

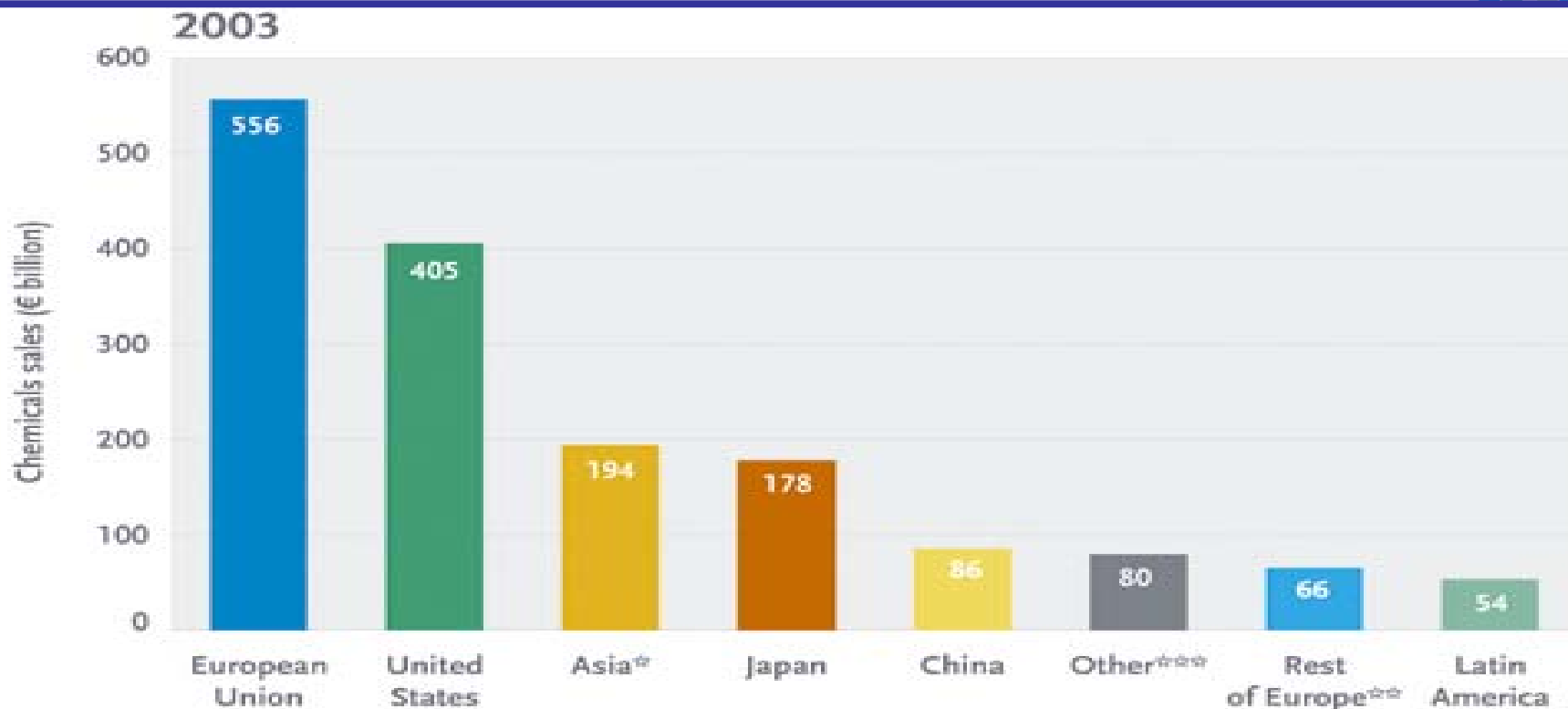
Cefic

REACH: Challenges and opportunities  
Madrid, 30 September 2004  
Lena Perenius, Chemicals Policy/Regulatory Affairs



