

# Updates on Global Compliance



“ REACH goes global ? “

M.Ruiz Cuevas  
2 February 2018  
ICEX ,Madrid



# Content



- Global trends
- Issues of concern
- REACH – like (?) Regulations
- Regulations outside the EU
- Global Regulatory Cooperation
- Outlook

# Global trends



**The chemical regulatory landscape has become increasingly complex in recent years**

- Rising number of new regulatory schemes/ amendments of existing regulations (China, Korea, Australia, Thailand, USA , Turkey, Brazil, etc.)
- General perception that prior/ existing regulations were not adequate
- More stringent requirements driven by the need to manage risks related to public health and environment
- Pressure for transparency from authorities, downstream industry, consumers
- Increasing interest in sustainability (Circular Economy, Waste Management, Microplastics...)

# Global trends



## Existing chemicals

- Chemicals in commerce (“existing” chemicals) were presumed safe, therefore exempt from new chemicals notification requirements
- Presumption questioned due to rising issues and debate on certain chemicals that existed for long time on the market (e.g. PFOA/ PFOS, BPA)
- Tendency to prioritise and review existing chemicals, to generate more data and register those substances
- Pressure from consumers / retailers to substitute certain substances.
- International Governmental Agenda :UNEP (SAICM, Rio2020),OECD, WTO, APEC....

# Issues of concern



## **CBI protection**

- Certain erosion of CBI due to the need for transparency (from both regulators and downstream users)
- Limited acceptance of trade secret claims that involve health & safety data
- Inconsistent requirements for CBI substantiation
- CBI protection limited in time
- Inconsistent rules on data dissemination/ protection

# Issues of concern



## Data Sharing

- Contractual agreements in EU
- Different market share/ interests of companies
- Inconsistent acceptance of read-across, QSAR

Need for a clear framework on data sharing.

Data requirements compatible among regulations.

## Risk of disruption in the supply chain or market loss

- legal and regulatory liability (customers/ authorities)
- reliability of appointed third parties/OR
- legal rights to the necessary data

**Formats/ Software** : need of harmonisation (e.g. OECD templates)

# Issues of concern



- Globalization of market – more sets of rules to comply with  
**Regulatory compliance is not a one-time event!**
- Stay compliant: challenges for the global companies
  - Closely monitor the international developments
  - Acquire knowledge, develop strategy
  - Generate data
  - Put in place strong processes, applications, systems
  - Streamline the costs

# “REACH-like” chemical control regulations



**Development of industrial chemical regulations having a registration component are called REACH-like**

- Notification of new chemicals
- Registration/or not of existing chemicals
- Inventory based system combined with REACH-like elements
- Periodic reporting of volumes
- Data requirements depending on volume and hazard
- Supply Chain Communications

# “REACH-like” chemical control regulations



**Some similarities but many differences (in important ways!)**

- definitions
- timing for notifications/ registrations. Validity of registrations
- thresholds
- exemptions
- data requirements (local ecotox, acceptance of QSAR, defining product composition/ impurities, etc)
- communication in the supply chain
- etc...



# Comparable with REACH?



EU REACH	China MEP order 7	Korea AREC	Taiwan
Registration of new and existing chemicals > 1MT/ y	Notification of new existing substances (no threshold)	Registration of new and priority existing chemicals >1MT/ y. AMENDMENT ! Low volume registrations	Registration of new (no threshold) and priority existing chemicals > 1MT/ y
Inventory system replaced	Inventory in place	Inventory system will be replaced	Inventory in place
Polymers exempted (registration of monomers and reactants)	Polymers not exempted	"Polymers" not exempted UVCB, Multi constituents	Polymers not exempted
Higher volume, more data (+ hazard category)	Higher volume, more data	Higher volume, more data (+hazard category)	Higher volume, more data (+hazard category for CMR only, + use)
Reduced data requirements for intermediates	No special provision for intermediates	Onsite isolated intermediates are exempted from annual reports and registrations.	No special provision for intermediates
OR	Appointed agent	OR/ Appointed agent	OR appointment not allowed to foreign manufacturer .TPR
Test data, QSAR	International GLP studies are acceptable. Additional environmental data are mandatory to be carried out by accredited local labs.	Test data (+ possibly accredited local labs), limited QSAR	Test data, QSAR (Few endpoints RA )

# Joint registration/data sharing options



	<b>EU</b> (new & existing substances)	<b>Korea</b> (new and priority existing substances)	<b>Taiwan</b> (new and priority existing substances)	<b>China</b> (new substances)
<b>Joint registration</b>	Mandatory Opt-out possible but strongly justified	Mandatory Optional individual registration	Optional	No
<b>Data sharing/ cost sharing</b>	Mandatory (New implementing act on cost sharing!)	Mandatory (if joint registration)	Mandatory (if joint registration)	No

# Current Chemical Regulatory Situation Asia:



## China

- Expected to publish the amendment of MEP order 7
- During the next 3 years China to work on a Hazard Chemical Management Law
- Dec. 28th, 2017, MEP, issued List of Priority Chemicals for Management (First Batch) and Risk Management Policy and Measures of the Priority Chemicals  
<http://www.cirs-reach.com/news-and-articles/China-MEP-Published-List-of-Priority-Chemicals.html>
- China MEP Released the Inventory of Toxic Chemicals Restricted to Import/Export 2018 <http://www.cirs-reach.com/news-and-articles/China-MEP-Released-the-Inventory-of-Toxic-Chemicals-Restricted-to-Import-Export-2018.html>

