

Asia regulatory updates:

GHS and REACH development

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Guest Speaker



Sookie Hong:

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- Ms. Hong is responsible for researching, analyzing, and monitoring overall chemical and other EH&S related governmental legislations and regulations of the Asia Pacific region. She is also tasked with delivering the most accurate and timely regulatory content to support 3E WebInsight and other products and solutions, as well as with providing customer support for any Asia Pacific-related content and product inquiries.
- Prior to joining 3E Company, Ms. Hong worked with an international trade compliance company as a Regional Trade Manager, overseeing global trade and governmental regulations of 20 Asia Pacific countries for 10 years.
- Ms. Hong earned her Bachelor of Arts in South Korea and Japan, and her Master of Arts in International Affairs with concentration of Asia political economy from American University in Washington DC.
- Ms. Hong is fluent in English, Korean, Japanese, and Chinese.

Topics



GHS updates and...

- China new chemical substance notification
- Japan CSCCL amendment
- Korea “K-REACH” draft
- Taiwan existing chemical substance inventory and new chemical substance notification
- Malaysia EHSNR



- Chemical Safety Data Sheets (CSDS) and Precautionary Labels are required by
 - Regulations for safe Handling of Chemicals in the Workplace (Decree No 423 of Ministry of Labor of Dec 20, 1996, and effective 1997, Jan.1)
 - Chemical Safety Data Sheets (CSDS) are also required by
 - Registration of Hazardous Chemicals, Management Regulation on the Registration of Hazardous Chemicals (Decree No. 35 of SETC, State Economic and Trade Commission)
 - Regulations on the Control over Safety of Dangerous Chemicals (Decree No. 591 of the State Council of the People's Republic of China) published on March 2, 2011 and entering in force on December 1, 2011
 - The Decree No 591 gives legal force to the two standards GB 13690-2009 Classification and Hazard Communication of Chemicals and 15258-2009 Precautionary Label for Chemicals.
- Between May 1, 2011 and December 1, 2011 – GHS compliance based on two GHS standards required but without penalty

China/GHS (cont'd)



Classification:

- ***26 GB (GB 20576- GB 20602)**
 - Effective from Jan 2008 (1 year of transitional period from the effective date)
 - These standards translate the UN Purple Book's (1st version) 26 hazard categories.
- ***GB 13690-2009 (Classification and Hazard Communication of Chemicals).**
 - Effective from May 1, 2010 and provides the guidance for classification.
 - Based on the 2nd revision of the UN Purple Book
 - The 2009 version does not include a list of GHS classifications (1992 version did)
- GB/T 24774-2009 (Classification and hazard pictograms for chemicals - General specification)
 - Published Dec 15, 2009 & Effective from July 1, 2010

SDSs:

- GB /T 16483-2008 (Safety data sheet for chemical products content and order of sections)
 - Issued: June 6, 2008; Implemented: Feb. 1, 2009
 - Appendix A: "Guidance of SDS Preparation"

Labels:

- GB/T 22234-2008 (Labeling of chemicals based on GHS)
 - Effective from Feb. 1, 2009 and Equivalent to the Japanese JIS Z 7251:2006
- ***GB 15258-2009 (Precautionary Label for Chemicals)**
 - Published Dec 2009 & Effective from May 1, 2010 (1 year of transitional period from the effective date)

* : Compulsory



- SDSs are required by three laws in Japan:
 - the Industrial Safety and Health Law (ISHL by MHLW),
 - the Pollutant Release and Transfer Registry and Promotion of Chemical Management Law (PRTR Law by METI and MOE),
 - the Poisonous and Deleterious Substances Control Law (PDSCCL by MHLW)
- Labels are required by
 - the Industrial Safety and Health Law (ISHL by MHLW),
 - the Chemical Substance and Control Law (CSCL by MHLW, METI and MOE),
 - the Poisonous and Deleterious Substances Control Law (PDSCCL by MHLW)
 - the Fire Services Law (Dangerous Goods)
- Only the ISHL implements GHS as the classification system but GHS classification is accepted under the other laws.

