The European Union’s Registration, Evaluation and Authorization of Chemicals (REACH) Proposal….

What does it mean for US Businesses, Sustainable Chemistry and Product Design?

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Contents

• Part 1: What is the European Union and why is it important?
• Part 2: What is REACH, how will it affect you and when will it happen?
• Part 3: Preparing for REACH compliance
• Part 4: Indirect impacts of REACH on US businesses
• Conclusions
Part 1

- What is the European Union?
- Why is it important for chemicals?

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
    - Such as actions relating to Microsoft, or prosecution of cartels

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 setting global standards on environment
- Control of the production and use of chemicals is controlled at EU level
  - not within individual Member States
Current EU Chemicals regulation - in brief

- Standardized classification and labeling system since 1967 *(but inconsistent application by industry)*
- New chemicals (since 1981) require safety data *(penalizes new chemicals over existing)*
- Existing chemicals (Pre 1981) do not require specific safety data *(lack of safety data)*, priority chemicals can be assessed then restricted *(slow and inefficient)*
- Process to restrict certain uses of chemicals (since 1976) *(Too slow, also lack of data)*
- 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. *(but inadequate safety measures, particularly downstream)*
- Legislation to ban Stockholm Convention Persistent Organic Pollutants

Part 2:

- What is REACH?
- How will REACH affect a US exporter to the EU?
- When will REACH happen?
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)
- Internet consultation on draft text (summer 2003)
- Publication of Commission proposal (October 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
  - Greater control of the use of chemicals in articles (e.g. furniture and TVs)
- Reach is not simple (nor is the current EU system) -
  - See briefing for a brief explanation of REACH
  - See resources mentioned later for more details
Current responsibilities of exporters to EU - in brief

- **An exporter of substances to Europe:**
  - Check if substance is on EINECS, if not then notifying it as a new substance if marketing >10kg/year
  - Check if uses restricted under 76/769 or under other directives, e.g. ROHS
  - Classify and labeling substance, and ship with safety data sheet

- **An exporter of preparations to Europe:**
  - Check if all ingredient substances are on EINECS, if not then notify any new substances if marketing >10 kg/year
  - Check if uses of ingredient substances are restricted under 76/769 or under other directives
  - Classify and labeling preparation, and ship with safety data sheet
  - [In the case of cosmetics, pesticides, biocides, pharmaceuticals, food additives - check legislation]

- **An exporter of articles to Europe.**
  - Check if uses of ingredient substances are restricted under 76/769 or under other directives, e.g. ROHS

What difference will REACH make to exporters of substances to EU?

- To be discussed in small groups
- See also information in:
  - “Introduction to REACH” briefing
  - REACH process description
  - REACH Q&A
  - The REACH text itself
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REACH timetable and process - current guess

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Description</th>
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<tbody>
<tr>
<td>Jan-Jun 2005</td>
<td>Parliament begins first reading with discussions in committees, followed</td>
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<tr>
<td>(Luxembourg)</td>
<td>by votes on amendments. Member States continue detailed analysis</td>
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<tr>
<td>Jul-Dec 2005</td>
<td>Plenary vote ends Parliament’s first reading</td>
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<tr>
<td>(UK)</td>
<td>Member States finalise agreement on key issues, followed by</td>
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<td>Common position after Parliament’s first reading</td>
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<tr>
<td>Jan-Jun 2006</td>
<td>Commission modifies REACH proposal based on Common position and internal</td>
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<tr>
<td>(Austria)</td>
<td>Commission debate</td>
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<tr>
<td>Jul-Dec 2006</td>
<td>Parliament Environment and Industry Committees vote, followed by plenary</td>
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<tr>
<td>(Finland)</td>
<td>second reading vote. Member States reach common position on second reading.</td>
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<td>Conciliation to resolve differences and finalise REACH</td>
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<td>Early 2007</td>
<td>REACH regulation published in Official Journal</td>
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<td></td>
<td>20 days later, REACH is legally binding in all EU and EEA states</td>
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<td></td>
<td>RIP process complete - Guidance finished.</td>
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What will the final REACH regulation look like?

- Probably fairly similar to the current proposal
- Some elements may change, e.g.:
  - Registration - One Substance One Registration is popular, and may be implemented in some way.
  - Substances in articles - likely to be some sort of change in ‘article 6’, but not yet clear in which direction.
  - Further prioritization in registration timing and data requirements - strong lobby from chemical producers, but not much support from decision makers.
    * Suggested changes would also remove or reduce industry responsibility
  - Authorisation - getting an authorisation may become more demanding, substances meeting authorisation criteria may be listed.
Finding out about REACH

• Much of what has been written about REACH is inaccurate
  • Be very careful about using secondary sources of information
    • There are many misunderstandings of the REACH proposal
• The most authoritative source of information on REACH is the European Commission
  • They wrote it
  • They understand how it works, in comparison to the current EU regulatory system
  • They are having to explain REACH to industry, Member State experts and parliamentarians
  • However, Commission resources will defend the proposal, so are not good for explaining potential changes e.g. One Substance One Registration.