# Current Chemical Regulatory Situation Asia:



**Korea – K-REACH** implemented Jan 2015.

➤ Amendments published on December 2016

- All  $\geq 1\text{t/y}$  existing chemical substances will require registration.
- A pre-registration system will be introduced to existing substances.
- $\geq 1\text{t/y}$  existing substances must be registered within below proposed deadlines:
  - 2021:  $\geq 1000\text{ ton/y}$  and CMR (carcinogenic, mutagenic or toxic for reproduction)
  - 2024:  $100 \sim 1000\text{ ton/y}$
  - 2027:  $10 \sim 100\text{ ton/y}$
  - 2030:  $1 \sim 10\text{ ton/y}$
- For  $< 100\text{kg/y}$  new substances, a notification system will be introduced to replace current small quantity registration.
- Data requirements depend on tonnage bands and classification. (\*For substances which are not classified as hazardous according to GHS, required data could be significantly reduced)
- Annual volume reporting will not be required once amendments enter into force.

# Current Chemical Regulatory Situation



## Asia:

- Taiwan – “REACH like regulation” implemented Dec 2014 .Amendment of the TCSCA registration regulation expected in 2018 together with the first Priority list of existing substances subject to registration.
- Thailand – Preparing a regulatory management scheme including REACH-like elements. Ongoing GHS implementation
- Vietnam - Working on Existing chemical inventory and New chemical Registration law
- Philippines - Updates to the new chemical registration process . Several important issues surrounding polymers, low volume chemicals and some of the issues at hand will undermine current CBI policies.
- Indonesia - Government Regulation No. 74/2001 regarding Management of Hazardous & Toxic Material under revision
- Malaysia - Authorities discussing a larger framework for chemicals
- Japan - Amendment of CSLC (Chemical Substances Control Law )
- Myanmar , Cambodia Laos also developing Chemicals Management laws /frameworks

# Current Chemical Regulatory Situation South America



- Brazil - It is expected that in March/April 2018 the Regulation of Industrial Chemical Substances will be published in . Expected to be based on Canadian system and certain similarities with European
- Colombia- Progress is continuing of the Chemical Management Decree in a bid to become an OECD member.
  - Government proposed to start developing the inventory from January 2018 to Dec 2019 with the associated Law to be published by end of 2018. Risk based registration needs starting in 2020
- Chile- Working on GHS implementation

# Current Chemical Regulatory Situation



- EAEU (Eurasian Economic Union\*)-Drafting of the second tier legislation to continue in 2018. It includes the procedure for formation and maintenance of a register of chemicals and the procedure for notification of chemicals (Supposed to have similarities with “REACH”)
- US – TSCA Reform in 2017
- Turkey – KKDİK REACH published in 2017
- Australia – NICNAS revision ongoing
- South Africa – Preparing a chemicals management bill
- India – preparing an inventory
- UK ???

\*Armenia,Belarus, Kazakhstan, Kyrgyzstan, Russia

# Global Regulatory Cooperation



Principles of regulatory cooperation

**TRANSPARENCY:** Mechanisms to increase transparency will build confidence

**PRIORITISATION:** Collaboration → Common approach → Burden sharing

**CHEMICALS ASSESSMENT :** Shared approaches to chemicals assessment → mutually-beneficial economic integration

It is designed to benefit regulators, industry and society

**ICCA** (International Council of Chemical Associations )

<https://www.icca-chem.org/chemicals-management/>

Objective is to make regulation more efficient and effective and eliminate trade barriers ; not to decrease the level of environmental or human health protection

-Workshops : ASEAN (since 2015 ) LATAM (expected in 2018)

# Global Regulations



- ICCA is also working on harmonising Global Regulations
  - It provides governments with step-by-step guidance for implementing risk assessment and product stewardship best practices into a risk-based, national chemical safety program.
    - Cooperation with OECD, UN, WHO...
    - GPS <https://www.icca-chem.org/wp-content/uploads/2015/08/Global-Product-Strategy-ICCA-Guidance-on-Chemical-Risk-Assessment.pdf>
    - Regulatory toolbox <https://www.icca-chem.org/wp-content/uploads/2015/08/ICCA-Regulatory-Toolbox-Guidance-on-Chemicals-Management-for-Developing-Countries.pdf>
- Regulators should also consider some basic issues:
  - We live in a digital world, the OECD developed IUCLID, allow the use for facilitated exchange of information
  - Follow the OECD test guidelines and accept tests done according to these guidelines
  - There is a world wide interest in non animal testing strategies, this is a powerful tool to create additional information on substances.

# Outlook



- ✓ Rules globalization will not always reconcile global agendas with local needs and capacities
- ✓ Increasing complexity of the regulatory landscape will put more pressure on the business (increased compliance costs, slows down innovation, disrupt supply chain)
- ✓ Regulatory cooperation and common approaches will benefit regulators, industry and society

Thank you!

