Experience with REACH
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Outline

• REACH procedures
• Recent legal developments
• Hot issues
  – First Phase-in Registration
  – SVHCs
  – Enforcement
  – Litigation
  – Review
• REACH and other EU legislation
REACH Procedures

- **Registration and chemical safety reports**
- Information through the supply chain
- Obligations on downstream users
- Evaluation
- Authorization
- Restrictions
- of Chemicals

Recent Legal Developments

- Safety Data Sheets Regulation (May 2010)
- Annex XIV Authorization List (Feb. 2011)
- Annex XIII PBT vPvB Criteria (March 2011)
- Annex XVII (March 2011)
- Updated ECHA Guidance, e.g.:
  - Intermediates (Dec. 2010)
  - Substances in Articles (Apr. 2011)
- Two Board of Appeal Decisions in 2011
  - One in 2009
  - Two pending appeals
- Several cases before EU Courts
First Phase-In Registration: Criteria

• By Nov. 30, 2010, the following substances had to be registered:
  – 1000 tons
  – Toxic to aquatic organisms (R50-53) and 100 tons
  – Cat. 1A and 1B CMRs
• Provided they were pre-registered

First Phase-In Registration: Numbers

• > 2,6 million pre-registrations by Dec. 1, 2008
• 24,675 registrations by Nov. 30, 2010
  – Covering 4,300 substances
    • 3,400 phase-in substances
    • 4,500 substances expected
  – 1,500 testing proposals
• ECHA conducted completeness checks (Feb. 28, 2011)
  – Intermediates
• ECHA to decide on testing proposals (until Dec. 2012)
SVHCs: Criteria and Obligations

• Substances of Very High Concern may include:
  – Cat. 1A and 1B CMRs
  – PBTs
  – vPvBs
  – Substances raising an equivalent level of concern (e.g., endocrine disrupters)
• Identification of SVHC may trigger different obligations
  – Candidate List
  – Annex XIV Authorization List
  – Restrictions

SVHCs: Progress

• Candidate List
  – 46 substances (+7)
    • Updated twice a year after consultation
  – Still far smaller than SIN list (ChemSec) (circa 378)
• Annex XIV Authorization List
  – 6 substances (musk xylene, MDA, HBCDD, DEHP, BBP, DBP)
  – Around 16 months between application and sunset date
  – ECHA recommendation for 8 more substances
SVHCs: Some Issues

- How many substances in Candidate List?
- Should all Cat. 1A and 1B CMRs be included?
- Should substances mostly used as intermediates be included?
- How to choose between Authorization and Restrictions?
- How long periods for Authorization applications and sunset dates?
- How to measure concentration limits in articles?

Enforcement: REACH Forum

- Network of MS authorities responsible for enforcement
- Minimum Criteria for REACH & CLP Inspections (2011)
  - Risk analysis
  - Recall if serious risk (Market Surveillance Regulation)
- Strategies for REACH Enforcement (2011)
  - Priorities set in accordance to risk of non-compliance
  - Name and shame
- REACH Enforcement Projects
  - REACH En-Force 1 (2009) (pre-registrations and SDS)
  - REACH En-Force 2 (Apr. 2011) (downstream users)
  - REACH En-Force 3 (imports)
Enforcement

- Limited harmonization on penalties and enforcement
  - Penalties vary significantly
    - Less than 5,000 Euros (Romania)
    - Up to 55 million Euros (Belgium)
    - Imprisonment for serious breaches in many MS
  - Different enforcement approaches
- High profile enforcement cases
  - Belgium blocked goods at border (2009; reported)
  - NGO complaint against shoemaker in Sweden
  - Dutch investigation of ORs of Chinese manufacturers (2010)
- Need to check RAPEX system

REACH Litigation: BoA

- Board of Appeal
  - Three decisions
    - All on incompleteness of registration
    - In all three cases ECHA Executive Director rectified
  - Two pending appeals
    - Late payment of registration fee/rejection of registration/refusal to reimburse
    - Data sharing/ECHA permission to refer to data of lead registrant/every effort for fair sharing of costs
Litigation: EU Courts

- Monomer Case C-558/2007 (2009)
  - Inclusion of reacted monomers is proportionate and non-discriminatory
- Acrylamide Case T-1/10R (2010)
  - No urgency justifying interim measures in case of inclusion of substance in Candidate List
- Several cases on inclusion of substances in Candidate List (e.g., boric acids, acrylamide, pitch coal, anthracene oil)
- Commission actions against Belgium and Portugal

REACH Review: June 2012

- Reviews and Reports by June 2012:
  - Scope of REACH
    - www.reachscope.eu
  - Data requirements for low volume substances (1-10 tons)
  - Operation of REACH and funding for alternative testing methods
  - Implementation of REACH and costs and impacts on innovation
- May be followed by legislative proposal
REACH and Other EU Legislation

- Data Sharing
- Joint Registration Dossier
- CLP notification
- CLP Harmonized Classification
- Substance Evaluation
- Compliance Check
- SVHC Candidate List
- Authorization
- Restrictions

Spill over between REACH/CLP and other EU vertical/horizontal regulatory regimes:
- Cosmetics
- Medical Devices
- RoHS
- Toys
- Detergents
- Fertilizers
- Biocides
- Food contact materials
- Food
- Product Safety
- ... other

REACH and Other EU Legislation

Registration → Evaluation → Restrictions → RoHS Directive restrictions on EEE

Registration → CLP Harmonized Classification → Restrictions for Cat. 1A 1B CMRs in wide range of products (e.g., medical devices, detergents, foods, tobacco)

Identification of SVHCs → Authorization → Restrictions for Cosmetics, Paper and wide range of other products
Conclusion

• REACH establishes a regulatory framework
  – No data – no market
  – Progressive substitution of dangerous substances
  – Scientific review and procedural rights
• Perhaps too early to assess economic impact
• Other countries adopting REACH alike laws
  – Switzerland, Turkey, U.S., Korea
• Likely biggest impact will be seen in context with other EU environment and safety rules

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Dr. García Molyneux holds a PhD in Law from the European University Institute, an LLM from the University of Georgetown, and a Law Degree from the Autonomous University of Madrid. He is an external professor of environmental law and policy at the College of Europe.

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