Bridging the Risk-Hazard Divide

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Introduction

The often referred to risk-hazard divide is commonly exaggerated. With some exceptions, few in the risk camp argue against hazard classification as basis for labelling of e.g. carcinogenic substances (which has been the case for decades[1]) and few in the hazard camp criticise the use of risk assessments, once they are established. Agencies and politicians commonly look at both sides of the coin in practise. However, improved chemicals management would benefit from further bridging the risk-hazard divide. Professor Lofstedt does a good job in arguing from a risk perspective, but he leaves out much of the other side of the coin, so in the following, I will discuss his perspectives and try to complement his recommendations.

The two cases

In practise, it may be difficult to draw a line between hazard and risk assessments. Standards for risk assessments vary considerably and so do management conclusions based on similar scientific findings. The case of BPA illustrates this. Lofstedt concludes that advocates of restrictions use hazard-based arguments, whereas their opponents require risk assessments. However, a recent comparative analysis of the BPA controversy showed that studies, which Lofstedt places in either hazard or risk categories, rather are various forms of risk assessments, and that conclusions depended on how uncertainties of low-dose effects were evaluated[2]. Among the assessments, the one stating the highest risks was done by academics who frequently had published scientifically on BPA, and it recognised scientific data that were excluded by other assessment groups that relied on standardised methods.

Consequently, the conclusions on BPA were rather related to interpretations of risk assessments and connected uncertainties, than to whether assessments were risk or hazard-based.

In the second case, Lofstedt concludes that "BFRs, and in particular Deca-BDEs, have been regulated in Europe based on a hazard", and that this, for Deca-BDE, is due to the "class stigmatisation effect". While public debate and politicisation did play a role in this case[3], it doesn't validate the conclusion that regulations were based on solely hazard assessments. Some notes:

- The comprehensive EU Risk Assessment Reports for Penta-BDE and Octa-BDE each showed "a need for limiting the risks"[4].
- Concerning Deca-BDE, a number of technical experts were explicitly referred to in the 2002 EU Risk Assessment Report on Deca-BDE to consider a need for "risk reduction measures directly..."[5]
- Furthermore, in its opinion on the updated 2004 Risk Assessment Report on Deca-BDE, the Commission's Scientific Committee on Health and Environment Risks (SCHER) stated that it "strongly recommends further risk reduction"[6].
- The Swedish unilateral partial ban of Deca-BDE in 2006 was preceded by an analysis of risks, based on the EU reports, and it also discussed risks of potential substitutes[7].

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1 Council Directive 67/548/EEC on dangerous substances, OJ 1967 196/1.

2 A. Beronius, C. Rudén, H. Håkansson and A. Hanberg, "Risk to All or None? A Comparative Analysis of Controversies in the Health Risk Assessment of Bisphenol A", 29 *Reproductive Toxicology* (2010), pp. 132–146.

3 See J. Eriksson, M. Karlsson, and M. Reuter, "Technocracy, Politicization, and Non-Involvement: Politics of Expertise in the European Regulation of Chemicals", 27 *Review of Policy Research* (2010), pp. 167–185.

4 European Commission, *EU Risk Assessment Report, Diphenylether, pentabromoderivate*, Volume 5 (Luxembourg: European Communities 2001); European Commission, *EU Risk Assessment Report, Diphenylether, octabromoderivate*, Volume 16 (Luxembourg: European Communities 2003).

5 European Commission, *EU Risk Assessment Report, Bis(pentabromodiphenyl)ether*, Volume 17 (Luxembourg: European Communities 2002); see also C. Rudén and M. Gilek, "Scientific Uncertainty and Science-Policy Interactions in the Risk Assessment Process", in J. Eriksson, M. Gilek and C. Rudén (eds), *Regulating Chemical Risks: Multidisciplinary Perspectives on European and Global Challenges* (Dordrecht: Springer 2010).

6 SCHER, *Opinion on 'Update of the risk assessment of bis(pentabromophenyl)ether'* (European Commission: SCHER 2005).

7 Swedish Chemicals Agency, *Dekabromdifenyleter – underlag till ett nationellt förbud* (Stockholm: SCA 2004).

Clearly, the EU restrictions[8] of Penta-BDE and Octa-BDE were not hazard-based. Regarding Deca-BDE, the partial EU restriction was informed by the risk assessment and in line with the recommendation of the principal scientific committee in the field, so it can hardly be considered as purely hazard-based. The same goes for the previous[9] Swedish ban of Deca-BDE; it is better explained as a more protective normative conclusion based on risk assessments, than as an exclusively hazard-based decision. Moreover, the fact that Deca-BDE degrades to, e.g., already banned Penta-BDE informed the interpretation of risks[10].

