Are you going Up or Down the REACH Curve?

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Darden II

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PTK
Protection Through Knowledge

Why I am here

- **PTK Ltd:** consultancy on regulatory chemicals issues **(e.g. REACH, GHS, SAICM)**
  - Special Advisor to the Finnish Presidency, to end 2006, on plans to finalise the REACH negotiations
  - Advice to companies, trade associations and other stakeholders on implications of, and preparing for, REACH and GHS
- **DG ENTR (until September 2004)**
  - author (1 of) of REACH
  - co-decision process (Council & EP)
  - implementation of GHS in EU
- **UK Government (HSE): international chemicals policy**
  - policy on chemicals strategy White Paper
  - author (1 of) of GHS: IOMC drafting group
  - Acting head of UK delegation to IFCS III
- **DG ENV chemicals unit (94 – 97)**
  - NONS, ESR, C&L

Session

- **What are the implications of REACH for manufacturers and users of chemicals in the US? What impacts will it have?**
- **How have companies turned REACH into an opportunity?**
- **How have companies used REACH to communicate with their supply chains and create improved materials management schemes?**
- **How can companies not just comply with REACH, but stay ahead of regulation, on the innovators curve?**
- **How can REACH benefit those companies that do not have European markets?**

REACH: flash fire or eternal flame?

Presentation

1. Why REACH is important
2. Cultural Change
3. Global REACH?
4. Company Preparation
5. Environmental Regulation
6. Costs and Benefits of REACH
7. Staying Ahead of the Regulator
8. REACH => Substitution?
9. REACH => Innovation?
10. Opportunities
11. Alternatives
12. And the Winner is…

REACH

Why REACH is important?

- **REACH will impact chemical use and supply globally (EU and wider markets)**
- **Withdrawal of substances inevitable; in your supply chain?**
- **Greater information will affect liability**
- **Imports to EU; importers and customers will require help (scientific, technical etc)**
- **Opportunities and threats**
- **Costs and benefits**

Cultural Change

- **Most health, safety and the environment (HSE) legislation is largely ‘technical’ in nature**
- **Usually delegated to HSE departments and professionals**
- **REACH is different…**
- **Organisations have to think differently and across all operations**

Cultural Change

1. **No data = No market**
   - Not an ‘open’ market but a tightly regulated one
2. **Pre-manufacture, not pre-marketing**
3. **Responsibility placed on industry and manufacturers or importers in particular**
4. **Role of national authorities ‘one step’ removed**
5. **Greater sharing of information on substances in products (preparations and articles), including to customers**

Cultural Change

5. **‘Forced’ cooperation between companies (OSOR, data sharing)**
6. **‘Forced’ communication along the supply chain (e.g. on properties, identified uses, risk management measures (RMM))**
7. **Business decisions feeding into technical areas and vice versa (e.g. uses to support, relationship with customers and suppliers)**
8. **Legal considerations (how work together, confidentiality, supply contracts)**
9. **Ongoing/continuous obligation (i.e. not a one-off ‘fix’)**

Global REACH?

- **Product Stewardship (PS) made ´real´**
- **Addresses failings of industry AND Government (EU). Similar failings in the US?**
- **If you believe in PS you at least should believe in the objectives behind REACH even if not how these have been implemented**
- **Weaknesses? Get right next time? Learn from our mistakes? or reinvent your own?**
- **Consumer pressure? Industry pressure? Government pressure?**

Company Preparation

1. **Supply chain mapping**
   - Where will REACH ‘bite’
   - Identify substances for pre-registration (by you or your suppliers)
2. **Vulnerable products**
   - Threat of withdrawal from your supply chain
3. **Identification of alternatives**
   - Substances
   - Suppliers
   - Processes
4. **Substance inventory/portfolio**
5. **Identification of future activities**

MOST IMPORTANT NOW!!

Pre-registration

Pre-registration

- **Timing? 1 June 2008 – 30 Nov 2008**
- **Why?**
  - To allow phase-in substances (EINECS listed substances on own, in preparations, intended to be released from articles) to take advantage of the phase-in deadlines
  - To enable all registrants of the same substance to prepare a single hazard data-set
- **Who?**
  - Potential registrant (M, I, only representative)

Pre-registration

- **What?**
  - Substance name
  - Potential registrant details (or 3rd party representative)
  - Deadline for registration
  - Similar substances (for read-across).
- **How?**
  - Agency form on website
  - Agency publishes list of information on website
- **Next?**
  - 'Pre-SIEF': sameness check. One SIEF may require several SIEFs in practice
  - Start of the SIEF (Substance Info Exchange Forum); can also include DUs and other non-registrants

Why is Pre-registration so Important?

