

REACH

Kees van Leeuwen

Tim Bowmer

Dinant Kroese

TNO Quality of Life
Zeist, The Netherlands

Why are we here today?

- **The REACH legislation is complex**
- **Most guidance documents are not yet available**
- **We will try to explain it**
- **Because of our intensive involvement in REACH we realize that there are many devils in the details.**

Presentations and questions on:

- A. General introduction on REACH**
- B. Registration and pre-registration**
- C. Data requirements & exposure scenarios**
- D. Chemical safety assessment**

REACH

GENERAL INTRODUCTION

Kees van Leeuwen

**TNO Quality of Life
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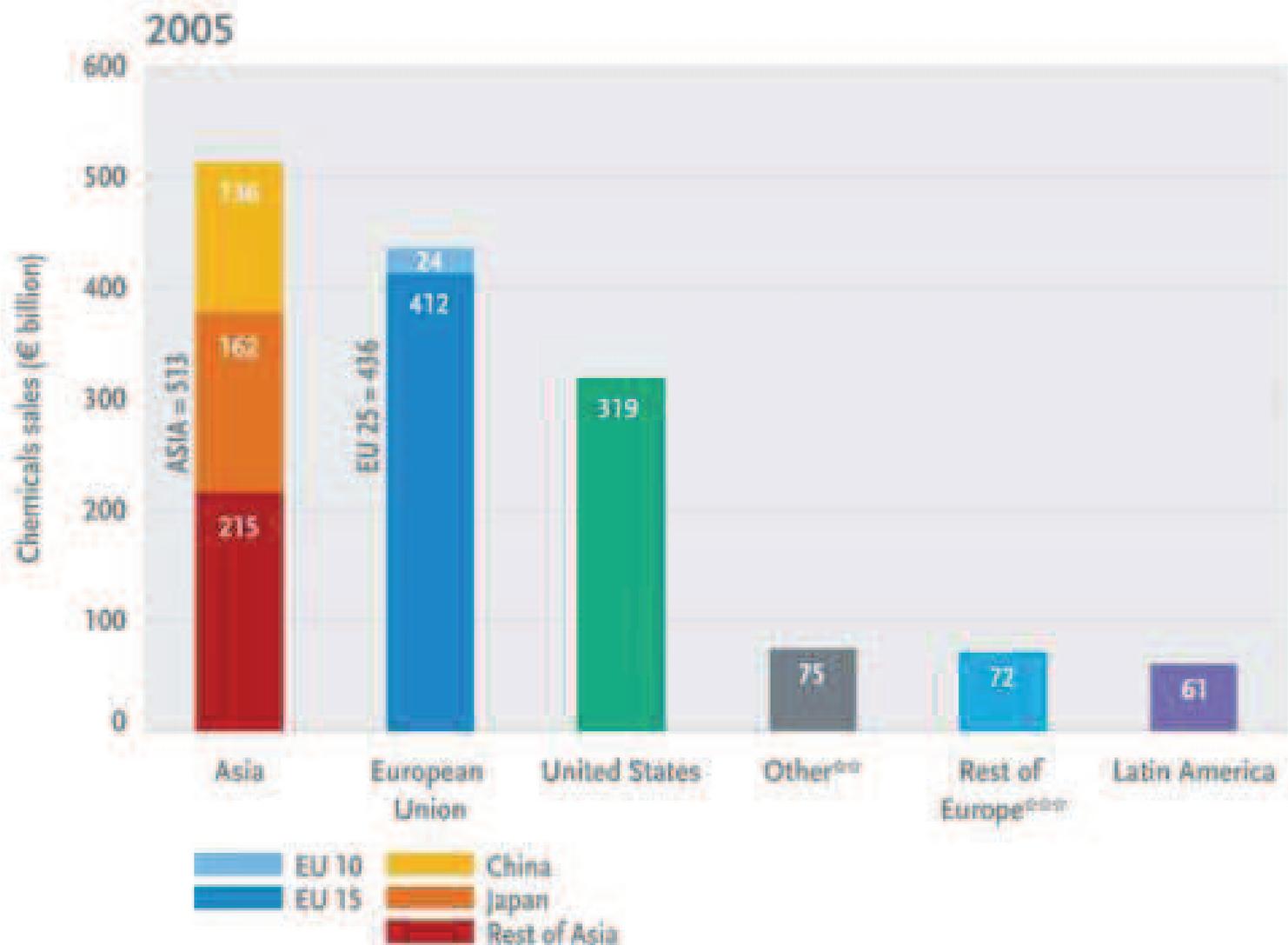
- 1. History**
- 2. Key elements of REACH**
- 3. Basic structure of REACH**
- 4. Stakeholders in REACH**
- 5. Timelines for REACH**
- 6. Guidance and tools**

