Risk versus Hazard – How to Regulate in the 21st Century

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In Europe, debate as to whether one should regulate chemicals based on intrinsic hazard or assessment of risk, or possibly a combination of both, has been gaining momentum. This article first provides a brief history of this risk versus hazard debate. Secondly, it examines how European regulators are currently handling the regulation of two chemical compounds, namely Bisphenol A and Deca BDE (a brominated flame retardant), based on forty-five expert interviews with regulators, policy makers and industry representatives in eight Member States, as well as with European Commission officials. The paper shows that there is no clear consensus as to when risk or hazard considerations should be the basis for regulatory decision-making, with wide discrepancies between Member States (e.g. the UK is overall more risk based than Sweden) and between regulatory agencies within Member States. The penultimate section puts forward a series of recommendations to help regulators and policy makers develop more consistent and science based regulations for Europe.

I. Introduction

Since the early 1970s with the formation of environmental regulatory agencies in many European states, there has been a lively debate about how best to regulate chemicals, including metals, food additives and preservatives, as well as certain foods themselves[1]. Should regulations be based on a hazard classification (that is the potential for a substance, activity or process to cause harm or adverse effect) or a risk (a combination of the likelihood and the severity of a substance, activity or process to cause harm) assessment[2][3]? In other words, should regulators ban substances that have an intrinsic ability to cause harm, or should they examine whether there is a real probability that these substances will actually cause harm, in part based on exposure[4]? To be clear hazard assessment and risk assessment are not mutually exclusive. In order to assess risks, it is necessary to first understand the hazard, so advocates of risk-based regulation are dependent on hazard classification taking place. The key component of the debate centres around whether regulatory decision-making can/should be based on hazard classification alone, eschewing risk assessment. From an economics perspective, decision making on the basis of just hazard classification usually ignores impact assessment, which is a distinct factor and in so doing often contributes to poor regulatory policy-making[5].

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1 J. McCormick, *Environmental Policy in the European Union* (Basingstoke, UK: Palgrave 2001); A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EU and the WTO* (London: Cameron May 2007).

2 K. Nordlander, C. Simon, and H. Pearson, "Hazard vs Risk in EU Chemical Regulation", 1 *European Journal of Risk Regulation* (2010), pp. 239–250.

3 UK Royal Society, *Risk: Analysis, Perception, Management* (London: Royal Society 1992).

4 This paper focuses specifically on approaches to regulation of industrial chemicals rather than providing a broad brush approach examining European regulation.

5 For an in-depth historic account of how regulations are developed in Europe please look at G. Majone (ed.), *Regulating Europe* (London: Routledge 1996).

Some environmental non-governmental organisations (NGOs) and environmental lobby groups denounce risk assessments and argue for more hazard-based controls. For example, the International Chemical Secretariat, one such NGO based in Gothenburg, Sweden, argues against risk assessment noting:
"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 anticipate.[6]"

It is clear that in Europe there has been a rather long, and at times acrimonious discussion, as to the merits of risk assessments for regulatory purposes especially with regard to chemical substances. Indeed until the early 1990s neither risk assessment nor risk management featured in European law[7]. In the case C-180/96 *UK v. Commission* in 1998, for example, there was no mention of the term risk assessment[8]. During the 1980s and 1990s some Member States eagerly adopted the risk assessment methodology. In 1995, for example, the Health Council of the Netherlands took the view that risk assessment was an integral part of the policy-making process[9]. Risk assessment as a key policy-making tool was accepted in the early 1980s in the UK and made more popular due to the seminal 1983 Royal Society study on the topic[10]. Similarly, regulatory agencies in a number of smaller Member States came to accept risk assessment methodologies and most of these now follow the risk assessment guidelines outlined by the United Nations Food Agricultural Organisation (FAO) and the World Health Organisation (WHO)[11].

In other European nations, however, the use of hazard classifications has dominated the regulatory discussions. Particularly interesting was the decision to use hazard classifications in the formulation of Sweden's goal to develop a toxic-free society by the year 2020[12], as it arguably served as a basis for the development of the European Union's (EU) Chemical White Paper of 2001[13][14][15].

The first significant use of risk assessment in the EU was associated with the 1993 Existing Substances Regulation[16]. However, arguably it did not grow in popularity until the early part of this century following the Commission's publication of its Communication on the precautionary principle[17]. This was in part due to the need to regain regulatory legitimacy in Europe following considerable criticism[18][19], as well as to proactively address the call for harmonisation of this and related risk-based tools by the World Trade Organisation's (WTO) Agreement on Sanitary and Phytosanitary Standards[20]. Indeed in that same year the European Commission published its path breaking study *First Report on the Harmonisation of Risk Assessment Procedures* which had an aim to:
"...promote an active debate on current practices for risk assessment used by the Scientific Committees of DG SANCO and to make proposals for developing convergent approaches which will aid harmonisation[21]*".*

The use of risk assessments and science-based risk management tools began to gain further ground in

6 International Chemical Secretariat, "Risk vs hazard", available on the Internet at <www.chemsec.org/chemsec/the-toxic-issue/risk-vs-hazard> (last accessed on 31 March 2011).

7 European Council, "Council Regulation (EEC) no 793/93 of 13th March 1993 on the evaluation and control of the risks of existing substances".

8 E. Fisher, "Risk, Regulatory Concepts and the Law", in OECD (eds), *Risk and Regulatory Policy: Improving the Governance of Risk* (Paris: OECD 2010).

9 Health Council of the Netherlands, *Not All Risks are Equal*, Publication No. 1995 06E, Committee on Risk Measures and Risk Assessment (The Hague: Health Council of the Netherlands 1995).

10 UK Royal Society, *Risk Assessment* (London: The Royal Society 1983).

11 FAO/WHO, *Application of Risk Analysis to Food Standard Issues. Report of the Joint FAO/WHO Expert Consultation* (Rome and Geneva: FAO/WHO 1995).

12 Swedish Cabinet Bill, *Svenska Miljomal: Miljopolitik for ett hallbart Sverige* [1997/1998 145] (Stockholm: Riksdagen 1997).

13 European Commission, *White Paper: Strategy for a future chemicals policy* (Brussels: COM 2001 88 Final).

14 R. Lofstedt, "Swedish Chemical Regulation: An Overview and Analysis", 23 *Risk Analysis* (2003), pp. 411–421.

15 I. Schorling, "The Green's Perspective on EU Chemicals Regulation and the White Paper", 23 *Risk Analysis* (2003), pp. 405–409.

16 European Council, "Council Regulation (EEC) no 793/93 of 13th March 1993 on the evaluation and control of the risks of existing substances", *supra* note 7.

17 European Commission, "Communication from the Commission on the Precautionary Principle" (Brussels: COM 2000 1 Final).

18 E. Fisher, "The Rise of the Risk Commonwealth and the Challenge for Administrative Law", 30 *Public Law* (2003), pp. 455–478.

19 G. Majone, *Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth* (Oxford: Oxford University Press 2005).

20 European Commission, "Communication from the Commission on the Precautionary Principle", *supra* note 17.

21 European Commission, "First Report on the Harmonisation of Risk Assessment Procedures" (Brussels: DG SANCO), p. 6.

2002 with the growing popularity of the so-called "Better Regulation Agenda" and with it the use of regulatory impact assessments (RIAs). These were seen as mechanisms to reduce regulatory burdens within the Commission and elsewhere[22]. In the same year the Commission adopted the General Food Law (GFL)[23]. The GFL followed the Commission's White Paper on Food Safety, which in turn was prompted by a number of food scandals, most notably the spread of BSE (mad cow disease) in Europe. It called for the separation of risk assessment from the risk-management process as a way to regain the trust of European food consumers[24]. This risk assessment/management separation led to the establishment of the European Food Safety Authority (EFSA). Since 2002 this Authority has become the eminent scientific risk-assessment authority for food policy issues in Europe and has been involved in a number of controversial issues ranging from genetically modified foods to Bisphenol A[25]. As a result there has been a rich and far ranging discussion regarding risk assessment within the European food sector involving academics, stakeholders, regulators and industry[26]. These discussions have not spread widely to other regulatory domains, however. There has, for example, been limited case law discussing the use of risk assessment and management tools in setting regulation in the non food sector, with the Pfizer, Alpha Pharma and Gowan cases being notable exceptions[27][28].

In Europe, many food, pharmaceutical and health regulators as well as policy makers are concerned about basing regulations on hazard classifications and implementing them via tools such as the precautionary principle "better safe than sorry"[29]. As the House of Lords Select Committee on Economic Affairs argued in 2006:
"In our view, the use of ill-defined and ambiguous terms in risk management and regulatory documents is generally unhelpful. There is a danger that they can induce an excessively cautious attitude to risk"[30].

Similarly the UK House of Commons Science and Technology Select Committee took the view:
"We believe that it is best to use the term precautionary approach, but with a consistent explanation of the degree and nature of the risks, benefits and uncertainty and an explanation of the concept of proportionality. It should never be considered a substitute for thorough risk analysis which is always required when the science is uncertain and the risks serious"[31].

German policy makers working in the food area also view risk assessment as an integral part of the risk management process. As one policy maker noted:
"I have my doubts as to whether you can take informed management decisions if you don't have relevant knowledge, i.e. no competence in risk assessment ... you just can't take management decisions without having sufficiently detailed knowledge on risk assessment.[32]*"*

Many environmental regulators and Green politicians, however, do not share this view. They see risk assessments as inherently complex, non scientific and costly, and contend that regulations should be based on hazard assessments and substitution principles. Inger Schorling, who for 10 years served as a Swedish Green MEP has argued:
"The only reasonable goal is to make the environment free from dangerous man-made chemicals and to try to keep the levels of metals close to natural levels. When there is a risk, the precautionary principle should be

22 For a useful discussion see 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.

23 European Council, "Regulation (EC) No 2002/178 of the European Parliament and the Council of 28th January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in the matters of food safety" (Brussels: European Council 2002).

