



REACH-like regulations around the world



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Content



- ✓ Global trends and issues of concern
- ✓ Concept of recent “REACH-like” chemical control regulations
- ✓ Recent or emerging REACH-like regulations: examples

Global trends



Legislative landscape

- Increasing number of new regulatory schemes/ amendments of existing regulations (China, Korea, Malaysia, Russia, Taiwan, Turkey)
- 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
- Increasing interest in sustainability

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 prioritize and review existing chemicals, to generate more data and register those

Global trends



Pressure from retailers and consumer product companies to substitute certain substances

- restricted substances lists – apparel, footwear, automotive, cosmetics, toys, furniture, etc.
- ecolabel certification
- social responsibility claim

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.

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

Concept of recent “REACH-like” chemical control regulations



Development of industrial chemical regulations having a notification/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 or hazard

Concept of recent “REACH-like” chemical control regulations



Some similarities but many differences (in important ways!)

- ❑ timing for notifications/ registrations
- ❑ thresholds
- ❑ exemptions available or not
- ❑ data requirements (local ecotox, acceptance of QSAR, defining product composition/ impurities, etc)
- ❑ communication in the supply chain
- ❑ etc...

Recent or emerging REACH-like regulations: examples



- ✓ **China**
- ✓ **Malaysia**
- ✓ **Korea**

New Chemicals regulation – known as “China REACH”



Order No. 7 of MEP came into force on 15 Oct. 2010 and stipulates that new chemical substances have to be notified to CRC, irrespective of annual tonnage

Notification applies to:

- substances as such or in articles (intended to be released)
- ingredients or intermediates for pharmaceuticals, pesticides, veterinary drugs, cosmetics, food and feed additives

Exemptions:

- chemicals subject to other existing laws and regulations
- substances existing in nature (unprocessed or processed only physically)
- substances of noncommercial purpose or unintentionally produced
- special categories

IMPORTANT: Polymers are not exempt from notification, even if all monomers are listed in IECSC!

How to find out what are the “new chemicals”



- New Chemical = not listed in the **Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)**.
- There are **45612** substances in IECSC (31 Jan 2013).

Options: [Substance Search](#) or [Full List pdf format](#)

- There are **3270** substances in the **confidential section** of IECSC. Companies have to submit a formal enquiry to CRC to check whether a substance is listed in the confidential section of IECSC or not. CRC usually issues a letter of confirmation within 2 weeks after an enquiry is submitted.

Types of notifications for new chemicals



Type of Notification	Applicable Scope
<p>Typical notification</p> <p>8-36 months;</p>	<p>New chemical substances to be manufactured or imported at or above the annual volume of 1 ton. Based on tonnage band, there are four notification levels:</p> <ul style="list-style-type: none"> - First level (1~10 tons) - Second level (10~100 tons) - Third level (100~1,000 tons) - Forth level (>1,000 tons)
<p>Simplified notification basic condition</p> <p>3-4 months</p>	<p>New chemical substance with tonnage under 1 ton per year;</p>
<p>Simplified notification specific condition</p> <p>2-3 months</p>	<p>New chemical substance</p> <ul style="list-style-type: none"> - for export only with tonnage under 1 ton per year; - for scientific research with tonnage between 0.1 to 1 ton per year; - for technological research with tonnage less than 10 ton per year - for polymer consisting of monomers already listed in IECSC(if the polymer itself is not listed in IECSC); - for polymers containing less than 2% new chemical substance weight by weight; and - for low concern polymers (if the polymer itself is not listed in IECSC);.
<p>Scientific research record</p> <p>3-10 working days</p>	<p>New chemical substances used for scientific research with an annual quantity lower than 0.1 ton or if the sample is to be tested in laboratories in China.</p>

New Chemicals – Who should notify



- ✓ **Manufacturer** of new substance in China
- ✓ **Importer** of new substance in China
- ✓ **Foreign companies selling** new substances to China

Options for dossier submission:

1. companies in China can submit the notification on their own
2. foreign companies need to have a legal entity in China or to appoint a local agent (similar to the OR in EU)

IMPORTANT: The minimum registered capital of the local Chinese agent needs to be 3 million ¥ (around 360 000 €)



Post-notification Obligations

- After notification is completed, a registration certificate containing specific management category will be issued
- The post-notification obligations depend on the management category of the substance

