REACH: The new Chemicals Policy in Europe

Giuseppe Malinverno - Solvay S.A.
Chairman of CEFIC REACH Management Team

A brief introduction to REACH

Legal context of REACH

- **REACH Regulation adopted 18th Dec 2006 entered into force (EIF)**
  1st of June 2007

- Revolution of the European chemical policy: REACH becomes the legislative backbone for the production, import, marketing and use of chemicals

- **REACH will replace 40 legislative instruments currently in force and will affect a lot of downstream legislation**

- **REACH objectives shared by the chemical industry**
  - High level of protection of human health and the environment
  - Proper functioning of the internal market
  - Innovative and job-creating European chemical industry
  - Balance between H,S&E benefits
REACH features

(REACH states for

- Registration: coherent system designed to provide basic hazard and risk information on new and existing chemical substances manufactured in or imported into the EU
- Evaluation: in hands of the authorities to check the completeness of the registration dossiers and to ensure that risks raised by chemicals are safely controlled
- Authorization: procedure for the most hazardous substances with the aim to gradually squeeze them out of the market and consequently substitute them by safer substances, providing they are economically and technologically equivalent; Restriction process in parallel
- Burden of proof up to industry moving it away from Member States’ authorities to producing and importing companies, who will be responsible for demonstrating that substances can be used safely

European central entity (the Agency) located in Helsinki intended to facilitate the administration of REACH and ensure that the system is applied in a harmonized way across the EU

Rules for access to information: publicly available information system on internet; REACH-specific rules on the protection of confidential business information (CBI)

REACH process raises lot of legal issues (competition, intellectual property, cost compensation, …) and will be scrutinized by the general public

Changeover from the current legislation according to a transitional period over the next 15 years (deadlines for the repeal of various aspects of the current legislation and for the implementation of REACH provisions), providing pre-registration requirements are fulfilled
REACH: a compliance issue

Compliance workflow and Scope

- REACH Registration regime needs to be incorporated to the business plan since all substances and their applications need to be registered according to a clearly defined timeline.

- REACH Evaluation regime is a process organized by the Commission and National Competent Authorities ⇒ further testing (data generation).

- REACH Authorization & Restrictions regime are the two main legal systems in place for the Commission to control substances of very high concern ⇒ potential business threats.

- The communication requirements up- and down the supply chain will become more strict and demanding ⇒ concern with protection of Confidential Business Information (CBI) (composition data, uses and exposure data, ...)

REACH: a compliance issue

Workflow

- All substances
- Substances of very high concern
- Substances placed on the market
- Intended to be Released
- Candidate List
- C & L Inventory
- Restriction
- Authorization
- Registration
- Evaluation
- Substances P/H ≥ 1 t/y
- Substances in Articles ≥ 1 t/y
- Notification
- Candidate List
- Pre-Registration (phase-in S)
- C & L of CMR
- Candidate List
REACH : a compliance issue

Scope

- IN
  - All activities: manufacture, import, placing on the market, use of chemical substances
  - Chemical substances: on their own, in preparations, in articles

- OUT
  - Radioactive substances
  - Substances under custom supervision
  - Non-isolated intermediates
  - Transportation of dangerous goods by road, air, water
  - Waste
  - Substances necessary in the interest of defence (Member States decision)

Aim of Registration

- Responsibility for management of risks of substances is on the manufacturer, importer and those who place the substance on the market or use it for professional activities

- Therefore they
  - Gather and generate data on their substances
  - Use these data to assess the risks
  - Develop & recommend appropriate risk reduction measures
  - Document this information in a Registration dossier to be submitted to ECHA
What to register

- All substances manufactures
  - ≥ 1 tonne / year per manufacturer
    - Substances on their own
    - Substances in preparations
    - Substances in articles intended t

- About 30,000 substances
- Exemptions
  - Regarded as registered

- Biocides: Active substances included in Annex I, IA or IB (98/8/EC)
  - Substances on their own
  - Substances in preparations
  - Substances in articles intended t

- Pesticides: Active substances included in Annex I (91/414/EEC) or in the work programme evaluation

- New substances notified under 67/548/EEC

Who should register

- EU manufacturers and importers of substances on their own or in preparations
- EU producers and importers of articles
  (meeting criteria of Article 7(1))
- EU-based “only representatives” appointed by a manufacturer, formulator or article producer outside the EU to fulfil the registration obligations of importers
When to register

