

**Overview:
Global Industrial Chemical
Control Laws and Regulations**

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DISCLAIMER

This presentation is provided only for information purposes and is not a compliance guide. Laws and regulations change frequently. Always consult the original regulatory references that apply to your situation to determine requirements.

Overview: Global Industrial Chemical Control Laws and Regulations

- **Agenda:**

- **Key Points**

- **Product Registries**

- **Chemical Inventories**

Overview Focus

- ***Intention:*** Highlight similarities in approach and execution
- Exceptions are the rule!
- Change is constant!

Key Points

- Manufacture = Import
- There must be a legal entity in the country of registration
- A chemical (or all components) must be on the inventory or exempt
- Most inventories are listed by or referenced to CAS numbers

CAS Number

Chemical Abstract Services – a division of the American Chemical Society

- A unique number – xxxxx-xx-x
- Any unique chemical structure can have a CAS number assigned.
- Does not cover mixtures
- Most countries recognize CAS number
- Does not imply that material is registered

Requirements

- Law/Directive – High level, what is expected
- Regulation – What is required – more detailed interpretation of law– who, what, when, how
- Guidance documents – documents designed to help interpret the laws and regulations- more 'practical'

Types of Lists

- Product Registry
- Chemical Inventory – Chemical Control Laws (CCL)
- Other (not covered)
 - Food additives-direct and indirect
 - Pesticides
 - Labor (OSHA/MOL)
 - Site Related (PRTR/TRI)

Product Registration

Product Registration

- **List of products**
 - Product specific
 - **Industrial vs. Consumer products**
 - Consumer products may be subject to different/additional requirements
- **Hazard Communication – Required for hazardous products in commerce**
 - MSDS
 - Labels

Product Registries - Why?

Country requires information prior to import or annual submission of information

- Occupational health and safety
 - Emergency response and clean-up
 - Consumer protection
 - Provides authority with information about chemicals on the market
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- Can be as simple as a MSDS or require more (e.g., composition information)

Registrations - Details

May be needed by importer; may be needed by the end user

- May be company or importer specific
 - Each may need to register the product
- Sometimes not required unless the product is "hazardous"
- Data required varies
- Fees vary
- Duration varies
 - One time vs Annual

Product Registries (not an exhaustive list)

- Austria
- Belgium
- Bulgaria
- China
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Greece
- Hungary
- Italy
- Israel
- Korea (South)
- Latvia
- Lithuania
- New Zealand (HSNO)
- Norway
- Poland
- Romania
- Russia
- Slovenia
- Sweden
- Switzerland
- Taiwan
- Thailand

Hazard Communication

■ MSDS

- Most accept ANSI 16 section format but at a minimum require the local language(s) and contact phone number
- Some require classification and use of specific phrases

■ Labels

- Some require multiple languages, specific symbols and information

■ Some countries already requiring GHS compliant MSDS/Labels

MSDS and Label Laws (not an exhaustive list)

US	Korea	Colombia	Taiwan
EU+	Malaysia	Peru	Australia
Thailand	China	Argentina	Singapore
Japan	Mexico	Indonesia	India
Canada	Brazil	Hong Kong	Philippines

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Chemical Inventories

Industrial CCLs

■ List of substances

- Chemicals in commerce during a certain time period are nominated by industry. Assumed to be safe (“Amnesty”)
- Once the inventory is closed, chemicals on the inventory are *generally* OK for manufacture/import/processing (“Existing” substances)
- Substances not on list require notification (“New” substances)
- Exemptions and exclusions available

Chemical Inventories

- US – Toxic Substance Control Act Inventory
- Canada – Domestic Substance List
 - Non-Domestic Substances List
- Australia – Australia Inventory of Chemical Substances
- Korea – Existing Chemicals List

Chemical Inventories (2)

- Japan – Existing and New Chemical Substances (also known as METI list)
- Philippines – Philippines Inventory of Chemicals and Chemical Substances
- China – China Inventory of Existing Chemical Substances
- New Zealand – Inventory of Chemicals

Chemical Inventories (3)

■ ~~European Union~~

- ~~– European Inventory of Existing Chemical Substances~~
- ~~– European List of Notified Chemical Substances~~
- ~~– No Longer Polymers~~

★ **Registration, Evaluation, and Authorization of Chemicals**

Inventories – Details

- Inventory: List of discreet chemicals, polymers and UVCBs (Unknown, Variable, Complex, Biological)
- “Products” (mixtures or “preparations”) are excluded as long as all components are listed
- List includes
 - Existing substances (when inventory was initiated)
 - New substances added since inception (When listed they become “existing”- except EU)

Inventories - Details

- Applies to imports and manufactured (or marketed) substances
- Listing *can* include restrictions
 - e.g., SNUR (USA), SNAC (Canada), Toxic or Observational (Korea), Specified (Japan)
- Most have both public and "confidential" sections
 - Confidential listing may require justification, a fee, only last a period of time, require re-justification

Inventories - Details

- Number of substances vary by country
 - US ~80,000+, China ~40,000
- Listing on one inventory is *mostly* irrelevant for another
 - But it may lessen some notification and testing requirements (Canada, China, Korea, Philippines)
- Listings are *generally* Chemical Abstracts Service (CAS)-nomenclature based
 - Japan: METI or MITI numbers
 - Generic listings

REACH

Effective June 1, 2008

REACH

- REACH will take the place of the chemical notification process in the EU (takes the place of 40 different laws)
- Manufacturers and/or Importers must register chemicals
- Registration has to cover the USE/Exposure of the chemical
- Starts with the Registration of all chemicals above 1000/kg/yr (1 ton/yr) 60 days after entry into force of the regulation.
- Evaluation occurs when there is a reason to expect a risk to human health or the environment
- Authorization occurs for substances of very high concern – CMR, PBTs or vPvB
- Chemical Substance Based – not product based.
 - If product contains multiple components, each component must be considered

REACH Timeline

June 2007; Reach becomes effective

Nov. 2008 Preregistrations End

June 2009 First list of for Authorization

June 2013 Registration due for >100 ton/yr

June 2008 ECHA active. Preregistrations begin

Dec. 2008 Internet list published

Nov. 2010 Registration due for:
>1000ton/yr
>1 ton/yr CMR Cat 1&2
R50/53 > 100 ton/yr

June 2018 Registrations due for:
10-100 ton/yr – including CSR
1-10 ton/yr – no CSR

If <1ton/year nothing required

Thank you.

Questions?