

# **The new EU Chemicals Policy**

## **REACH**

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- **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**



**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

**Scope:** manufacture, import, placing on market and use of substances (on their own, in mixtures or in articles) in Europe

**Impacts every company doing business in or exporting to Europe**

- Introduces a Single Coherent System for new (non phase-in) and existing (phase-in) substances
- Registration of manufactured/imported chemical substances > 1 tonne/year (Various dead-lines over a 11 years period)
- Increased information and communication throughout the supply chain – changes to SDS requirements
- Evaluation of some registered substances
- Use of substances of very high concern will require Authorisation
- Restrictions: “Safety net”
- Classification and Labelling Inventory (GHS Regulation)
- Chemicals Agency to manage the system.
  - REACH-IT including IUCLID 5

- 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
- Documentation: Electronic Registration dossier submitted to the Chemical Agency
- Certain non-confidential information to central (largely public) database
  - Intermediate list of pre-registered substances is available
  - Final list will be published January 1, 2009

## Scope

- Substances M/I  $\geq 1$  tonne/year
- Exemptions: other law, Annex IV/V; polymers (review); PPORD (Product and Process Orientated Research and Development)
- Considered as registered: biocides, pesticides, notified substances.

## No formal acceptance - industry retain responsibility

- Substance Information Exchange Forums (SIEFs)
- Registration requirements started June 1, 2008
- Only EU companies can register
- Non-EU companies can choose to use an Only Representative

