



Introduction to REACH

13 October 2008



A New EU Chemicals System

- REACH regulation : **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals
- Aim : to improve protection of human health and the environment while enhancing competitiveness of the EU chemicals industry (Article 1)
- No data, no market (Article 5)



The REACH

- **Registration** – manufacturers or importers concerned to provide registration dossier, indicating the identity of the substances, classification and labelling, guidance on safe use, etc.
- **Evaluation** – ECHA to do a quality check of the registration dossiers and to co-ordinate further risk evaluation of substances
- **Authorisation** – For substances of very high concern (SVHC) being put into a list, an authorisation is required for their use and their placing on the market
- **Restrictions** – Regulate Community-wide conditions for manufacture, placing on the market or use of certain substances where there is an unacceptable risk to human or the environment or prohibit any of these activities



Understanding Substances (Article 3)

- Substance : a chemical element and its compounds in the natural state or obtained by any manufacturing process (e.g. Lead)
- Preparation : a mixture or solution composed of 2 or more substances (e.g. detergent)
- Article : an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical compositions (e.g. electronic products)



Registration – what?

Article 6 – Substances on their own or in preparations

All substances manufactured in or imported into the EU in quantities of 1 tonne or more per year, unless those exempted from the scope of registration (e.g. radioactive substances, waste, substances used for food or feeding stuff, medicinal products, etc.)

Article 7 – Substances in articles

For any substance contained in articles that meet the following conditions:

- > 1 tonne per producer or importer per year in those articles; and
- substance is intended to be released under normal or reasonably conditions of use