Chemistry making a world of difference

## 1.1 Geographic breakdown of world chemical sales



World chemicals production in 2003 is estimated at € 1619 billion

The EU accounts for 34% of the total

Source: Cefic

Definition: Asia\*: excluding Japan & China

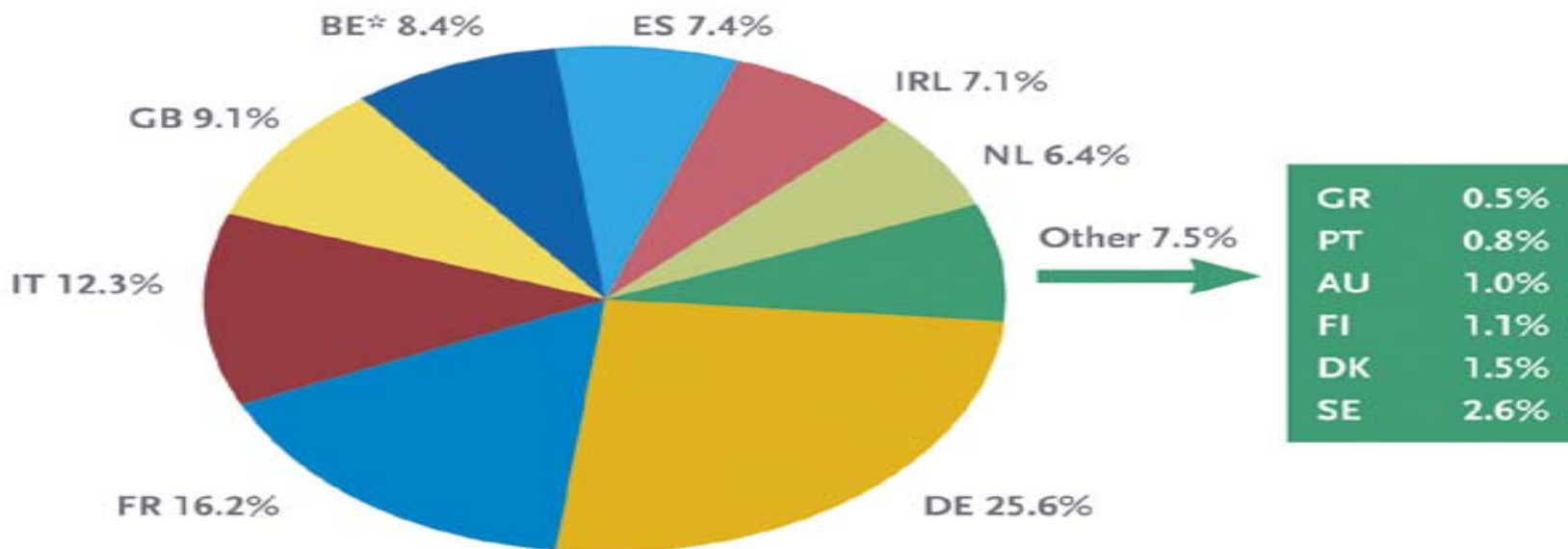
Rest of Europe\*\*= Switzerland, Norway, and other Central & Eastern Europe (excluding the accession countries EU 10)