24 E. Vos and F. Wendler, "Food Safety Regulation at the EU Level", in E. Vos and F. Wendler (eds), *Food Safety Regulation in Europe* (Antwerpen: Intersentia).

25 M. van Asselt and E. Vos, "Wrestling with Uncertain Risks: EU Regulation of GMOs and the Uncertainty Paradox", 11 *Journal of Risk Research* (2008), pp. 281–300.

26 M. Dreyer and O. Renn, *Food Safety Governance: Integrating Science, Precaution and Public Involvement* (Berlin: Springer 2009).

27 See, for example, E. Vos, "Antibiotics, the Precautionary Principle, and the Court of First Instance", 11 *Maastricht Journal* (2004), pp. 3–7.

28 The Pfizer and Alpharma judgments dealt with animal health issues while the Gowan judgment was triggered by the authorization process of a plant protection product.

29 UK HM Treasury, *Reducing Administrative Burdens: Effective Inspections and Enforcements* ((*The Hampton Review*) London: HM Treasury 2005).

30 UK House of Lords, Select Committee on Economic Affairs, *Government Policy on the Management of Risk, Volume 1 report* (London: The Stationary Office 2006), p. 25.

31 UK House of Commons, Science and Technology Committee, *Scientific Advice, Risk and Evidence Based Policy Making, Volume 1* (London: The Stationary Office 2006), p. 83.

32 This quote can be found in M. Dressel, S. Bochen, M. Schneider, W. Viehover, M. Wastian and F. Wendler, "Food Safety Regulation in Germany", in E. Vos and F. Wendler (eds), *Food Safety Regulation in Europe* (Antwerpen: Intersentia 2006), p. 318.

used. This means that the chemicals industry also has a special responsibility. They should stop producing persistent and bioaccumulating chemicals and try to find alternatives.[33]"

1. Why these differences?

Food and pharmaceutical regulators have a much narrower mandate compared to their environmental counterparts who operate in a very broad domain focusing on human and environmental risks in the air, water and land domains[34].

In terms of influence, budgets and policy interest there have been historically huge differences between these two areas. In Germany, for example, the state established its first food regulator in 1876 (Kaiserliches Gesundheitsamt) while the first national environment agency in that country did not come into existence until 1971 following the passage of the German Environmental Programme[35]. In addition, food and pharma regulators have generally had much bigger operational and research and development budgets than their environmental counterparts. In other words, quite rationally, people have preferred spending funds on protecting human health from direct exposure to substances rather than making environmental improvements. Is there any wonder that environmental regulators with limited budgets and less political power overall will use the cheaper, and thereby more efficient, hazard classifications and the precautionary principle as a basis to justify the banning of certain chemicals, metals and other materials?

2. Risk versus hazard: The key research questions

This study tries to address the following issues:

a) How rigorously are the various European and national bodies using scientifically-based risk analysis tools?
b) Which European regulators, either at the EU or national level really favour risk assessments over hazard classifications and what are the regulatory trends in the environment and food area?
c) Do these various regulatory bodies have different views on the use of risk vis-à-vis hazard than politicians – Members of the European Parliament or MPs and Ministers in the respective Member States?

This article attempts to answer these questions by examining in some detail two case studies namely: the phase-out of certain brominated flame retardants (in particular deca-BDE) and the partial ban of bisphenol A (BPA) first in Denmark and France and then in the EU as a whole from 2011. This study is based on reviews of relevant academic articles on these three topics, a survey of the grey literature, most notably policy statements and background reports from the European Chemicals Agency (ECHA), European Commission (in particular DG SANCO), European Food Safety Authority (EFSA), the Swedish Chemical Agency and the Swedish Food Administration as well as interviews with regulators, academics, policy makers, politicians and other stakeholders in Berlin, Brussels, Copenhagen, Helsinki, London, Madrid, Maastricht, Paris, and Stockholm. The majority of the research was conducted in the period between April and November 2010. In total forty-five expert interviews were conducted[36].

II. Background – risk vs hazard

What are some of the criticisms of risk assessments and hazard classifications and how long have they been used in influencing policy making? These questions are addressed in this section

1. A brief history of risk assessment

The tools and ideas used in risk assessment have been around for millennia, determining everything to whether housing in Babylon was safe, to estimat-

33 I. Schorling, "This Book: The Only Planet", in I. Schorling and G. Lind, *The Only Planet Guide to the Secrets of Chemicals Policy in the EU: REACH What happened and Why?* (Brussels: European Parliament, The Green/European Free Alliance 2004), p. 3.

34 In addition one could argue that assessing risks from substances that are directly ingested (via food or as a medicine) is less complex than evaluating exposure to substances via the environment.

35 R. Wurzel, *Environmental Policy Making in Britain, Germany and the European Union* (Manchester: Manchester University Press 2002).

36 These interviews were not recorded but summarized after the meeting in question. The information gleaned from them was primarily used to assist the author to gain a wider understanding of the regulatory environment in the country or agency in question. When a regulatory or policy maker was quoted in the text below, this was done so anonymously. Prior to scientific peer review the draft article was sent to the regulators and policy makers who were interviewed to ensure factual correctness.

ing shipping loss in the middle-ages and understanding the probability of gambling[37]. It did not start to gain regulatory importance until the 1950s, however, when it was seen as a useful tool in predicting failure of space bound vessels, as well as understanding the safety of nuclear power stations and chemical plants, work place safety, public health and environmental hazards[38]. Today risk assessments, based on toxicological and or epidemiological data, are used as a basis for many environmental and health regulations throughout the world[39].

2. History of hazard classification

The use of hazard classifications for the setting of regulation has been around for several hundreds of years. It served as a basis for setting chemical control laws in Sweden in 1756, for example[40], and has been increasingly used in Europe during the second half of the 20th century, including the 1967 European Council Directive (67/548/EEC) on labelling, classifying and packaging dangerous substances and the 1973 Swedish Act on hazardous chemical products[41]. In recent years hazard classifications have increased in popularity within the environmental arena where it is used in some European Member States as a reason to ban certain chemicals and metals on the basis that they are endocrine disruptive, bio-accumulative or cause cancer. In this regard regulators find that hazard classifications are cost effective and efficient for banning entire lines of chemicals[42]. The Danish prohibition of Pentachlorophenol (PCP)[43], the Swedish decision to aim for a toxic-free society by the year 2020[44], the Danish and French bans and the EU proposed ban of bisphenol A from baby bottles are all based on hazard assessments.

3. Confusing risk with hazard

What makes the discussion rather more complicated, however, is that the public and many stakeholders confuse the terms risk and hazard, particularly when applied to chemicals[45]. In a detailed study by Peter Wiedemann and his colleagues for the German Federal Risk Assessment Bureau, more than 80 % of German respondents confused the terms[46]. This is further complicated by the fact that most of the research done in the field of risk analysis is primarily American in origin. Until recently, 90 % of all research in the risk field was carried out in the United States for public and private bodies[47]. As a result the whole language around risk assessment is grounded in English, where there is a clear linguistic distinction between risk and hazard. That crucial linguistic distinction is not the same in Dutch, German or in Swedish, for example, which leads to greater confusion. As a case in point, the Swedish language does not have an expression for hazard, but rather the closest word is "fara" which means danger.

4. Criticisms of risk and hazard

One of the main problems with hazard classifications are that they are only one initial part of the risk analysis process. That is to say, policy makers can take the decision to ban certain chemicals and metals on the assumption or idea that they may be hazardous without testing whether this is actually

37 P. Bernstein, *Against the Gods: The Remarkable Story of Risk* (New York: John Wiley and Sons 1996).

38 For an in-depth discussion please see D. Paustenbach (ed.), *Human and Ecological Risk Assessment: Theory and Practice* (New York: John Wiley and Sons 2002).

39 US National Research Council, *Science and Decisions: Advancing Risk Assessment* (Washington DC: National Academy Press 2009).

40 M. Karlsson, "The Precautionary Principle, Swedish Chemicals Policy and Sustainable Development", 9 *Journal of Risk Research* (2006), pp. 337–360.

41 T. Christoforu, "The Precautionary Principle, Risk Assessment, and the Comparative Role of Science in the European Community and the US Legal Systems", in N. Vig and M. Faure (eds), *Green Giants: Environmental Policies in the United States and the European Union* (Cambridge, MA: MIT Press 2004).

42 Swedish Committee on New Guidelines on Chemicals Policy, *Non Hazardous Products: Proposals for Implementation of New Guidelines on Chemicals Policy [SOU 2000:53*] (Stockholm: Fritzes 2000).

43 96/211/EC, "Commission Decision of 26th February 1996 concerning prohibition of pentachlorophenol (PCP) notified by Denmark", *Official Journal* LO 68,19/03/1996, 0032-0040.

44 Lofstedt, "Swedish Chemical Regulation: An Overview and Analysis", *supra* note 14.

45 M. Tyshenko, K. Pillips, M. Mehta, R. Poirer, and W. Leiss, "Risk Communication of Endocrine-Disrupting Chemicals: Improving Knowledge, Translation and Transfer", 11 *Journal of Toxicology and Environmental Health Part B* (2008), pp. 345–350.

46 E. Ulbig, R. Hertel and G. Bol (eds), *Evaluation of Communication on the Differences between "Risk" and "Hazard"* (Berlin: Federal Institute for Risk Assessment 2010).

47 G. Majone, "Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth", *supra* note 19.

the case[48]. Obviously, hazard assessments are quicker and cheaper to implement, but in the long term they can have significant consequences as they tend to ignore risk-risk tradeoffs[49].