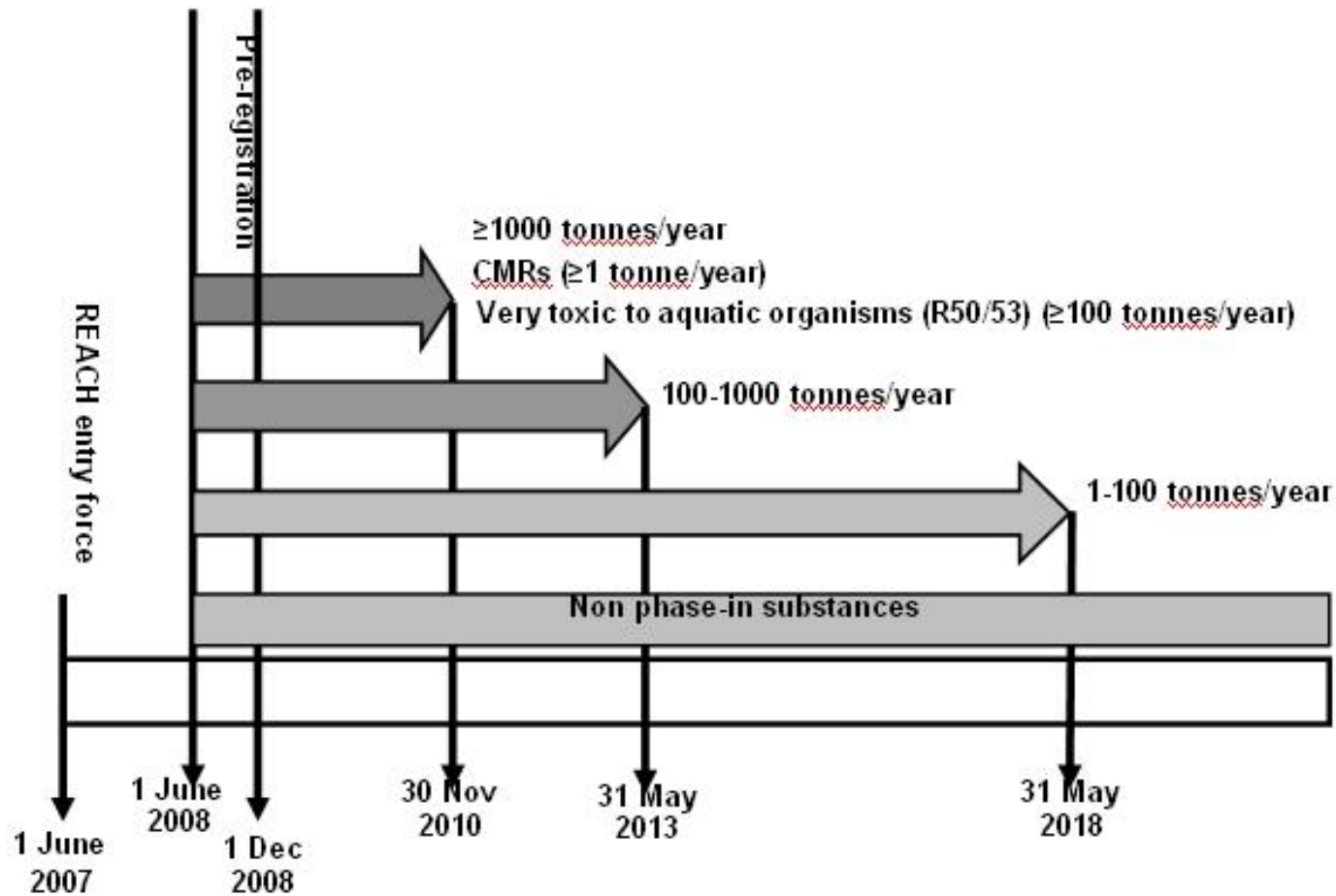


Registration – How?

- Registration documents
 - Technical dossier (for substances of 1 tonne or more)
 - Chemical safety report, CSR (for substances of 10 tonnes or more)
- Format
 - IUCLID 5
- To
 - ECHA via the REACH-IT portal



Registration – When?





Pre-registration

Why : To provide a special transition regime for substances which were being manufactured or placed on the market before 1 June 2007 and were not notified according to Directive 67/548/EEC (“Phase-in substances”)

Time : 1 June 2008 – 1 December 2008 (inclusive)

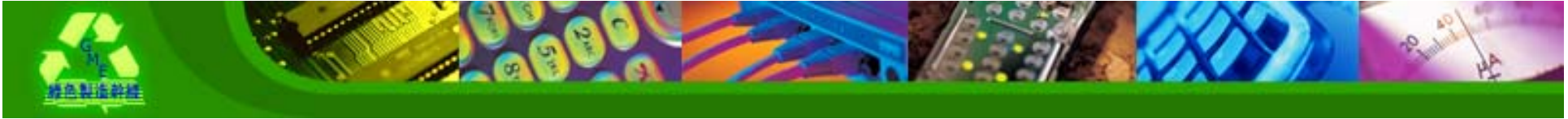
Target : phase-in substances

Do not pre-register on time will not be able to benefit from the transitional regime



Pre-registration vs Registration

	Pre-registration	Registration
Target	Phase-in substances	Non phase-in substances
Time	1 Jun – 1 Dec 2008	Starting from 1 Jun 2008
Information required	4 items	11 items
Remark	Voluntary	No data, no market



Information Exchange within SIEF

- Substance Information Exchange Forum (SIEF)
- Formation of SIEF for data sharing and avoidance of unnecessary testing or duplication of studies
- Exchange of information within SIEF facilitated by a co-ordinator



Total Tonnage Calculation (an example)

An EU company imports 3 articles A, B & C, each containing 60 tonnes of a substance x, but

- In article A, the substance x is not intended to be released
- In article B, the substance x is intended to be released and only 50% of the 60 tonnes are released normally
- In article C, the substance x is intended to be released and only 25% of the 60 tonnes are released normally

➤ Need to register the total tonnage of the substance in articles B and C : 120 tonnes (i.e. in the 100 – 1,000 tonnes band)



Notification

Scope : Substances in articles

Criteria :

- Candidate list for authorisation (i.e. SVHC);
- Substance in all articles totaling > 1 tonne per producer or importer; and
- Substance present in those articles > 0.1% w/w

Exempted :

- Can exclude exposure of the substances to humans or the environment during normal use; or
- Substance already registered for that use

Information to be Notified :

- Identity of producer or importer
- Registration no., if available
- Identity of substance
- Classification of substance
- Uses of the substance in article and uses of the article
- Tonnage band of the substance (e.g. 1-10 tonnes, 10-100 tonnes, etc)



What is SVHC

CMR

- Carcinogenic
- Mutagenic
- Toxic for reproduction

(category 1 and 2)