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

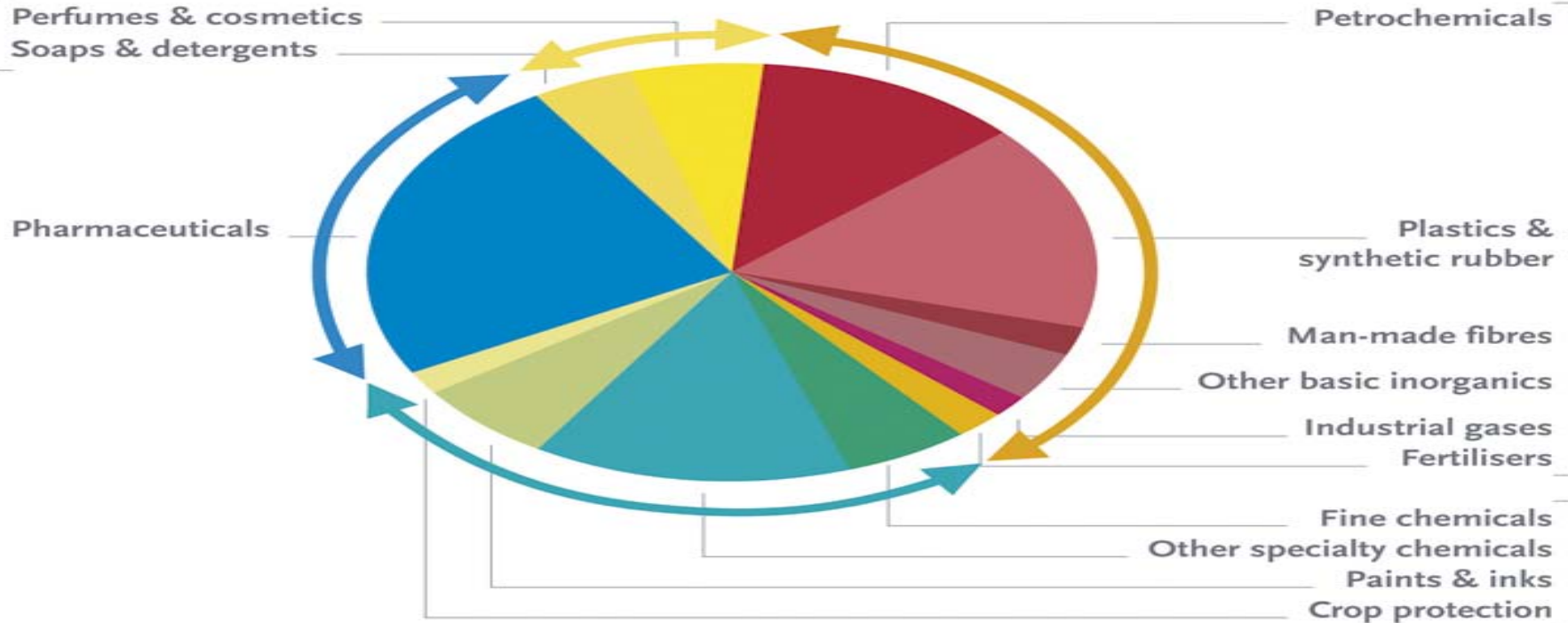
The data presented above are not perfectly comparable. Indeed, there is no common definition of the chemical industry across countries. In particular, fibres can be either included or excluded. Countries including