Risk assessment has its problems too. In effect both risk assessments and risk management strategies limit the power of the administrator. By arguing for these tools, administrators establish de-facto scientific boundaries for what they can and cannot regulate[50]. In other words, policy makers may have less freedom to politically regulate in a world where risk assessment and management tools are used. In addition, historically risk assessments have been based on a wide array of different methodologies leading in turn to different outcomes, which decrease their usefulness in terms of predictability[51]. Other critics of the model feel that the narrowness of the focus, often limited to what can be measured quantitatively[52], ensures that the issues that cannot be measured in this way (e.g. human values) are ignored[53]. Although risk assessments are more comprehensive to their very nature than hazard classifications, they are not always pure scientific affairs. In cases when there are high levels of scientific uncertainty, expert judgements are often used, which in turn can at times be incorrect[54]. Finally, as risk assessment are often expensive and time consuming, critics argue that they can be open to abuse by external bodies who may benefit from delay – for example, by injecting some form of scientific uncertainty they can delay regulation yet further. This does not therefore necessarily lead to better regulatory decisions[55][56].

III. The two case studies

To address the question of how European and national authorities actually regulate risk, two case studies were selected for examination following discussions with policy makers and regulators in both Brussels and London. Selection was based on the following criteria:

a) Is the case in question "European" in scope? That is has it been discussed in multiple Member States as well as within the European Commission?
b) Is it comparatively easy to get data on the case? Is there information in the public domain that can be gathered and analysed?
c) Are policy makers, stakeholders and regulators willing to speak about the case in question? and
d) Have the selected case studies received at least some media attention, ensuring that the non specialists interviewed will have a basic understanding of the topic at hand?

Based on these criteria the following case studies were selected: Bisphenol A and the Brominated flame retardant Deca-BDE. After an initial set of interviews with the UK Food Standards Agency and the UK Health and Safety Executive (the UK competent authority for REACH) it was clear that policy makers and regulators felt comfortable discussing these cases. Each case study is divided into three distinct sections: background, political and NGO attention and risk or hazard issue?

1. BPA

a. Background

Bisphenol A, or BPA, is a human-made chemical used in the manufacture of plastics, that was first developed in 1891[57]. It was initially intended as a useful synthetic oestrogen hormone to help women with a wide range of female sexual fertility issues[58]. By the early 1950s scientists were using BPA for

48 D. Paustenbach, "Human and Ecological Risk Assessment: Theory and Practice", *supra* note 38.

49 J. Graham and J. Wiener, *Risk vs Risk: Tradeoffs in Protecting Health and the Environment* (Cambridge, MA: Harvard University Press 1995).

50 J. Applegate, "A Beginning Not an End in Itself: The Role of Risk Assessment in Environmental Decision Making", 63 *University of Cincinnati Law Review* (1995), pp. 1643–1678.

51 P. Montague, "Reducing the Harms Associated with Risk Assessments", 24 *Environmental Impact Assessment Review* (2004), pp. 733–748.

52 W.K. Viscusi, *Rational Risk Policy* (New York: Oxford University Press 1998).

53 B. Ackerman and L. Heinzerling, *Priceless: On Knowing the Price of Everything and the Value of Nothing* (New York: The New Press 2004).

54 D. Michaels, *Doubt is Their Product: How Industry's Assault on Science Threatens your Health* (New York: Oxford University Press 2008).

55 T. McGarity and W. Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* (Cambridge, MA: Harvard University Press 2008).

56 W. Wagner, "The Science Charade in Toxic Risk Regulation", 95 *Columbia Law Review*, pp. 1613–1720.

57 For a good policy overview on BPA see A. Alemanno, "The Fabulous Destiny of Bisphenol A (BPA)", 1 *European Journal of Risk Regulation* (2010), pp. 397–400.

58 S.A. Vogel, "The Politics of Plastics: The Making and Unmaking of Bisphenol A 'Safety'", 99 *American Journal of Public Health*, S3, pp. 559–566.

the manufacture of epoxy resins. These resins were turned into long lasting and durable coatings found on anything from steel drums to false teeth. By 1957 chemists were using BPA in the manufacturing of hard, transparent, and rather heat resistant plastic material called polycarbonate to replace glass containers for food and electronic products, including baby bottles[59]. The epoxy resins found in packaging materials serve a variety of purposes. They act as a protective lining on the inside of metal-based food and beverage cans, halting the corrosion of cans and limiting the contamination of foods. When used in bottles polycarbonate can increase heat resistance and durability. Most studies indicate that BPA in food packaging provides high level of food safety and value to food supply[60].

The controversy surrounding BPA began in the early 1990s when a number of researchers at Stanford University in the United States realised that the chemical was migrating from the plastic (polycarbonate) laboratory bottles into the water that they were using[61]. This sparked concern that BPA might be migrating from packaging used for consumer products and that BPA, similar to other artificial and natural hormones (e.g. female birth-control pills), might also be an endocrine disrupter. At this time, endocrine disruption was starting to be much discussed in both the US and Europe by policy makers, regulators and academics following the publication of a number of books and articles, most notably *Our Stolen Future*[62]. One researcher who is highly active in the field of endocrine disruption is Dr. Frederic vom Saal of the University of Missouri, who began testing artificial oestrogens, including BPA, following the Stanford findings. His first paper on the topic, published in 1997, indicated higher than anticipated oestrogen responses[63]. Since this initial study, Dr. vom Saal and his colleagues at the University of Missouri have carried out a number of small scale studies on mice (and more recently in-vitro) examining how they respond to low doses of BPA. To date the majority of these studies have not been replicated by other researchers[64]. Most of these studies were carried out on a small number of mice and did not therefore meet the Organisation for Economic Cooperation and Development (OECD) defined Good Laboratory Practice (GLP). However, they indicate that very low levels of exposure to BPA, via injection into the blood stream of mice or (less often) given to them orally, may have significant health effects including reproductive abnormalities, obesity, breast and prostate cancer and neurobehavioral problems in mice[65] [66].

The studies by vom Saal and his colleagues did not initially change the regulatory policy climate regarding the safety of BPA. Regulators in the US (the FDA in particular) and elsewhere (e.g. the European Food Safety Authority (EFSA) examined the research findings but viewed them as somewhat unreliable[67]. They suffered from a combination of lack of reproducibility and small sample sizes. The studies focused on low doses and primarily addressed injection into the blood stream rather than oral administration, which may have better reflected real-world consumption[68]. The supposed level of BPA uptake is significantly different depending on the method of administration. For example, after reviewing the research conducted by vom Saal and his colleagues, EFSA's BPA 2008 panel took the view that BPA is safer than initially

59 K. Aschenberger, P. Castello, E. Hoekstra, S. Karakitsios, S. Munn, S. Pakalin, and D. Sarigiannis, *Bisphenol A and Baby Bottles: Challenges and Perspectives* (Ispra: European Commission, Joint Research Centre 2010).

60 For a good review see K. Aschenberger *et al.*, *Bisphenol A and Baby Bottles: Challenges and Perspectives*, *supra* note 59.

61 A. Krishnan, P. Strathis, S. Permuth, L. Tikes, and D. Feldman, "Bisphenol A: An Estrogenic Substance is Released from Polycarbonate Flasks during Autoclaving", 132 *Endocrinology* (1993), pp. 2279–2286.

62 T. Colborn, D. Dumanoski and J. Myers, *Our Stolen Future* (New York: Penguin Books 1996).

63 S. Nagel, F. vom Saal, K. Thayer, M. Boechler and W. Welshons, "Relative Binding Affinity: Serum Modified Access (RBA-SMA) Assay Predicts the Relative in Vivo Bioactivity of the Xenoestrogens Bisphenol A and Octylphenol", 105 *Environmental Health Perspectives* (1997), pp. 70–76.

64 See, for example, L. Gray jr., B. Ryan, A. Hotchkiss and K. Crofton, "Rebuttal of 'flawed experimental design reveals the need for guidelines requiring appropriate positive controls in endocrine disruption research' by vom Saal", 115 *Toxicological Sciences* (2010), pp. 614–620.

65 Vogel, "The Politics of Plastics: The Making and Unmaking of Bisphenol A 'Safety'", *supra* note 58.

66 F. vom Saal and C. Huges, "An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A shows the Need for a New Risk Assessment", 113 *Environmental Health Perspectives* (2005), pp. 926–933.

67 EFSA examined the research findings surrounding Bisphenol A on three separate occasions, most recently in 2010, eg., EFSA, "Scientific opinion of 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", 1829 *EFSA Journal* (2010), pp.1–110.

68 T. Butterworth, *Science Suppressed: How America Became Obsessed with BPA* (Washington DC: George Mason University's Center for Health and Risk Communication STATS 2009).

thought and suggested increasing the daily safety threshold of consumption by a factor of five[69].

Similarly two large studies, including one from Harvard University, question the validity of vom Saal's findings. They note that they are inconsistent and there are therefore doubts as to whether there are any real functional or physical impairments caused by BPA administered to mice[70][71]. Vom Saal and Hughes have in turn questioned these findings[72].

Environmental groups and a number of academics have taken the view that vom Saal's findings are correct and that the findings of other academics, industry, and the regulators are simply wrong. This argument became cemented in 2006 when 38 experts working on endocrine disrupters, led by vom Saal, met in Chapel Hill, North Carolina and put forward a consensus statement arguing that the levels of BPA at concentrations found in the human body correlated with:
"organisational changes in prostate, breast, testis, mammary glands, body size, brain structure and chemistry, and behaviour of laboratory animals.[73]*"*

This consensus statement combined with vom Saal's active media work and outcries from some environmental groups started to change the nature of the debate regarding the safety of BPA.

By mid 2008, several policy makers responding to expressions of public concern and media pressures, began arguing for local and country-wide bans of BPA-containing plastics. In October 2008, following a number of critical BPA articles in the *Toronto Globe and Mail* referencing the work of vom Saal and others, Health Canada (the Canadian food and health regulator) took the ground breaking decision to ban BPA from baby bottles citing the precautionary principle[74].

