



THE REACH PROCESS



What is REACH ?

- A new European regulation for the
 - **Registration, Evaluation and Authorisation of Chemicals**
 - In order to improve protection of human health and the environment from the risks of chemicals
 - replacing 40 existing legal acts
 - creating a single system for both all « existing » and « new » **Chemical Substances**

How will REACH work ?

- **Principle** : Industry is best placed to ensure that Chemicals manufactured and marketed have no adversely effect on human health and the environment
 - Industry develops knowledge of the properties of its substances and manages potential risks
 - European Authorities ensure industry are meeting their obligations and focus action on substances of very high concern and on Community action

Scope of REACH

- REACH covers all substances
 - whether manufactured or **imported**
 - on their own or in preparations or articles
- unless certain exemptions like
 - substances covered by other regulations
 - non-isolated intermediates
 - food
 - waste which is specifically exempted
- “Isolated intermediates” will have to be registered but with simplified information requirements

Scope of REACH

- REACH especially scrutinizes substances of very high concern
 - Carcinogens (category 1 and 2)
 - Mutagens (category 1 and 2)
 - Substances which are toxic to reproduction (category 1 and 2)
 - Persistent, bio-accumulative and toxic substances (PBTs)
 - Very persistent and very bio-accumulative (vPvB)
 - Substances identified from scientific evidence as causing equivalent concern (e.g. : endocrine disruptors)
- 900 very high concern substances are already listed, 600 more expected

REACH Agenda for phase-in* substances

* with EC # (EINECS or ELINCS)

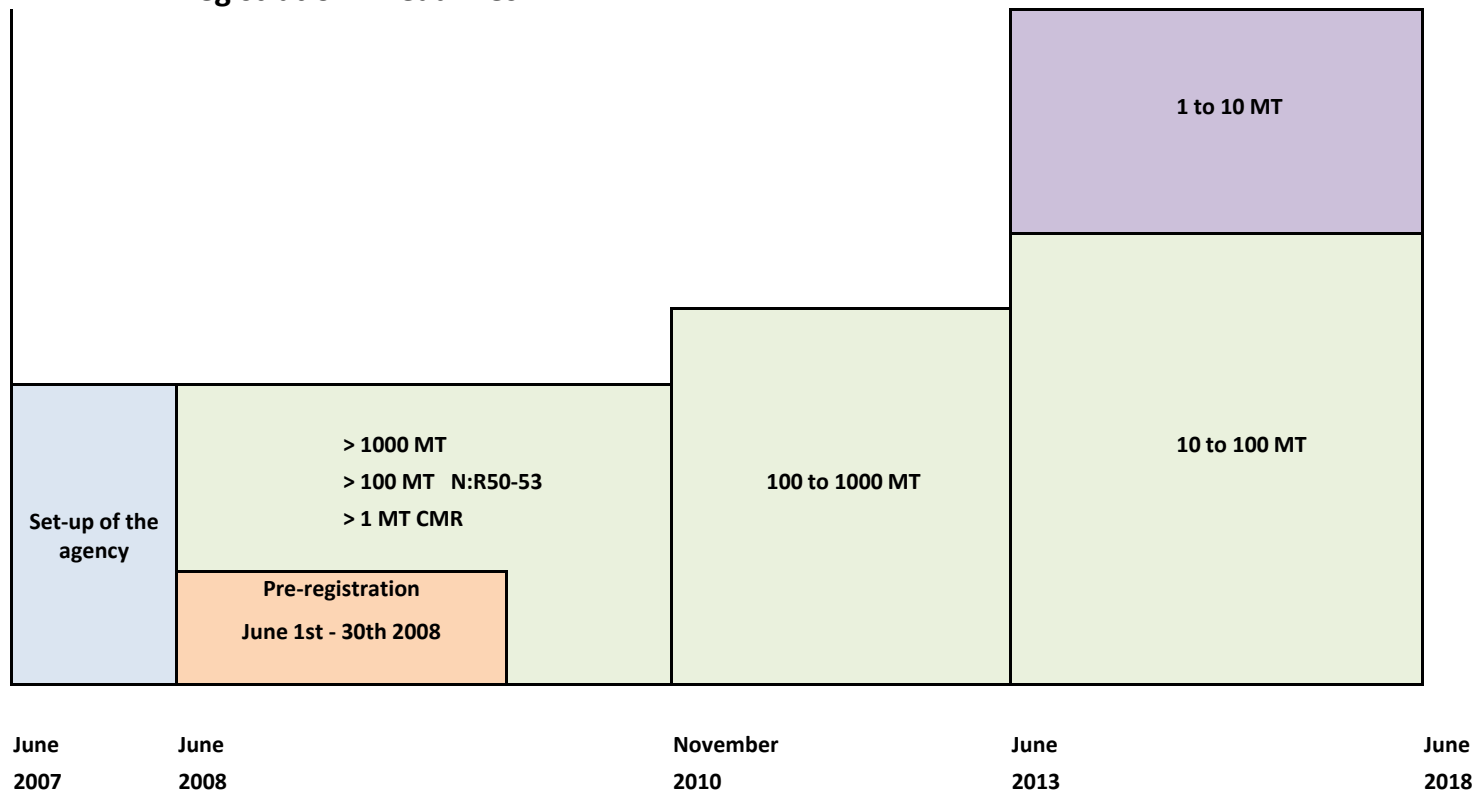
- June 2007 : Start-up of the process
- June 2007 - June 2008 : Agency (Helsinki) start-up
- June 2007 - June 2008 : Companies getting prepared
- June 2008 - Dec. 2008 : Pre-registration of substances/preparations