Information on REACH - Commission

• Both Enterprise & Environment departments have REACH web sites:
  • http://europa.eu.int/comm/enterprise/reach/index.htm
  • http://europa.eu.int/comm/environment/chemicals/reach.htm
• All key documents are accessible on both these sites:
  • REACH process description - probably the best place to start for a detailed understanding of responsibilities under REACH; includes flow charts.
  • REACH Q&A, November 2004 - answers to many key questions on REACH
  • The REACH proposal itself comes in 6 volumes:
    • Volume 1 - The REACH Regulation itself, the core legal text
    • Volume 2 - Annexes I-IX - including chemical safety assessment, information needs, exempted substances.
    • Volumes 3, 4, 5 - Annex X, detailed test methods
    • Volume 6 - Annexes XI - Authorisation criteria, dossier contents, restrictions brought forward from current legislation
Information on REACH - other EU sources

- The UK Government is an important player in the REACH debate:
- Euractiv, a free news website, has fairly accurate coverage of REACH:
- Environment Daily is probably the best paid-for source for EU Environmental policy news:
  - http://www.environmentdaily.com
- WWF has one of the most active campaign/news sites, with background info:
  - http://www.panda.org/detox
- CEFIC - the European Chemical Industry Association - is a major player in the REACH debate, but their website has limited practical information on REACH:
  - http://www.cefic.be

Part 3:

- Preparing for REACH compliance
Preparing for REACH, according to the European Chemical Industry Federation

- From CEFIC presentation, summer 2004*
  "Actions that companies should take now and in the immediate future"
  "It is certain that some form of REACH will become legislation, although it is not possible to predict at this stage in what form exactly or when
  Whatever final form REACH will take, it is likely that there will be still a very ambitious set of requirements to fulfill"
- Produce your own inventory of chemical substances that will be subject to REACH
- Establish which legal entity of your Group of companies is involved as manufacturer or importer
- Identify the CAS numbers of these substances
- Establish a list of your customers and what their uses are; also establish whether the substance is being sold to DUs and/or consumers via distributors. At this stage it would be sufficient if you would apply the following main use categories:
  - Non-isolated intermediates Substances included into matrix
  - Isolated intermediates Substances for/in non-dispersive use
  - Transported intermediates Substances for/in wide dispersive use

* Talk by Mr. Matjaž Podobnik, from the Slovenian Chemical Company Hebo, at conference on REACH in Slovenia, 2-3rd June 2004, based on talks at CEFIC’s “ChemFed-2, Training of Trainers on REACH, 29-30 April 2004

Preparing for REACH, according to CEFIC - continued

- Establish whether there are for your substances:
  - Hazard property information, i.e. any available studies according to Annexes V through VIII of REACH or other types of hazard information, e.g. human data or QSARs, of your own or others, including vertebrate animal tests
  - Classification & Labelling information
  - Safety data sheet (and, if necessary, bring them in line with existing regulation)
  - Exposure information across the supply chain i.e. exposures of your own workforce and exposures at your customers' workplaces and eventually in final uses
Planning for REACH - other ideas

• CEFIC advice focuses on understanding what chemicals you are using, and what you know about their properties
  • This advice is particularly aimed at chemical producers and formulators
  • This advice is clearly a good start, but tends to result in a view of REACH as a problem not as an opportunity

• REACH as an opportunity
  • REACH encourages the use of safer chemicals, through reduced regulatory requirements.
  • REACH offers a stimulus for you to examine what chemicals you are using - and decide those that you would rather move away from.

Planning for REACH through Toxics Use Reduction

• REACH offers a number of incentives to use safer chemicals:
  • The authorisation procedure will only affect chemicals meeting the criteria of very high concern
  • A detailed analysis of exposure is only required if a chemical has dangerous properties
  • The eventual regime for dealing with imported articles will, most probably, be primarily focused on chemicals of very high concern and those classified as dangerous

• Toxics use reduction (TUR) and alternatives assessment (AA) are methods for redesigning your products to use safer chemicals
  • E.g. the work done by the Toxics Use Reduction Institute in Massachusetts (www.turi.org)
  • E.g. Green chemistry to find safer alternatives

• A TUR/AA response to the REACH challenge will benefit your company.
Part 4:

- Indirect impacts of REACH on US Businesses

Impacts of REACH on the US market for chemicals

- REACH will provide US customers, workers and consumers with new safety information
  - E.g. in around 2010 there will be an internet database of the classification and labeling of every chemical on the EU market.
  - The REACH database will contain extend Safety Data Sheets, including information on safe uses

- REACH will lead to new controls on chemicals in Europe, with knock-on effects in the US
  - New restrictions will be put in place as a result of improved safety data
  - An effective ‘blacklist’ of chemicals will be created chemicals meeting authorisation criteria
  - Chemicals that enter the authorisation process will be under considerable pressure
Impacts of REACH on chemicals policy in the United States

- REACH is stimulating a debate on chemicals policy across the world
  - Most systems have similar problems, e.g. lack of safety data
  - Canada is currently reviewing their policy, and REACH will have some impact on the outcome
- REACH is also stimulating a debate on US chemicals policy
  - E.g. last week’s “Framing a future chemicals policy” meeting, hosted by LCSP, attended by more than 175 people from business, government, NGOS and academia.
- The current US regulatory system is 30 years old - it will have to be modernized at some point
  - State level initiatives are already creating new elements, such as toxics use reduction in Massachusetts

Conclusions

- REACH is happening, and will change the marketing and use of chemicals in the EU
  - Finding out about REACH is important if you export to Europe, but be careful of your sources
- REACH can be approached as a problem, or as an opportunity - the latter is more likely to have positive effects on your business
  - Using toxics use reduction, alternatives assessment and innovation into green chemistry are effective ways of benefiting from REACH
- REACH will affect chemicals markets in the US, and will eventually impact on US regulation
  - Preparing for REACH will therefore be of long term benefit for US companies
- REACH is only one element of the EU’s attempt to achieve sustainability - other elements include waste and energy regulations.
  - US businesses need to be aware of European developments in order to protect their long term competitiveness.