fibres in their definition are: Germany, UK, Italy, Belgium, Spain, Netherlands, Ireland, 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



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

Source: Cefic

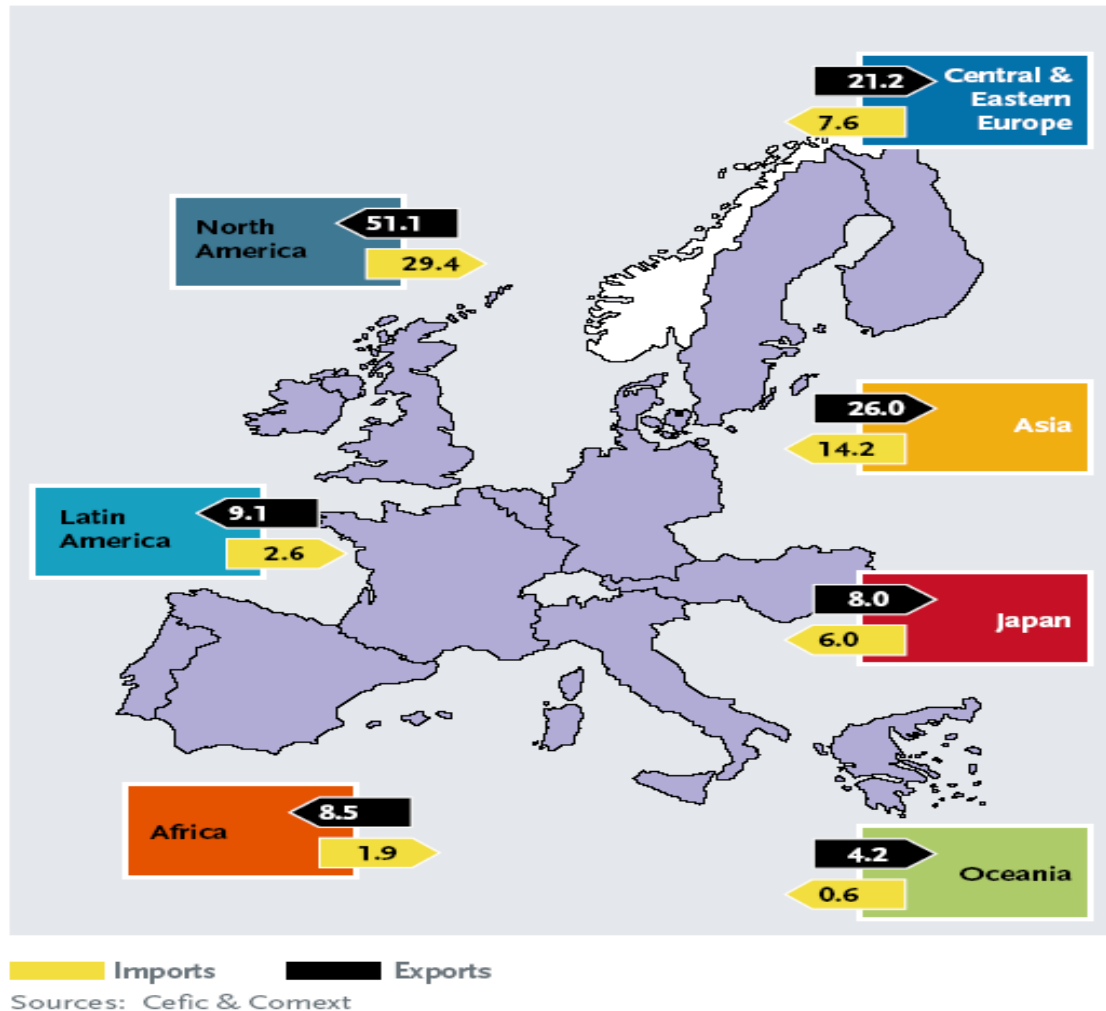
Note: Weighting factor = 2003 value of production