REACH Agenda for phase-in* substances

- Jan. 2009 : Publication by agency of pre-registration lists in order to facilitate partnerships (consortia)
- Dec 2008 -Nov 2010 : Registration of substances/preparations
 - 1000 tons +
 - CMRs 1 ton +
 - PBTs/vPVBVs (R50-53) 100tons +
- Nov 2010 - June 2013 : Registration of substances/preparations 100-1000 tons
- June 2013 - June 2018 : Registration of substances/preparations 1-100 tons

REACH Deadlines

Registration : Deadlines



REACH Pre-registration

- **Starting point for Manufacturers/importers**
 - Aim :
 - Share Data between registrants
 - Agree on generation of new test data in Substance Information Exchange Forums (SIEFs)
 - Joint registrations

In order to

- Reduce costs to industry
- Reduce testing on vertebrate animals

REACH Registration

- Manufacturers and importers obtain information on their substances and use this knowledge to ensure responsible and well-informed management of the risks these substances may present throughout their life cycle.
- The Registration Dossier is a documentation composed of
 - Technical Dossier (starting at 1 ton/year)
 - Chemical Safety Report (starting at 10 ton/year)

REACH Registration

- There is no formal acceptance, the industry retains responsibility
- The registrant must be an European entity
- About 30,000 phase-in substances are expected to be registered over the first 11 years after the entry into force of REACH + “non-phase-in” substances
- Will be done in an electronic format (IUCLID)
- Help and guidance will be provided

REACH Registration

- **Registration dossier content**
 - Technical Dossier about the substance to be registered
 - Identification of the manufacturer/importer
 - Identification of the substance
 - Information on manufacture and use of the substance
 - Classification and labelling
 - Guidance on safe use of the substance
 - Study summaries - substance properties
 - Test proposals (if relevant)
 - Exposure information

REACH Registration

- **Registration dossier content (continued)**

Additional information for substances above 10 tons

- Chemical Safety Report
- Hazard and PBT assessment

Additional information if substance is dangerous or PBT/vPvB

- Exposure assessment
- Risk characterization
- Exposure scenarios

Technical Dossier contents

- The technical dossier contains information about the properties, uses and classification of a substance as well as guidance for safe use (See annex VI pp 306-315)
 - New tests are only required when it is not possible to provide information in any other permitted way
 - Use of (Quantitative) Structure Activity Relationship (Q)SARs is encouraged
 - Certain tests may be waived if not required by the use of the substance
- List of information required depends on tonnage

Chemical Safety Report

- The Chemical Safety report
 - documents the hazards and the classification of a substance
 - assesses whether the substance is PBT or vPvB
 - describes the exposure scenarios for all « identified uses »

Exposure scenarios

- The exposure scenarios include appropriate risk management measures and operational conditions that ensure (when properly implemented) that the risks are adequately controlled
 - For all identified uses by the manufacturer /importer itself
 - For uses made known by downstream users
- Relevant exposure scenarios will be annexed to Safety Data Sheets

Information in the supply chain and downstream users (DUs)