Following the baby bottle ban in Canada, increased pressure was put on the European bodies to ban BPA-containing plastic containers used by small children as well. Due in part to the international pressure there have been five scientific evaluations of the safety of BPA in Europe all indicating that the dangers of BPA leaching out from baby bottles and other mechanisms have been overstated.

This, however, has not stopped critics from questioning the EFSA's findings. They argue, for example, that they do not take into account the low dose (non GLP) studies carried out by vom Saal that appear to show that BPA can have effects on rodents in laboratory studies[75]. Prior to the EFSA ruling, a letter authored by vom Saal and Breast Cancer UK, and signed by 60 scientists and international environment, health, and women's organisations to the EFSA on the 23rd June 2010, asked the Agency to push for a ban of the chemical noting:
"action is necessary to reduce the levels of Bisphenol-A exposure, particularly in groups at highest risk, namely young infants and pregnant mothers[76].

The issue is complicated by the fact that the opponents to BPA continue to attack scientific findings that do not agree with the earlier low dose findings, taking the view that regulatory agencies base their decisions on outdated guidelines that were established 50 years ago[77].

In addition, in 2010 there was a heated debate in the journal *Toxicological Sciences* regarding the effects of BPA as an endocrine disrupter in rats. One three-year study showed that feeding pregnant rats BPA at doses 4000 times higher than the maximum exposure to humans produced no adverse effects; while the positive control group of pregnant rats fed with the synthetic oestrogen used in birth controls

69 EFSA, "Scientific opinion of the panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to toxicokinetics of Bisphenol A. Question EFSA –Q-2008-382", 759 *EFSA Journal* (2008), pp. 1–10.

70 J. Goodman, E. McConnell, I. Sipes *et al.*, "An Updated Weight of the Evidence Evaluation of Reproductive and Developmental Effects of Low Doses of Bisphenol A", 26 *Critical Review of Toxicology* 2006, pp. 387–457.

71 G. Gray, J. Cohen, G. Cunha *et al.*, "Weight of the Evidence Evaluation of Low-Dose Reproductive and Developmental Effects of Bisphenol A", 10 *Human Ecological Risk Assessment* (2004), pp. 875–921.

72 Vom Saal and Hughes, "An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A shows the Need for a New Risk Assessment", *supra* note 66.

73 F. vom Saal, B. Akingbemi, S. Belcher *et al.*, "Chapel Hill Bisphenol A Expert Panel Consensus Statement: Integration of Mechanisms, Effects in Animals and Potential to Impact Human Health at Current Levels of Exposure", 24 *Reproductive Toxicology*, p. 134.

74 Health Canada, "Government of Canada protects families with bisphenol A regulations", Press release from Health Canada on 17 October.

75 See, for example, Vogel, "The Politics of Plastics: The Making and Unmaking of Bisphenol A 'safety'", *supra* note 58.

76 A. Carterbow, "Joint action of NGOs and scientists to call for a reduction of BPA exposure, especially for children and pregnant women" (Brussels: Women in Europe for a Common Future 2010).

77 F. vom Saal, B. Akingbemi, S. Belcher *et al.*, "Flawed Experimental Design Reveals the Need for Guidelines Requiring Appropriate Positive Controls in Endocrine Disruption Research", 115 *Toxicological Sciences* (2010), pp. 612–613.

did[78]. This study was attacked by vom Saal et al for having a flawed study design – the rats were insensitive to low dose oestrogens[79]. The study authors challenged this, noting that science is about replicating studies in order to verify them, and if this is not possible then the original science was incorrect[80].

In spring 2010 Denmark put forward a temporary national ban on BPA in materials that are in contact with food for children aged 0–3 years of age. The ban came into effect on July 1st 2010. In France on the 25th March 2010, the Senate forwarded a draft law to the National Assembly prohibiting the manufacture, importation or exportation of baby bottles, which was approved in May 2010. In the summer of 2010 the Swedish Environmental Minister, Andreas Carlgren, asked the Swedish Chemicals Agency to develop a proposal on how to best design a ban on BPA in baby bottles and other plastic products noting that:
"It is unacceptable that young children are exposed to the risks that have been proven to be associated with bisphenol A, especially when changing to alternative materials is easy. This is why we are now making the first move by preparing a national ban.[81]*"*

This Swedish analysis will be completed no later than 31st of March 2011. In 2009 the EFSA was asked once again to re-evaluate the safety of BPA, following a number of studies, notably Stump et al 2009, which examined a link between BPA in diets and development of neurotoxicity in rats. These studies were the same that led Denmark to impose the above mentioned temporary ban on BPA in food contact materials for children ages 0–3 years of age. On the 30th September 2010, the EFSA published its evaluation of these studies and concluded that no research could be identified that would lead to a revision of the current tolerable daily intake (TDI) levels based on a No-Observed-Adverse-Effect-Level (NOAEL) of 0,05 mg/kg b.w./day from a multi-generational reproductive study carried out on rats[82]. This opinion was questioned by both stakeholders and representatives from Denmark and France who noted that their bans would remain in place. Per Rosander of the International Chemical Secretariat argued:
"The EFSA decision is very unsatisfactory. There are a large number of studies showing health risks with BPA.[83]*".*

Following the EFSA decision, the EU risk management authority for food and consumer affairs (DG SANCO) instigated a discussion with EU Member States on how to best minimise exposure of infants to BPA focusing on the possibility of a ban. On the 26th November the Standing Committee on the Food Chain and Animal Health voted in favour of the Commission's proposal for a Directive that would ban BPA from plastic infant feeding bottles. This ban will go in effect as of mid 2011with Commissioner Dalli justifying it by arguing:
"... 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 promotion. The decision taken today is good news for European parents who can be sure that as of mid -2011 plastic infant feeding bottles will not contain BPA[84]*. (Dalli in European Commission 2010)*

b. Political and public outcry

In Europe BPA is a "hot" political topic, although the extent varies across Member States. Clearly the topic is hotter in Denmark than in the UK, for example, even though Breast Cancer UK is trying to widen its campaigning credentials by pushing for an anti BPA platform. And one of the main drivers for national bans on BPA is politics. In Denmark, for example, it was the far right People's Party (Dansk Folkeparti) that helped to hold up the centre-right coalition and pushed for a ban on BPA in baby bottles in order

78 B. Ryan, A. Hotchkiss, K. Crifton and L. Gray Jr., "In Utero and Lactational Exposure to Bisphenol A, in Contrast to Ethinyl Estradiol, does not alter Sexually Dimporphic Behaviour, Fertility, and Anatomy of female LE Rats", 115 *Toxicological Sciences* (2010), pp. 133–148.

79 Vom Saal *et al.*, "Flawed Experimental Design Reveals the Need for Guidelines Requiring Appropriate Positive Controls in Endocrine Disruption Research", *supra* note 77.

80 Gray *et al.*, "Rebuttal of 'Flawed Experimental Design Reveals the Need for Guidelines Requiring Appropriate Positive Design Controls in Endocrine Disruption Research' by vom Saal", *supra* note 63.

81 Quote from Andreas Carlgren comes from a press release issued by the Swedish Ministry for the Environment, "Government preparing a national ban on bisphenol A in baby bottles", 29 July 2010.

82 EFSA, "Scientific opinion on bisphenol A", *supra* note 67.

83 Quote from Per Rosander comes from a press release issued by the International Chemical Secretariat, "EFSA fails to lower EU limit on BPA and protect the health of EU's citizens", 8 October 2010.

84 Quote from Commissioner Dalli is taken from a press release issued by the European Commission, "Bisphenol A: Commission welcomes ban in baby bottles by Member States", 26th November 2010.

to attract votes[85]. Similarly in Sweden, Carlgren's announcement on the 29th July occurred in the run up to a national election (19th September 2010). In France the discussion surrounding BPA is the brain child of the French politician Yvonne Collin, of the Parti Radical de Gauche. Surprisingly, the debate surrounding BPA has not received much EU-wide media attention. There was a series of "scare" articles in the UK *Independent* in May 2010 attempting to get BPA on the national policy agenda, but these were not picked up by the other more influential media and soon fizzled out. Similarly the debate on BPA in Scandinavia has been largely muted. As one Swedish food regulator noted:

"This has been a political rather than a media issue. The main newspapers have been rather quiet about BPA, and it was only one of the tabloids that ran a front page cover story in August regarding the high levels of BPA found on shopping receipts." (Swedish Food regulator, September 2010).

c. Risk versus hazard and BPA

The discussions surrounding how to best regulate BPA have been largely based on a debate around whether to use risk or hazard classifications. Some regulators that have established controls based on data produced by small non-GLP studies[86], rather than large conclusive ones, using the argument that the substance is an endocrine disruptor and therefore can cause a hazard. This hazard classification is in their view sufficient for a ban. However, other regulators, most notably the EFSA and the UK Food Standards Agency, rely on the large studies that are available and also take into account exposure to make the judgement that current safety standards are acceptable.

2. Brominated flame retardants – The case of Deca-BDE

a. Background

Over the last hundred years there have been moves away from wood and metal products to synthetic carbon-based polymers with high fuel values, including automotive parts, textiles, furniture fabrics and housings for electronic equipment and surface coatings of other materials[87]. Because of the high fuel values of these substances (plastics for example are mostly petrol-based products) in combination with the fact that they are often located near or part of heat and electricity sources (e.g. televisions and computers) there has been a significant amount of legislation introducing ever stricter fire safety requirements associated with the use of these appliances and other products. One of the most popular ways to satisfy these requirements is through the use of flame retardants, and of these brominated types account for 32 % of all those used[88]. The popularity of brominated flame retardants (BFRs) is down to their inherent thermal stability, overall strong performance (compared to the alternatives) and cost effectiveness[89].

