REACH: Challenges and opportunities
Madrid, 30 September 2004
Lena Perenius, Chemicals Policy/Regulatory Affairs
1.1 Geographic breakdown of world chemical sales

World chemicals production in 2003 is estimated at €1,619 billion. The EU accounts for 34% of the total.

Source: Cefic
Definition:
- Asia*: excluding Japan & China
- Rest of Europe**: Switzerland, Norway, and other Central & Eastern Europe (excluding the accessing countries EU 10)
- Other***: including Canada, Mexico, Africa, & Oceania
1.2 Geographic breakdown of EU chemical industry sales

Sales 2003: €534 billion
Percentage shares

Source: Cefic
Notes: Big 8: Germany, France, UK, Italy, Belgium, Spain, Ireland and the Netherlands
The data presented above are not perfectly comparable. Indeed, there is no common definition of the chemical industry across countries. In particular, fibres can be either included or excluded. Countries including fibres in their definition are: Germany, UK, Italy, Belgium, Spain, Netherlands, Ireland, Portugal, Greece, Sweden, Austria, Finland. Countries excluding fibres are: France and Denmark.
* The Belgian chemical turnover calculated by Fedichem includes both rubber & plastic products and excludes fibres. To make a relatively homogenous & coherent comparison across EU countries, Cefic does not include the rubber & plastic processing in the calculation of EU chemical turnover.
1.3 Sectoral breakdown of EU chemical industry sales

2003

- Perfumes & cosmetics
- Soaps & detergents
- Petrochemicals
- Plastics & synthetic rubber
- Man-made fibres
- Other basic inorganics
- Industrial gases
- Fertilisers
- Fine chemicals
- Other specialty chemicals
- Paints & inks
- Crop protection

Base Chemicals 37.8%
Specialty & Fine chemicals 27.8%
Pharmaceuticals 24.1%
Consumer Chemicals 10.3%

Source: Cefic
Note: Weighting factor = 2003 value of production
Chart 2.2: Extra EU chemicals trade with major geographic blocs
Chemicals Policy - REACH

- Background
- Challenges and suggestions for improvement
- Possible Trade implications
Background and history

Objective of current EU Chemicals Legislation

- High level of protection to man and environment
- Prevention of barriers to single European market
History of EU Chemicals Control Legislation

- Notification of new substances
  - 79/83/EEC - 6th Amendment
  - 92/32/EEC - 7th Amendment

- Hazard assessment:
  - 67/548/EEC Classification, packaging & labelling of Dangerous Substances

- Risk assessment:
  - 93/67EEC (new subst)
  - Reg 793/93 (existing subst)

- Restriction on Marketing and Use:
  - 76/769/EEC

Revision
Chemicals policy review

Commission Proposal for a Regulation on REACH


A single system for new and existing manuf./import. substances

Registration  substances > 1t/y/manuf.import.  30,000
Evaluation    substances > 100t/y and of “suspicion”  5,000
Authorisation of substances of “very high concern”  1,500
Chemicals
Main Features of REACH

A single system for new (non-phase-in) and existing (phase-in) manufactured/ imported substances "on their own", in preparations or in articles

- Legal basis Article 95 – ensures single EU market
- Pre-registration: data sharing and avoidance of unnecessary testing
- Registration of substances of 1 ton or more per M/1/year
- Information in the supply chain; downstream users
- Evaluation of dossiers by Member States
- Authorisation for substances of very high concern
- Restrictions – the safety net

Agency to manage the system
### Selected features of today’s and the future framework *)