# Extra-EU chemicals trade with major geographic blocs



Chart 2.2: Extra EU chemicals trade with major geographic blocs

2003  
in € billion





# Chemicals Policy - REACH

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

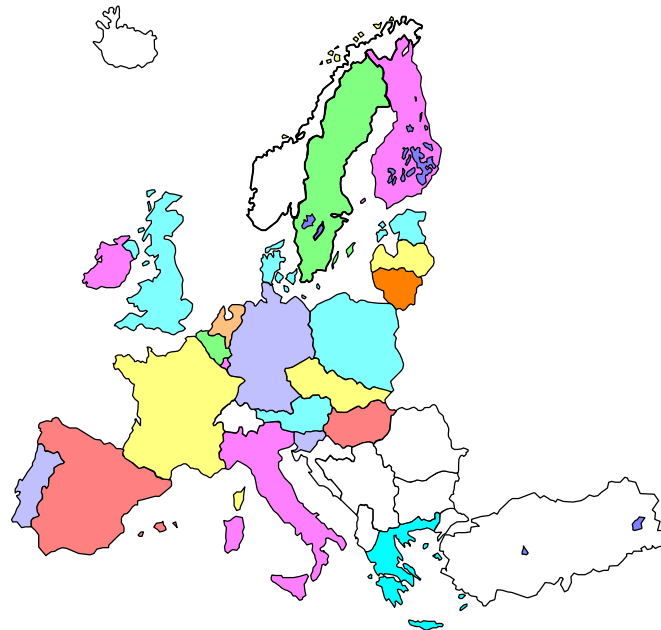


# Background and history

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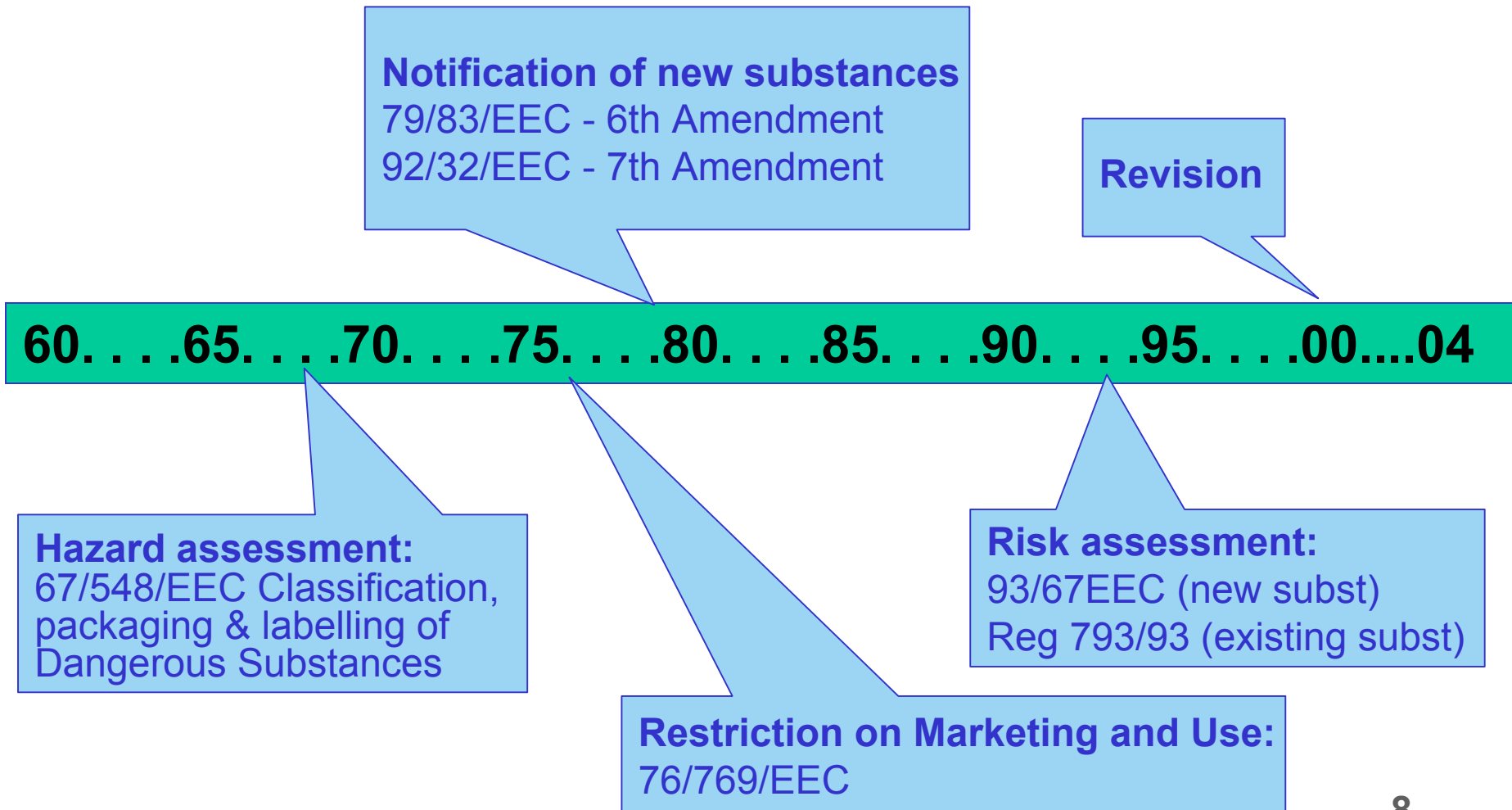
## Objective of current EU Chemicals Legislation

- High level of protection to man and environment
- Prevention of barriers to single European market