Japan/GHS (cont'd)



- Japan Industrial Standard (JIS) Z 7250:2010 – Material Safety Data Sheets
 - JIS Z 7250:2005 Until December 31, 2015 (2000 version could be used till end of 2010)
- Japan Industrial Standard (JIS) Z 7251:2006 – Labeling of Chemicals based on GHS
 - MLHW Notice No. 619: Z 7251 is mandatory from Dec. 1, 2006
- Japan Industrial Standard (JIS) Z 7252:2009 – Classification
 - Provides classification for Health Hazards and Environmental Hazards
 - Excludes the following categories:
 - Acute hazards category 5
 - Skin irritation category 3 (Mild Irritant)
 - Aspiration hazards category 2
- Japan Chemical Industrial Association (JCIA) - GHS Guideline for MSDS and labeling (2nd edition – Oct. 2008) based on JIS Z 7250 and Z 7251 – Reference only



Ministry of Labor (MOL) (new name: Ministry of Employment and Labor):

- Industrial Safety and Health Law
- Pure substances: July 1, 2010; Mixtures: July 1, 2013
- MOL Notice No. 2009-68 published October 2009 provided new format of MSDS and new category adoption.

Ministry of Environment (MOE):

- Toxic Chemical Control Law
- Classification and labeling of new chemicals under the revised TCCL is mandatory since July 1, 2008.
- Existing chemicals : Single toxic chemical (July 1, 2011); Mixtures (July 1, 2013)

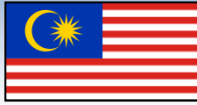
Ministry of Public Administration and Security (MoPAS):

- NEMA (National Emergency Management Agency) Notice No. 2008-18 on November 13, 2008
- Fully adopt GHS classification and labeling requirements for the explosives and dangerous goods under the Dangerous Substances Safety Management Act (DSSMA)
- Effective from the date of notice publication (November 13, 2008)

- Lists of GHS classifications:
 - MOE classification – **mandatory from July 1, 2011** ; so far approx. 535 substances (with major update of additional 318 chemical substances published in April 15, 2011)
 - KOSHA – advisory; approx. 6,500 subs
 - NEMA – advisory; approx. 1,000 subs (DG)
- GHS categories not adopted by MOL (MOEL) and MOE
 - Flammable liquid category 4
 - Acute hazards category 5
 - Skin irritation category 3 (Mild Irritant)
 - Acute aquatic toxicity category 2 and 3



- Regulation of Labeling and Hazard Communication of Dangerous and Harmful Substances (effective on December 31, 2008) (“CLA Regulation”)
- Management Measures on Toxic Substances Labeling and Material Safety Data Sheet (EPA No. 0960095329) (Effective Date: December 31, 2008) (“EPA Regulation”)
- MSDSs and labels are required for (Phase I and II implementation)
 - Phase I: 1,062 substances specified by the CLA (Council of Labor Affairs) and for products containing these substances. Transition period expired on December 31, 2009.
 - Phase II: 1,089 substances. The grace period for Phase II will end on December 31, 2011.



- Department of Health and Safety (DOHS)
 - Draft regulation for the implementation of GHS to workplace chemicals: Occupational Safety and Health (Classification, Labeling and Safety Data Sheet for Hazardous Chemicals) Regulation 20xx [“CLASS”] (not finalized & published yet)
 - To replace 1997 Regulations on Classification, Packaging, Labeling and Safety Data Sheets for Chemicals
- Standard on Globally Harmonised System (GHS) for Classification and Labelling of Chemicals has been issued (MS 1804:2008)
- Compliance to the standard is still on a voluntary basis
- Implementation is expected?

GHS classification list



- Japan NITE
 - advisory (widely used by industry); 1,980 subs classified
- Korea
 - MOE classification – **mandatory**; so far approx. 538 subs up to May 17, 2011 (MOE No. 2011-12)
 - KOSHA – advisory; approx. 6,500 subs
 - NEMA – advisory; approx. 1,000 subs (DG)
- Taiwan CLA – advisory; approx. 4,000 subs
- China – next year?