1. HISTORY

- Feb 2001 White Paper published
- Summer 03 Internet consultation
- 29/10/2003 Proposal adopted by Commission
- 17/11/2005 Parliament Opinion in First Reading
- 26/06/2006 Council Common Position adopted
- 13/12/2006 Parliament Opinion in Second Reading
- 18/12/2006 Regulation adopted

Importance of the chemical industry

- In 2005 world production of chemicals reached €1500 billion
- Employment: approximately 12 million people world-wide (OECD 1998)
- In OECD countries, chemicals and chemical products represent 14% of total imports and exports of manufactured goods.
- According to the OECD chemicals make up as much as 12% of some countries' gross domestic product (GDP)."



World chemicals sales (excluding pharmaceuticals) in 2005 are estimated at € 1476 billion
The EU accounts for 30% of the total

Sources: Cefic, ACC, VCI and Global Insight

^{*} Excluding pharmaceuticals

^{**} Including Canada, Mexico, Africa & Oceania

^{***} Switzerland, Norway, and other Central & Eastern Europe (excluding the new EU 10 countries)

2. Key elements of REACH

- **Single Coherent System** for new (non phase-in) and existing (phase-in) substances
- **Responsibility** for all manufacturers and importers
- **Registration** of substances produced/imported above 1 tonne/year
- **Evaluation** by the Agency and Member States
- **Authorization** for substances of very high concern
- **Restrictions** - the safety net
- **Agency** to manage the system

Scope of REACH

- **REACH has a very wide scope.** It applies to all chemical substances which are manufactured, imported, placed on the market or used within the European Community, either on their own, in a preparation or in an article.
- **Some substances are exempted** from the overall scope of REACH while others are exempted from certain provisions

Core tools under REACH

- The Chemical Safety Assessment (CSA) is the tool used to ***determine***
- The Chemical Safety Report (CSR) is the tool used to ***record/document***
- The Safety Data Sheet (SDS) is the tool used to ***communicate***

3. Basic structure of REACH

- Final version (corrigendum) published in OJ L136, volume 50, on 29 May 2007
- 141 articles
- In 15 Titles
- With 17 annexes

OJ = Official Journal of the European Union

Structure of REACH

Title I	General issues
Title II	Registration of substances
Title III	Data sharing and avoidance of unnecessary testing
Title IV	Information in the supply chain
Title V	Downstream users
Title VI	Evaluation
Title VII	Authorization
Title VIII	Restrictions on the manufacturing, placing on the market and use of certain dangerous substances and preparations

