



# REACH and the Future of the Metals Industry

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## REACH Objectives

### Sustainable Development

- Protect human health and the environment
- Maintain/enhance innovation/competitiveness
- Increase transparency and consumer awareness
- Integrate with international efforts
- Promote non-animal testing
- Conformity to WTO obligations

## **REACH Principles**

- **Industry ensures that the manufacturing and use of metals and metal compounds (ex. Mn alloys) do not adversely affect human health or the environment**
  - **Manufacturers and importers must assess and document that risks are adequately controlled**
  - **Manufacturers and importers must communicate to downstream users how to control risks**
  - **Downstream users must apply measures to control risks and communicate this further downstream**

## What is REACH?

- **REACH** stands for **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals.
- **One single and coherent system** for new and existing chemicals
- The REACH Regulation was adopted by the European Parliament on 18th December 2006.
- **REACH will Enter Into Force on 1st June 2007.**
- REACH requires all companies producing metals and/or metal compounds in Europe, or importing metals, etc. into Europe to prove that their products are safe for use. If companies fail to register their products, by providing the necessary scientific data, they will not be allowed to sell them on the EU market.
- **Your importers will be asking you to provide them with this data so they can register your products. Otherwise, they cannot sell them.**

**NO DATA, NO MARKET**

## REACH Core Elements:

Registration by industry of manufactured/imported chemical substances > 1 tonne/year

Evaluation of some registered substances (Agency and Member States)

Authorisation only for use of substances of very high concern

Chemicals Agency to efficiently manage the system

### Focus on priorities:

High volumes

Greatest concern (Carcinogenic, Mutagenic and Reprotoxic )

Shift of responsibilities from public authorities towards industry

## REACH Timetable

- After Entry Into Force of REACH legislation, existing substances must be pre-registered in a transition period starting 12 months after the initial entry and ending 18 months after this date. (June 2008- 30 Nov 2008).
- All Manufacturers/Importers that have submitted information on the same substance in the pre-registration phase must participate in the **Substance Information Exchange Forum -SIEF**.

One SIEF per Substance. The aims of SIEF are to share existing data, avoid duplication of tests and facilitate registration.

- Agency will publish the list of substances 19 months after REACH enters into force (January 2009)

# REACH REGISTRATION

## Pre-Registration : Information Required

- Submission within 18 months of entry into force of a simple pre-registration dossier to the Agency:
  - Substance identity
  - Name and address of registrant
  - Expected dead-line for registration (tonnage dependant)

## Registration : Information Required

- Data on physicochemical and toxic properties
- The higher the tonnage, the higher the standard information requirements (REACH Annex VII-X)

## REACH Timetable

### Focus on priorities:

- **Highest concern** (Carcinogenic, Mutagenic and Reprotoxic register first)

Timeline is 3,5 years (Dec 2010)

- **High volumes** (chemicals with greatest likely exposure register first)

Registration depends on tonnage bands

**>1000 t**

Timeline is 3.5 years ( Dec 2010)

