

# MSDS Management in the Era of REACH

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# Agenda



- REACH Overview
- Registration Requirements
- Supply Chain Communication
- MSDS Management
- Authorization
- Restrictions
- Enforcement

# REACH



- Regulation (EC) No 1907/2006 of the European Parliament and of the Council, concerning the **Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**
  - establishing a European Chemicals Agency (ECHA), 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

# Previous Legislature



- Regulation (EC) No 793/93
  - Distinction between so called “existing” and “new” chemicals based on cut-off date of 1981
- Lack of publicly available information on “existing” chemicals (about 100,000 as of 1981)
- No obligations on downstream users (industrial users and formulators)

# REACH Basics



- **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 – Key Elements



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 – Registration



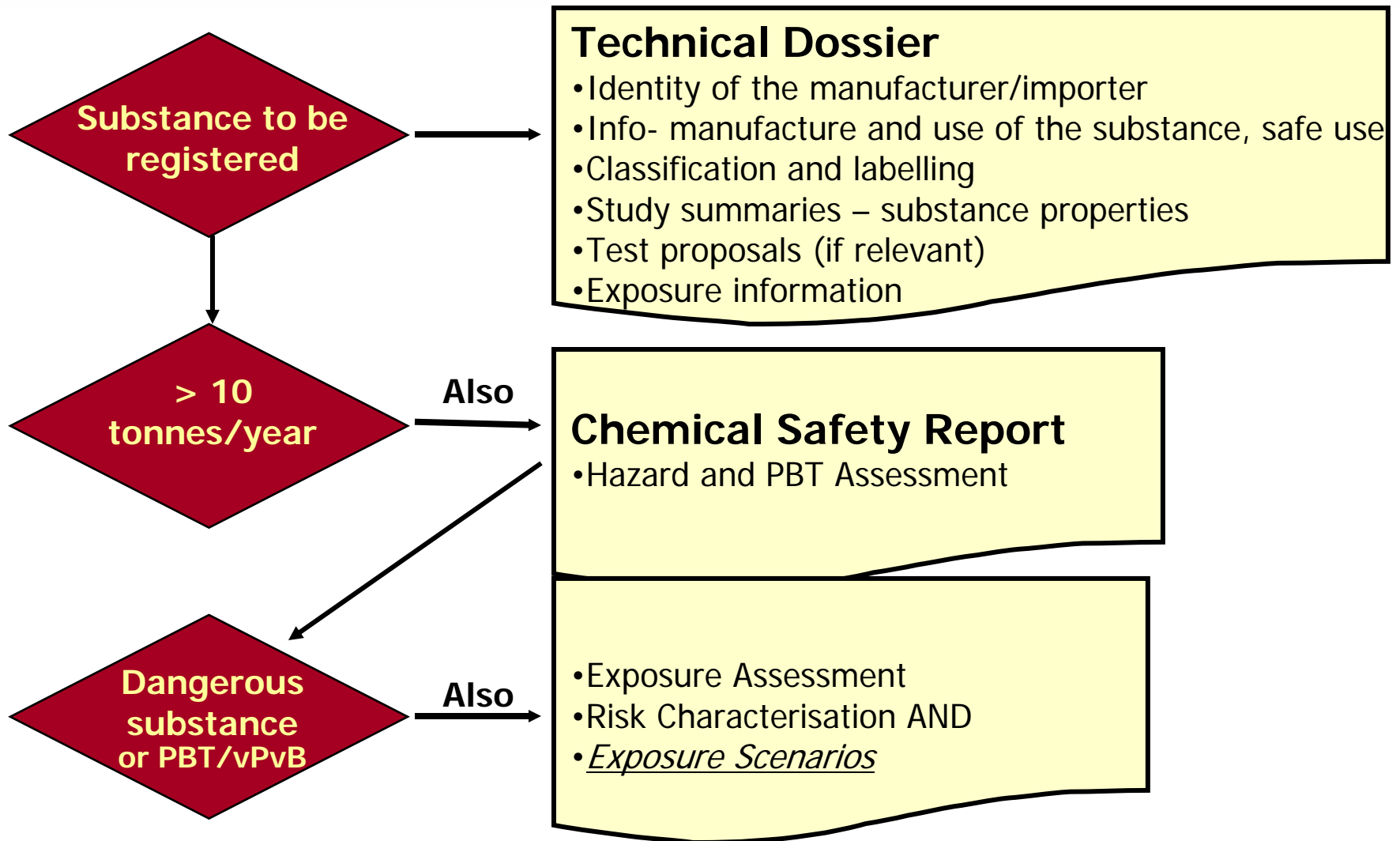
- Registration of manufactured/imported chemical substances > 1 tonne/year - various dead-lines over an 11 years period
  - May also apply to substances in articles
  
- Registration requirements started June 1, 2008
- Only EU companies can register
- Non-EU companies can choose to use an Only Representative
- One Substance Information Exchange Forum (SIEF) for each pre-registered substance with the same identity
- Joint submission of:
  - Classification and Labeling (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 - Registration



- “Phase-in substances” pre-registered before December 2008 are subject to the following deadlines:
  - **December 2010:**
    - All substances >1000 tonnes
    - Carcinogens, Mutagens, Toxic to Reproduction (CMR cat. 1 or 2) >1 tonne
    - Very toxic to aquatic organisms (R50/53)> 100 tonnes
  - **June 2013:**
    - Substances 100 - 1000 tonnes
  - **June 2018:**
    - Substances 1 - 100 tonne
- Late pre-registration does not apply to companies that failed to meet the pre-registration deadline of December 1, 2008 for substances.
- These companies cannot continue producing or importing the substances until they have submitted a full registration dossier.

# Registration Dossier



# REACH - Registration (cont'd)



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

- 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 – 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 – Information in the Supply Chain



What should downstream users do?

- Track the use of your vendor supplied products
- Support supplier requests for information about these uses
- Maintain exposure scenarios for confidential uses

# REACH – (M)SDS Management



What should downstream users do?

- Ensure you have the most current (M)SDS for your products
- Verify a exposure scenario exists for your particular use
- Review (M)SDS against REACH/GHS requirements
- Provide access to (M)SDS and exposure scenario to employees

# REACH - 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 authorization (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 authorized
  - 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 – Authorisation (cont'd)



What should non – EU manufacturers/downstream users 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 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 – Authorisation (cont'd)



How do you leverage your MSDS Management program to accomplish these tasks?

- Obtain SVHC list from ECHA website, or utilize 3<sup>rd</sup> party MSDS management system for list access
- Compare SVHC list to the current MSDS for each product to determine products that may be impacted
- Locate and review MSDS for possible substitutions

# REACH – Authorisation (cont'd)



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# REACH – Restrictions



## 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 – Restrictions



How do you leverage your MSDS Management program to manage substance restrictions?

- Review Marketing & Use Restrictions
- Compare substance list to the current MSDS for each product to determine products that may be impacted
- Evaluate product and its uses to make impact determination
- If necessary, review MSDS for possible substitutions

# 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 time