

# EU chemical regulation- REACH – Brief Overview and Q&A

Jytte Syska, 3E Company

# REACH



- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- Entered into force June 1, 2007

# REACH (cont'd)



- Scope:  
Manufacture, import, placing on market and use of substances (on their own, in preparations or in articles)
- Two roles:
  - Manufacturer/Importer (M/I): for the chemicals the European company produces or imports (into EU)
  - Downstream User (DU): for the chemicals the European company buys from an EU supplier
- Impacts every company doing business in or exporting to Europe

# REACH (cont'd)



Key elements:

Title II: Registration of substances

Title III: Data sharing

Title IV: Information in the supply chain

Title V: Downstream users

Title VI: Evaluation

Title VII: Authorisation

Title VIII: Restrictions in marketing and use

Title XIV: Enforcement

# REACH exemptions



Substance group	Title II Registration	Title IV SDS	Title V DU	Title VI Evaluation	Title VII Authorisation
Radioactive substances	Exempted	Exempted	Exempted	Exempted	Exempted
Under customs supervision and intended for re-exportation, or in transit	Exempted	Exempted	Exempted	Exempted	Exempted
Non-isolated intermediates	Exempted	Exempted	Exempted	Exempted	Exempted
Carriage of dangerous substances according to ADR, RID, IMDG or IATA	Exempted	Exempted	Exempted	Exempted	Exempted
Waste	Exempted	Exempted	Exempted	Exempted	Exempted
Certain substances in the interests of defence	Exempted	Exempted	Exempted	Exempted	Exempted
In medicinal products	Exempted	1)	Exempted	Exempted	Exempted
Food additives & Flavourings in food and feedingstuffs	Exempted	1)	Exempted	Exempted	Exempted
In Cosmetic or n medical devices		1)			
Annex IV or Annex V	Exempted		Exempted	Exempted	
Re-imported substances	Exempted		Exempted	Exempted	
Re-imported substances & Substances which have been registered and which are recovered	Exempted		Exempted	Exempted	
On-site isolated intermediates and transported isolated intermediates	"Light" registration				Exempted
Pesticides & Biocides	Exempted				
On ELINCS	2)				
Polymers	Exempted 3)			Exempted	
Product and process oriented research and development (PPORD)	4)				

- 1) Exempted in the finished state, intended for the final user 2) Exempted from registration by the notifier.  
 3) The monomer substances might have to be registered see Title II, article 6.3 4) Exempted for up to 5 years

# REACH (cont'd)



## Title II: Registration of substances

- Registration of manufactured/imported chemical substances > 1 tonne/year (Various dead-lines over a 11 years period)
  - May also apply to substances in articles
- Registration requirements started June 1, 2008
- Only EU companies can register
- Non-EU companies can choose to use an Only Representative
- One Substance Information Exchange Forum (SIEF) for each pre-registered substance with the same identity
- Joint submission of
  - the classification and labelling (must)
  - Study Summaries (must)
  - Robust study summaries and proposal of testing where listed in the relevant annexes (must)
  - Guidance of safe use of the substance (may)
  - Chemical Safety Report when required (may)
- SIEFs shall remain operational until 1 June 2018