Lofstedt claims that the two cases of BPA and Deca-BDE "carry a strong Scandinavian flavour". It is true that chemicals control in, e.g., Sweden dates back long and is ambitious[11], but regarding BPA, the debate started in the U.S. and Canada, rather than in (Northern) Europe, and Deca-BDE was restricted early in, e.g., Canada, Oregon, Washington and Maine, and the U.S. EPA is promoting voluntary phase-out, since "decaBDE persists in the environment, potentially causes cancer and may impact brain function"[12].

While media framing, lobbyism, politicisation and culture influence the understanding of risks, there is little support that the two cases concern a black and white risk-hazard divide between stakeholders or countries, and there is even less support that any hazard focus would be unscientific and invalid, whereas a risk focus would be the opposite. The cases rather relate to a core question in chemicals policy – how should uncertain inherent properties and exposure conditions be managed? I have discussed this challenge in detail elsewhere[13] and I will now relate it to Lofstedt's recommendations.

The recommendations

Lofstedt wants to place science centre stage in society and that risk assessments must precede decisions on restrictions. While I agree with Lofstedt that science education and peer review of risk assessment documents is truly valuable, it must be acknowledged that scientists themselves view assessment results and policy measures through normative lenses[14]. To allow purportedly objective science to guide media and societal debate would therefore be misleading, and I would rather recommend public scrutiny of which norms that underlie science-based advise, e.g., in expert committees. Here, the problem is not that experts are influenced by norms, but that these often are unseen by decision-makers. Consequently, democratic political presence in scientific bodies would be preferred over an allegedly "neutral and independent" advisory body for the European Parliament, as Lofstedt proposes. Similarly, I would prefer scientists being held democratically accountable, rather than "ensuring that regulators become more scientifically accountable".

When it comes to the European Commission's interpretation of the precautionary principle[15], I advise to play it down since it restricts the principle to management issues, meaning that interpretation of assessment uncertainties would not be guided by precaution and that problems therefore may be underestimated. Lofstedt's interpretation that "invocation of the precautionary principle must be preceded by a risk assessment" is problematic (and not in line with the communication[16]), since it requires data whose absence is the main reason for invoking precaution. According to numerous studies it is precisely in cases of uncertainty that the principle has been useful for assessment and management. Invoking the principle doesn't necessarily imply bans, but to apply default values (e.g., group classification), substitution (including assessing risk-risk trade off), alternative decision

8 Directive 2003/11/EC on restrictions of dangerous substances and preparations, OJ L42/45.

9 The ban was annulled in 2008.

10 Confer U.S. Environmental Protection Agency, *Polybrominated Diphenyl Ethers, Action Plan* (Washington: EPA 2009).

11 M. Karlsson, "The Precautionary Principle, Swedish Chemicals Policy and Sustainable Development", 9 *Journal of Risk Research* (2006), pp. 337–360; see also Eriksson *et al.* (2010), *supra* note 3.

12 U.S. EPA 2009, *supra* note 10; quote from S. Owens, EPA, "DecaBDE Phase-out Initiative", 2009, available on the Internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/deccabde.html> (last accessed on 29 March 2011). One reason for the voluntary line may be the strong burden of proof placed on the EPA under the Toxic Substances Control Act, see M. Karlsson, "The Precautionary Principle in EU and U.S. Chemicals Policy: A Comparison of Industrial Chemicals Legislation", in J. Eriksson, M. Gilek, and C. Rudén (eds), *Regulating Chemical Risks: European and Global Challenges* (Dordrecht: Springer 2010).

13 See Karlsson (2006 and 2010), *supra* notes 11 and 12.

14 The SCHER is an obvious example, see J. Eriksson, M. Karlsson, and M. Reuter, "Scientific Committees and EU Policy: The Case of SCHER", in J. Eriksson, M. Gilek, and C. Rudén (eds), *Regulating Chemical Risks: European and Global Challenges* (Dordrecht: Springer 2010).

15 *Communication from the Commission on the precautionary principle, COM(2000)1.*

16 *Ibid.*, p. 13, "The principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified …".

criteria and reversed burden of proof[17]. Furthermore, the Communication gives cost-benefit analysis a central role, which is also problematic since precautionary assumptions would hardly be needed if existing data would allow such an analysis, and why should restrictions require cost-benefit analysis, when market introduction of substances doesn't? This asymmetry is difficult to defend.

Finally, Lofstedt makes a case for a Scandinavian chapter of the Society for Risk Analysis. I would like to close by supporting that idea. It would stimulate further dialogue on the questions discussed by Professor Lofstedt in his article.

17 See Karlsson (2006 and 2010), *supra* notes 11 and 12, and references therein.