Structure of REACH

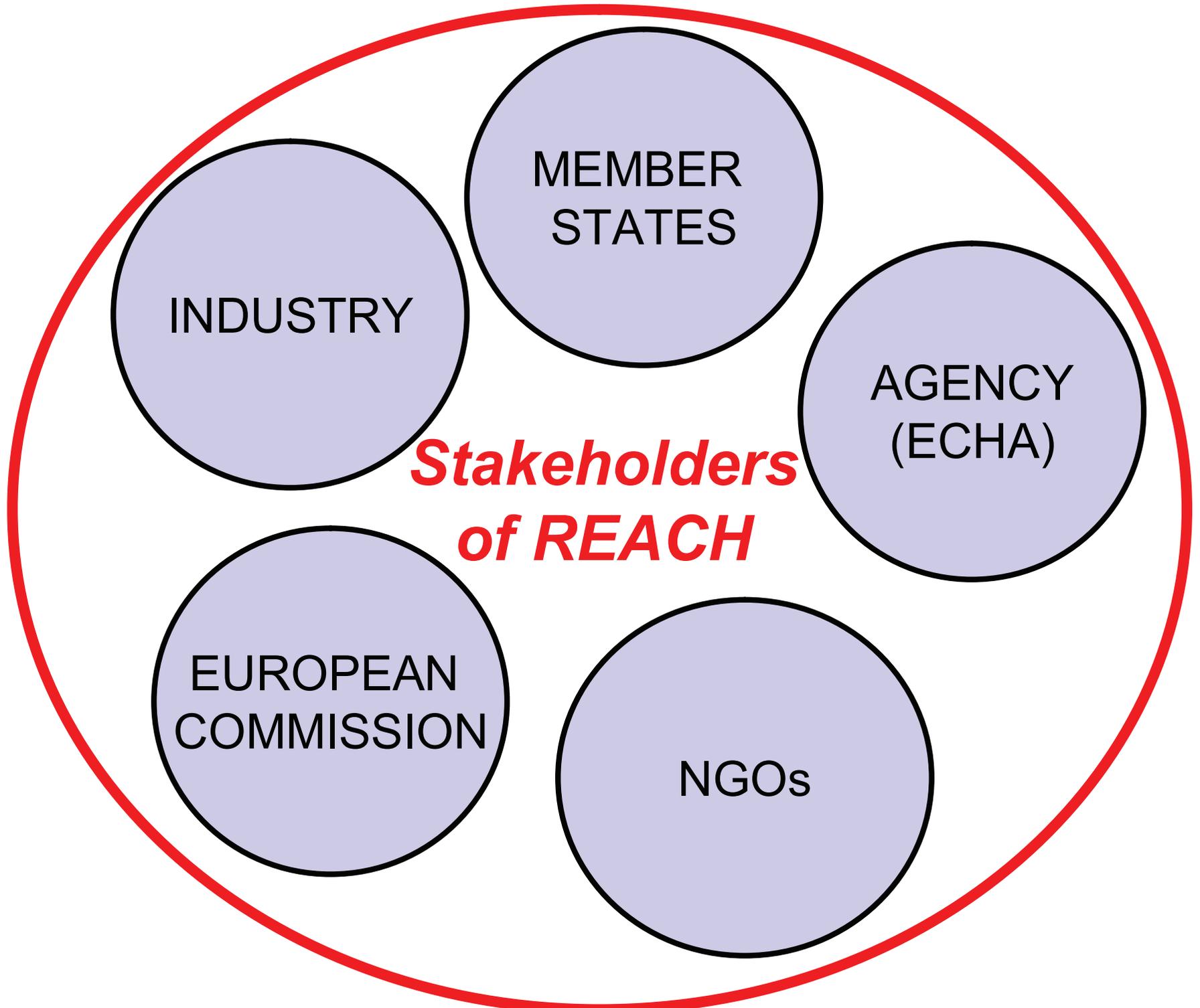
Title IX	Fees and charges
Title X	Agency
Title XI	Classification and labelling inventory
Title XII	Information
Title XIII	Competent authorities
Title XIV	Enforcement
Title XV	Transitional and final provisions
Annexes	There are 17 annexes

4. Industry stakeholders in REACH

1. Manufacturers and importers of substances in quantities < 1 tonne/y
2. Manufacturers of substances in quantities of ≥ 1 tonne/y
3. Importers of substances and preparations in quantities of ≥ 1 tonne/y
4. Producers of articles
5. Importers of articles
6. Downstream Users

Appendix 1 of the Guidance on Registration

(see Websites of ECB & ECHA) provides detailed guidance on the different roles and responsibilities



5. Timelines for REACH

1 June 2007

Titles I, IV, XII, XIII commence
Agency (Title X) commences in Helsinki, FIN

1 June 2008

Titles II, III, V, VI, IX, XI commence
Begin registration of new substances

1 December 2008

Deadline for pre-registration of all phase-in substances

1 June 2009

First recommendation for Annex XIV substances (every 2 y)
Title VIII and Annex XVII applies (76/769 repealed)

Timelines for REACH

30 November 2010

Registration deadline for substances of 1000 tonnes and more
+R50/53 substances 100 tonnes and more
+CMR substances 1 tonne or more