China new chemical notification



- Order of the Ministry of Environmental Protection (No. 7)
 - Effective from October 15, 2010
- Guidance for New Chemical Substance Notification and Registration (MEP Notice No. 2010-124, November 15, 2010)
 - From September 30, 2010, application for registration under Order No. 17 (the “old” procedure from 2003) will NOT be accepted. Industry who sent an application before then but could not complete registration due to the failure of document completion and data errors can be processed under Order No. 17 until April 15, 2011. Those who can not meet April 15, 2011 should be processed under Order No. 7
 - 三、自2010年9月30日起，不再接收17号令要求下的正常申报和免于申报手续申请。此前受理的新化学物质申报，由于资料不合格、数据不完整等原因导致2010年10月15日前不能取得登记的，
补正资料时间可延至2011年4月15日，按17号令的程序办理；
2011年4月15日后仍不能取得登记的，按7号令和相关文件要求办理。

China NCS Order No. 7



- **Scope** – extended to raw materials and intermediates of Pesticides, medicine, veterinary drug, cosmetics, food additives, feeds
- **Registrant** - Only registered manufacturer, importer, or representative in domestic China (similar to EU “OR” policy)
- **General Notification**
 - 1 ton =< quantity < 10 tons
 - 10 tons =< quantity < 100 tons
 - 100 ton =< quantity < 1,000 tons
 - 1,000 tons =< quantity

Still, no low volume exemption from testing data requirement.
- **Simplified Notification**
 - Annual volume of manufacture or import below 1 ton
 - Requires only eco-toxicology testing data

Burdening to industry:

 - 1) China’s eco-toxicology requires lots of testing items and data
 - 2) Some eco-toxicology testing such as bioaccumulation, fish acute toxicity, or biodegradability are required to perform in China
 - Intermediates, Export-only <1 ton or Scientific research purpose <0.1 and >1 ton
 - monomer below 2% in polymer or low concern polymer, technical dev below 10 ton in 2 yrs
- **Scientific Research Notification** - below 0.1 ton

Japan CSCL



- **Japan CSCL (“Chemical Substance Control Law” – “*Kashin ho*”)**
2009 amendment

New structure under 2009 CSCL amendment from April 1, 2011

1) Restricted Chemicals

- Class I and II Specified chemicals
- Monitoring Chemicals (from former “Type I Monitoring”)
- PAC (Priority Assessment Chemicals – some are from Type II and III Monitoring which are repealed by PAC)

2) General Chemicals – Existing chemicals in Inventory and are not subject to Restricted Chemical group. Some former Type II and III Monitoring substances not selected as PAC will be a part of this category.

3) New Chemicals – Chemicals not falling under listed above

Japan CSCL (cont'd)



- Mandatory annual reporting of **all chemicals (new and existing)** that are manufactured and imported over 1 ton in the previous year (Phase II implementation effective from April 1, 2011)
 - Exemption: R&D purpose, low risk (i.e. water and carbon dioxide)
 - Notification period: April 1 – June 30 every year
 - Reporting Exemption List – published on March 23, 2011, update every year
 - The substances on the Priority Assessment Chemical Substances (PACS) (88 substances in first version) requires more detailed information (Notice No. 7 published April 1, 2011)
 - General chemicals – Report Form 11, around 50 use categories
 - PAC – Report Form 12, around 280 use categories
- http://www.meti.go.jp/policy/chemical_management/english/cscl.html

Post-reporting



Evaluation

- First step) Screening “General Chemicals”
Second step) Risk Assessment on “PAC” (I and II rounds) → designates Class II Specified substances

Authorization/Restriction

- Class I and II Specified Chemicals, Monitoring (from existing chemicals in inventory)

Korea AREC – “K-REACH” (1)



Korea AREC (“Act on Registration and Evaluation of Chemicals” – “*Hwa Pyung Bup*”) Feb 2011 draft