As modern day flame retardants are found in a wide array of products, both in homes and businesses, they are widely dispersed. Because they can be removed through leaching, abrasion or volatilisation, and are inherently stable – they are designed to last for the life time of a product, they can, albeit in small amounts, be found more or less anywhere[90]. To make matters worse, some flame retardants are bio-accumulative[91]. As a result there are health and environmental concerns regarding the use of flame retardants, particularly brominated ones. These are particularly stable and have a high affinity for fats compared to other flame retardants, tending towards a greater degree of bio-accumulation[92]. These concerns have led to generalisations made about bromi-

85 Please see press release from the Dansk Folkeparti, "DF sikrer forbud mod Bisphenol A I sutteflasker", 26th March, 2010.

86 For an illuminating discussion on the pros and cons of GLP, please see R. Alcock, B. MacGillivray and J. Busby, "Understanding the Mismatch Between Demands of Risk Assessment and Practice of Scientists – The Case of Deca-BDE", *Environment International*, doi: 10.1016/j.envint.2010.06.002.

87 P. Fisk, A. Girling, and R. Wildey, *Prioritisation of Flame Retardants for Environmental Risk Assessment* (Wallingford, UK: UK Environment Agency 2004).

88 UK Royal Society for Chemistry, *Environmental Health and Safety Committee Note on: Why do we worry about brominated flame retardants?* (London: Royal Society for Chemistry 2008).

89 Fisk *et al.*, "Prioritisation of Flame Retardants for Environmental Risk Assessment", *supra* note 87.

90 Alcock *et al.*, "Understanding the Mismatch Between Demands of Risk Assessment and Practice of Scientists – The Case of Deca-BDE", *supra* note 86.

91 See, for example, M. Ikonomou, S. Rayne, and R. Addison, "Exponential Increases of Brominated Flame Retardants and Polybrominated Diphenyl Ethers in the Canadian Arctic from 1981 to 2000", 36 *Environmental Science and Technology* (2002), pp. 1886–1892.

92 International Chemicals Secretariat, *Electronics Without Brominated Flame Retardants and PVC – A Market Review* (Gothenburg: International Chemicals Secretariat 2010).

nated flame retardants (BFR) (which number some 75 commercialised substances) and the even broader one of the halogenated flame retardants (i.e. including chlorinated substances).

A number of national regulators have called for bans or substitutions of several brominated flame retardants (BFRs). For example, the Swedish Chemical's Agency recommended a ban of two BFRs in 1999[93], while in the same year the Danish Environmental Protection Agency published a study reviewing their marketing, properties and uses[94]. In Germany the Environmental Ministry published a multi-volume study assessing the hazards of BFRs[95]. BFRs, however, are not identical and therefore should not be treated as such. In Europe, the penta- and octabromodiphenyl ethers have more or less been taken off the market, while the most widely use BFR, deca-Brominated Diphenyl Ether (deca-BDE) has less hazardous properties[96]. A number of studies over the past 15 years have shown that deca-BDE does not pose human and environmental health risks and therefore does not need to be further regulated[97].

93 Swedish Chemicals Agency, *Phase-out of PBDEs and PBBs: Report on a Governmental Commission* (Sundbyberg: Swedish Chemicals Agency 1999).

94 Danish Environment Agency, *Brominated Flame Retardants: Substance Flow Analysis and Assessment of Alternatives* (Copenhagen: Danish Environment Agency 1999).

95 German Environment Ministry, *Substituting Environmentally Relevant Flame Retardants: Assessment and Fundamentals* (Bonn: German Environment Ministry 2000).

96 R. Alcock and J. Busby, "Risk Mitigation and Scientific Advice: The Case of Flame Retardant Compounds", 26 *Risk Analysis* (2006), pp. 369–382.

97 See, for example, US National Academy of Sciences, *Toxicological Risks of Selected Flame-Retardant Chemicals* (Washington, DC: National Academy Press 2000).

98 European Commission, "European Commission Risk Assessment Report Bis (pentabromophenyl) ether" (Luxembourg: Office of the Official Publications of the European Communities 2002).

99 European Commission, "Commission Decision 2005/717/EC-exemption of DecaBDE from the prohibition of use" (Brussels: European Commission).

100 B. MacGillivray, R. Alcock, and J. Bussby, "Is Risk-Based Regulation Feasible? The Case of Polybrominated Diphenyl Ethers (PBDEs)", 31 *Risk Analysis* (2011), pp. 266–281.

101 Case C-14/06 and C-295/06, *Parliament v. Commission* [2008] ECR p. I-1649.

102 University of Surrey, *The Effectiveness of the Furniture and Furnishings (Fire)(Safety) Regulations 1988* (London: Department of Trade and Industry 2000).

103 Greenstreet Berman, *A Statistical Report to Investigate the Effectiveness of the Furniture and Furnishings (Fire) (Safety) Regulations 1988* (London: Department of Business, Innovation and Skills 2009).

104 Fisk *et al.*, "Prioritisation of Flame Retardants for Environmental Risk Assessment", *supra* note 87.

In 2002 the European Union passed the so-called Restriction of the use of certain Hazardous Substances (RoHS) Directive which calls for a restriction on the use of a number of hazardous substances found in electrical and electronic equipment, including some flame retardants. When the Directive passed, however, it required a review of the substances pending restriction in order to take into account any EU risk assessments[98] that had been conducted before the RoHS came into effect in 2006. When this review was completed, the European Commission concluded that Deca-BDE should be exempted from the RoHS Directive because there were no human or environmental risks justifying a restriction[99]. In 2008, however, following complaints from the European Parliament and Denmark, supported by Finland, Portugal, Norway, and Sweden, the European Court of Justice decided to annul it[100]. This led to a ban on the use of Deca-BDE in electrical and electronic equipment from 1st July 2008. The annulment, however, was not based on scientific grounds but on procedural issues concerning how Deca-BDE became exempt outside of the purview of the European Parliament[101].

The debate regarding Deca-BDE stems from variations in fire safety requirements across the EU due in large part to divergent perceptions regarding its benefits. The UK, for example, has particularly strict fire standards, especially related to furnishings as a consequence of observed rises of fires in dwellings in the 1960s and 1970s with deaths peaking at 865 in 1979. A large number of these fatalities involved foam-filled furniture (furniture accounted for 7.5 % of the fires but 35 % of the deaths)[102] leading to the introduction of the 1988 Furniture and Furnishings Fire Safety Regulations (FFRs), which are above the European fire safety standards. Results of the FFR regulations indicate, that accounting for fire alarms and more educated publics, that in the period of 1988-1997 approximately 710 lives had been saved and in the period 2002-2007 the FFR regulations have led to an additional 54 fewer deaths and 1065 fewer fires each year[103]. Based on the UK concerns with regard to fire safety it is not surprising that the UK was the only member State country supporting the European Commission over its exemption of Deca-BDE in the European Court of Justice 2008 court case. Many others, such as Denmark and Germany, have much weaker fire safety standards, while others do not have any fire safety requirements on certain products[104]. As there is no consensus about how tough fire safety standards should be, it will be dif-

ficult to get a consensus on whether flame retardants such as Deca-BDE should be used. As one anonymous Danish regulator noted:

"The Brits are much more worried about fire safety than us. They want to use even more flame retardants than are presently used today, rather than following our example of trying to minimise the risk in the first place, such as, by asking our stereo manufacturers to move all combustible materials far away from the heat source." (Interview September 2010).

b. Political and public outcry

There has been a considerable amount of pressure from NGOs, policy makers and regulators to ban and substitute BFRs, because of the bio-accumulation issue. This pressure has been particularly strong in the Nordic countries where there have been a number of leading research institutions looking into the hazards of BFRs[105], and strong support from environmental NGOs, regulators (such as the Swedish Chemical Agency) and other bodies. BFRs have also received a significant amount of media attention following the World Wildlife Fund (WWF) bio-monitoring (blood) campaigns which show that we have some BFRs in our bodies, leading to further media amplification and rising public concern[106]. These concerns are based on the hazard as opposed to any calculation of the actual risk.

c. Risk versus hazard

BFRs, and in particular Deca-BDEs, have been regulated in Europe based on a hazard. Arguably Deca-BDE has been banned from electronic goods and products based on the so-called class stigmatisation effect[107]. In a classic article on the topic, Gregory *et al.* argue that the initial cause of technological stigma is some form of event or occurrence that becomes amplified by the media, sending a strong signal of abnormal risk. Stigmatised products usually have highly hazardous properties and are perceived negatively by the public[108]. Deca-BDE ticked all of these boxes. There have been a multitude of scientific studies, most of them based on small samples and drawn up in laboratory facilities rather than actual field exercises and making in some cases allegedly unsubstantiated claims[109]. In addition Deca-BDE is often clumped together with the other BFRs that do have certain hazardous properties as discussed previously, and research shows high levels of public concern towards these type of chemicals[110][111].

3. Risk and hazard assessment – Is it predictable?

In both of these case studies hazard was advocated to justify bans. Both cases carry a strong Scandinavian flavour – that is to say that either Denmark and/or Sweden were heavily involved for pushing for the ban of both chemicals. These nations are not always in favour of hazard assessments and bans. When the substances concerned impact on the economies or heritage of these nations they, like other Member States, will base their regulatory decisions on risk assessments. One example of this is the Finnish and Swedish temporary exemption (needs to be renewed every 5 years) on Baltic herring and salmon containing high levels of PCBs and dioxin within their Member States. In 2001 the Commission put forward a regulation that set maximum levels of contaminants including dioxins and furans in food stuffs, including fish[112].

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105 P. Eriksson, E. Jakobsson, and A. Frederiksson, "Brominated Flame Retardants: A Novel Class of Developmental Neurotoxicants in our Environment?, 109 *Environmental Health Perspectives* (2001), pp. 903–908.

