Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt

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Introduction

When called upon to regulate risk, the EU carries the threefold onus to (i) protect its people(s); (ii) ensure the functioning of the internal market; and also (iii) to allocate the resources available wisely and efficiently.

This creates a number of pressures and dilemmas for the EU, notably for the Commission when initiating legislation and for the EP and the Council when co-legislating.

According to a familiar script – faithfully narrated by Ragnar Lofstedt in his opening article –, the EU has, in recent years, been subscribing to a progressive ideal of regulation based on evidence. As a result, by making a commitment to the use of optimization tools, such as risk assessment and regulatory impact assessment, the EU has been gradually developing a European risk regulation model that seems to put the EU at the forefront of a wider move towards evidence-based policy-making. Given the historical affection of the EU integration process to technocratic modes of governance, this choice is not surprising.

Yet, as it emerges from the powerful *j'accuse* delivered by Lofstedt, the EU's turn towards evidence-based regulation has been accompanied by a parallel trend towards a more flexible, precautionary-oriented approach vis-à-vis the government of risk. Although not necessarily anti-scientific, this "other soul" of EU risk regulation is messy, pluralistic (it accepts "other legitimate factors"), and pragmatic (it is sensitive to public demand). Moreover, although highly contested (especially by the industry) – given its inherent unpredictability –, it clearly expresses a variety of wisdoms that fail to be apprehended by the rationale soul. This parallel dimension of EU risk regulation has been well portrayed by the General Court of the European Union when stating that – in the EU – "scientific legitimacy is not a sufficient basis for the exercise of public authority". This is because experts "although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities"[1]. In other words, in the EU risk decision-making the rational, technocratic soul is matched by another soul, which is less systematic, less predictable, in short, more human.

As a result, the EU risk regulation identity has been shaped and is evolving under the often-contradictory directions provided by its dual souls. Therefore it is no surprise that today the resulting tension between the necessity for a rational, evidence-based decision-making and the wider demand for a flexible, precautionary-oriented regulatory approach stands as the defining feature of the EU risk regulation. In particular, by allowing restrictive regulatory action in situations of documented scientific uncertainty, the precautionary principle embodies the uneasy co-existence between the two souls[2].

In our view, to be fully apprehended, the "hazard vs risk" debate should be measured against this dual nature of EU risk regulation.

As he did in the past when juxtaposing the precautionary principle to regulatory impact assessment[3], Lofstedt ably spots an on-going trend (yesterday, it was less precaution and more RIA; today, it is more hazard classification and less risk assessment) to cater attention to the fragile nature as well to the inherent limits of EU risk regulation. This is a commendable effort.

Yet by failing to frame the "hazard vs risk" debate within the above-described dual nature of EU risk regulation, his analysis may fall short in suggesting a way out of the conundrum he meritoriously denounces.

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1 Case T-13/99 *Pfizer Animal Health v. Council*, 2002 ECR II-3305, para. 201.

2 G. Majone, "What Price Safety? The Precautionary Principle and its Policy Implications", 40(1) *Journal of Common Market Studies* (2002), pp. 89–109.

3 R. Lofstedt, "The swing of the regulatory pendulum in Europe: From precautionary principle to (regulatory) impact analysis", 28 *Journal of Risk and Uncertainty* (2004), pp. 237–260.

The two souls of EU risk regulation in the BPA case study

From a strictly legal point of view, it is not correct to argue – as Lofstedt does – that BPA and Deca-BDEs "have been regulated in Europe based on hazard". Indeed, as it emerges from the recorded legislative history[4], both substances have been subject to a risk assessment, not to a mere hazard classification[5]. Although lengthy and complex, fully fledged risk assessments were carried out. Yet, on both occasions, they reached a conclusion not justifying a restriction.

If this is the case, how can one explain the adopted bans? That's where Lofstedt's critique kicks in.

Let's focus on the most recent case: BPA. Here, the final decision (Directive 2011/8) clearly departs from the outcome of the scientific process. Although the EFSA Panel on food contact materials, enzymes, flavourings and processing aids concluded that no new study could be identified which would call for a revision of the current tolerable daily intake, the Commission, acting under comitology and in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health (consisting of member states' representatives), adopted a ban on BPA-made baby bottles.

In Lofstedt's view, this outcome is to be ascribed to the EU legislator embracing "hazard classification", instead of relying on "risk assessment". Although "hazard concerns" have certainly played a role in the adoption of this decision – notably in the Commission's mind as well in those of the member states' representatives, it is suggested instead that its outcome has more to do with a EU decision-making process which allows the regulators to depart from the evidence gathered during the risk assessment procedure.