1 December 2011

First Community Rolling Action Plan

31 May 2013

Registration deadline for substances of 100-999 tonnes

31 May 2018

Registration deadline for substances of 1-99 tonnes

Registration under REACH

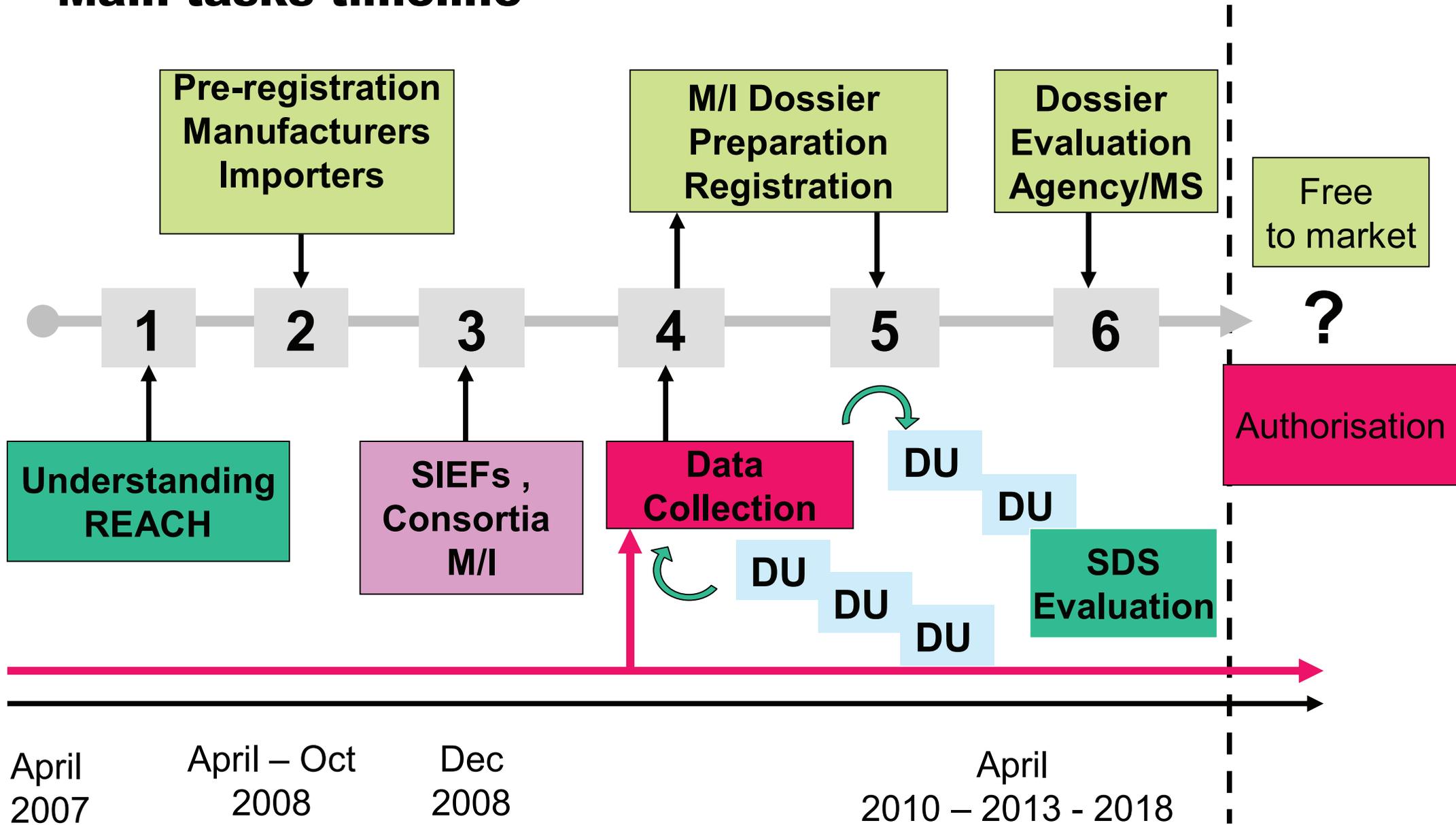
Aim: to ensure that industry adequately manages the risk arising from its substances (starting at 1 tonne/y)

Method:

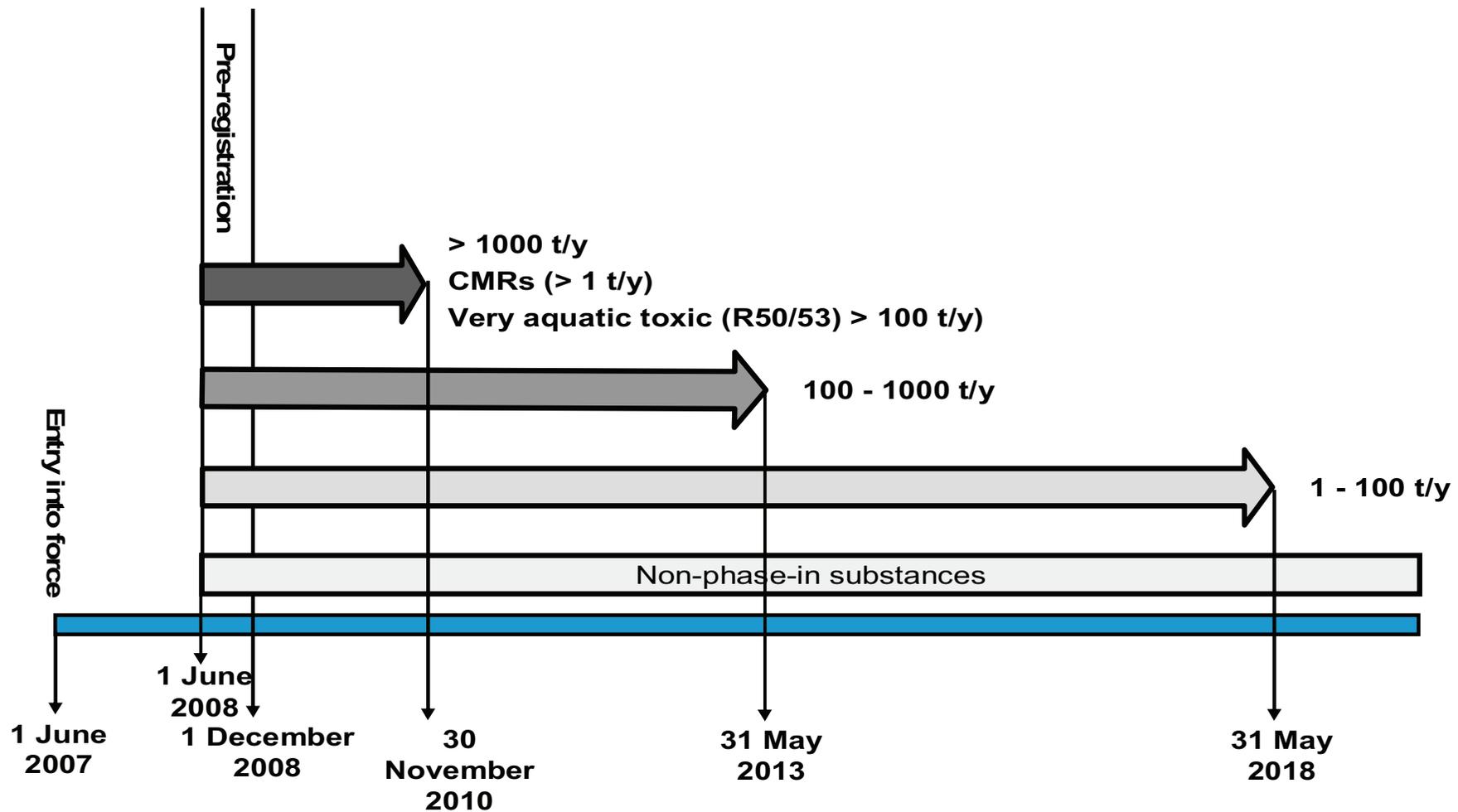
- Manufacturer/importer obtains adequate data
- Provides a registration dossier which includes a chemical safety report for substances above 10 tonnes/y
- Submits to authorities (enforcement, transparency)
- Increased info requirements according to tonnage (testing proposal)
- Reduced requirements for polymers and intermediates