- **Supplementing the current TCCL, it aims to better control on existing chemicals**
 - **TCCL: covers already-tested/proven hazardous chemicals**
 - **AREC: handles semi-tested or not proven but suspected hazardous chemicals from existing, PEC, etc.**
- **New chemical notification under TCCL will be repealed, and hazard evaluation integrated to AREC**
- **Public consultation until April 26, 2011**
- **Implementation effective 2 years after promulgation**

Definitions of “Existing chemical”

- **A Chemical distributed for commercial purposes domestically before February 2, 1991 and announced by the MOE on December 23, 1996.**
 - **A Chemical for which the hazard evaluation has been completed under the Toxic Chemicals Control Law after February 2, 1991 and was published by the MOE**
- **Basically it is listed in KECI (Korea Existing Chemical Inventory)**

Korea AREC (2)



- Annual reporting requirement for **all chemicals (including new and existing)** manufactured or imported
 - No tonnage exemption
 - Exemption not specified yet
 - Notification information: quantity, hazard testing data, etc
- PEC (Priority Evaluation Chemicals)
 - Among reporting existing chemicals, the government designates PEC list for chemicals with pose potential risks to human and environment

Korea-unique requirement (1)



- Identification of chemicals

- Same requirement to the current TCCL

Industry must submit identification to the MOE whether substance or an ingredient is listed in:

- ❖ TCCL – new chemicals, toxic, **observational**, restricted or banned chemicals

- ❖ AREC - new chemicals, **existing chemicals**, **PEC**, **permitted chemicals**, restricted or banned chemicals, as well as **accident-prone chemicals**

- Very important. If not complied, heavy penalty imposed. The MOE even conducts site inspection.

Korea-unique requirement (2)



- Confirmation in prior to Registration
Any person who intends to manufacture or import a chemical substance that falls under any of the following items must request confirmation from the MOE whether such chemical substance has been registered prior to submission of data
 - New chemicals
 - Existing chemical substances indicated by their generic names
 - PEC that have not been pre-registered

Pre-registration



- Only PEC listed chemicals
- minimum tonnage: > 0.5 ton
- Proposed pre-registration period: Jan 1, 2014 – June 30, 2014 (6 months)
- within 6 months since PEC published, but for the first time manufacture and import of the PEC, within 6 months since the day of manufactured and imported (still need to be at least 12 months before expiration of the grace period)
- MOE posts pre-registered chemical names within 3 months after the closing of pre-registration
- Registration grace period granted if pre-registered (maximum 8 years)
- During the grace period, manufacture or import is allowed without registration

Registration



- Only PEC list and new chemicals
- Required documents:
 - Intended use of chemical substances
 - Data regarding physical-chemical properties of the chemical substances
 - Data regarding toxicity of chemical substances
 - Data regarding classification and labeling of the chemical substances
 - Data regarding risk of chemical substances (Limited to the chemical substances imported or manufactured in the annual amount of 100 tons or more)
 - Other information stipulated by the Enforcement Rule
 - “Test Plan” in lieu of certain Registration Data.

Evaluation, Authorization, Restriction



Evaluation

First step) Hazard evaluation on reported chemicals within 30 days → MOE posts chemical name, hazard, toxic chemical or not.

Second step) Risk assessment on PEC → designates permitted, restricted, or banned chemicals

Authorization/Restriction

- Banned, Restricted, Permitted Chemical lists, etc (CMR, etc)

I,e) SVHC → permitted chemicals

Taiwan ECS and NCS



- Direction for Existing Chemical Substance Nomination (11/02/2009)
 - All Existing Chemical Substances (ECS) that was imported into, manufactured, processed, used or sold within Taiwan between January 1st 1993 and December 31, 2010 have been nominated
 - Deadline for ECS nomination was Dec 31, 2010
 - By December 31st, 2010, more than 200,000 dossiers were accepted representing 57,000+ chemical substances
- Draft regulation “New Chemical Substance Notification” has been published by the Council of Labor Affairs (CLA)
 - New chemical substances (NCS) are defined as substances that are not listed on the existing chemical substance list (to be published June/July 2011).