- **First duty for most**
- **Vital for all**
- **Importer: have to pre-register ‘all’ substances in preparations**
- **Manufacturer: have to pre-register all substances**
- **Downstream User: have to ensure the substances supplied to you are registered (threat of substance withdrawal)**

Pre-registration: Notes

- **Identify substances essential to you as a downstream user as well as your own**
- **Identify substances 'intended to be released' from articles - few?**
- **Consequences of failure to pre-register**
  - Withdrawal of substance from market?
  - No registration no market
  - Early registration; from 1 June 2008
  - Uncertainty
  - N.B. possibility of DUs being able to react to list of pre-registered substances
- **Some substances 'regarded as being registered' so no need to pre-register (but can presumably operate in the SIEF)**
- **If in doubt pre-register**

Priorities?

- **Supply chain mapping is on its own a major task**
- **You may have to prioritise your resources**
- **Know what you don't know**
- **Make decisions consciously, not by default**
- **Priorities to identify?**
  - Substances you manufacture => pre-registration?
  - Substances you import => pre-registration?
  - Substances intended to be released from imported articles => pre-reg?
  - Substances/preps made to your demands => supplier to pre-register?
  - Substances/preps essential/important to your business (key substances) => supplier to pre-register?
  - Substances/preps with few suppliers => supplier to pre-register?
- **Lower priorities?**
  - SVHC in articles (timing)
  - Commodity chemicals (many sources of supply)
  - Products for generic uses and standard processes (e.g. oxidisers, degreasers) (many sources of supply and products)

The Big Problems…(include)

- **Substance identity and characterisation (RIP 3.10)**
- **SIEFs: sameness check**
- **SIEFs: practicalities (e.g. language, deadlines and urgency, same place & time, confidentiality, legal constructs, non-registrants)**
- **SIEF transition to consortium**
- **Data and cost sharing (RIP 3.4)**
- **Articles: identify, pre-registration (RIP 3.8)**
- **Guidance, IT etc ready?**

Opportunities

Opportunities

Internal

- **Better understanding of REACH and its implications than competitors**
- **Holistic organisation to bring company benefits**
  - Efficiency gains
  - Joined-up working
- **Flexibility in REACH, for example**
  - Data requirements
  - R&D exemption (very wide, use it!)
  - Generic vs. specific chemical safety assessments (CSA)
- **Remove SVHC from supply chain (REACH is the spur and the tool)**
- **Rationalise purchasing decisions (in future cannot just purchase on price: registered? use covered? supply vulnerable? SVHC?)**

Opportunities (cont.)

Existing and New Business

- **Better supply chain communication**
  - Trust
  - Understanding of SC
  - Systems in place
- **Good quality information**
  - Safety Data Sheets ((M)SDS)
  - Exposure scenarios
- **Competence on, confidence in, and support to, REACH**
- **Help suppliers and customers meet REACH requirements**
  - Generic / Customised CSAs
  - Registration
  - Data collection, generation and assessment

Opportunities (cont.)

Existing and New Business

- **Customers affected by other suppliers**
  - Be the solution not the problem
- **Alternatives - provide alternative substance, process or supply**
- **Marketing - demonstrate CSR (corporate social responsibility), Product Stewardship etc**
- **Service - competence and understanding, 'on top of' REACH, targeted CSA, support offered**
- **Alternative (substance, supplier or process) substitutes and innovatory solutions to REACH 'problems'**

Wider Regulatory Pressures…

Environmental Regulation

Benefits:

- Methiocarb => £hundreds of thousands
- TBT => £tens of millions
- DDT => £hundreds of millions
- PCBs => £1 billlion+

Lancaster University, Centre for Chemicals Management

Hard to argue against? Maybe not?

=> Continuing pressure on management of chemicals?

Lancaster Study: Conclusions

1. **Regulation of chemicals which persist and travel in the environment generates greater benefits**
2. **Human health benefits significant but not enough information to say is greater than avoided environmental health costs**
3. **Very large costs identified for damage to functioning of the ecosystem**

BUT ARE THESE BENEFITS WEIGHED THE SAME AS INDUSTRIAL COSTS?