106 J. Busby, R. Alcock, and B. MacGillivray, "Interrupting the Social Amplification of Risk Process: A Case Study in Collective Emissions Reduction", 10 *Environmental Science and Policy* (2009), pp. 297–308.

107 J. Flynn, P. Slovic and H. Kunreuther (eds), *Risk, Media and Stigma: Understanding Public Challenges to Modern Science and Technology* (London: Earthscan 2001).

108 R. Gregory, J. Flynn and P. Slovic, "Technological Stigma", 83 *American Scientist* (1995), pp. 220–223.

109 A. Williamns and J. DeSesso, "The Potential of Selected Brominated Flame Retardants to Affect Neurological Development", 13 *Journal of Toxicology and Environmental Health Part B* (2010), pp. 411–448.

110 P. Slovic, "Perception of Risk", 236 *Science* (1987), pp. 280–285.

111 Not all EU institutions are supportive of precautionary decisions against brominated flame retardants. In a recent decision by the European Parliament and the EU Council of Ministers regarding the Restriction of Hazardous Substances in electrical and electronic equipment (RoHS Directive) the Green MEP rapporteur, Jill Evans, proposed a total ban of all brominated flame retardants which was refused as was her compromise position to list all brominated and chlorinated flame retardants in an annex as priority substances for review. Such an approach would have employed a precautionary hazard approach by targeting these substances as leading candidates for future restriction (Chemical Watch 2010).

112 EC 2375/2001 of 29th November 2001 amending Commission Regulation 466/2001 setting the maximum levels for dioxin and furans (Brussels: European Commission).

Finland and Sweden, backed by risk assessments noting that the benefits of eating contaminated fish (e.g., Omega 3s) outweighed the risks[113], initially received an exemption until 2006 initially, and subsequently extended till 2011[114]. As one Swedish regulator interviewed for this study candidly noted:

"It is in a way odd that we have double standards. We will use science based risk assessments to defend products that we care about and which have direct impact on our economy such as forest products, but for products that have no notable impacts on our economy but which we as regulators or as members of the public are concerned about we invoke hazard classifications to ensure that they are banned" (Swedish regulator September 2010).

IV. Discussion and analysis

The two case studies show significant inconsistencies in the application of risk and hazard assessments for regulation setting throughout Europe. EU Member States have different concerns about risk topics. UK authorities, for example, worry about fires while Swedish policy makers are concerned by man-made chemicals. What are the reasons for these differentiating cultural views on regulations, and what are the consequences of them? Is more dialogue between regulators and policy makers needed?

1. The pushers and pullers for chemical and environmental regulation

Although Europe is now seen as the leading environmental regulator in the world[115] all European Member States do not agree with the regulations put forward by the European authorities. Rather it is more the case that some nations attempt to win green credit by attempting to ban certain chemical substances. As these nations are members of the wider European Union, it makes no sense to push only for a domestic ban, as there is always the legal threat that the European Union could call for a ban to be revoked (as was the case with Sweden putting forward an unilateral ban on Deca-BDE a few years ago). Rather these Member States try to win over their domestic audiences by pushing through European-wide bans. For example, the Swedish socialist MEP, Asa Westlund, argued as part of her re-election campaign that she was helping the Swedes from being inundated by dangerous chemicals by her political efforts in the European Parliament[116]. Indeed, Danish and Swedish regulatory authorities are widely regarded as the pioneers of present day EU chemical regulation[117] [118]. These Member States have also put forward European legislation to ban Deca-BDE (Denmark led the effort in getting the Deca-BDE exemption revoked), the phase-out of antibiotics in animal feed[119], as well as a host of other chemicals (e.g., paraquat)[120]. The reason why these Scandinavian regulatory bodies have been so successful in their European banning efforts is a combination of three distinct factors.

a. The rise of the post-trust society

Regulators who are seen to be tough on industry, such as the Swedish Chemicals Agency (KemI), have a high level of public credibility, as they are viewed to have the public's best interest at heart[121]. Therefore the decisions they make, some based on good science and others based on weak science, are not questioned by policy makers, academics or other stakeholders. Some regulators, on the other hand, who are seen to be influenced by industry are viewed by the public and stakeholders as weak, are less trusted and are increasingly marginalised. Similarly, policies and scientific arguments put forward by "low-trust" bodies, such as the chemical industry and its consultants, even though they may be based on stronger scientific evidence than those made by the Scandinavian reg-

113 O. Leino, M. Tainio, and J. Tuomisto, "Comparative Risk Analysis of Dioxins in Fish and Fine Particles from Heavy-Duty Vehicles", 28 *Risk Analysis* (2008), pp. 127–140.

114 I. Anderson and M. Aune, *Redovisning av uppdrag rorande gransvarden for langlivade miljoforengar I fisk fran Ostersjoomradet* (Uppsala: Swedish Food Administration 2010).

115 M. Schapiro, *Exposed: The Toxic Chemistry of Everyday Products and What's at Stake for American Power* (White River Junction, VT: Chelsea Green Publishing 2007).

116 Naturskyddsforeningen, *Rapport: Miljoloften for Europa* (Stockholm: Swedish Society for Nature Conservation 2009).

117 Danish Environmental Ministry, *Kemikalie-Handlingsplan 2010–2013. Sikkerhed i Danmark-samarbejde internationalt* (Copenhagen: Danish Environmental Ministry 2010).

118 D. Liefferink and M. Andersen, "Strategies of the 'green' Member States in EU Environmental Policy Making", 5 *Journal of European Policy* (1998), pp. 254–270.

119 Vos, "Antibiotics, the Precautionary Principle and the Court of First Instance", *supra* note 27.

120 J. Zander, *The Application of the Precautionary Principle in Practice* (Cambridge: Cambridge University Press 2010).

121 R. Lofstedt, *Risk Management in Post Trust Societies* (Basingstoke: Palgrave/MacMillan 2005)

ulators, are increasingly being questioned by stakeholders, academics and other bodies[122]. Industry can no longer be trusted as they have vested interests in the product being questioned, and increasingly industry funding is seen as biased[123].

Industry's credibility has not been helped by the fact that a number of industry bodies have misused science to delay the regulation of hazardous substances such as tobacco, a fact that has only became widely known over the past fifteen years or so[124]. Finally the accusers, that is primarily academics and stakeholders, have been gaining public and political credibility following a number of European scandals ranging from BSE (mad cow disease) to dioxin in Belgian chickens and tainted blood in France[125]. This is a profound shift compared to just over 30 years ago, when the public more or less expected a close working relationship between regulators and industry[126].

Due to these three reasons it has become easier for nations such as Denmark and Sweden to push through regulation as they are trusted, while their industry counterparts are not. In addition these Scandinavian regulators have been, and continue to be, ably assisted by stakeholders and academics who are also trusted. Following the passing of the Lisbon Treaty granting increased power to the European Parliament, it is likely that it will be even easier to push through tough hazard-based regulations.

b. Lack of interest in environmental regulatory issues on the centre right

Setting Scandinavian countries aside, the call for tougher European chemical and environmental regulations is coming unsurprisingly primarily from politicians that are from the centre left, left and the greens[127]. The Greens, for example, have one main platform, that of promoting tougher environmental regulation, while the EPP parliamentarians spend a large amount of their time focusing on a number of economically-based platforms, be it internal markets, competition or trade policy[128]. There are a number of examples of this. The rapporteur for the European Parliament's report on the European Commission's 2001 Chemical White Paper was a Swedish Green MEP, Inger Schorling, while the rapporteur on the REACH Regulation was Guido Sacconi, an Italian Socialist MEP. Similarly, the European Greens have a political spokesperson (a former director of Greenpeace Germany) whose role is to debate, lobby and push forward tougher environmental regulation. The Centre right parliamentarians do not have a similar spokesperson to counter these arguments.

c. The politics of regulation

Politicians will push for bans or fight for certain environmental/chemical/ energy issues which do not affect the economic well being of their country. Sweden has strong positions on phasing out chemicals which it can afford to do as it has only a small chemical industry[129]. Similarly, Austria richly endowed with hydropower, has a strong anti-nuclear policy. Its Eastern neighbours, Czech Republic and Slovakia, do not have the Alps and are therefore to a greater extent reliant on nuclear power[130]. At the same time Sweden would not dream of having tough controls on mobile telephone base stations as one of the world's largest mobile telephone systems providers, Ericsson, is based there[131]. In other words, it is easy for Denmark and Sweden to take strong Anti-BPA and Anti-Deca-BDE positions at the European level as there are no economic consequences for their domestic markets in doing so, and at the same time they gain domestic "green" credentials. An example of this political game playing is one Swedish EPP

122 It is interesting to note that EFSA was specifically set up to provide credible scientific advice, yet government and EU agencies feel comfortable over ruling EFSA's scientific opinions as was the case of Bisphenol A.

123 Vom Saal and Hughes, "An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment", *supra* note 66.

124 See, for example, N. Oreskes and E. Conway, *Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming* (New York: Bloomsbury 2010).

125 R. Lofstedt, F. Bouder, J. Wardman and S. Chakraborty, "The Changing Nature of Communication and Regulation in Europe", Forthcoming *Journal of Risk Research*.

126 J. Hayward and R. Berki, *State and Society in Contemporary Europe* (Oxford: Robertson 1979).

127 Schorling, "The Green's Perspective on EU Chemicals Regulation and the White Paper", *supra* note 15.

128 McCormick, "Environmental Policy in the European Union", *supra* note 1.

129 Lofstedt, "Swedish Chemical Regulation: An Overview and Analysis", *supra* note 14.

130 R. Lofstedt, "Are Renewables an Alternative to Nuclear Power? An Analysis of the Austria/Slovakia Discussions", 36 *Energy Policy* (2008), pp. 2226–2233.