Category	Post-notification Obligations/ Requirements
Typical notification	
General new chemical substances	<ol style="list-style-type: none">1. Communicate MSDS to downstream users;2. Implement risk management measures;3. Submit first-activity report;4. Keep documents on file for over 10 years;5. Do not sell chemicals to downstream users who are not capable of implementing risk management measures;6. Submit updates if new hazard arises;
Hazardous new chemical substances	<ol style="list-style-type: none">7. Submit annual report (for previous year);8. Comply with <<The Measures for The Administration of Registration of Hazardous Chemicals>>;
Priority hazardous new chemical substances for environmental management	<ol style="list-style-type: none">9. Submit report on disposal information;10. Submit substance flow chart;11. Submit annual plan (for next year);
Simplified Notification	
Not applicable	<ol style="list-style-type: none">1. Submit annual plan (for previous year);2. Keep documents on file for over 10 years;
Scientific Research Record	
Not applicable	<ol style="list-style-type: none">1. Requirements of professionals and facilities;2. Can only be used for scientific research purposes;

Chemical Management in Malaysia (EHSNR)



Regulation on "Environmentally Hazardous Substances Notification and Registration " (EHSNR) started in January 2009 (voluntary notification scheme) and became mandatory in 2011, when the regulation came into force

Notifications apply to all environmental hazardous substance on their own , in mixtures and products and above 1 tonnes per year

What is defined as Environmentally Hazardous Substance?

- a substance that is included in the [EHS Reference List](#)
- a substance listed in the [CMR Reference List](#)
- a substance assigned a GHS classification



Exemptions

- naturally-occurring substances
- incidental/ end-use reaction products
- substances formed during the manufacture of an article
- mixtures (but not components)
- impurities and by-products
- substances meant to export only
- intermediates (non-isolated, contained site-limited, and transported)
- R&D, test marketing
- low-volume substances
- polymers

IMPORTANT: Substances in “articles” and “finished products” are listed as exempt in some guidance (but not in all)



Who should notify?

domestic manufacturers or importers of substances ≥ 1 metric tonne per year, alone or in a mixture at 1% (0.1% for CMRs)

■ “Substance” has the same meaning as in EU REACH.

IMPORTANT: Early guidance suggested 0.1 mty is the threshold, but latest guidance gives no registration deadline for 0.1 – 1 mty.)

Primary Requirements:

- First, *register the manufacturer or importer, and*
- Second, *notify the substance*

IMPORTANT: Non Malaysian exporters can appoint third party representatives (TPR) to submit external notifications on behalf of Malaysian importers. Malaysian legal entity is not required.

Notification timeline



ANNUAL TONNAGE (MT)	PROPOSED YEAR FOR NOTIFICATION						
	2009 - 2012	2013 - 2014		2015 - 2016		2017 - 2018	
> 100	Initial Baseline Data Collected	*	*				
10 -100		*	*				
1 - 10		*	*				

Types of notification and data requirements



Basic notification (for substances from the EHS / CMR Reference lists)

- Substance Identification
- Year of Notification
- Occurrence: pure substance, mixture or constituent of finished product (concentration range)
- Annual Tonnage of Substance
- Details on uses
- Country of export (if imported)

Detailed notification (In addition to the Basic notification data – for substances with an assign GHS classification and not listed on the Reference Lists):

- Substance Molecular Formula, Molecular Structure, Molecular Weight
- Physical and Chemical Properties
- Physical Hazards
- Hazards to Human Health
- Hazards to Aquatic Environment

Notification and Registration Road Map



- ❖ 2009 to 2013 – set up initial inventory
- ❖ 2013 to 2015 – DOE starts evaluating substances and establish a priority list base on certain criteria for risk assessment
- ❖ 2015 to 2017 – propose risk assessment measures on selected substances ; control measures (on uses) will be introduced
- ❖ 2017 onward – control measures on selected substances, such as regulation to control single substance, will be introduced.

AREC - "Korea REACH"



The Act on the Registration and Evaluation of Chemicals passed the plenary session of the National Assembly in Korea on April 30, 2013 and will come into force on January 1, 2015

Provisions:

- ✓ Registration of existing and new chemical substances
- ✓ Screening of hazardous chemical substances
- ✓ Hazard and risk assessment of products containing chemical substances and hazardous substances
- ✓ Sharing information of chemical substance

Scope and exclusions



Applies to:

