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**TUESDAY REFRESHMENTS**



# ILMA Annual Meeting 2016

October 15-18, 2016

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## **New Developments in the Global REACH Landscape: Asia-Pacific and Beyond**

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# The Americas

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# USA



## Toxic Substances Control Act (TSCA) Post-Lautenberg

- Alternative nomenclature rules remain the same.
- 90-day EPA review period required for each PMN. EPA extension is very limited.
- Full exemptions (no EPA application) are still available for qualifying polymers, R&D activities and Export Only
- No minimum data or testing mandate
- Confidentiality of information requires more justification, and must be re-asserted in 10 years.
- Inventory Reset – Does not impact status as Existing Chemical
- Four EPA options for Section 5 Notice Applications (PMN, Low Volume, Low Exposure – Low Release, and Test Market exemptions):
  1. Approval;
  2. Information insufficient, but restricted use approved under a 5(e) order;
  3. May present an unreasonable risk, but approve restricted use under a 5(e) order;
  4. Presents an unreasonable risk, and issue a 5(f) order to address such risk(s).
- Limited time to extend review period = more limited approval

# East and Southeast Asia

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# South Korea



## Existing Substances

- Toxic Chemicals Control Act Registered Chemicals - any chemical substance listed on the Korea Existing Chemical inventory (KECI), or approved and published by MoE under TCCA registration process prior to 1/1/2015.
- K-REACH Re-registration – Priority Existing Chemicals List – List of chemicals published on June 30, 2015, and in 3-year intervals following that require registration under K-REACH within 3 years following publication. Joint registration is required with special exceptions subject to approval.
- Annual Report – **Due June 30, of each year** - K-REACH requires all Korean manufacturers, importers and sellers of Existing Chemicals in excess of 1 ton/year (some have lower or no threshold) to submit an annual report concerning their prior year's volumes. Korean language required. Required data includes CBI.
- K-REACH is a registration-based system not an inventory creation system. K-REACH registration does not add substances to the KECI. Inquiry concerning prior registration of a substance might reveal late joint registration and data sharing opportunity.

# South Korea



## New Substances

- Any chemical substance within scope and not exempt that is not an Existing Chemical Substance (Listed on KECI).
- All New Chemical Substances must be registered – **no minimum threshold**.
- All New Chemical Substances are subject to annual report, regardless of volume.
- Ministry of Labor registration also required, unless exempt. MoL Criteria can differ from MoE criteria.

## Only Representatives

- Dual Role – Represent: Korean Importers by law / non-Korean Exporter or Manufacturer by contract.
- Registrations must identify each covered Importer



# K-REACH Coverage and Responsibility

## OUT-OF-SCOPE

- Pharmaceutical & Quasi-Drug Products
- Cosmetic Products & Certain **Related Raw Materials** ← **CAUTION !!**
- Pesticides & Active Ingredients
- Fertilizers
- Food, Food Additives, and Device & Container Packaging
- Feeds
- Health Functional Foods
- Medical Devices
- Narcotics
- Radioactive Substances
- Gunpowder
- Military Supplies

## SUBSTANCES

### TO REPORT & REGISTER



Report – Manufacturer, Importer, Seller  
 Register – Manufacturer, Importer  
 (Foreign Entity via OR)

## EXEMPTIONS

### (Reporting & Registration)

#### Automatic

- Chemical Substances Imported in Machinery
- Chemical Substances Imported together with machines or equipment for trial operation
- Articles - Chemical Substances Contained in Product performing specific function in particular sold form, without release during use

#### Approval Required:

- Polymers of Low Concern
- Substances Imported or Manufactured entirely for export and ≤ 10 t/yr.
- Testing & Research Use
- R&D Use
- Surface treated Substances
- Non-Isolated (and some Isolated) intermediates used under strict controls

## South Korea (cont'd)



### Products Requiring Notification

- Consumer products containing hazardous substances above applicable thresholds.
- Any product designated as “Product of Concern”.
- Full disclosure of product content is required.
- Limited confidentiality may be requested, but not guaranteed.