131 Zander,"The Application of the Precautionary Principle in Practice", *supra* note 120.

MEP who put forward a parliamentary question on the 27th May 2010 asking how the Commission will safeguard against imports of BPA material to the EU (following the Swedish agenda on chemicals). On 3rd September she put forward a question on how the Commission will safeguard an important part of Swedish heritage, namely the fermented Baltic herring, by extending the exemption past 2011, acknowledging in her question the fact that the herring contains higher levels of dioxin than the European Union allows[132].

When politicians push for these types of bans (or exemptions from a ban) on the European stage the economic consequences are significant. The chemical industry, for example, is Europe's fourth largest industrial sector and is particularly significant for Germany. It accounts for 11 % of Europe's manufacturing capacity, and employs 1.6 million individuals[133]. Strong opposition from those nations who are affected by these bans and regulations would be expected, but in many cases this has not been the case. Denmark, for example, was able to push through the annulment of the Deca-BDE exemption in the face of UK opposition, Sweden was able to drive through the ban of the pesticide paraquat, and REACH was passed following modest policy changes on the part of the Germans[134].

2. Ignoring the risk-risk trade-off

The so-called risk-risk trade-off occurs when a regulator focuses on decreasing one specific risk (e.g., chlorinating drinking water to make it safer) and unintentionally increases a risk elsewhere (e.g., human cancers caused by substances being generated during the chlorination). The concept builds on risk-risk analysis put forward by Lester Lave[135] and, according to Graham and Wiener who popularised the concept, requires regulators and policy makers to systematically:

"Evaluate in weighing the comparative importance of target risks and countervailing risk when hard choices must be made[136]*".*

Over the years risk-risk tradeoffs have been and are frequently ignored by regulators, be they based in Europe, North America or elsewhere. This is despite the fact that over the years there have been a number of studies from authorative sources stating that they need to be properly and systematically addressed in the making of regulations[137].

Both the case studies discussed above are riddled with risk-risk tradeoffs. With regard to the ban on Deca-BDE two issues stand out. The ban is being put in place because of environmental and public concerns associated with other BFRs, yet to date there appears to have been no studies demonstrating the consequences of the ban in terms of increased appliance fires. Similarly, it is not the case that Deca-BDE can be simply substituted for safer and better proven retardants[138]. Deca BDE is one of the world's most studied flame retardants, yet the alternatives being promoted, such as phosphorous-based compounds have not been equally studied. Would it not be wise to do more in-depth studies examining the possible environmental and health risks associated with those phosphorus-based flame retardants before the substitution principle can be activated[139]? With regard to BPA, aside from replacing BPA plastic baby bottles with glass ones (and resulting problems associated with consequences of breakage) manufacturers have in many cases struggled to find suitable alternatives. In addition, these alternatives have not been tested and researched to the same degree as BPA, and may in fact be riskier for human health and the environment[140]. The causes of these unintentional risk-risk tradeoffs are two fold. Firstly, special interest groups focused on single source pollution end points rather than the broader environmental problem at hand[141].

132 The 2 parliamentary questions from A. Corazza-Bildt (MEP-EPP) were "Ban on bisphenol A (BPA) in infant feeding bottles" – Parliamentary question 27th May 2010 and "Fermented Baltic herring" – Parliamentary question 3rd September 2010.

133 K. Geiser and J. Tickner, *New Directions in European Chemicals Policies: Drivers, Scope and Status* (Lowell MA: Lowell Center for Sustainable Production 2003).

134 Zander, "The Application of the Precautionary Principle in Practice", *supra* note 120.

135 L. Lave, *The Strategy of Social Regulation: Decision Frameworks for Policy* (Washington DC: Brookings 1981).

136 Graham and Wiener, "Risk vs Risk: Tradeoffs in Protecting Health and the Environment", *supra* note 49, p. 19.

137 See, for example, F. Cross, "Paradoxical Perils of the Precautionary Principle", 53 *Washington and Lee Law Review* (1996), pp. 851–921.

138 Busby *et al.*, "Interrupting the Social Amplification of Risk Process: A Case Study in Collective Emissions Reduction", *supra* note 106.

139 Alcock and Busby, "Risk Mitigation and Scientific Advance: The Case of Flame Retardant Compounds", *supra* note 96.

140 Ryan *et al.*, "In Utero and Lactational Exposure to Bisphenol A, in Contrast to Ethinyl Estradiol, Does Not Altersexually Dimporphic Behaviour, Fertility and Anatomy of Female LE Rats", *supra* note 79.

141 Viscusi, "Rational Risk Policy", *supra* note 52.

Secondly, the risk-risk trade-offs were in these two cases products of incomplete, and to a certain degree unscientific, decision making. Regulations were driven too quickly without taking into account all the possible unintended consequences, by political, media and stakeholder concerns rather than evidence-based policy making – sometimes referred to as the "risk of the month concern"[142]. As a result, the so called substitution principle is not a risk free solution as some regulators imply[143].

3. The many cultures of Europe

Europe is not one entity, but the European Union is made up of 27 Member States populated with individuals who have different values and ideas. This in turn complicates matters for the making of consistent environmental chemical regulations. Be it with regard to environmental issues or food concerns, there is not one united Europe[144]. The Swedes, for example, are more concerned about the welfare of farmed animals than the Hungarians; while the Latvians are much more worried about the freshness of food than the Dutch. Similarly, the Portuguese worry more about genetically modified food than the British do[145]. These types of cultural differences will impact on regulation.

4. The silo effect of regulatory agencies

Research for this study has identified a problematic lack of communication between domestic regulators working on similar issues and between member State regulators targeting similar issues. With regard to BPA, the Swedish Chemical Agency (KemI) had a different perspective on how this chemical should be regulated to their counterparts at the Swedish Food Agency (SLV). The KemI wants to regulate based on a hazard classifications and the precautionary principle, while the SLV wants to use a risk assessment and risk management approach. If the precautionary principle is to be used, the SLV is insisting on a EU-agreed definition that includes a clause for cost effectiveness, which would require some sort of risk assessment[146], while the KemI did not have a definition as such. The same split with regard to BPA occurred in Denmark where the Danish Food Agency was forced to call for a temporary ban for political rather than scientific (risk analysis) reasons. The study also showed that there was a lack of coordination on the use and type of risk assessments with regard to BPA or Deca-BDE, be the regulators based in Denmark, Finland, Germany, Sweden or the UK. The regulators did not know what their counterparts were doing on these issues.

5. The stigmatisation of products

A number of environmental regulators, environmental stakeholders and academics are attempting to stigmatise particular products, such as Deca-BDE and BPA. These groups do two things. Firstly they attempt to make a general link between BPA or Deca-BDE with environmental effects or human health issues. For example the International Chemical Secretariat argued that:
"...brominated flame retardants tend to be particularly able to bio-accumulate and to be persistent. This means they stay in the environment for a long time and accumulate in animals and humans. Many brominated flame retardants are also toxic.[147]"

Frederic vom Saal argues with regard to BPA:
"The science is clear and the findings are not just scary, they are horrific. Why (would) you feed a baby out of a clear, hard plastic bottle – it's like giving a baby a birth control pill.[148]"

At the same time these and other campaigners argue that there are much safer alternatives available, and

142 L. Lave and E. Males, "At Risk: The Framework for Regulating Substances", 23 *Environmental Science and Technology* (1989), pp. 386–391.

143 For an excellent historical discussion on the substitution principle please see A. Nilsson, *Att byta ut skadliga kemikalier: Substitutionprincipen-en miljorattslig analys* (Stockholm:Nerenius and Santerus forlag 1997).

144 Eurobarometer, "Special Eurobarometer 354: Food-Related Risks" (Brussels: TNS Opinion and Social 2010).

145 Eurobarometer, "Special Eurobarometer 354: Food-Related Risks", *supra* note 144.

146 European Council, "Regulation (EC) No 2002/178 of the European Parliament and of the Council of 28th January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety", *supra* note 23.

147 International Chemical Secretariat, *Electronics Without Brominated Flame Retardants and PVC – A Market Review*, *supra* note 92, p. 2.

148 The quote from Frederick vom Saal can be found in R. Sharpe, "Let Common Sense Guide you in the Saga of Bisphenol A", *Independent*, 13 April 2010, p. 39.

hence these substances can simply be substituted for something better. They do not go into any detail about the possible negative environmental and public health consequences of the substitute products. In so doing they put pressure on corporations to shift from one chemical compound to another, as demonstrated by the International Chemical Secretariat overview of electronics without brominated flame retardants[149]. These campaigns are increasingly successful. The plastic's industry in Europe, for example, has been removing BPA from baby bottles as it anticipated a European wide ban on the chemical[150].

6. Public perceptions of chemicals

Over the past 40 years there has been much social science research discussing why the public perceives some risks differently to others[151]. This research shows, for example, that the public is more concerned about involuntary risks than voluntary ones, it fears technological hazards more than natural ones, and that it is more frightened of unfamiliar than familiar risks[152]. Chemicals tick all these boxes: they are involuntary, technical and highly unfamiliar, with most members of the public not having much information on, or understanding the use of, the chemical in question. In addition, science shows that these types of unfamiliar, technological and involuntary risks are often socially amplified by the media[153 154]. As a result the public is on the whole worried about the effects of chemicals. The whole situation has been made more complicated by environmental campaigners, academics and journalists. They have launched controversial and highly publicised campaigns against chemicals including BPA and Deca-BDE, through bio-monitoring schemes (be it blood or breast milk) to gain yet further media attention[155]. Is it therefore any wonder that the public is fearful of BPA and Deca BDE, which in turn justifies the environmental groups' campaigns?

V. Recommendations

As seen in the two case studies, there is no such thing as uniform European-wide science-based risk regulation. Rather there are multiple actors at different member state and European levels pushing their own views and opinions of how regulations should be formed, resulting in the passing of bans/directives and regulations that are at times hazard based and at other times risk based. What is needed to ensure greater consistency in the European regulatory process? What is needed to ensure greater science- and risk-based regulatory thinking? This final section will address these questions.