# History of EU Chemicals Control Legislation

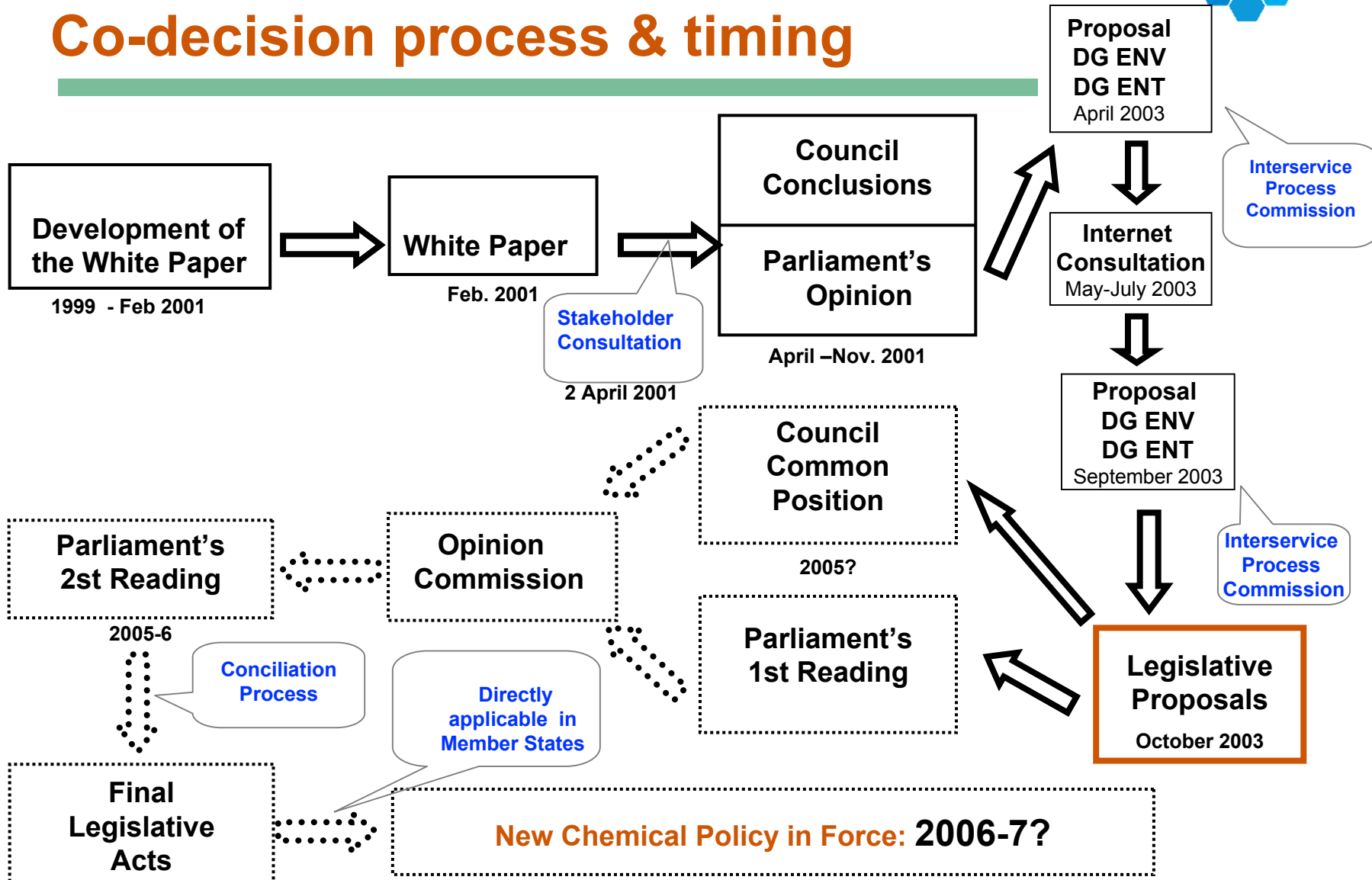






# EU Chemicals Policy Review

## Co-decision process & timing





## Chemicals policy review

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# Commission Proposal for a Regulation on REACH

COM(2003) 644 (29 October 2003)

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

|  |  |        |
|--|--|--------|
| <b>R</b> egistration                                       | substances > 1t/y/manuf.import.        | 30,000 |
| <b>E</b> valuation   | substances > 100t/y and of “suspicion” | 5,000  |
| <b>A</b> uthorisation of substances of “very high concern” |  | 1,500  |
| <b>C</b> hemicals  |  |        |



## Main Features of REACH

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**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//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 \*)

|  | today                                     | in future   |
|--|---|---|
| • responsibility   | mainly the regulator                      | mainly industry   |
| • scope  | pre-market                                | pre-manufacturing   |
| • registration & testing requirements <ul style="list-style-type: none"> <li>• new substances</li> <li>• existing subst.</li> <li>• new &amp; existing subst.</li> </ul> | ≥ 10 kg/a<br><u>none</u><br>C & L (mktg.) | } ≥ 1 t/a for <u>all</u> substances<br>tailored for higher volumes<br>C & L all |
| • exemptions   | new substances for R & D                  | flexibility for R&D subst. & intermediates, polymers                            |
| • restriction  | mktg. & use (76/769)                      | <u>manuf.</u> , mktg. & use.  |
| • authorisation  | none                                      | for CMRs cat 1&2, PBT, vPvB   |

\*) according to the COM proposal



# Chemicals Policy - REACH

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



## REACH - challenges

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### 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

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### 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

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- 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 straight forward 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

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



# Possible Trade Implications of REACH

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- **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

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## 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

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- **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)

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- **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



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