# Taiwan



## Existing Substances

- All chemical substances included in the CSNN (Chemical Substance Nomination & Notification database maintained by the NCSR (National Chemical Substance Registry)
- Phase 1 Notification – Initial was **due March 31, 2016. Failure to report → lost market access.**

**After March 31, 2016,** Each first-time shipment of an existing substance requires pre-filing of a Phase 1 Registration. **This includes previous Phase 1 substances to a new importer.**

- | Category | Class 1                                                                                               | Class 2                                | Class 3                                               | Class 4                                 |
|----------|-------------------------------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------|-----------------------------------------|
| Hazard   | Danger to human health or environment due to bioaccumulation, bio concentration, or biotransformation | CMR or cause of other chronic diseases | Poses immediate danger to humans upon single exposure | Risk to human health or the environment |

## Taiwan (cont'd)



### **New Substances:**

- Any chemical substance not included in the CSNN
- Registration must occur 90 days prior to production or import
- 3 Types of registration: Standard, Simplified and Small Volume
- Non-Taiwan manufacturers may submit registration information through local Agent, but registration is specific to importer(s). (Very detailed and formal process)
- \*\* Taiwan OSHA now requires dual, concurrent registration \*\*

### **Exemptions from Registration**

- Naturally occurring substances
- Chemical substances accompanied in machines and equipment for test-run purposes
- Inseparable intermediates from the chemical reaction in the reaction vessel or in the production process
- Chemical substances for national defense purpose
- Chemical substances under customs supervision
- Wastes
- Incidental reaction products or impurities without intended commercial purpose
- Mixtures (not applicable to chemical substances in the mixture containing a new chemical substance)
- Certain Articles
- Certain Polymers

# CHINA



## Existing Substances

- Inventory of Existing Chemical Substances Manufactured in or Imported into China (IECSC).
- Currently ~ 45,000 chemical substances listed **\*\*Public and Confidential Portions\*\***.
- **[CAUTION]** Public Inventory searches by CAS RN have limited accuracy. Proper results might require search by chemical substance name (in Chinese) – Requires 2 business days.
- Confidential inventory search must be in Chinese and in writing – Requires 7 to 10 business days.
- Numerous subcategories within the IECSC with associated regulations restricting manufacture, import and use of each subcategory.
- **Complex matrix of interwoven regulations between Ministry of Environmental Protection (MEP) and State Administration for Work Safety (SAWS).**
- Territorial and Provincial and Economic Zone regulations can differ and sometimes contradict.

# CHINA (cont'd)



## New Substances

- MEP Order 7 - REACH - like registration of all chemical substances that are manufactured or imported at > 1 tonne, not listed on the IECSC, and are within scope and not exempt
- \*\*\* No Polymer Exemption \*\*\* but Simplified Notification (registration) is available with limited data and evaluation requirements for certain polymer
- Party responsible – manufacturer or importer (**export manufacturer may register through China agent (Redstone can provide)**)

# CHINA (cont'd)



## Additional Noteworthy Control Laws

- **SAWS Order 60** (1 September 2013) – Requires hazard assessment (physical chemical) of any product or chemical substance about which there are suspected hazards, or new or additional hazards, or for which no hazard information is known prior to manufacture, import or use. Hazard assessment must be confirmed by SAWS appointed lab.
- **SAWS Order 53** – Requires registration of any hazardous chemical product or substance.
- **MEP Order 22** – Requires additional registration for production, use, import, or export of any substance or product containing Hazardous Chemicals Severely Restricted from Import into or Export from China (a subcategory of the chemical inventory).
- **SAWS Order 57** – Manufacture, use or purchase (including import) of Hazardous Chemicals for Priority Management requires a safe use permit from SAWS.
- **Parties Responsible** – Manufacturer, user, importer (or exporter for Order 22), and foreign export manufacturer selling to China may register through use of China agent (Redstone can provide)



**Existing Substances**

- The Chemical Substance Control Law (CSCL) is the primary law covering general industrial chemicals
- The second law is the Industrial Safety and Health Law (ISHL)
- No comprehensive chemical inventory exists
- Three separate and distinct chemical inventories are maintained (in Japanese) by each of:
  - Ministry of Environment (MOE), primarily responsible for CSCL compliance
  - Ministry of Health, Labor and Welfare (MHLW), primarily responsible for ISHL compliance
  - Ministry of Economy and Trade (METI), functioning under separate authority
- An Existing Substance must be included on one of the three inventories (3<sup>rd</sup> party databases exist that are searchable in English, but they are not official or determinative for compliance)
- Ministry of International Trade and Industry (MITI) is an integrated enforcement agency that assigns import numbers to all approved chemical substances. This “MITI number” is required to appear on import documents as a condition of entry.
- MITI sometimes assigns a number to groups of chemical substances, making search for approved chemical substances more difficult. (Composite inventory databases maintained by 3<sup>rd</sup> parties often do not include the MITI number)