100t< <1000t

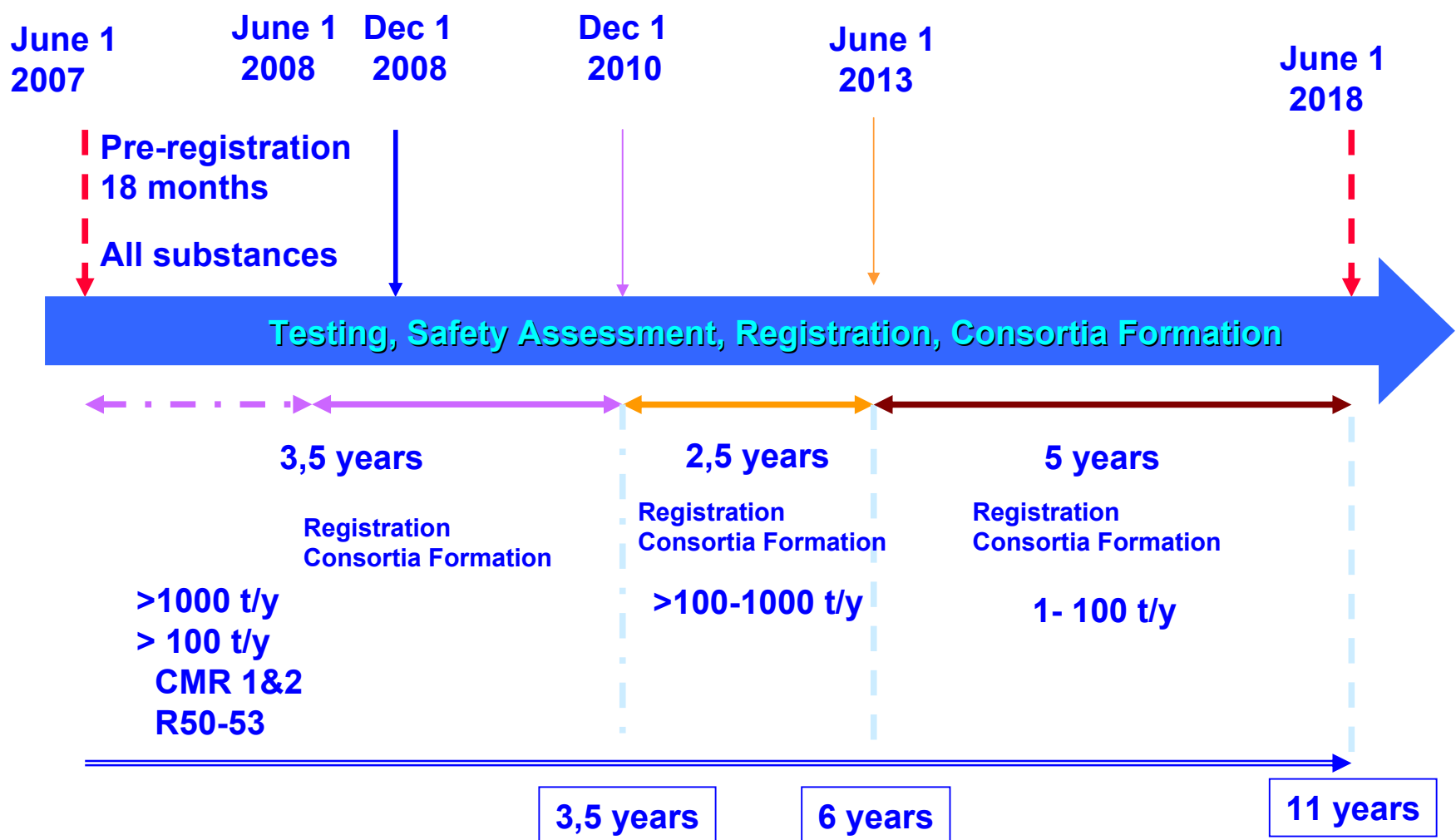
Timeline is 6 years (Dec 2013)

1< <100 t

Timeline is 11years ( Dec 2018)



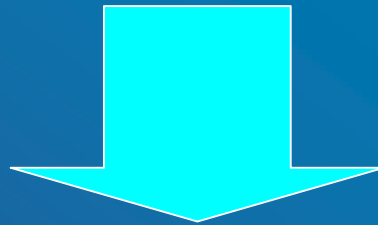
## REACH Time-Line



## JOINT SUBMISSION

**OSOR (One Substance = One Set of Data to Register)**

**Joint Submission of Registration Data and Consortia Formation  
are Strongly Encouraged.**



**Reduction in Number of Tests & Testing Costs**

## Estimated Average Testing Costs per Substance

**Physico Chemical Properties**

**35 196 €**

**Toxicological Studies**

**1 629 788 €**

**Ecotox and Environmental Studies**

**276 369 €**

**TOTAL COSTS**

**1 941 353 €**



## Consortium REACH Registration Costs

March 1<sup>st</sup> 2007 to Dec 2010

### CONSORTIUM

Set Up, Management, Resources                      2,000,000 €

### TESTING, ASSESSMENT & REPORTING PROGRAMMES

1,000,000 to 2,000,000 € per substance

### 5 Substance Equivalents for Manganese

5,000,000 € to 10,000,000 €

**TOTAL            7,000,000 € to 12, 000,000 €**  
**(March 1<sup>st</sup> 2007 to Dec 2010)**

Based on European Commission costs estimates AND experience with mandatory and voluntary risk assessments of a number of metals and their compounds. Includes allowance for consultant/expert adviser fees



# REACH: IMnI's Action Plan

## IMnI Aims to Provide Full-Scale REACH Support for All Producers or Importers of Mn into the EU

- Presently Preparing a Draft Consortium Agreement (Operating Rules for the Consortium)
- Determining the Mn Substance Portfolio: 15-20 Substances
- IMnI will be coordinating the REACH Mn Consortium

For more Information about REACH contact us at:

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Questions?

Thank You!