/english/db.html">http://www.safe.nite.go.jp/english/db.html</a>	Kimyasal Envanter (2887 substances) Excel available on request
<b>Polymer status</b>	Register monomers	Register new polymers if not specifically exempted	Register new polymers	Notify new polymers. Polymers of Low Concern are exempt from notification	Notify monomers. Polymers as such exempted.
<b>Main authorities</b>	ECHA, EU Commission, enforcement by EEA Member State authorities	NIER (new substances), MoE-KCMA (existing substances)	MEP-CRC	METI	MOEU
<b>Administrative fees</b>	1) ECHA Fee Regulation 2) Data costs (LoA, consortium) - substance specific 3) compliance management (in-house or consultant)	No fee information available yet for K-REACH	Search fee is applied for searches of the confidential part of IECSC	Notification is free of administrative charge	Notification is free of administrative charge
<b>Other specific requirements</b>	Evaluation of registered dossiers and substances, Authorisation for Substances of Very High Concern (SVHC), Restrictions, downstream / article user obligations	Evaluation, Authorisation and Restriction processes similar to EU REACH	Use of government approved Chinese labs for ecotoxicological testing	New chemical substances will be added to the list of notified substances (CSCL) after 5 years New chemical should be also notified in ISHL.	Information about Turkish importers to be provided to MOEU database
<b>Post-notification requirements</b>	Continuous update of registration dossier and SDS; compliance with authorisation, restrictions, downstream / article user obligations	Annual updates of volumes produced and imported	Annual activity reports and updates of registration information	Annual updates of volumes for last fiscal year (1st April – 31 March), shipment and usage	Every 3 years updates of volumes produced and imported
<b>Deadline</b>	Depending on the process, e.g. registration of pre-registered existing substances by 30.11.2010, 31.5.2013 or 31.5.2018 (depending on tonnage and hazard)	Deadlines not yet finalised for K-REACH	15 October 2010	30 June 2011	31 March 2011

## Japan

Chemical Substances Control Law (CSCL) is in force since 1973 and was amended in 2009. It requires manufacturers and importers to submit the notification to the concerned agency. The law applies to both new as well

as existing substances (already manufactured/imported at the time of the promulgation of the CSCL). Chemical Inventory is named Japanese Existing and New Chemical Substances Inventory (ENCs) which has approximately 20,600 existing substances. The type of registration depending on the nature of the substance and

## Global Regulations

Table 3: GHS Comparison: EU, Korea, China, Japan & Turkey					
Details	EU GHS (CLP)	Korea GHS	China GHS	Japan GHS	Turkey GHS
<b>Implemented</b>	Start 20 January 2009 Complete 1 June 2017	1 July 2011	1 December 2011 (Decree No. 591)	1 December 2006	Not yet implemented. Existing system harmonised with DSD and DPD from 26 <sup>th</sup> Dec 2009.
<b>Main authorities</b>	ECHA, EU Commission, enforcement by EEA Member State authorities	MoE, MoL and NEMA	SAWS-NRCC, local SAWS authorities	MHLW	MOEU
<b>Harmonised C&amp;L list available at</b>	CLP Annex VI Table 3.1, in: <a href="http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory">http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory</a>	<a href="http://ncis.nier.go.kr/ghs">http://ncis.nier.go.kr/ghs</a>	2012 Catalogue to be released soon by SAWS	Searchable compilation of the lists is available at: <a href="http://www.safe.nite.go.jp/english/db.html">http://www.safe.nite.go.jp/english/db.html</a>	Not available online
<b>C&amp;L Mandatory?</b>	Yes: classified substances / mixtures; certain non-classified mixtures	Yes, for TCCA, ISHA classified substances / mixtures	Yes: classified substances / mixtures; certain non-classified mixtures	Yes, for ISHL classified substances / mixtures	Yes: classified substances / mixtures; certain non-classified mixtures
<b>Category of substances where SDS is required</b>	Substances and mixtures, if classified or meeting other criteria in REACH Article 31(1) or (3)	Substances and mixtures, if classified under the above regulations	Substances and mixtures, if classified in the 2012 Catalogue	640 substances	Dangerous substances and mixtures under the current classification and labelling regulation
<b>Who is responsible for SDS preparation?</b>	EEA supplier of substance or mixture	Manufacturer or importer (in practice prepared by manufacturer)	Chinese importer, but needs information from manufacturer	Manufacturer or importer (in practice prepared by manufacturer)	Manufacturer or importer (in practice prepared by manufacturer)
<b>Who is responsible for SDS communication?</b>	EEA supplier of substance or mixture	Korean supplier of substance or mixture	Chinese supplier of substance or mixture	Japanese supplier of substance or mixture	Turkish supplier of substance or mixture
<b>Other specific requirements</b>	C&L notification to ECHA for substances hazardous or subject to REACH before registration	SDS required in addition to TCCA for ISHA and HMA substances	Registering the hazardous chemicals at SAWS-NRCC	SDSs required for further 400 substances under PRTR regulation	Entry of SDSs in MOEU database; SDS must be prepared / certified by a licensed specialist
<b>Other important information</b>	CLP is updated regularly through "Adaptations to Technical Progress" (ATP), incl. new harmonized C&L in CLP Annex VI Table 3.1	Korean SDS standard updated in line with GHS at the start of 2012, local contact to be named and receipt of SDS to be acknowledged	Chinese standards: Classification GB 13690-2009, labelling GB 15258-2009 and SDS GB/T 16483-2008	Japanese standards: Classification (JISZ7252), SDS (JISZ7250) and labelling (JISZ7251)	Turkey GHS (harmonised with EU CLP) is due to be published in the first half of 2012
<b>Deadline</b>	1.12.2010 for substances 1.6.2015 for mixtures - 2 years extension, if already in the supply chain Notification within 1 month after supply in EEA	1 July 2011 (substances), 1 July 2013 (mixtures)	1 December 2011	1 December 2006	26 <sup>th</sup> December 2009



tonnage is shown in Figure 3.

## Turkey

The chemical regulation is Inventory and Control of Chemicals nicknamed Turkey "REACH" and is in force since March 2011. The law requires manufacturers and importers to submit the notification to authority in Turkish for > 1000 tpa and 1-1000 tpa band. The Ministry of Environment and Urbanization governs the law. There is also a requirement for SDS in Turkish language to be prepared by person certified by Turkish authority.

## Korea

Korea has Toxic Chemicals Control Act (TCCA) in force and Korea "REACH" in draft stages. Ministry of Environment is the authority responsible for the law. The proposed modification involves (pre-) registration of new and existing chemicals. A non-Korean manufacturer can appoint an only representative in the same way as in EU REACH.

## Summary

Many companies are running short of time to meet the REACH deadline of May, 2013 as well as are short of resources to comply with the upcoming REACH-like regulations across the world. Due to language issues, most of the guidance and regulatory documents are difficult to understand and impede planning of necessary compliance measures. Our recommendations to the industry players who are exporting globally is that they must start checking their regulatory compliance status for China, Turkey, Japan, Taiwan without delay as these countries have adopted and implemented REACH-type regulations and for most of them the deadline has already passed. In addition to inventory listing/notification/registration requirements it is equally important to keep your (M)SDS in line with the regulatory compliance for each country. Just preparing a 16 point SDS does not mean fulfillment of SDS requirements, as each country has altered the format while implementing UN GHS or EU 453/2010. So there is no master SDS which can be used for all countries and your present SDS may require significant improvement. Please refer the tables for REACH and GHS comparison analysis including website listing for references.



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