# Japan (cont'd)



## New Substances

- Any chemical substance (regardless of volume) not included on any of the three official inventories must be registered (New Substance Notification, or NSN)
  - \*\*\* No Polymer Exemption \*\*\* - however Polymers of Low Concern may receive a streamlined registration and approval process
  - New Substance Notifications must be submitted to each of MOE, MHLW and METI concurrently
  - \*\*\* Existing chemical substances under the CSCL are automatically deemed existing substances under the IHSL – but not the reverse \*\*\*
  - \*\*\* A New Chemical Substance that is exempt under the CSCL will require registration under the IHSL an exemption is not available \*\*\*
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## **Existing Substances (Already Notified Substances)**

- EHSNR (Environmentally Hazardous Substances Notification and Registration Scheme) created the EHS (Environmentally Hazardous Substance) Registry, comprised of previously notified substances
- Substances listed on the EHS Registry require annual Basic Notification (see below)

## **New Substances (Hazardous and other Identified Harmful Substances not Already Notified)**

- Any substance classifiable as hazardous pursuant to GHS classification standards, or otherwise designated by the Department of Environment as a substance of concern, is subject to Basic Notification (described above) or Detailed Notification
- Basic Notification – annual Notification that primarily includes substance identity, annual volume, and uses – required for prior notified substances
- Detailed Notification – one time notification for substances covered, but not EHS Registry listed, that requires full physical chemical properties, physical hazards, and human and environmental hazards (including aquatic hazards)

## **Exemptions**

- Polymers – but not monomers in scope and above concentration thresholds
- Mixtures – but not substance within a mixture
- Any substance not in scope (non-hazardous, or otherwise regulated in Malaysia)

## **Party Responsible for Compliance**

- Resident Manufacturer or Importer
- Foreign Manufacturer through resident agent (Redstone)

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# Philippines



## **Governing Agency & Law**

Department of Environmental and Natural Resources (DENR); Administrative Order 29

## **Existing Substances**

- Any chemical substance in PICCS (Philippine Inventory of Chemicals and Chemical Substances)
- Public Portion - searchable / Confidential Portion – DENR search on request – non-traditional)
- PICCS is updated semiannually from Pre-Manufacture Pre-Import Notifications (PMPINs)

## **New Substances**

- Registration Required – Any substance not included in PICCS requires PMPIN

## **Exemptions Applied to PMPIN Rule (DENR Pre-Approval Required)**

- Specific Polymers and Polymeric Reactants (Monomers all on PICCS)
- Non- Isolated Intermediates
- New chemical substance that is part of an article.

## **Party Responsible for Compliance**

- Resident Manufacturer or Importer
  - Foreign Manufacturer through resident agent (Redstone)
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# Singapore



## **Governing Agency & Law**

National Environmental Agency

**Existing Substances:** No national chemical inventory

**New Substances:** Not managed as such

**Current Focus:** Very Hazardous Substances (Analogous to EU Candidates List)

## **Party Responsible for Compliance**

- Resident Manufacturer or Importer
  - Foreign Manufacturer through resident agent (Redstone)
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## **Governing Agency & Law**

Department of industrial Works; B.E 2558 – Hazardous Substances Act (Issued & Effective 19 February 2015)  
**(REACH - like registration regulation is expected to be announced and effective in 2016.)**

**New: Inventory Nomination Window Open Until December 31, 2016. New Substance Notification process will be published in 2017.**

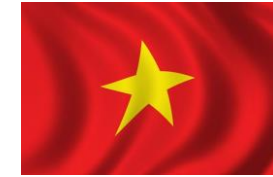
## **Notification Required: All substances listed on Annex 5.6 of the Thailand Substances List**

- Generic entry covering any industrial chemical meeting “hazardous substance” definition of the Hazardous Substances Act (BE 2558)
- Essentially all substances and mixtures meeting GHS classification criteria per GHS Version 3.
- Onetime notification – w/in 60 days of manufacture or import of >1t/yr.
- Information Required: Mostly same as required in SDS (some greater detail); 100% composition.

**Non-Hazardous Substances & Mixtures:** Require supplier statement as such.

## **Party Responsible for Compliance**

- Resident Manufacturer or Importer
  - Foreign Manufacturer through resident agent (Redstone)
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## **Governing Agency & Law**

