Promoting innovation to safer chemicals

Dr A. Michael Warhurst
Executive Director, CHEM Trust

Contents

• About CHEM Trust
• Innovation case studies
• Innovation towards what?
• Drivers for innovation
• Conclusion
About CHEM Trust

- A charity working at UK, EU & Global levels to protect humans & wildlife from harmful chemicals
- Working with scientists, technical processes and decision makers, in partnership with other civil society groups
- Focus on identification of, and action on, endocrine disrupting chemicals
- See blog for more: www.chemtrust.org.uk
Innovation

• Innovation
  – It’s new, but does that always mean it’s good?
• Some case studies, then a look at lessons learnt:
Case 1: True innovation

“x remains a growth industry. The “x as a service” business model, which grants easy access to x products and services, enables a broad base of unskilled, entry-level .. to launch .. of a scale and scope disproportionate to their technical capability and asymmetric in terms of risks, costs and profits.”

“at the top of the pyramid there resides the smaller group of highly-skilled individuals that exist within tight circles of trust and where the true potential for innovation lies.”
Sounds impressive?

- Innovative industry
- Creating growth and jobs for wide range of people, even those with low skills
- Combines latest technology with sophisticated psychological understanding of the customer
- Surely a good thing?
“Cybercrime remains a growth industry. The Crime-as-a-Service (CaaS) business model, which grants easy access to criminal products and services, enables a broad base of unskilled, entry-level cybercriminals to launch attacks of a scale and scope disproportionate to their technical capability and asymmetric in terms of risks, costs and profits.”

Case 2: Animal food

- 1960s and the protein problem:
  - WHO concern about protein availability in future
  - ICI had idea of making animal feed, tried synthesis (too difficult), moved to fermentation
- What feedstock?
  - “a substance containing carbon that can be metabolized that had just appeared in abundant quantities under the North Sea – natural gas”
- A plan to make animal food from methane - ‘Pruteen’
  - Pilot plant operational in 1971; oil price shock 1973; go-ahead for manufacturing plant 1976 – Pruteen project later abandoned and used for other projects (e.g. Quorn) [1]
- Innovative, but not very sensible?
Case 3: Cosmetic innovation

• Innovation in consumer products
  “Starting in the 1990s, manufacturers of consumer products began to replace natural materials such as ground almonds, oatmeal and sea salt in personal care products with plastic microbeads” [2]

• Now microbeads are one part of a massive plastic pollution problem

• Who made the decisions? What factors did they consider???
Innovation towards what?

- Innovation is not good in itself
- Innovation needs the right direction to be societally beneficial
- How about towards sustainability?
Environmental sustainability

- One model:
  - “Four footprints” measurement of resource use [3]
  - Nature
  - Non toxic environment

- Sustainability is not just environment..
Broad sustainability/wellbeing

Different ways of doing this; try a facilitated discussion [see 4]
Regulation & innovation

• Commission’s “Better regulation toolbox”

“performance or outcome-based regulations grant greater flexibility to businesses in how they achieve the desired outcome, stipulating only at a relatively high-level what they can and cannot do. For their success, business activities must be appropriately incentivised and enforced.”

“Developing new products and improved processes is a risky and costly process and regulatory delay and uncertainty can add to this.”

“it appears that more stringent regulations are likely to induce radical innovations, provided that the distance between regulatory requirements and the status quo is not excessive and that the outcome is specified in a technology-neutral manner.”
Implications for chemicals

• Need to set the direction of innovation:
• A clear policy direction towards a non-toxic environment
• Action against problem chemicals without delay and uncertainty
• Minimising risk of moving from one problem to another
• Focussing on the future, not the past
• Improving public and environmental protection,
Economic challenge

• A competition in the market:
  – 1) Well established chemical group, produced cheaply with existing plant
    • Producer making money, plenty of resources to lobby for continued use; low price
  – 2) New chemical, new plant
    • Risky investment, lack of resources; higher price

• Who wins?
  – Number (1) – unless clear, predictable, pressure against substance (1) & maybe help to (2)
Promoting innovation

• Damage economics of (1)
  – Phase out the chemical in certain uses (toys, etc)
  – Identify as SVHC in REACH, partially restrict
  – *Tax (not at EU level, not in most countries)*
  – Full restriction

• Improve economics of (2)
  – Public subsidy to R&D, to demonstrating efficacy, to building plant etc
  – Public procurement, ecolabel etc
Acting on problem chemicals

- Current regulatory approaches are not acting fast enough to deal with problem chemicals
- Too many chemicals – and groups of chemicals – are discussed for years or decades
  - Bisphenols, Brominated Flame Retardants, Fluorocarbons, Phthalates
- Without action the cheap, old chemicals will win over the new ones
Ideas for speeding up action

• A. Accept reality of ‘currently estimated toxicity’
  – Delay is not protective
  – Acknowledge mixture effects, and EDCs