<table>
<thead>
<tr>
<th></th>
<th>today</th>
<th>in future</th>
</tr>
</thead>
<tbody>
<tr>
<td>• responsibility</td>
<td>mainly the regulator</td>
<td>mainly industry</td>
</tr>
<tr>
<td>• scope</td>
<td>pre-market</td>
<td>pre-manufacturing</td>
</tr>
<tr>
<td>• registration &amp; testing requirements</td>
<td>• new substances</td>
<td>≥ 10 kg/a</td>
</tr>
<tr>
<td></td>
<td>• existing subst.</td>
<td>none</td>
</tr>
<tr>
<td></td>
<td>• new &amp; existing subst.</td>
<td>C &amp; L (mktg.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>¬ ≥ 1 t/a for all substances</td>
</tr>
<tr>
<td></td>
<td></td>
<td>tailored for higher volumes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C &amp; L all</td>
</tr>
<tr>
<td>• exemptions</td>
<td>new substances for R &amp; D</td>
<td>flexibility for R&amp;D subst. &amp; intermediates, polymers</td>
</tr>
<tr>
<td>• restriction</td>
<td>mktg. &amp; use (76/769)</td>
<td>manuf., mktg. &amp; use.</td>
</tr>
<tr>
<td>• authorisation</td>
<td>none</td>
<td>for CMRs cat 1&amp;2, PBT, vPvB</td>
</tr>
</tbody>
</table>

*) according to the COM proposal
Chemicals Policy - REACH

- Background
- Challenges and suggestions for improvement
- Possible Trade implications
REACH - challenges

Present achievements – existing law

- Classification and Labelling (approx. 7000 in 30 years)
- New Substances Notification (approx. 3700 in 20 years)
- Existing Substances Reg. (approx. 80 RA in 10 years)
- ICCA HPV (210 since 2000)
REACH - challenges

The challenge for chemical industry

- assess (including data generation)
- document (Chemical Safety Report)
- register (together with other producers and downstream users)
- communicate (via Safety Data Sheet)

30,000 substances in 11 years
Key elements to improve REACH

- Rationalise the **Scope** of REACH
- **Prioritisation of substances** to be based on risk (including use & exposure) and requirements to be proportionate
- **Authorisation** - Decisions must be based on sound science
- **Central Agency**
  - Efficiency – a straightforward approach is needed, not “ping-pong” between different authorities
  - Must have full responsibility for all aspects of the management of the system
Chemicals Policy - REACH

- Background
- Challenges and suggestions for improvement
- Possible Trade implications
Possible Trade Implications of REACH

- White Paper stated that any new policy should conform with WTO rules.
- WTO allows its members to set a level of health, safety and environmental standards that they deem necessary, provided such standards are applied in a non-discriminatory manner.
- The WTO Technical Barriers to Trade Agreement provides that members shall ensure that technical regulations are not used to create unnecessary obstacles to international trade.
- Technical Regulations shall therefore not be more trade restrictive than necessary to fulfill a legitimate objective (e.g. health or environment).
Possible Trade Implications of REACH

REACH requirements apply to manufacturers and Importers

- With impact on global chemicals trade, effects might differ
  - Sometimes advantages for EU manufacturer, e.g. preparations and polymers
  - Sometimes advantages for third country manufacturer, e.g. articles, if no release, production of speciality and fine chemicals for non-EU markets
Possible Trade Implications of REACH

- Polymers exempted from registration and evaluation (Art. 14 & Art. 37)
- However: Registration of all the monomers and raw materials
- De facto advantage for EU producers as with the registration of a limited number of monomers/raw materials many polymers can be produced
- Import of polymers disadvantageous certainly in case of importation of only one or a few grades of a polymer as all monomers/raw materials need registration
- Risk of WTO dispute
Substances in articles (Art. 6)

- Registration of substances if they meet the criteria for classification as dangerous in case of intended release and presence $\geq 1$ tonne

- Notification of Agency if substances in articles meet same criteria and are known to be released during normal use and may adversely affect health or environment and presence $\geq 1$ tonne

- Cefic proposal: Delete notification requirement as impracticable, unnecessarily burdensome and little environmental/health benefit
Conclusion

REACH must be improved to make it work and to ensure level playing field in global trade!