1. Phase-in substances ≥ 1 tonne CMRs ≥ 1 tonne Very toxic to aquatic organisms (R50/53) ≥ 100 tonnes
2. Phase-in substances 1-100 tonnes
3. Non phase-in substances
4. 1 June 2008
5. 1 June 2007
6. 2 routes for registering

- **Non phase-in** (or phase-in substance not pre-registered)
  - Inquiry
  - Information to be provided online in REACH-IT
    - Contact details
    - (Detailed) information on substance identity
    - Relevant information requirements
2 routes for registering

- **Non phase-in**
  - Inquiry
  - Contact of previous registrants (if appropriate)
  - Data sharing (if appropriate)
  - Registration
  - Manufacture or import

  Wait for registration number

- **Phase-in**
  - Pre-registration
  - Information to be provided online in REACH-IT
    - Contact details
    - Information on substance identity

2 routes for registering

- **Non phase-in**
  - Inquiry
  - Contact of previous registrants (if appropriate)
  - Data sharing (if appropriate)
  - Registration (joint submission if appropriate)
  - Manufacture or import

  Wait for registration number

- **Phase-in**
  - Pre-registration
  - List of pre-registered substances
  - pre-SIEF (ECHA website)
  - Contact details of:
    - other pre-registrants
    - early registrants
    - biocides, pesticides
    - Data holders after 1 Jan 09
2 routes for registering

- **Non phase-in**
  - Inquiry
  - Contact of previous registrants (if appropriate)
  - Data sharing (if appropriate)
  - Registration (joint submission if appropriate)
  - Manufacture or import
  - Wait for registration number

- **Phase-in**
  - Pre-registration
  - List of pre-registered substances
  - pre-SIEF (ECHA website)
  - SIEF (industry platform)
  - Registration (joint submission)
  - Manufacture / import

**Joint submission**

<table>
<thead>
<tr>
<th>Joint information</th>
<th>Hazard information &amp; testing proposals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Classification and labelling</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Choice</th>
<th>Chemical Safety Report</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Guidance on safe use</td>
</tr>
<tr>
<td></td>
<td>Quality assessed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company specific</th>
<th>Company and substance identity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Manufacture and uses</td>
</tr>
<tr>
<td></td>
<td>Exposure information</td>
</tr>
</tbody>
</table>
Joint submission

<table>
<thead>
<tr>
<th>Joint information</th>
<th>This part must be submitted by the Lead registrant</th>
</tr>
</thead>
</table>
| Choice            | Chemical Safety Report  
|                   | Guidance on safe use  
|                   | Quality assessed |
| Company specific  | Company and substance identity  
|                   | Manufacture and uses  
|                   | Exposure information |

Separate submission

- A registrant may submit information separately (opt-out) if:
  - Joint information would be disproportionally costly for him
  - Information is commercially sensitive
  - Disagreement with the lead on selection of this information

- Justification of the above must be provided along with the dossier
**Notified substances**

- **Considered as registered**
- **ECHA must assign a registration number by 1 December 2008. To receive this number:**
  - Notifiers must identify themselves in REACH-IT
  - Claim their registration number
  - If no issue with notifier identity, registration number is sent
  - In case of problem, the Competent Authority is informed for verification

  **Contact your Competent Authority:**
  your current notifications must be up-to-date, in particular the identity of the notifier!

**Notified polymers**

- **Considered as registered**
- **Registration number assigned by ECHA (same as notified substances)**
- **When the notified polymer passes the next tonnage threshold,**
  - a registration is required for the monomer(s)

  **Updated guidance available on ECHA website**
PPORD notifications

- 2 routes to prepare the notification
  - Offline in your IUCLID installation, starting now!
  - Online in REACH-IT, starting 1 June 08
  - Submission process: same as for the registration dossier, incl. fee payment

- Manufacture or import may start 2 weeks after notification if no indication of the contrary by ECHA

PPORD notifications

- Extension of current PORDs
  - Must be submitted as PPORD by 2 June 2008 at latest
  - with an indication of the current PORD number
  - Contact your Competent Authority for further information
REACH: a compliance issue

Benefits of pre-registration
- Supply continuity: it allows manufacturing/importing/using of substances to continue after 1 June 2008; supply chain is secured
- SIEF set up to organize the registration phase (collection and selection of available data, existing data sharing and collective generation of missing information)

Drawbacks of non-registration
- Supply discontinuity: from 1st December 2008, activities (manufacture/import) are suspended up to the substances is registered; break down of supply chain
- Breach of the REACH Regulation: no pre-registration by 1st December 2008 but continuation of manufacturing/importing; downstream uses of these substances are at risk