• B. Greater use of generic risk assessment

• C. Don’t leave gaps

• D. Act on groups
A. Currently Estimated Toxicity

- Risk = Hazard x Exposure?
  - No - we almost never know these numbers for certain

- Currently estimated risk (CER) = currently estimated hazard (CEH) x currently estimated exposure (CEE)
  - The reality

- Currently Estimated Toxicity CET often increases over time [5], but real toxicity is a stable fact
  - Increases in CET = levels not protective in the past – e.g. Lead

- Mixtures and subtle developmental effects (e.g. EDCs) increase the problem of accurately estimating these numbers

- How address?
  - Less confidence in risk assessment, more precautionary action
A probability exercise

• What should be the currently estimated toxicity of a unknown chemical?
  – Zero, or an average toxicity for chemicals, or a worst case?

• If you know the structure, but not much more?
  – Zero, or an average of similar chemicals, or the worst in the group?

• There is no scientific justification for zero
  – Therefore we must do something else

• Implication for innovation
  – We need innovation towards low hazard groups of chemicals
  – And innovation away from problematic groups
B. More generic risk assessment

- E.g. for products with clear exposure to vulnerable groups
- Generic risk approach (hazard based cut off)
  - Already the case for toys
    - Needs better enforcement e.g. 3rd party testing (US approach)
  - What about furniture, carpets, food contact materials?
- Much faster, more protective & more predictable approach
C. Don’t leave gaps

- Chemical use in most non-plastic food contact materials is effectively not regulated at EU level
  - i.e. paper, card, ink, glue, coatings
- Chemical safety of recycled non-plastic food contact materials (e.g. pizza boxes) effectively unregulated
- Idea that food contact materials not important enough to be regulated is bizarre
  - EU Parliament now doing own initiative report
  - More info: http://www.chemtrust.org.uk/tag/packaging/
- NB: mixtures, impurities, reaction products are also a hole in the chemicals regulatory system
D. Acting on groups

• Innovation isn’t moving from one problem chemical to a not-yet controlled one in a group
  – E.g. Perfluorocarbons (PFCs), Brominated flame retardants (BFRs), Phthalates etc

• At the moment it often is
  – Making innovation to safer alternatives more difficult
Acting on groups in REACH

• Substance evaluation is a potential route, as long as the results can be acted on
• But we need decent data…
Deca BDE in REACH

- Deca BDE is a brominated flame retardant which is currently in the restrictions procedure.
- The summary of RAC & SEAC opinions [6] points out problems with the industry registering this chemical:
  - "It should be noted that REACH registration dossiers for decaBDE do not contain information on the environmental exposure of decaBDE, either on a per use, or on an aggregated basis. This is because the current registrations are based on the information requirements prior to the decision to identify decaBDE as a PBT/vPvB substance (in December 2012), i.e. as decaBDE was not classified as hazardous by the registrants, exposure assessment (including exposure scenario development) and risk characterisation were not required. As a consequence of the identification of decaBDE as a PBT/vPvB updates to the registration dossiers of decaBDE are now pending, but have not been received by the Agency at the time of publication of the opinion. RAC notes that this legal update of the registration dossiers would have helped the evaluation."
- A high profile, controversial chemical - how many other registration dossiers are hiding important problems? Where are the prosecutions?
Using evaluation

- Identify groups of concern
  - E.g. Announce a 10 year programme to evaluate all organo-fluorine, -bromine & -chlorine substances
    - Predictable timetable allows companies to make sure their dossiers really do demonstrate adequate control
  - If SVHC, then on candidate list, if adequate control not demonstrated in dossier, then restrict

- Use new approaches to identify new chemicals & groups for evaluation
  - Expression profiling, genomic techniques, computer based
  - Including a focus on EDCs, mixtures etc
Burden of action in REACH

- REACH was intended to reverse the burden of proof, creating industry responsibility to demonstrate safety
  - Ensuring that chemicals are used safely
- Implementation approach means that regulator must demonstrate risk to get restriction – and then argue about socioeconomic implications
  - What about restrictions as a result of chemicals safety reports not showing adequate control?
  - Socioeconomic assessment too focussed on unrealistic assumptions, including economic costing, e.g. doesn’t consider CET, can’t cope with vPvB.
- Example of PFCs shows that a more effective approach is needed [7]
  - Companies are moving from one persistent PFC to another
  - REACH was supposed to stop this happening – and encourage innovation, not encourage inaction.
Conclusions

• Innovation is not a good thing in itself
  – It must be in the right direction, sustainability

• Chemical regulations should help set this direction
  – But at the moment it’s no data, no action – not no data, no market & REACH is permitting this

• Key improvements:
  – Acknowledge reality of CET, expand generic risk assessment, close gaps (food contact)
  – Act on groups – evaluation, then restriction/authorisation

• REACH has changed many things, but lack of data is still rewarded, and burden of proof for authorities is still too high
  – This damages innovation to safer alternatives
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