- REACH requires that not only Manufacturers and Importers but also their customers (users and distributors) have the information they need to use Chemicals safely
 - The primary tool for information transfer is the Safety Data Sheet (SDS)
 - Where Chemical Safety Assessment are performed, exposure scenarios shgall be annexed to the SDS

REACH Evaluation

- **Dossier evaluation** : the agency (ECHA) will do a quality check of the registration dossiers
 - Compliance check (at least 5% of the dossiers should be checked)
 - Checking of testing proposals
- The agency will do **substance evaluations** to clarify suspicions of risks to human health or the environment

REACH Authorisation

- Around 1500 substances of very high concern may become subject to Authorisation
- These substances to be progressively replaced wherever they cause unacceptable risks to human health
- Authorisation will be granted to manufacturers/importers that can show that the risks in question can be adequately controlled and no safer alternative exists

REACH Classification and labelling

- REACH builds on existing legislation
 - Industry will be required to submit all its classifications to the agency, to be included in the inventory 3,5 years after entry into force of REACH
 - A Global Harmonised System for classification and labelling (GHS) has been put in place by the European Commission

REACH Sources of information

- ESIS (European Substance Information System) :
<http://ecb.jrc.it/>
- OECD : <http://www.oecd.org>
- Guidance for importers : <http://ecb.jrc.it/REACH/>
- ECHA (European Chemicals agency) :
<http://www.echa.europa.eu>

REACH : Commented Glossary 1

- **CMR substances : Carcinogenic, Mutagenic or Toxic to Reproduction**
 - CMR substances class 1 and 2 are especially under scrutiny
 - A complete list of the substances classified as CMRs can be found, for example, on the French INERIS or INRS websites

- **CSR : Chemical Safety Report**
 - Obligation to present a CSR starts at 10 tons quantities for manufactured or imported substances. It documents the hazards and classification of a substance and assesses whether the substance is PBT or vPvB. It also describes exposure scenarios (ES)

REACH : Commented Glossary 2

- **CSA : Chemical Safety Assessment**
 - Basis of Chemical Safety Reports
- **DU : Downstream Users**
 - Downstream users are brought into the system by REACH
- **ECHA : European CHemicals Agency**
 - This Agency is created within the REACH process to monitor REACH implementation. It is currently put in place and due to be operational by June 2008. It will be located in Helsinki (Finland)
- **EINECS : European Inventory of Existing Chemicals**
 - An European inventory of substances put on the market from 1/1/71 through 18/9/1981. It encompasses more than 100,000 substances with information about their physical and ecotoxicological properties

REACH : Commented Glossary 3

- **ELINCS** : European List of Notified Chemical Substance
 - Created since 1981 for new substances (4,000). Forms with EINECS the “CE”#
- **ES** : Exposure Scenario
- **ESIS** : European Substance Information System

REACH : Commented Glossary 4

- **GLP : Good Laboratory Practice**
 - A set of laboratory conditions that guarantee the quality of tests performed. Only mandatory for toxicological and eco-toxicological tests and analyses
- **HPV Chemicals : High Production Volume Chemicals**
 - OECD has initiated a co-operative programme for testing and assessing **HPVs**. For most HPV Chemicals, data sharing agreements exist as data submissions have taken place several times in the past (ESR, ICCA, US HPV,...)
- **IUCLID : International Uniform Chemical Database**
 - IUCLID is a software programme for the administration of database on chemical substances. This is the electronic tool for data submission, evaluation and exchange used in the HPV chemicals programme. It will also be used for the REACH process

REACH : Commented Glossary 5

- **PBT substance : Persistent, Bioaccumulative and Toxic substance**
 - Those Substances of very high concern may become subject to authorization as a priority
- **vPvB substance : very Persistent and very Bioaccumulative substance**
- **(Q)SAR : (Quantitative) Structure Activity Relationship**
 - (Q)SAR models are used to estimate properties of a chemical from its molecular structure. They have the potential to provide information on hazard of chemicals while reducing time, costs and animal testing
- **REACH : Registration, Evaluation and Authorisation of CHemicals**

REACH : Commented Glossary 6

- **SDS : Safety DataSheet**
and **e-SDS : extended Safety DataSheet**
 - SDSs are the tools to communicate hazards of chemicals and methods to control them. Exposure scenarios and specific recommendations must be attached to the existing SDSs and communicated to Downstream Users
- **SIEF : Substance Information Exchange Forum**
 - Forums of manufacturers, importers, downstream users, distributors,... encouraged by REACH to share information on substances and save costs