

# Experience with REACH

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Cándido García Molyneux  
[Cgarciamolyneux@cov.com](mailto:Cgarciamolyneux@cov.com)  
Covington & Burling LLP

COVINGTON & BURLING LLP

BEIJING BRUSSELS LONDON NEW YORK SAN DIEGO SAN FRANCISCO SILICON VALLEY WASHINGTON

## 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

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## 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

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## 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 disruptors)
- 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)
  - COM Agreement: 136 substances by Dec. 2012
- 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

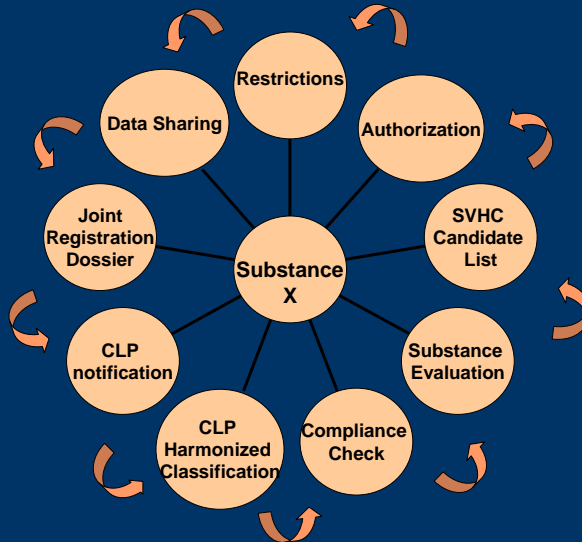
## Litigation: EU Courts

- 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](http://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

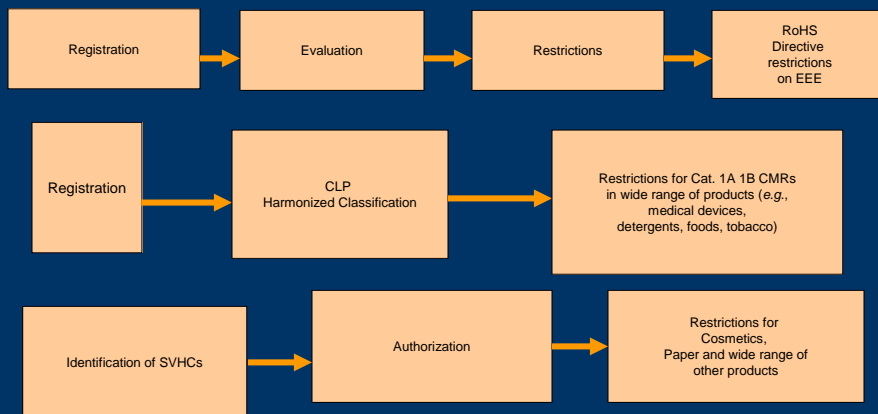
# REACH and Other EU Legislation



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



## 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



Dr. Cándido García Molyneux  
Covington & Burling LLP  
44 Avenue des Arts  
1040 Brussels Belgium  
+32.2.549.5261  
cgarciamolyneux@cov.com

Cándido García Molyneux is a Spanish Of Counsel in the Brussels office of Covington & Burling LLP. His practice focuses on EU environmental law and Spanish and Italian food and drug law. He advises clients on legal issues concerning environmental product regulation, chemical law, waste management, climate change, renewable energies, and energy efficiency. Cándido was actively involved in the legislative process resulting in the REACH Regulation, and now advises chemical manufacturers and downstream users and their trade associations on the impact of the REACH/CLP regime and on how to best ensure compliance and defend their products.

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.