REACH

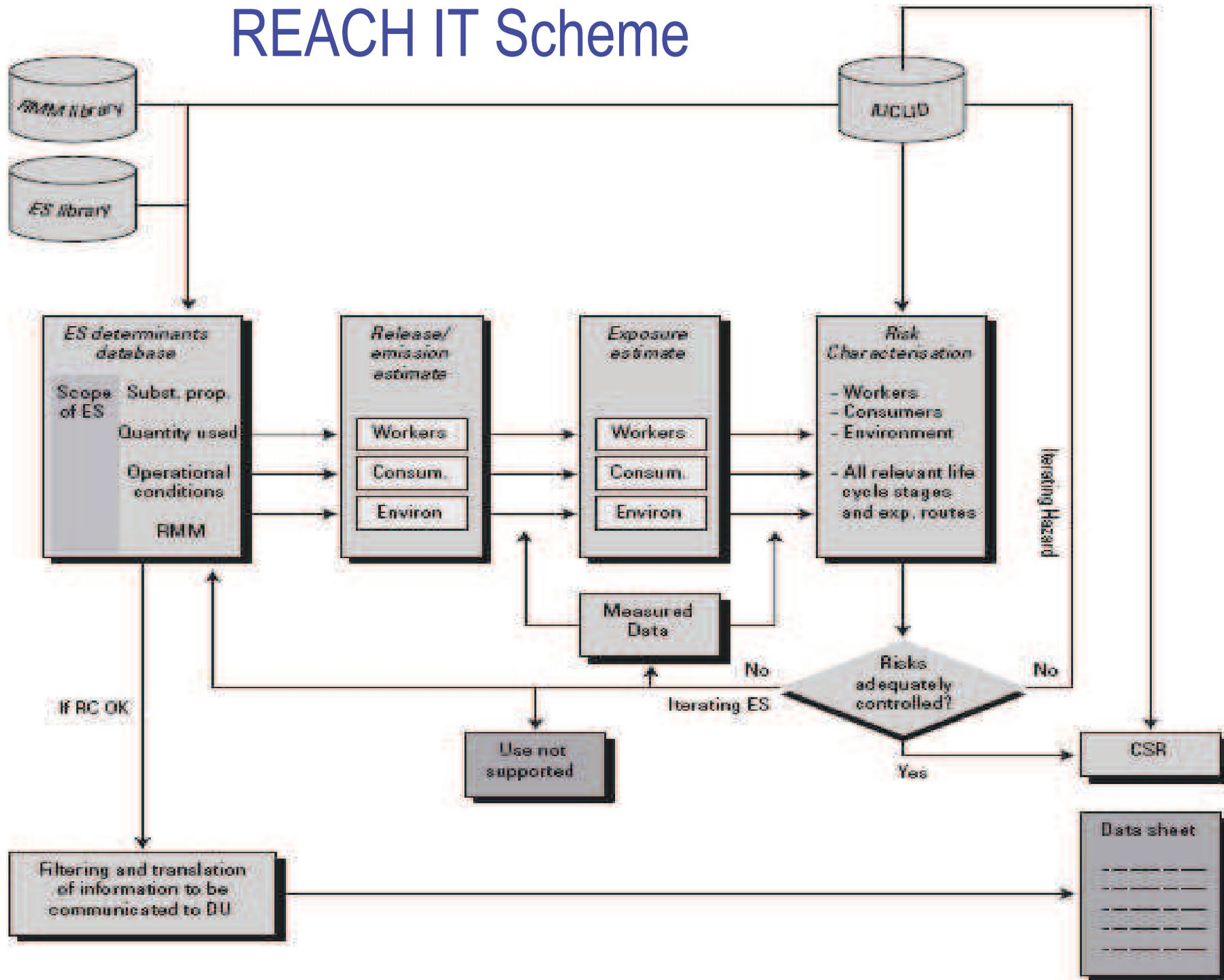
Main tasks timeline



Registration timelines



REACH IT Scheme



Authorization under REACH

- Deals with CMR (category 1 or 2), PBT, vPvB, and substances of “equivalent concern”
- Focus on wide dispersive use and high volumes
- Prioritized by the Agency with input from the Member States
- Considerations:
 - The risks and adequate control of these risks
 - Social and economic benefits/implications
 - The analysis of alternatives submitted
 - Available information on risks of any alternative substances or technologies
- Commission decision on authorization based on Agency opinion (Inclusion in Annex XIV)

6. REACH guidance and tools

- RIP 1: Process description
- RIP 2: Development of REACH-IT
 - IUCLID-5
 - Reach Navigator
 - REACH-IT
- RIP 3: Guidance documents for industry
- RIP 4: Guidance documents for authorities
- RIP 5/6: Setting up the Agency

Comprehensive guidance and tools

Multi-stakeholder process of over 200 experts

- 6 RIP Projects finalised
- REACH Navigator Tool is ready
- IUCLID 5 is ready

Sources:

