Europe, Chemicals Policy and REACH

why they are relevant to the USA

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What is the European Union?

- The European Union was created by intergovernmental treaties between the Member States
  - These treaties defined a number of institutions, and defined their competence.
- The EU is a unique institution
  - It is a free trade area
  - It is an area with free movement of labour
  - It defines environmental standards
  - It defines social standards
  - It is increasingly developing a unified foreign policy (with many problems)
- EU Member States continue to exist
  - But in some areas - e.g. internal market - they have very little freedom to go against agreed EU regulation.
- Who is in the EU?

The EU and European Economic Area (EEA)
How does the EU make decisions?

- **Three key pillars of EU Governance:**
  - The European Commission
    - Divided into departments or “Directorate Generals” e.g. DG Environment and DG Enterprise
    - Drafts legislation, often after a request from Council. Most implementation and enforcement is done by Member States
  - Council
    - Member State governments, e.g. Environment Council = Environment Ministers
    - One of the two “chambers” of EU policy making
  - European Parliament
    - Elected by the people of Europe every 5 years
    - The second chamber of most EU policy making.
  - **Most legislation must be agreed by both Council and Parliament.**
  - In a few areas the Parliament has no power - notably agriculture.

How is EU legislation implemented and enforced?

- **Two main types of legislation**
  - Directives must be incorporated in Member State law
  - Regulations are immediately legally binding in all Member States (and EEA countries if appropriate)
  - Commission can take Member States to court and fine them if legislation is not implemented
  - **Most enforcement is at Member State level**
    - Member States are unwilling to give up this power
  - **A few areas are enforced at EU level**
    - E.g. Competition law
      - Fining Microsoft
      - Fining chemical companies over illegal cartels
What is chemicals policy?

- The network of regulations and other measures that act to identify the properties of chemicals and encourage safe use and disposal
  - (Precise definition not too important)
- “Chemicals management” has a similar meaning
- The aims of chemicals policy tend to include:
  - The protection of human (including worker) health
  - The protection of the environment
  - The promotion of the competitiveness of the chemical industry
  - The promotion of the competitiveness of downstream users of chemicals.

Components of chemicals policy include

- Gathering information on the hazards of chemicals
- Assessing exposures to chemicals
- Assessing risks and risk management measures
- Classification and labeling chemicals and preparations when supplied to customers
- Occupational health controls
- Legal restrictions on the use of chemicals
- Phasing out of certain chemicals
- Green Chemistry and Clean technology programs
Chemicals policy in the USA

- Some aspects are the responsibility of the EPA, through the Toxic Substances Control Act (TSCA), e.g.
  - Allowing new chemicals onto the market
  - Restricting new uses of old chemicals
  - Restricting current uses of old chemicals
    - With very limited success
  - Clean technology and green chemistry programs
- Others are the responsibility of OSHA, e.g.
  - Classification and labeling of chemicals for workers, material safety data sheets - but no single list of single US standard
  - Worker protection
- Also consumer safety, cosmetic chemicals etc by other departments and agencies

Some problems:
- Very limited safety data available on most chemicals
- Extremely difficult for EPA to restrict chemicals (e.g. asbestos)

Current EU Chemicals policy

- Standardized classification and labeling system since 1967
  - Several thousand chemicals classified by regulators, the rest only by industry (inconsistently)
- New chemicals (since 1981) require safety data
- Existing chemicals (Pre 1981) do not require specific safety data, but priority chemicals can be assessed then restricted
- Process to restrict certain uses of chemicals (since 1976)
- Safety Data Sheets (defined format) must be provided to customers of chemicals and preparations (poor quality)
- Occupational health regulations obliging companies to assess chemical risks, substitute carcinogens etc.
- Legislation to ban Stockholm Convention Persistent Organic Pollutants
What is the problem?

• Many problems, including
  • Lack of safety data
  • Environmental contamination
  • Contamination of human tissues
  • Debates on endocrine disruption
  • Poor downstream management of chemicals
  • Little information on chemical uses

• For example..

Chemical ignorance

• There are more than 30,000 industrial chemicals in use in Europe - but we lack safety data on them
  • We have very little safety information on most of these chemicals, those first produced prior to 1981
  • The European Chemicals Bureau found that only 14% of HPV chemicals had a basic set of data publicly available - there is even less information available on lower volume chemicals
  • These chemicals have been in production for over 20 years - often 50 or 60 years, yet we have insufficient information to assess their safety
Contamination

- A growing number of industrial chemicals are known to contaminate wildlife and people, for example:
- Brominated flame retardants
  - Contaminating people and wildlife across the world
  - Two phased out in Europe (penta and octa)
  - Deca is in increasing use, despite contamination of polar bears, birds of prey and people
    - Even though the industry claimed it wouldn’t accumulate
- Perfluorinated chemicals (PFCs)
  - Including PFOS (Scotchguard) PFOA (used in teflon manufacture and telomers (used in coatings, break down into PFOA)
  - Contamination by PFOS and PFOA exists across the world
  - PFOS has been voluntarily phased out, PFOA and telomers are in widespread use
    - MacDonalds have admitted using telomers in their food packaging

My perfluorinated chemicals

- From WWF’s sampling of the blood of 47 people for 101 chemicals.
- All 45 samples (including mine) analysed for PFCs contained these 7 PFCs:
  - PFHxS, PFOA, PFNA, PFOS
  - PFOSA, PFDA, PFUnA
- All unregulated in EU
- Limited regulation in US
My PDBEs

34% of samples contained ‘Deca’, including one with the highest concentration ever published.