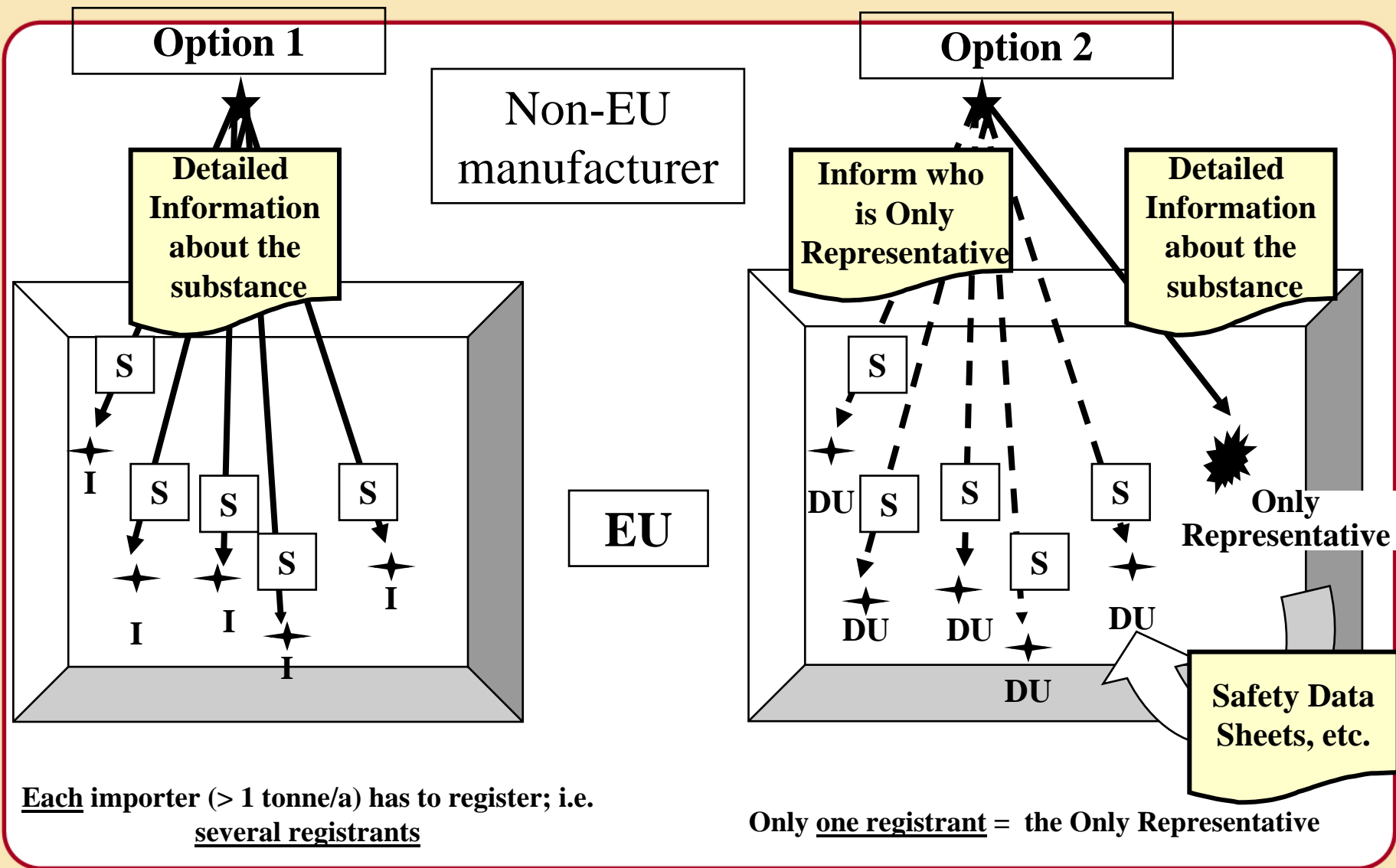
## TITLE II

### REGISTRATION OF SUBSTANCES

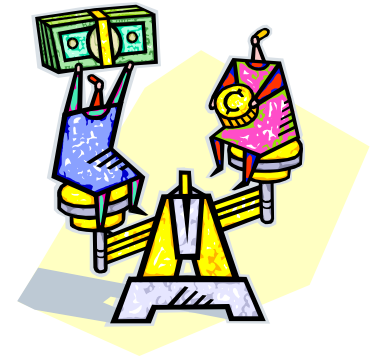
#### *Article 5*

#### **No data, no market**

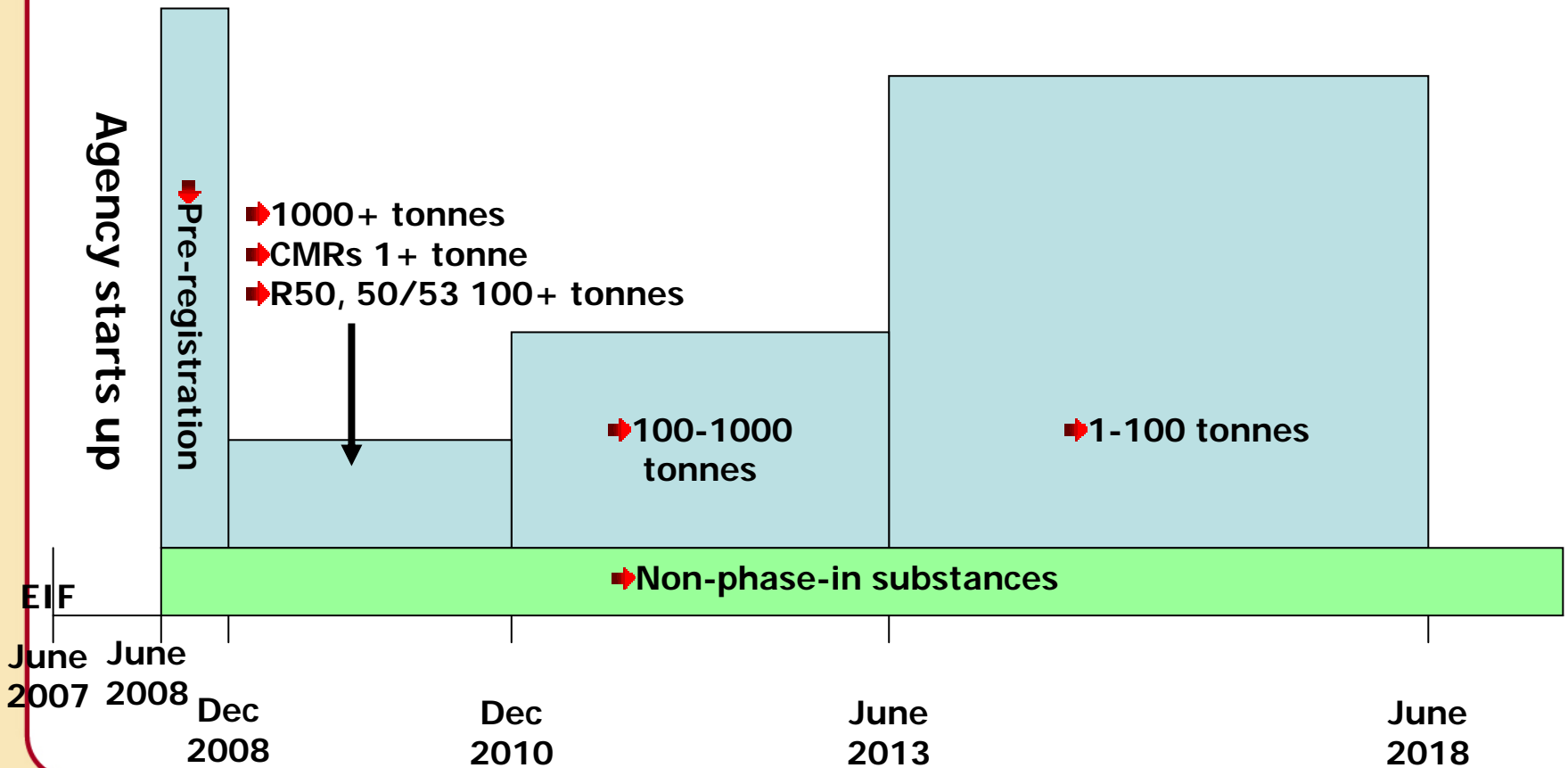
Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.