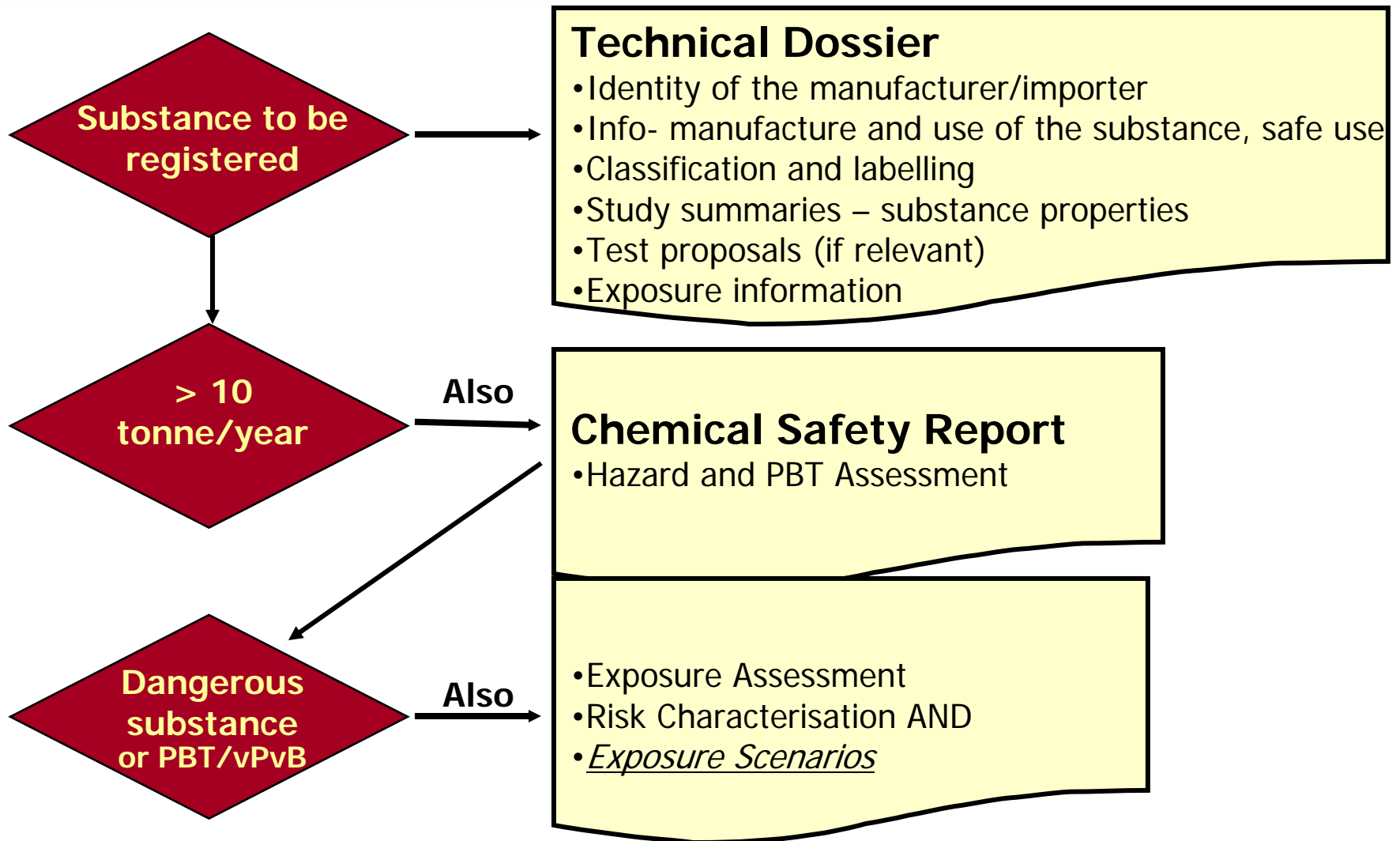
# REACH (cont'd)



## Title II: Registration of substances

- “phase-in substances” pre-registered before December 2008 allows for the following dead-lines:
  - **December 2010:**
    - All substances >1000 ton/a
    - Carcinogen, Mutagen, Toxic to Reproduction CMR cat. 1 or 2 >1 ton/a
    - Very aquatic toxic (R50/53) > 100 ton/year
  - **June 2013:**
    - Substances <1000 ton/a, but > 100 ton/a
  - **June 2018:**
    - Substances <100 ton/a, but > 1 ton/a
- Late pre-registration an option for companies that manufacture or import for the first time a phase-in substance in quantities of one tonne or more per year after 1 December 2008
- Late pre-registration does not apply to companies that failed to meet the preregistration deadline of 1 December 2008 for their substances. These companies cannot continue producing or importing the substances until they have submitted a full registration dossier

# Registration dossier



# REACH (cont'd)



## Title II: Registration of substances

What should non – EU manufacturers do?