Why is the EU important for chemicals?

- A major producer
  - The EU produces 29% of the world’s chemicals - the largest chemical industry in the world
- A major market
  - Currently 25 countries, around 450 million people
    - (the US population is 275 million)
- The EU is becoming the global leader on environmental policy
  - The EU is willing to legislate for environmental improvement
- Control of the production and use of chemicals is controlled at EU level
  - not within individual Member States
EU Chemicals policy reform - the history

- Building pressure for reform (-1999)
  - Failure of current system
    - Lack of safety data
    - Lack of action on worst chemicals
- Creation of new approach (1999-2001)
  - Stakeholder meetings (e.g. Feb 1999)
  - The White paper - Registration Evaluation Authorisation of Chemicals (Feb 2001) REACH concept created
  - Council and parliament support (2001)
- Aggressive lobbying 2001 -
  - Aggressive attack on REACH from chemical industry, focusing on exaggerated claims on costs and jobs
  - High profile US Government attack on REACH, using inaccurate analyses provided by the American chemical industry
  - Internet consultation (2003)
  - Publication - October 29th 2003
- Discussions start in Parliament and Council (2004-)

What is REACH?

- A new regulatory system that will control the production, marketing and use of chemicals in Europe
- Key elements include:
  - Registration of safety data for all chemicals on market >1 tpa over an 11 year period (ignorance is not evidence)
    - Includes promotion of in vitro testing, grouping, data sharing etc.
  - Obligation on chemical producers & importers to define safe use for their chemicals (producer responsibility)
  - An improved procedure for restricting individual uses of chemicals where there are safety problems.
  - Identification of chemicals of very high concern - CMRs, vPvB, PBT, EDC
  - An authorisation procedure to deal with the use of these chemicals of very high concern
  - Greater information flow up and down the supply chain, and - to some extent - to consumers
  - Greater control of the use of chemicals in articles (e.g. furniture and TVs)
REACH - what will it mean for occupational and public health?

- A new comprehensive database of chemical properties, available on the internet
- Increased regulatory and market pressure in Europe for the development of safer chemicals
- Better quality safety data sheets in Europe
- Unsafe uses of chemicals restricted more rapidly, in Europe.
- New criteria to identify chemicals of highest concern
  - Use of some of these chemicals controlled through ‘authorisation’
  - Possibly - a list of substances meeting these criteria.
- An increase in producer responsibility for chemicals producers and importers in Europe, encouraging producers to ensure that their chemicals can be used safely.

The politics of REACH

- REACH has been the most controversial EU policy of recent years.
- Much of the debate on REACH has been based on inaccurate or exaggerated analyses
- However, as REACH - and the reasoning behind it - have become better understood, opposition has subsided somewhat.
- Major drivers for REACH include:
  - No-one likes the current system
  - Member States experts support the REACH approach
  - NGOs (and now Unions) support REACH + improvements
  - Downstream users are beginning to realise the benefits of REACH
REACH timetable and process - current guess

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<tr>
<th>Time Frame</th>
<th>Event Description</th>
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<tr>
<td>Jan-Jun 2005</td>
<td>Parliament begins first reading with discussions in committees, followed by votes on amendments. Member States continue detailed analysis.</td>
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<tr>
<td>(Luxembourg)</td>
<td>Commission works on “REACH implementation Plans (RIPs)”</td>
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<td>(UK)</td>
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<td>(Austria)</td>
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<td>Jul-Dec 2006</td>
<td>Parliament Environment and Industry Committees vote, followed by plenary second reading vote. Member States reach common position on second reading. Conciliation to resolve differences and finalise REACH.</td>
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<tr>
<td>(Finland)</td>
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<td>Early 2007</td>
<td>REACH regulation published in Official Journal. 20 days later, REACH is legally binding in all EU and EEA states. RIP process complete - Guidance finished.</td>
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Impacts of REACH on the USA

- New safety information on chemicals, easily available on the internet
- New restrictions on chemicals in Europe
- A new ‘blacklist’ of chemicals created by the authorisation process
- A driver for the production and import of safer chemicals in Europe
- A driver for US companies to produce safer chemicals to market in the EU market
- An encouragement for a reform of US chemicals policy - at State or Federal level
Conclusions

- The European Union is a major global market
- The EU is also a major source of new regulation
  - On working time
  - On chemicals
  - On electronics, etc
- The size of the EU market means that these new regulations have global impacts - including on the USA
- REACH will change chemicals use - and regulation - in the USA
- The big question is - how will US government and companies respond?
  - By re-starting the regulatory debate in the US?
  - By following EU regulations?
  - By fighting the EU approach through the World Trade Organisation?