<http://csnn.cla.gov.tw/content/englishHome.aspx>

Taiwan NCS Notification (1)



- Three types of notifications:
 - 1) **Notice**: 10-100 kg per year
 - 2) **Simplified**: 0.1 to 1 ton per year, excluding carcinogen, reproductive mutagenicity, reproductive toxicity, aquatic hazards based on GHS classification
 - 3) **Complete**: if a substance listed in at least TWO Inventories of six jurisdictions (US, EU, Japan, PRC, Canada, and Australia), expedited review and registration process may be granted.
- **However, full data and approved documents are still required.**

Taiwan NCS Notification (2)



- **Foreign entity is allowed to notify without local agency in Taiwan**
- **Notification Review timetable**

Type	Details	Review Period
Notice	10 to 100 kg per year	10 days
Simplified Notification	0.1 to 1 ton per year	30 days
	Others eligible for S.N (i.e. high molecular)	
Complete Notification	At least two foreign inventories	30 days
	Others than above	90 days

Malaysia EHSNR



- Draft regulation on the Environmentally Hazardous Substances Notification and Registration (EHSNR) under the Environment Quality Act 1974, Department of Environment
- New Notification and Registration Scheme regulation
- Establishes a chemical inventory listing of all hazardous chemical substances imported into and manufactured in Malaysia
 - Basic Notification (on EHS Reference List)
 - Detailed Notification (NOT on EHS References List; GHS - hazardous)
- The notification scheme has been introduced as a voluntary scheme starting 2010
 - Is expected to become mandatory in 2011
 - Notification is done on-line
- Allows for companies outside Malaysia to register on behalf of the Malaysian importer

https://www.e-ehs.doe.gov.my/homepage/ehs_procedure/

Conclusion – important timetable



April 1, 2011	Japan CSCL phase II implementation (PAC list, mandatory reporting) starts
April 15, 2011	China new chemical notification to follow Order. No. 7
May 1, 2011	China two GHS standards effective date
June 30, 2011	Japan CSCL mandatory annual reporting deadline
July 1, 2011	Mandatory Korea MOE GHS classification starts
June/July 2011	Taiwan existing chemical inventory publication
Dec 1, 2011	China Decree No 591 implementation starts (GHS compliance mandatory)
Jan 1, 2012	Mandatory Taiwan Phrase II GHS implementation starts

Acronyms (1)



- GHS – Globally Harmonized System of Classification and Labeling of Chemicals
- (M)SDS – (Material) Safety Data Sheet
- ISHL – Industrial Safety and Health Law (Japan, Korea)
- MHLW – Ministry of Health, Labor, and Welfare (Japan)
- METI – Ministry of Economy, Trade and Industry (Japan)
- MOE – Ministry of Environment (Japan, Korea)
- NIER – National Institute of Environmental Research (under Korea MOE)
- MOEL – Ministry of Employment and Labor (Korea – former MOL)
- KOSHA – Korea Occupational Safety and Health Association (under Korea MOL)
- MoPAS – Ministry of Public Administration and Security (Korea)

Acronyms (2)



- NEMA – National Emergency Management Agency (under Korea MoPAS)
- NITE – National Institute of Technology and Evaluation (Japan)
- CLA – Council of Labor Affairs (Taiwan)
- EPA – Environmental Protection Administration (Taiwan)
- REACH - Regulation on **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals
- GB – Guo Biao (National Standard – China)
- MEP – Ministry of Environmental Protection (China – former SEPA)
- Japan CSCL – Chemical Substance Control Law (*Kashin-ho*)
- Korea AREC – Act on Registration and Evaluation of Chemicals (*Hwa Pyung Bup*)
- Korea TCCL – Toxic Chemical Control Law (under MOE)
- EHNSR - Environmentally Hazardous Substances Notification and Registration (Malaysia)

Thank you!

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