

## Chemical industry and REACH implementation in the European Union

### Facts on the chemical manufacturing sector in Europe in 2009

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- **1<sup>st</sup> market:** \$591 Billion sales – 24 % of world sales (NAFTA: 21%)
- **1<sup>st</sup> exporter:** 46 % of world exports (NAFTA: 13%)
- **1<sup>st</sup> importer:** 38% of world imports (NAFTA: 11%)
- + \$56 Billion trade balance
- SME: 96% of industries (< 250 employees)
- **1,205,000 employees** (USA: 518'000) / - 5% compared to 2008 (USA: -7%)

### REACH regulation:

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- Adopted in December 2006, entry into force June 2007
- **Registration of chemical substances** produced in quantities of 1t/y or more,
- **Registration of chemical safety report** for quantities of 10 t/y or more
- **Control by European Chemical Agency (ECHA): statistical approach.** Evaluation of 5% of the submitted dossiers in each tonnage range
- **Step by step approach for phase-in substances.** Registration deadlines depend on tonnage: December 1<sup>st</sup> 2010 ( $\geq 1.000$  t/y and CMR cat.1 or  $2 \geq 1$  t/y), June 1<sup>st</sup> 2013 ( $\geq 100$  t/y), June 1<sup>st</sup> 2018 ( $\geq 1$  t/y).
- **Restriction process** for substances submitted by Member States and ECHA
- **Authorization process** for substances of very high concern
- Specific **data sharing** tools

### REACH Implementation:

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- 24 675 files submitted by 2010, November 30th
- **4 400 substances registered by November 30th 2010**
- Animal testing requests: 1 548
- **4 substances under restriction process**
- **46 substances on the candidate list for authorization process.** 7 substances subject to authorization.

### Industry's reactions

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- **BASF:** *“The main aims of REACH are to ensure the high level of protection of human health and the environment [...], to promote alternative test methods and strengthen the innovativeness and competitiveness of the EU. BASF supports these goals without reservations.”*
- **Arkema:** *“Much more than a regulation, REACH helps improve comprehensive, systematic and in-depth knowledge of all our products. This approach [...] will help restore the confidence of end-users”*(Arkema's Vice President Safety and Environment, 11/26/2010)
- **Rhodia:** *“The regulation has [...] enabled us to improve our understanding of each individual step of our product supply chain and to strengthen our relationships both with our suppliers and with our customers. In Rhodia, we view REACH as a business opportunity and as a catalyst for innovation”* (REACH Project Manager in Rhodia, 11/26/2010).

### An example: how the EU could ban Dimethylfumarate (DMFu)

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- A **fungicide** used in leather and fabric treatments and found, e.g., in boots, clothes and leather sofa
- Turned out to **give strong allergic dermatitis:** DMFu exposure identified as possible cause of skin manifestations in 97 cases between 01/01/08 and 01/10/09. It was confirmed as a certain cause in 28 cases.
- To address this risk, France sent a **proposal for restriction** on 04/15/10 to the ECHA peer review's Committee, where it is currently under review. The ECHA opinion is to be published next April; the European Commission decision is expected summer 2011.
- No restriction proposal for the use of DMFu in pharmaceutical products.