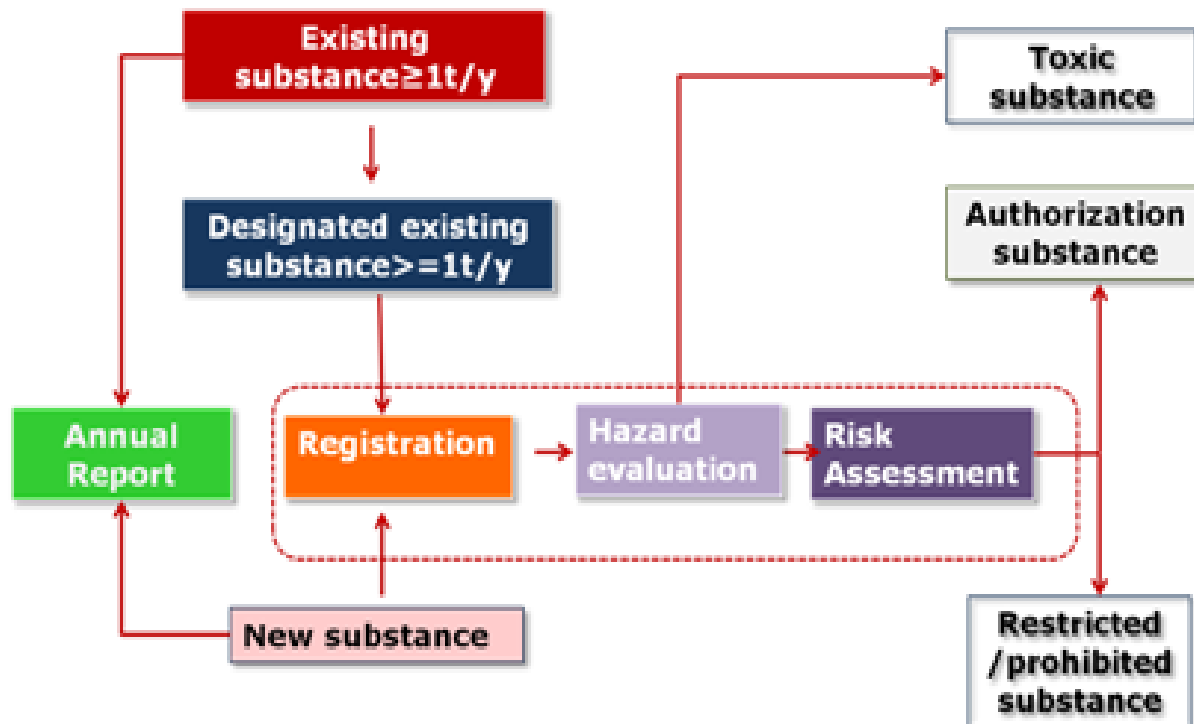
- New chemical substances
- Designated existing substances manufactured, imported or sold more than 1 ton per annum
- Polymers are not exempt

IMPORTANT: designated existing substances will be decided in subsequent decrees

Exclusions:

- Substances subject to other regulations (Atomic Energy Act, Pharmaceutical Affairs Act, Act on Control of Narcotics, Cosmetic Act, etc.)
- Military supplies, ammunition, livestock feeds, medical devices

Overview



Registration process



- ❖ new substances must be registered prior to production or importation
- ❖ designated existing substances benefit of a grace period (max. 8 years).
- ❖ foreign manufacturers may appoint an Only Representative to fulfill relevant obligations under K-REACH
- ❖ registration can be waived in special cases
- ❖ exemption for substance manufactured or imported less than 10 tons per year and exported entirety - an application of exemption must be submitted to the MOE.

Deadlines of Registration



Prior to manufacturing/ importing for new substances

According to specified deadlines for designated existing substances are to be set by MOE.

- **The 1st list: 2 years from the publication date**
- **The 2nd list: 5 years from the publication date**
- **The 3rd list: 8 years from the publication date**

Information requirements



- ✓ the name, address and representative of a manufacturer or an importer or an only representative
- ✓ information that identifies a chemical substance including its name, molecular formula and graphic formula
- ✓ identified uses of the chemical substance
- ✓ classification and labeling of the chemical substance
- ✓ physical and chemical properties
- ✓ hazard data (tox./eco-tox. data)
- ✓ risk assessment report including exposure scenarios (> 10 tonnes / year)
- ✓ guidance on safe
- ✓ other information specified in the Environment Ministerial Decree
 - data requirements for some specific chemical substances designated by Presidential Decree will be reduced;
 - test proposal including test information and schedules may replace certain data endpoints.

Deadlines of Risk Assessment Report



Tonnage	Deadline of risk assessment report submission
≥100 ton per year	1st Jan 2015
70 ~100 ton per year	1st Jan 2017
50 ~70 ton per year	1st Jan 2018
20 ~50 ton per year	1st Jan 2019
10 ~20 ton per year	1st Jan 2020

Evaluation



Based on the registration data received, MoE will assign the substances to the following categories:

- **Toxic substance**
- **Authorization substance**
- **Restricted substance**
- **Prohibition substance**

Product management



- ❖ **Product notification: product containing hazardous substance > 1tonne / year**
- ❖ **Risk assessment will be performed on risk-concerned products by institutions or experts appointed by the Ministry of Environment**
- ❖ **List of risk-concerned products to be decided by Ministry of Environment**



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