PBT

- Persistent
- Bioaccumulative
- Toxic

vPvB

- very persistent
- very bioaccumulative



First Candidate List of SVHC for Consultation

Substance name	CAS number	EC number
Anthracene	120-12-7	204-371-1
4,4'- Diaminodiphenylmethane	101-77-9	202-974-4
Dibutyl phthalate	84-74-2	201-557-4
Cyclododecane	294-62-2	206-33-9
Cobalt dichloride	7546-79-9	231-589-4
Diarsenic pentaoxide	1303-28-2	215-116-9
Diarsenic trioxide	1327-53-3	215-481-4
Sodium dichromate, dihydrate	7789-12-0	
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4
Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0
Hexabromocyclododecane (HBCDD)	25637-99-4	247-148-4
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5
Bis(tributyltin)oxide	56-35-9	200-268-0
Lead hydrogen arsenate	7784-40-9	232-064-2
Triethyl arsenate	15606-95-8	427-700-2
Benzyl butyl phthalate	85-68-7	201-622-7

http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp



Authorisation

- For substances listed in Annex XIV (SVHC), an authorisation is required for their use and their placing on the market
- First list expected to be released by 1 June 2009
- Applications for authorisations (Article 62)
- Holders of an authorisation shall include the authorisation number on the label (Article 65)
- Downstream users using a substance shall notify the ECHA with 3 months (Article 66)



Restriction

- Inventory of restrictions (1 June 2009)
- Annex XVII
- Regulate Community-wide conditions for manufacture, placing on the market or use of certain substances where there is an unacceptable risk to human or the environment or prohibit any of these activities



Requirements for Substances in Articles

4 Potential Types of Requirements

- Register substances contained in articles to ECHA (Article 7)
- Notify substances contained in articles to ECHA (Article 7)
- Communicate specific information related to the content of some specific substances to customers (Article 33)
- Comply with any Community-wide restriction (Annex XVII)



Communication Obligations under Article 33

- Articles containing SVHC included on the candidate list for authorisation in a concentration $> 0.1\%$ (w/w) have to provide the recipient with sufficient information to allow safe use of the articles
- Information available to the article supplier necessary to ensure safe use of articles has to be provided to consumers upon request, within 45 days, free of charge
- Example:
 - Imported buttons for jackets contain SVHC in a concentration of 0.5% (need communication)
 - Buttons are imparted as part of jackets and such substance in the imported article (jacket) is $< 0.1\%$ w/w (no communication obligation)



Understanding Your Role and Obligations

The role of a company includes:

- Manufacturer, importer, only representative, downstream user

Who should register:

- 1) EU manufacturers and importers of substances/ preparations
- 2) EU producers and importers of articles
- 3) EU based “ only representatives” appointed by a non-EU manufacturer

Non-EU manufacturer can:

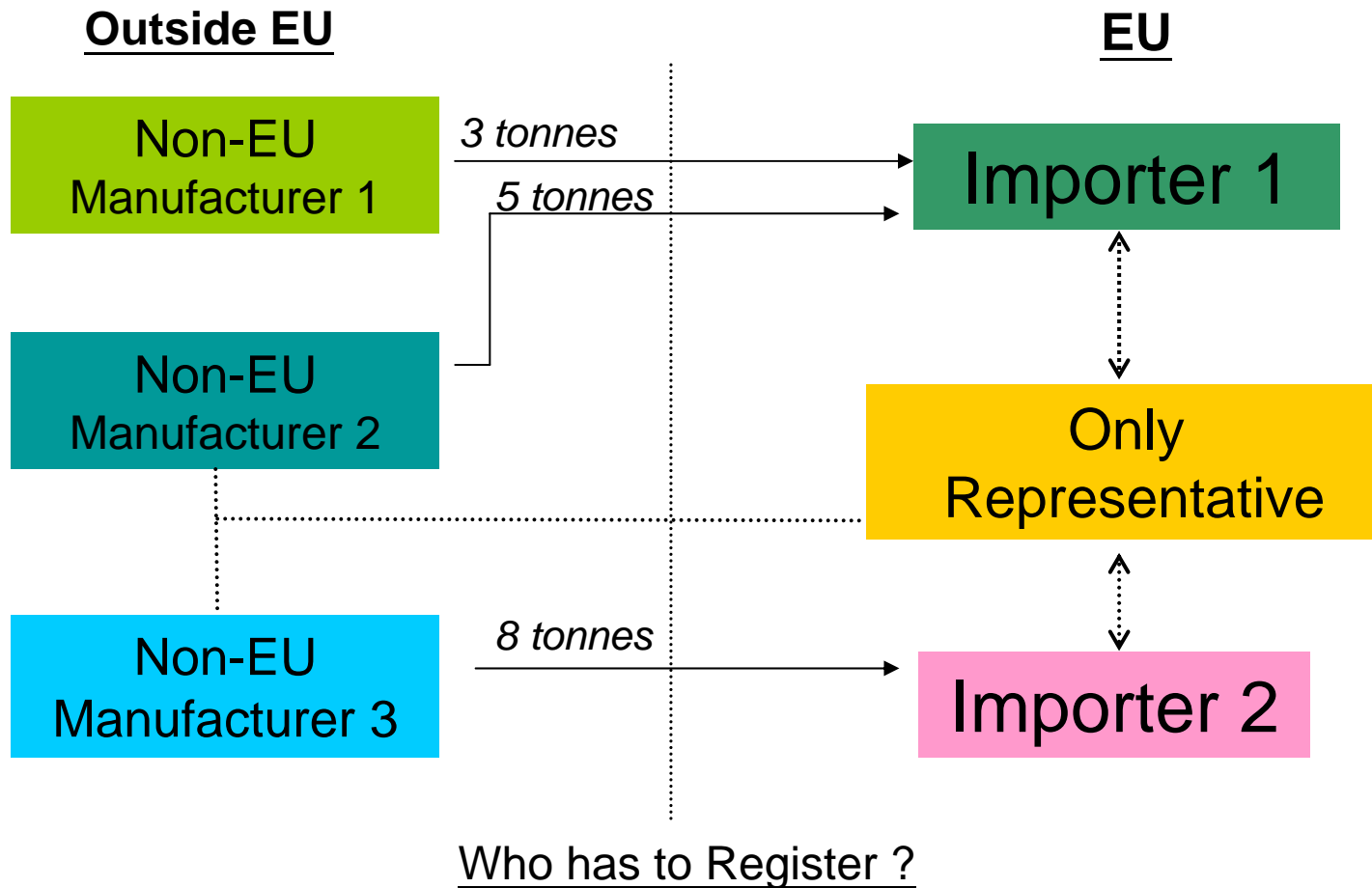
- 1) appoint an “Only Representative” for Registration; or
- 2) register through their “subsidiaries” located in EU

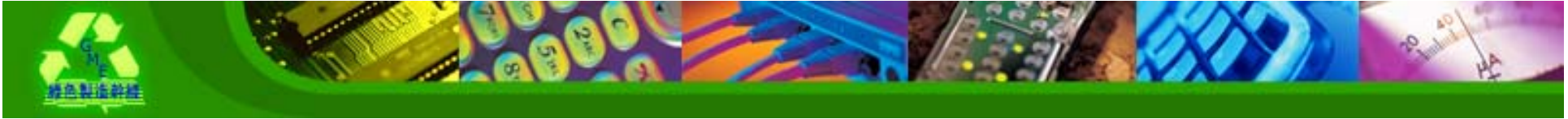
The “ Only Representative” should:

- a) be located within the EU
- b) have sufficient background in the practical handling of substances and related information
- c) keep available and up-to date information on quantities imported and customers sold
- d) keep the latest information of safety data sheet



Identify Your Role & Registration Obligations





Manufacturers of Articles – Know Your BOS

- Know your products; start from BOM
- Prepare BOS – materials list down to substances level



Manufacturers of Articles – Analyze Your BOS

Part	Substance	CAS#	% w/w	SVHC	Potentially Requiring	
					Registration	Notification
A						
B						
C	S1	...	xx%		✓	
	S2	...	xx%	✓	✓	✓
	S3	...	xx%		✓	
⋮	⋮	⋮	⋮	⋮	⋮	⋮



Check Registration



Check Notification



**Further Enquiry :
2788 5615**

Thank You!