Costs and Benefits of REACH

- **Variable approaches and methodologies (all open to criticism)**
- **Costs:**
  - £2.1 – £8 billion
- **Benefits:**
  - £4.8 – £283 billion (!!)
- **Hard to argue against even if you believe REACH approach is flawed?**
- **Again, are costs and benefits genuinely given the same weight?**

Staying Ahead of the Regulator

- **Does this all point to the likelihood of further Regulation?**
- **Does REACH point the way?**
- **Direct effects of REACH significant**
- **Indirect effects may be even greater**

The Up Side?

REACH => Substitution?

REACH is structured to encourage replacement of dangerous substances with safer ones…

- Improved hazard data so we all know what we are dealing with
- Further evaluation of likely dangerous substances
- Information to ‘recipients’ and consumers on substances of very high concern (SVHC)
- List of SVHC…’black list’
- Authorisation by use of a few targeted SVHC; weighty and expensive process will discourage all but a few ‘key’ uses

REACH => Innovation?

- **Safer the substance the cheaper the REACH process => develop and use ‘safer’ substances**
- **Safer the substance the less under threat it will be => less uncertainty, commercial advantage**
- **Safer the substance and/or process the cheaper the risk management measures (RMM) required per use => commercial advantage**

REACH => Innovation?

- **Substance withdrawal inevitable => gaps to fill with ‘better’ alternatives**
- **Costs encourage the removal of SVHC and other dangerous substances from the supply chain => substances or processes to replace use(s) of SVHCs**
- **Requirement to demonstrate adequate control (= risk) means that processes (= exposure) will need to be considered as well as substance properties (= hazard)**

REACH => Innovation?

Authorisation:

- **requires analysis of alternatives**
- **substitution plan if suitable alternatives identified**
- **research and development into alternatives may be required**

N.B. Third parties can input into the authorisation process

Alternative: a definition?

An Alternative is a substance that is capable of providing " a level of performance that is acceptable to the regulator, the user, (and the consumer if relevant) at a cost that is not prohibitive and whose supply is adequately assured."

Alternatives

- **REACH encourages search for ‘better’ alternatives**
- **‘Better’ means a balance of:**
  - Safer (by effect can be difficult)
  - Availability
  - Price
  - Performance
  - Business costs (e.g. reformulation, process change)
  - Impact of substance withdrawal
  - Reputation, PR etc
  - New markets

A Simple Example

	Toxicity	Ecotoxicity	Volatility
HIGH	Dichloromethane	Monochlorobenzene	Dichloromethane
	Trichloromethane	Trichloromethane	Acetone
	Monochlorobenzene	Toluene	Trichloromethane
	Toluene	Dichloromethane	Toluene
LOW	Acetone	Acetone	Monochlorobenzene

Royal Society of Chemistry

And the Winner is…

- **REACH will lead to substance withdrawal**
- **Some uses will no longer be ‘supported’ (legally or practically)**
- **Some substances or uses will be shown to no longer be ‘safe’**
- **Costs will change**
- **Just going the ‘substitution route’ may not be enough (high costs, performance?)**

…better performance with reduced human and environmental impact

How?

1. **Environmental/human health issues are not just overhead**
2. **Don’t just fix the problem**
3. **There is no waste**
4. **Reduced impact and higher value is possible**
5. **Think service not product**
6. **Think lifecycle**
7. **Downstream benefits?**

Chemistry Innovation Knowledge Transfer Network & others

Dimensions of Design

- **Compare what you are doing now with a new approach:**
  - Service not a product (see “Chemical Leasing”, Jakl et al 2004)
  - Durability (less disposal and replacement costs)
  - Reuse (design for end of life)
  - Mass (per service of the product)
  - Energy (per service of the product)
  - Safety (avoid toxicants and emissions)
  - Resource use (renewable, recyclable, biodegradable etc)

Innovation

- **REACH makes your life harder the more dangerous a substance is**
- **Designed to encourage safer substances**
- **REACH will create a greater market for alternatives (e.g. safer substances and processes)**
- **Awareness of composition and effects will rocket => pressure for safer products**
- **REACH => global pressure?**
- **Business will adapt even if Governments do not**

Changes in the way chemicals are used, perceived and managed as a result of REACH is inevitable. Anticipate it and work with it. The successful companies will…

REACH: up in a puff of smoke?

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