- Registration (only) by M/I
- DU has to make their use “Identified”
- Registration requirements started June 1, 2008
  
- “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



## Tonnage per manufacturer/importer



- ➡ Art 7 (1) Any article producer or importer shall Register substances contained in articles if
  - There is intended release under normal and reasonably foreseeable conditions of use AND
  - > 1 t/a per producer or importer AND
  - if not exempted (substances already registered for that use (Article 7(6)))
- ➡ Art 7 (2) Any article producer or importer shall Notify Substances of Very High Concern (SVHC) in articles if
  - they are present in those articles in amounts totalling >1 t/a per producer or importer
  - present in those articles above a concentration of 0.1% weight by weight
  - The obligation to notify shall not apply if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use and disposal of the article – but appropriate instructions must be given to the user
- ➡ Notification to take place from June 1, 2011 and six month after the substance is identified as a SVHC

Any supplier of an article must:

- Provide the recipient of the article with sufficient information to allow safe use of the article, including, as a minimum, the name of the substance, **if** the article contains SVHC in a concentration above 0.1% (w/w)
- NB!
  - There is no tonnage trigger for this requirement, which consequently also applies to < 1 tonne/year situations.
  - No exemption via article 7(6) (substance already registered)



Substance to be registered

### Technical Dossier

- Identity of the manufacturer/importer
- Info- manufacture and use of the substance, safe use
- Classification and labelling
- Study summaries – substance properties
- Test proposals (if relevant)
- Exposure information

Technical Dossier: starting at 1 tonnes per year

Data requirements described in:

Annex VI: Guidance note & Basic Information

Annex VII: 1 tonne or more

Annex VIII: 10 tonnes or more (and substances in articles)

Annex XI: 100 tonnes or more

Annex X: 1,000 tonnes or more

NB! **All available** data regardless of tonnage (REACH Annex VI – step 1) must be included

Substance to be registered



### Technical Dossier

- Identity of the manufacturer/importer
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> 10 tonne/year