Ministry of Industry and Trade

## **Horizon: Completion of National Inventory and New Substance Registration**

**Existing Substances:** Chemical Substance Inventory Still Formative

**New Substances:** Not managed as such

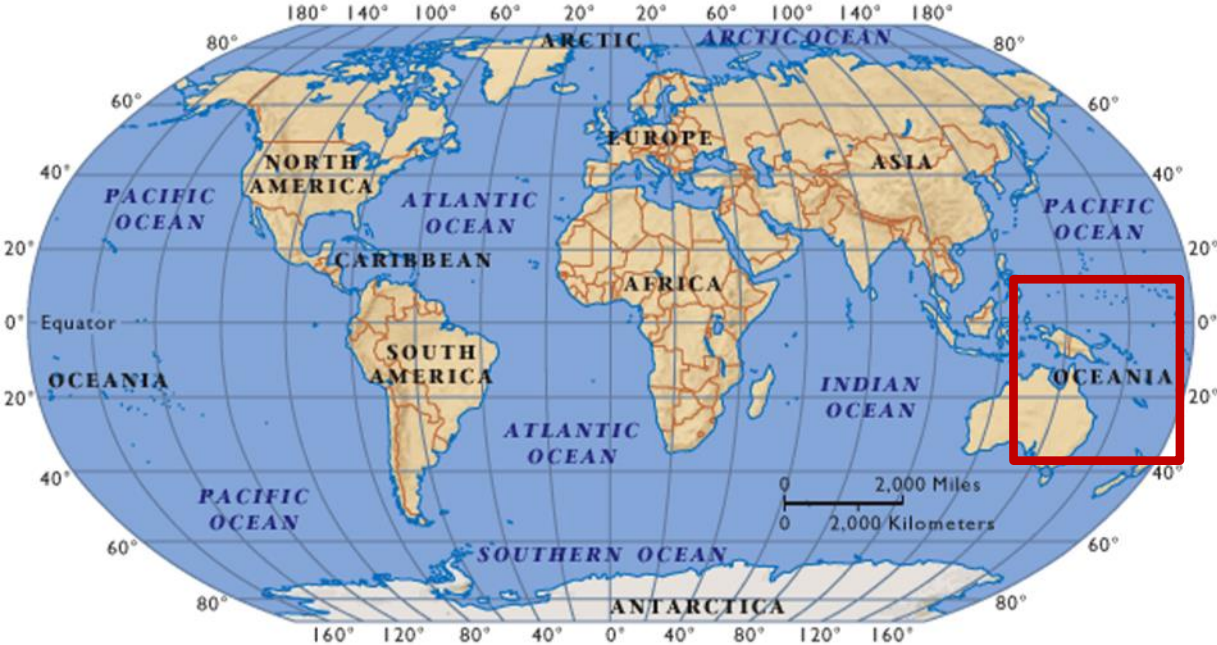
## **Regulatory Focus:** Specified List of 117 Hazardous Substances (Analogous to EU Candidates List)

- The list of chemicals subject to conditional production or import (1);
- The list of chemicals restricted from production or trade (2);
- The list of banned chemicals;
- The list of hazardous chemicals for which chemical incident prevention and response plans are required;
- The list of chemicals subject to compulsory declarations;

## **Party Responsible for Compliance**

- Resident Manufacturer or Importer
  - Foreign Manufacturer through resident agent (Redstone)
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# Oceania



# Australia



## Existing Substances

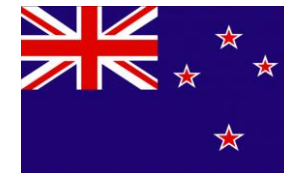
- Any chemical substance in AICS (Australian Inventory of Chemical Substances) ~40,000 Chemicals  
Public Portion - searchable / Confidential Portion – search through NICNAS (National Industrial Chemicals Notification and Assessment Scheme on request)
- All certificate assessed chemicals are added to AICS on 5<sup>th</sup> anniversary unless notifier opts for immediate listing.

## New Substances

- Registration Required – Any substance not included in AICS that is defined as an “industrial chemical” by NICNAS and does not qualify under an exemption
  - \*\*\* Polymers of Low Concern and non-hazardous chemicals and polymers are eligible for expedited certification or self-assessed certification \*\*\*
  - Polymers of Low Concern enjoy reduced certification cost
  - Permits are available as alternative to Certificates of Assessment – less stringent review, less, costly, expire, do not result in AICS listing.
  - Registration maintenance fees based on annual volume value (separate from Certification costs)
  - Statutory time-frames for Certificates and Permits range from 28 days to 90 days
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# New Zealand



## Existing Substances

- Chemical Inventory (Public - searchable online / Confidential – EPA search on request)
- Hazardous Substances (All) – must fit a predefined hazard group or a pre-existing individual substance approval prior to manufacture or import, or the substance must be specifically approved through application process as a new substance.
- Assignment of Classification – Self Classification or EPA Assisted Classification

## New Substances

- Registration Required - HSNO (Hazardous Substance and New Organism Act)
- Exemptions from Registration – Research & Development, Teaching, Manufactured Articles (limitations apply to each type), non-hazardous substances.

## Party Responsible for Compliance

- Resident Manufacturer, Importer
  - Foreign Manufacturer through resident agent (Redstone)
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# ILMA Annual Meeting 2016

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Thank You!

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