Preparing for REACH

CEFIC: “The 12-step programme”

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Produce your company inventory of chemical substances and preparations</td>
</tr>
<tr>
<td>Step 2</td>
<td>Define for each substance &amp; preparation your status (M/I, distributor, DU, legal entity) and your position in the supply chain</td>
</tr>
</tbody>
</table>
| Step 3 | Establish whether individual substances & preparations fall into following categories:  
  - Manufactured by your company in the EU  
  - Imported by your company to the EU  
  - Purchased by your company from a supplier established in EU |
| Step 4 | Establish for manufactured and/or imported polymers from which monomers they are made |
| Step 5 | Establish for manufactured or imported substances and preparations also their composition, i.e. the substances contained in each preparation |
| Step 6 | Identify the CAS numbers of manufactured and imported substances and, if possible, the EINECS or ELINCS number |
Preparing for REACH

♦ CEFIC: “The 12-step programme”

<table>
<thead>
<tr>
<th>Step 7</th>
<th>Identify and list your customers (per substance and/or preparation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-If you are Manufacturer/Importer (Registrant): Go to step 8</td>
<td></td>
</tr>
<tr>
<td>-If you are a Downstream user: Go to step 11</td>
<td></td>
</tr>
<tr>
<td>Step 8</td>
<td>Collect all available information regarding intrinsic properties</td>
</tr>
<tr>
<td>Step 9</td>
<td>Ensure that data/information owned by your company remains the property of the company</td>
</tr>
<tr>
<td>Step 10</td>
<td>Establish which legal entity of your group of companies is involved as a manufacturer or importer or both for which substance/preparation</td>
</tr>
<tr>
<td>-If you are Manufacturer/Importer (Registrant): Go to step 12</td>
<td></td>
</tr>
<tr>
<td>-If you are a Downstream user: Go to step 11</td>
<td></td>
</tr>
<tr>
<td>Step 11</td>
<td>Identify and list your suppliers (per substance/preparation)</td>
</tr>
<tr>
<td>Step 12</td>
<td>Compile readily available information on uses and conditions of uses</td>
</tr>
</tbody>
</table>

How to be prepared “The 12-step programme”

After the 12 steps, initial inventory is complete

Next steps:

A. If unclear how raw materials need to be registered, registrant must contact supplier to find about its intentions regarding pre-registration and registration

B. Communicate user and exposure information through the value chain

C. Communicate draft exposure scenarios for final confirmation through value chain to check that all their uses are covered
Preparing for REACH – Solvay

- **Status**
  - 12 Business Units involved
  - Around 600 Pre-Registration dossier submitted

- **Critical issues and action plan**
  - Imports from SLV non-EU manufacturing sites
  - Import of purchased materials
  - Structure and implement a REACH alerting process for tracking new chemicals: raw materials, by-products & intermediates, changes in manufacturing processes, end-products, imports,…
    - In connexion with the alerting process on volume tracking of existing products (implementation of SVT module of SAP)

REACH and R&D

R&D activities are defined under REACH as following

- **Scientific R&D (art 3, 23)**
  - Scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year
    - Development of analytical method
    - Intrinsic properties (phCh, tox, ecotox,…)

- **PPORD (art 3, 22)**
  - Product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance
    - Development and testing of new manufacturing process (new catalyst, raw material, control of manufacturing parameters optimisation,…)
    - Testing of a new intermediate
    - Development and testing of a new application for a substance
REACH and R&D

R&D criteria according to REACH regulation

- Agreed unlimited volumes for 5 years extendable for an additional 5 years (10 years for medicinal products)
- Technological R&D (production/application) carried out under controlled conditions
- Covers manufacture / import / supply
- Includes non-pre-registered EINECS listed chemicals (strategic business decision)
- <1 ton/year: same obligation as for scientific R&D (exempted from R, E, may be subject to A, Re)
- ≥1 ton/year: PPORD notification submission to the Agency by the M/I or in cooperation with listed customers
- M/I/U within 2 weeks after notification date of receipt (communication by the Agency with notification number) and in absence of any indication of the contrary
- SDS or relevant info to the users of the substance (if relevant R number, authorisation granted/denied, restriction, RMM)
- Delivery not allowed to the general public
- Remaining quantities collected for disposal after exemption period
- Request for PPORD extension to be justified by the R&D programme

Thanks for your attention!