Risk versus hazard: The case of BPA in Europe

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Background

- There has been a lively debate within regulatory agencies in many European countries whether regulations should be based on:
  - Hazard classification: that is the potential for a substance, activity or process to cause harm or and adverse effect; or
  - Risk assessment: A combination of the likelihood and the severity of a substance, activity or process to cause harm;

Background 2

- Hazard classifications and risk assessments are not mutually exclusive: to be able to assess risks one first need to understand the hazard; yet
- Many NGOs argue against risk assessments:

  "The basis for risk assessment is the un-scientific belief that risk can be foreseen and controlled. In an infinitely complex system, such as chemicals, the risk is simply impossible to contemplate." (International Chemicals Secretariat 2010)

* Yet risk assessments are slowly growing in popularity;

Background 3

- Risk assessment has a shorter policy history in Europe than in the US;
- Popularised in the UK following the Royal Society 1983 study;
- Widely used and discussed in the Netherlands in the 1990s (e.g. Health Council of the Netherlands 1995;1996);
- Did not feature in EU case law until the early 1990s (Fisher 2010);
- Grew in popularity following the Commission's White paper on the precautionary principle as well as the establishment of the European Food Safety Authority (EFSA);

Background 4

- As risk assessment is a fairly new field, how rigorous are the various European bodies in applying the methodology?
- Do some European regulatory bodies/member states favour risk assessments over hazard classifications and vice a versa?
- Are there differences in the application of risk assessments in the food and environmental sectors?

Methodology

- To address these questions the following research methodologies were employed:
  - Examination of relevant academic articles;
  - Survey of grey literature (most notably policy statements and background reports from DG SANCO, ECHA, EFSA, FSA, HSE, Swedish Chemicals Agency;
  - Interviews with 45 policy makers/stakeholders in Berlin, Brussels, Copenhagen, Helsinki, London, Paris and Stockholm including high ranking officials at: DG Enterprise, Danish Env Ministry; DG SANCO, ECHA, EFSA, Finnish Food Safety Authority, FSA, HSE, KemI, Secretariat General, SFA, Swedish Env. Ministry and a number of senior politicians;

BPA background

- BPA controversy began in the US in early 1990s when it became clear that BPA migrated from plastic laboratory bottles into water (Krishnan et al 1993);
- Sparked concern that BPA could be an endocrine disruptor;
- A number of US studies using low doses of BPA (yet not meeting Good Laboratory Practice) indicate that the chemical can cause a number of significant health effects on laboratory animals;

BPA background 2

- EFSA was asked to examine these studies. Took the view that they suffered from a combination of lack of reproducability and small sample sizes;
- EFSA also questioned the primary method of administration (injection into blood stream over oral administration);
- EFSA BPA panel 2008 took the view that BPA is safer than initially thought;

BPA background 3

- Political pressure to regulate BPA in Europe did not disappear -made worse by Canadian decision to ban BPA from baby bottles;
- In spring 2010 Denmark put forward a temporary ban on BPA materials that are in contact with food for children 0-3 years of age-following the Stump et al 2009 study focusing on the development of neurotoxicity in rats who had BPA in their diets;
- France puts forward a similar law in March 2010;

BPA background 4

- Seeing these regulatory policies coming into place DG SANCO asks EFSA to:
- Check recent scientific literature on the toxicity of BPA to assess whether the tolerable daily intake (TDI) should be updated;
- To assess a new study on possible neurodevelopment effects (Stump study);
- To advice on the risk assessment carried out by Denmark’s DTU Food Institute;

BPA background 5

- EFSA concludes on Sept 30th, 2010 that there is no convincing evidence that it would change the TDI of 0.05 mg/kg bodyweight;
- Denmark and France are outraged;
- DG SANCO decides on the 26th November 2010 to ban BPA from baby bottles by mid 2011 siting the EFSA study;

BPA Background 6

- As Commissioner Dalli argued at the time of the announcement:

  "In the view of the recent opinion of EFSA, I had stressed that there were areas of uncertainty, deriving from new studies, which showed that BPA might have an effect on the development, immune response or tumour production. The decision taken today is good news for European parents who can be sure that as of mid 2011 plastic infant bottles will not contain BPA."

General Results: 1

- Confusing risk with hazard-Field of risk analysis is very US/Anglo Saxon focused. Some languages (e.g. Dutch,French,German, Swedish) does not differentiate between risk and hazard but rather risk vs danger;
- Some nations more risk based (UK) while others much more hazards based (Denmark/Sweden);

Results BPA 1

- There are clear pushers and pullers for chemical and environmental regulation in Europe-e.g. Denmark called for a ban of BPA from children's sippy cups;
- The rise of the "post trust society" leading to risk averse regulators-one reason for French pushing for a BPA sippy cup ban;
- Political brownie points: easy to push for bans or fight certain environmental issues that do not effect the economic basis of the country in question;

Results BPA 2

- “To be honest the Swedes are hypocrites. On substances that are of no importance to their economy or culture they argue for blanket bans, but when it comes to their beloved fermented herring they use risk assessment arguments to keep the product, even if the fish are heavily contaminated.” (British regulator September 2010)

Results BPA 3

* The silo effects of regulatory agencies: KemI wants to use hazard assessment to ban BPA, while SFA wants to use a risk assessment. Similar split occurred in Denmark. In addition there was a clear lack of coordination between the various nation states;
- BPA (particularly with regard to baby bottles) has been stigmatised;
- DG SANCO, although noting that it is science based, used a hazard assessment to justify a sippy cup ban;

Recommendations and conclusions

- Need to develop a European led understanding of risk assessment;
- Ensure scientific peer review of the science used in the making of European regulatory decisions;
- Develop media guidelines to help ensure journalists to become better communicators of risk, science and uncertainty;

Recommendations and conclusions

- Need to improve risk communication capacity and competences;
- Properly interpreting and implementing the Commission’s communication on the precautionary principle;
- Establish a scientific advisory board for the European Parliament;
- Establishing a chapter of the Society for Risk Analysis in Scandinavia