In other words, the EU did its scientific home works, but it is not bound by them.

Let's zoom into the adopted Directive banning BPA-made baby bottles. To justify the ban, the Commission expressly invoked the precautionary principle as the correct legal basis for its decision. It did so after spinning the "uncertainties in the present state of scientific research with regard to the harmfulness of BPA exposure to infants" and emphasising the "particular vulnerability of infants to potential effects of BPA"[6].

Although the legality of this Directive might be questioned (notably on the ground of its conformity with the precautionary principle's requirements), the possibility of departing from the evidence gathered in the regulatory process is recognized today – not least from settled EU case law – and fully reflects the "other soul" of EU risk regulation.

Indeed, as acknowledged by Lofstedt, not without some disillusionment: "it is far too easy at the present time to create regulations that are not science base".

Yet what Lofstedt suggests to do to prevent this situation from happening, i.e. requiring the regulators to provide the explanation for their differences, has already been codified in some EU risk regulations, such as the GM Food and Feed regulation, the Nutrition and Health Regulation as well as the Medicines Regulation[7]. Interestingly enough, also the Food Contact Materials Regulation, governing BPA, foresees such a duty in its Article 11(2)[8]. Given the inherently procedural nature of such a duty, it is unlikely that this alone will magically contribute to "the making of more scientific and risk-based European-wide policy making".

4 Commission Decision 2005/717/EC of 13 October 2005 amending for the purposes of adapting to technical progress the Annex to Directive 2002/95/EC of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment, OJ 2005 L 271, p. 48; Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, OJ 2011 L 26/11.

5 Communication from the Commission on the results of the risk evaluation of chlorodifluoromethane, bis(pentabromophenyl)ether and methenamine and on the risk reduction strategy for the substance methenamine, 29 May 2008; EFSA, "EFSA Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A", 8(9) *EFSA Journal* 2010; p. 1829.

6 Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles, OJ 2011 L 26/11.

7 See, for instance, Art. 7, para. 1 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ 2003 L 268, p. 1; Art. 17, para. 1 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ 2006 L 404, p. 9; Art. 10, para. 1 and Art. 35, para. 1 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L 136, p. 1.

8 Article 11, para. 2, Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ 2004 L 338, p. 4.

Don't kill the "other soul" of EU risk regulation, make it visible

The "hazard vs risk" debate evokes other classic themes of risk regulation characterised by a dichotomy structure, such as "lay people vs expert judgment"[9] and "science vs other legitimate factors"[10] – just to mention a few. Similar to these grand dichotomies, also the "hazard vs risk" is inherent in all systems of risk regulation and, being an expression of the dual nature of EU risk regulation, seems here to stay. What is needed is a way to solve the tension existing between these two souls and make them talk to one another. Most of Lofstedt's recommendations may sensibly contribute to this objective. Yet it would be a mistake to believe that the "other soul", the less technocratic but more democratic, of EU risk regulation should be sacrificed on the altar of rationality.

Rather, in a model characterised by a dual and inherently conflicting nature – where the lines between hazard classification and risk assessment are often blurred –, what is needed is to inject more transparency into the decision-making process so as to make visible what is the role, and exact weight, that each "soul" plays in the process of adopting risk regulations. In particular, there is an urgent need – which is also increasingly felt by the EU Courts when called upon to review the legality of risk-based measures –, to know where, in any given risk regulation decision, the scientific evidence stops and where other concerns kick in.

I would like to add this recommendation to the other valuable ideas advanced by Lofstedt in his article.

The addressees of my humble recommendation are virtually all actors involved in the EU risk decision-making process, from the scientific agencies to the Commission committees, from the Commission officials to the MEPs.

The innovative changes brought about by the Lisbon Treaty on the workings of "comitology", where most of risk regulations are adopted, may contribute favourably to this process[11]. Although it is too early to predict the impact of "new comitology" on EU risk regulation decision-making, the process might become under the pressure of the EP more transparent and accessible.

In sum, the debate over "hazard versus risk" cannot escape a EU decision-making system where the concerns stemming from hazard classification can legally override the outcome of the evidence-based risk assessment procedures.

9 C. Sunstein, "The Laws of Fear", 2001, University of Chicago Law & Economics, Olin Working Paper No. 128.

10 A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO* (London: Cameron May 2007).

11 Following the entry into force of the Lisbon treaty, the so-called "Comitology system", the execution of delegated competence from the Council, has been reformed. In particular comitology was abolished, and the Treaty instead distinguishes between "delegated" acts (Art. 290 TFEU) and "implementing" acts (Art. 291 TFEU), subject to entirely different legal frameworks.