- Be sure to have good records of which substances are exported into EU and in what amounts
  - Also in articles
- Collect and evaluate available data
- Consider how/if to get involved in the registration work
- Follow the work in the SIEFs
- Consider if an only representative should be engaged

# REACH (cont'd)



## Title IV: Information in the supply chain

- Safety Data Sheets are still regulated by REACH
  - Art 31 is updated to include all chemicals classified under 1272/2008 (CLP)
  - Annex II is in the process of being updated
- Additional/new requirements to the EU SDS under REACH:
  - Certain information must be included now
  - Certain information must be added once/if the substances in the product are registered
  - Exposure scenarios (ES) to be attached

# REACH (cont'd)



## Title IV: Information in the supply chain

### What should non – EU manufacturers do?

- Be sure their products are supplied in Europe with a compliant SDS (and label)
  - REACH compliant
  - Including proper declaration of ingredients
  - GHS compliant
  - Including national regulations
  - In the proper languages
  - Kept up to date

# REACH (cont'd)



## Title VII: Authorisation

- Candidate list - Substances of Very High Concern (SVHC)
  - Available on the ECHA web site
- Substances on the Candidate List may subsequently become subject to authorisation (Annex XIV) by decision of the European Commission
  - Continued use of substances included in Annex XIV requires that after the “sunset date” the use has been authorised
  - First issue of Annex XIV is June 2009
- Substances of very high concern (SVHC)
  - CMRs (carcinogens, mutagens and reproductive toxins – categories 1 or 2)
  - PBTs (persistent, bioaccumulative and toxic substances)
  - vPvBS (very persistent & very bioaccumulative substances)
  - Some substances of concern → irreversible serious effects on humans & the environment (e.g. endocrine disruptors)

# REACH (cont'd)



## Title VII: Authorisation

What should non – EU manufacturers do?

- Track and understand which substances are considered SVHCs
- Understand if any candidate substances are in your products
- Prepare to re-formulate – consider substitution
- First 7 substances:
  - 4,4'- Diaminodiphenylmethane (MDA) (Carc)
  - Dibutyl phthalate (DBP) (Rep)
  - 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) (vPvB)
  - Bis (2-ethylhexyl)phthalate (DEHP)
  - Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (PBT)
  - Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) (PBT & vPvB)
  - Benzyl butyl phthalate (BBP) (Rep)

# REACH (cont'd)



## Title VIII: Restrictions in marketing and use

- A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction.
- Example:

'53. 2-(2-methoxyethoxy)  
ethanol (DEGME)  
CAS No: 111-77-3  
Einesc No: 203-906-6

Shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by mass.

# REACH - Enforcement



## Press Release:

ECHA/PR/09/05

Helsinki, 30 April 2009

### FIRST COORDINATED REACH ENFORCEMENT PROJECT STARTED

**REACH-EN-FORCE-1**, a joint REACH enforcement project, has started across Europe. National inspectors are checking pre-registrations, registrations and – where applicable – the provisions for Safety Data Sheets. The Forum for Exchange of Information on Enforcement, meeting for the fourth time this week in Helsinki, reviewed the start of the project and agreed on the further steps.

The enforcement project of the Forum enforces the core principle of REACH: *no data, no market*. Inspectors in the participating countries will focus on the phase-in substances (existing substances) and check through inspections whether companies have submitted a pre-registration or a registration and, where necessary, whether a Safety Data Sheet has been supplied.

The project will thus give a first impression of the level of compliance by manufacturers and importers (including only representatives) with REACH in the European Union and European Economic Area. At the same time, the capacity of the enforcement authorities to enforce REACH will be enhanced.

Questions &  
Thank you for your attention!

Jytte Syska  
3E Company Europe  
Email: [jsyska@3ecompany.com](mailto:jsyska@3ecompany.com)  
Phone: +45 70 22 81 70  
Cell: +45 21 64 25 26