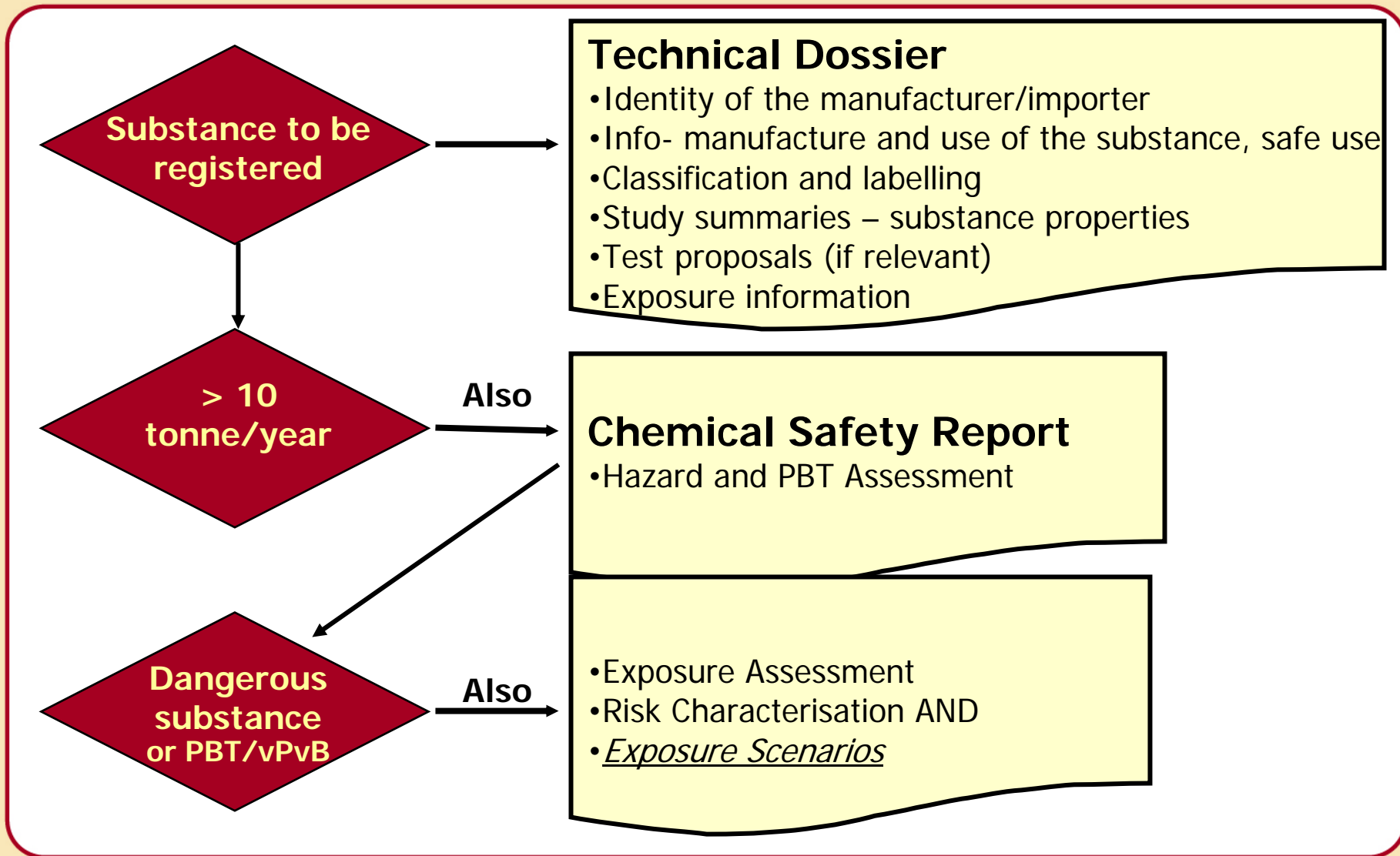
Also



### Chemical Safety Report

The CSR must document the results of the Chemical Safety Assessment. Objectives of the assessment are:

- Human health hazard assessment: determination of the classification and labelling of the substance (67/548/EEC) & derivation of no effect levels (DNELs)
- Physicochemical hazard assessment: determination of the classification and labelling of the substance (67/548/EEC)
- Environmental hazard assessment: determination of the classification and labelling of the substance (67/548/EEC) , derivation of predicted no effect concentrations (PNECs)
- Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) assessment (or substances of similar concern): comparison of the data on degradation, bioaccumulation and toxicity with the criteria available in Annex XIII of the REACH Regulation.



## Safety Data Sheets (from June 2007)

- ▶ Section 2 and 3 exchanged
  - ▶ eSDS for substances with CSR (> 10 tonnes):
    - ▶ Additional requirements for several sections of the SDS
    - ▶ Exposure scenarios to be attached (and translated)
- Applies when the substances have been registered

Authorization for use - the candidate list will be published and periodically updated by ECHA

Classification and Labeling Inventory – will be transferred to EU/GHS Regulation

- ▶ Notification of the Agency (June 2010)
- ▶ Applies to substances that have to be registered and all hazardous substances that are placed on the market
- ▶ GHS classification and labeling expected to come into force with REACH



http://echa.europa.eu/



European Chemicals Agency

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## 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](#)

### How to discover the ECHA website

The ECHA website is a single point of entry for all information on REACH. It provides access to technical guidance, frequently asked questions (FAQs), software tools and helpdesks. Here you will also find the latest updates on guidance, tools, data on chemicals and the Regulation.

[More](#)



## NEWS

- o Candidate List of Substances of Very High Concern brings new duties for companies 28/10/2008.
- o Socio-economic Analysis for restrictions begins to take shape 27/10/2008.
- o New Version of REACH-IT improves processing of pre-registrations in ECHA

- Substance Information Management (SIM) is key
  - Establish and maintain an inventory of substances: identity (cas number), tonnage, known classification (EU)
  - Develop capability to “deformulate” mixtures used in EU or exported to EU, with volume
  - Decide own REACH role for each substance (can be a dual role for same substance) – M/I or DU
  - Check if any of the substances are (likely to get) on the candidate list (for authorization) – new product development
- If Importer or Manufacturer in EU:
  - Register and participate in SIEF’s
  - Follow how REACH is implemented
- If Downstream User in EU:
  - Inform suppliers of use
- Update Safety Data Sheets

**Thank you for your attention!**