<http://iuclid.eu>

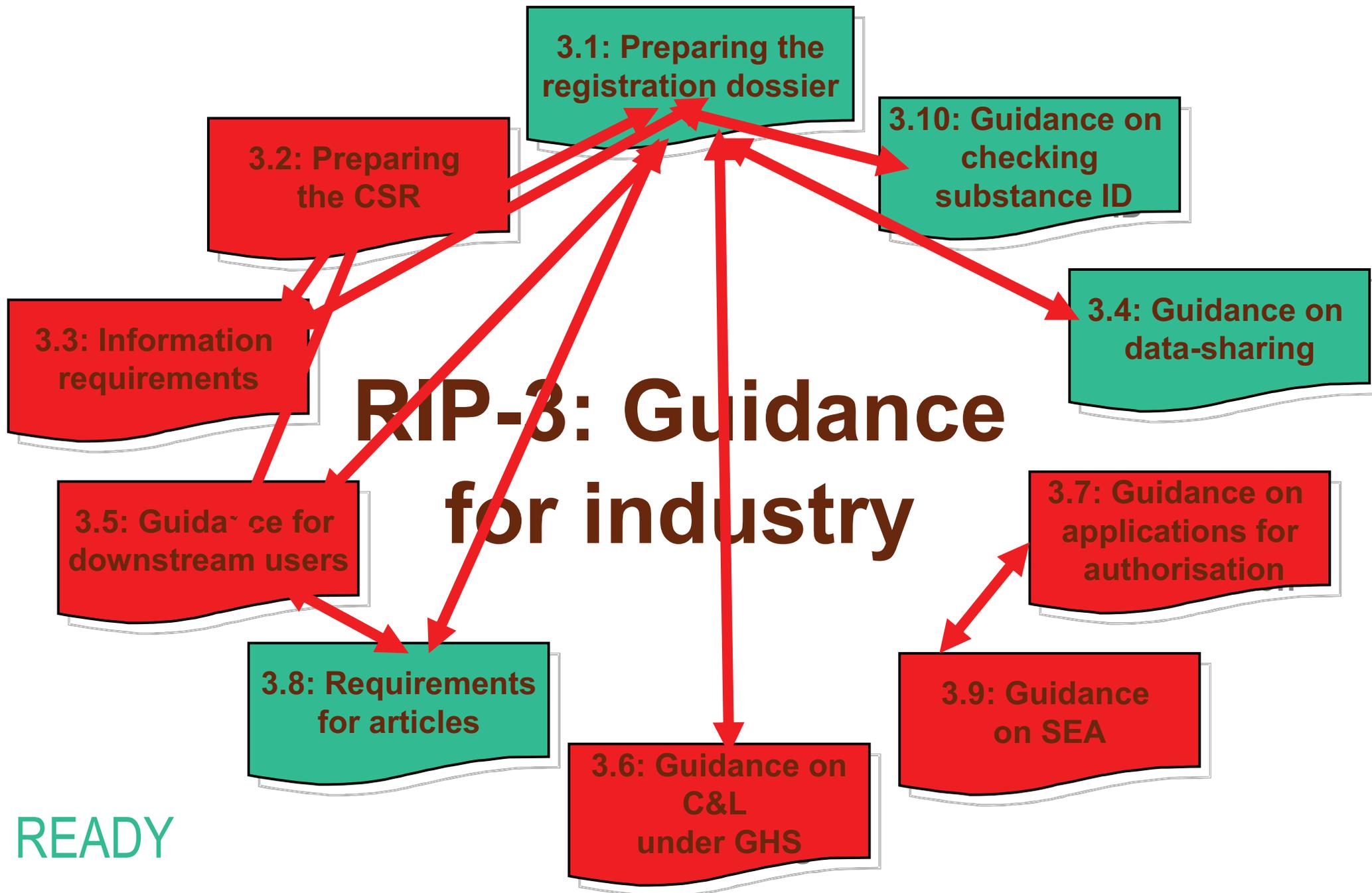
<http://ec.europa.eu/echa>

<http://ecb.jrc.it/reach/>

Comprehensive guidance and tools

But also:

- 8 RIP Projects still running
 - 1 RIP Project (3.6) still to start
 - Not all guidance is comprehensive and concise
1. Implementation will be a long process
 2. A process of “learning by doing”
 3. Quality and acceptance take time



- READY

- PENDING

4.1: Guidance on dossier evaluation

4.2: Guidance on substance evaluation

4.3: Inclusion of substances in Annex XIV

4.4: Preparation of Annex XV dossiers

4.5: Priority setting for evaluation

RIP-4: Guidance for authorities

- **READY**
- **PENDING**

Further information on guidance and tools:
<http://ecb.jrc.it/REACH/>

REACH (Registration, Evaluation and Authorisation of CHEMICALS) 

HOME DOCUMENTS CALLS FOR TENDER REACH PROPOSAL RIP PROJECTS STRATEGIC PARTNERSHIPS USEFUL LINKS

Biocides
Classification & Labelling
Existing Chemicals
Export-Import
New Chemicals
Testing Methods
QSARs
REACH
EB18
INFOCAP
Contacts
Documents
Legislation

A proposal on a new EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH) was adopted 29 October 2003. REACH aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. ECB has the responsibility of developing methodologies, tools and technical guidance needed for REACH through a number of REACH Implementation Projects (RIPs). This is managed under Action no 1313 - Support to future chemicals legislation (REACH) or in short *REACH Support*.

Contact Person - Action Leader: [Jack de Bruijn](#)

REACH Overview

On 27 February 2001 the Commission issued a White Paper on a Strategy for a future Chemicals Policy. This has subsequently been developed and extensively discussed with major stakeholders, resulting in the release on 29th Oct 2003 of the Commission's proposal (REACH).

Under REACH enterprises that manufacture or import more than one tonne of a chemical substance per year would be required to register it in a central database. REACH would furthermore give greater responsibility to industry to manage the risks from chemicals and to provide users in the supply chain with safety information on the substances.

The proposal is now being considered by the European Parliament and the Council of the EU for adoption under the so-called co-decision procedure

<http://ec.europa.eu/echa/>



HOME

REACH

CLASSIFICATION

PRESS & EVENTS

ABOUT ECHA

WORKING WITH US



European Chemicals Agency (ECHA)

The Agency, located in Helsinki, Finland will manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry.

In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimize animal testing.

During the first 12 months the Agency is building up its organisation and recruiting personnel to be ready to accept registrations from 1 June 2008.

[More](#)

Relevant websites

- ❑ Website of the European Chemicals Bureau: <http://ecb.jrc.it/reach/>
- ❑ Website of the European Chemicals Agency: http://ec.europa.eu/echa/home_en.html
- ❑ Websites of the European Commission
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
http://ec.europa.eu/enterprise/reach/index_en.htm
- ❑ http://ecb.jrc.it/DOCUMENTS/REACH/REACH_in_brief_0207.pdf
- ❑ Helpdesks of the EU member states, i.e.:
<http://www.reachright.ie>
<http://www.senternovem.nl/reach>

Relevant references

- ❑ Haigh N Baillie A. 1992. Final report on chemicals control in the European Community in the 1990s. Institute for European Environmental Policy, London, UK.
- ❑ Van Leeuwen CJ, Bro-Rasmussen F, Feijtel TCJ, Arndt R, Bussian BM, Calamari D, Glynn P, Grandy NJ, Hansen B, Van Hemmen JJ, Hurst P, King N, Koch R, Müller M, Solbé JF, Speijers GAB, Vermeire T. 1996. Risk assessment and management of new and existing chemicals. *Environ Toxicol Pharmacol* 2: 243-299
- ❑ Allanou R, Hansen BG, Van Der Bilt Y. 1999. Public availability of data on EU high production volume chemicals. Report EUR 18996 EN, European Commission, Joint Research Centre, Ispra, Italy.

- ❑ Commission of the European Communities. 2007. Corrigendum to 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 (OJ L 396, 30.12.2006). OJ L136, volume 50, 29 May 2007.
- ❑ Van der Poel, P, Brooke, D and Van Leeuwen, C.J. 2007. Emissions of chemicals. In: Risk assessment of chemicals. In: Risk Assessment of Chemicals. An Introduction (2nd edition). Van Leeuwen, C.J. and T. G. Vermeire, eds. Springer Publishers, Dordrecht, The Netherlands, pp 37-72.
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- Greim, H. et al. 2006. Toxicological comments to the discussion about REACH. Arch Toxicol 80:121-124