1. Importance of education

If European regulators are to be successful in increasingly basing environmental and health regulations on risk assessments then there is a need for the public and stakeholders to actually understand what risk assessment is, something that is clearly not the case at the present time. One way around this would be to push for the introduction of risk assessment as part of the science curriculum in the final years of school (last two years of high school/gymnasium) as well as by encouraging European universities to teach risk assessment as part of the undergraduate or graduate curriculums, something that the Commission is also actively promoting[156]. At the present time there is little teaching activity on this topic with just a handful of universities teaching risk assessment. What is interesting is that there is clearly a demand for such courses. Because of new regulations such as REACH, there are more risk assessments than ever before being performed in Europe. To generate funding in the risk assessment area it would be good for a number of academic institutions to encourage the Commission's DG Research and Innovation to host a workshop on this topic to see what such a proposed funding stream in this area would look like.

149 International Chemical Secretariat, "Electronics Without Brominated Flame Retardants and PVC – A Market Review", *supra* note 92.

150 One could also argue that another form of stigmatisation is related to the so called REACH "Candidate List of potential substances for substitution" which is nothing more than a "blacklisting" as chemicals put onto that list are almost impossible to take off.

151 Slovic, "Perception of Risk", *supra* note 110.

152 See, for example, B. Fischhoff, P. Slovic, S. Lichtenstein, S. Read and B. Combs, "How Safe is Safe Enough? A Psychometric Study Towards Technological Risk and Benefits", 9 *Policy Studies* (1978), pp. 127–152.

153 R. Kasperson, O. Renn and P. Slovic *et al.*, "The Social Amplification of Risk: A Conceptual Framework", 8 *Risk Analysis* (1988), pp. 177–187.

154 N. Pidgeon, R. Kasperson, and P. Slovic (eds), *The Social Amplification of Risk* (Cambridge: Cambridge University Press 2003).

155 Alcock and Busby, "Risk Mitigation and Scientific Advance: The Case of Flame Retardant Compounds", *supra* note 96.

156 European Commission, *Maximising the Contribution of Science to European Health and Safety* (Brussels: DG SANCO 2005).

2. Scientific peer review of risk assessments used for regulations

One way to ensure that the risk assessments being put forward by regulators remain of the highest quality (and therefore cannot be undermined by stakeholders and special interest groups) is to ensure that the risk assessments and other underlying scientific arguments used as the foundations for the environmental and health regulations are based on appropriate peer review. Such a peer review could be based on the US Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) 2004 "Final Information Quality Bulletin for Peer Review". This bulletin:

"... establishes government wide guidance aimed at enhancing the practice of peer review of government science documents .... Peer review can increase the quality and credibility of the scientific information generated across the federal government. This Bulletin is one aspect of a larger OMB effort to improve the quality of the scientific information upon which policy decisions are based[157]*."*

The then Administrator of OIRA, Professor John Graham, was concerned about the varying quality of the underlying science used in the development of regulations and felt that by having a peer review system in place, the overall policy decisions could be improved. The Bulletin was signed into law in December 2004, after having benefited from extensive agency, stakeholder and public comments on two prior drafts. The idea is probably worth introducing in Europe, as long as the peer review guidelines are developed in tandem with a number of key regulatory agencies so they have some ownership of the project and are not merely dictated to by a central oversight authority. One way to proceed with the introduction of an EU wide peer review bulletin would be to bring together a number of key EU risk assessment institutions such as the EFSA, the German Federal Institute for Risk Assessment, the UK Food Standards Advisory Board (COT) and DG SANCO to discuss the proposal.

3. Media guidelines

The European public does not need to be "educated" in the way that many policy makers seem to believe[158]. Rather many public outcries or alarms that are prevalent in today's Europe are perpetuated by undue media attention and amplification of risks which could be better and more responsibly communicated[159]. Was it ethically correct, for example, for the *Independent* to publish a series of alarmist articles on the supposed dangers of BPA in April 2010? The articles were not scientifically balanced and were arguably designed to put pressure on the UK FSA to regulate it. Other examples of unnecessary media amplification include the mishandling of the measles, mumps and rubella (MMR) vaccine scare in the UK[160] and the communication of the Y2K or millennium computer bug[161]. Effective media amplification in such cases is often undermined by poor handling of science, not helped by the fact that due to recent budget cuts there are less and less broadsheet science editors than ever before.

One way of addressing poor communication would be through the development of reporting guidelines, similar to those agreed by the BBC in 2003[162] and by Harvard and IFIC[163] that would help journalists to become more attuned to communication pitfalls[164]. Another way to do so would be to use more science-media forums to encourage greater critical dialogue between scientists and journalists on topics such as the intricacies of risk assessment, such as those promoted by the European Science Forum.

4. Improving risk communication capacity and competences

One of the main reasons why regulators and politicians are under pressure to regulate based on hazard

157 US Office of Management and Budget-Office of Information and Regulatory Affairs, *Final Information Quality Bulletin for Peer Review* (Washington, DC: OMB-OIRA 2004).

158 D. Taverne, *The March of Unreason: Science, Democracy and the New Fundamentalism* (Oxford: Oxford University Press 2005).

159 Kasperson *et al.*, "The Social Amplification of Risk: A Conceptual Framework", *supra* note 153.

160 R. Horton, *MMR Science and Fiction: Exploring the Vaccine Crisis* (London: Granta 2004).

161 N. Davies, *Flat Earth News* (London: Chatto and Windus 2008).

162 R. Harrabin, A. Coote and J. Allen, *Health in the News: Risk Reporting and Media Influence* (London: King's Fund 2003).

163 H. Fineburg and S. Rowe, "Improving Public Understanding: Guidelines for Communicating Emerging Science on Nutrition, Food Safety, and Health", 90 *Journal of the National Cancer Institute* (1998), pp. 194–199.

164 For an in-depth discussion on media communication guidelines please see: R.Lofstedt, "Risk communication guidelines for Europe: A modest proposition", 13 *Journal of Risk Research* (2010), pp.87-109.

rather than risk is the simple fact that the promoters of hazard classifications are better communicators of the potentially resulting risk in question[165]. In addition it should be noted that hazard classification is easier to communicate than risk assessment, as because it is less complicated, as given that elements of uncertainty (in particular linked to exposure) are not discussed. These stakeholders are in many cases professional public relations machines that excel in courting media attention and framing public opinion, debate and controversy. By being fast and nimble they can consistently engage in proactive risk communication attuned to the demands of a 24-hour news cycle, and they understand that the public perceives some risks more than others[166]. What makes them even more effective is that in many cases they are more trusted than the regulators and the risk imposers (usually industry)[167].

Regulators and policy makers, on the other hand, are generally poor communicators. Indeed, apart from anything else, they are often too slow to communicate, because in many cases held back by the vast bureaucratic machinery that makes up most government departments. By being slow in their communication strategies officials spend more time firefighting and engaging in reactive communications. The problem with this strategy is that reactive risk communication destroys public trust whereas proactive risk communication gains public trust[168]. This is complicated by the fact that many regulatory bodies do not understand the importance of risk perception and staff has not been trained in risk communication. They therefore often find it difficult to convey clear and concise messages needed for the modern media. To address this problem, regulators could either be encouraged to participate in existing continuing education risk communication courses for professionals such as those developed by Harvard University, or by developing customised risk-communication and risk-analysis guidelines, something that the EFSA is presently doing[169].

5. Establish a scientific advisory board for the European Parliament

There is a need to increase the scientific competency of the European Parliament. Based on the interviews with European Commission officials, European parliamentarians and senior officials in the Member States, there is a clear growing concern that in line with increased parliamentarian power, there needs to be an increased understanding of the science underlying the amendments, laws and suggestions that parliamentarians are making. One key way of helping parliamentarians gaining this competence would be through the establishment of a neutral/independent scientific advisory board that would produce opinions and suggestions on the various proposed directives and regulations made by the Commission. This advisory board could work in close collaboration with the Science and Technology Options Assessment (STOA) panel within the European Parliament.

6. Properly interpreting and implementing the Commission's communication on the precautionary principle

The seminal European Commission Communication on the precautionary paper needs to be properly interpreted and implemented. When it was published the Commission noted that the Communication should be seen as an "input into the ongoing debate"[170] rather than the definitive statement on the topic. Since that time there have been multiple studies evaluating the usefulness of the Communication[171] and whether the Commission is actually following the Communication[172]. One of the key provisos was that any invocation of the precautionary principle must be preceded by a risk assessment[173]. These published studies, along with the case studies discussed above indicate that the Communication is in many cases being ignored. Different guidelines and legal cases are

165 For a discussion see: Lofstedt et al, "The changing nature of communication and regulation in Europe", *supra* note 125.

166 G.Jordan, *Shell, Greenpeace and the Brent Spar* (Basingstoke: Palgrave/MacMillan 2001).

167 UK House of Lords, *Select Committee on Science and Technology: Science and Society* (London: House of Lords 2000).

168 B.Fischhoff, "Risk perception and communication unplugged: Twenty years of research", 15 *Risk Analysis* (1995), pp. 137-145.

169 EFSA, *Draft Risk Communication guidelines* (Parma: EFSA 2010).

170 European Commission, "Communication from the Commission on the Precautionary Principle", *supra* note 17, p. 3.

171 See, for example, J. Graham and S. Hsia, "Europe's Precautionary Principle: Promise and Pitfalls", 5 *Journal of Risk Research* (2002), pp. 371–390.

172 G. Marchant and K. Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Courts* (Washington, DC: AEI 2004).

173 European Commission, "Communication from the Commission on the Precautionary Principle", *supra* note 17.

being agreed on without a clear coherent policy as to when the Commission should be using risk assessments let alone the precautionary principle. To address these ambiguities, there is a need to form an independent academic expert group that would discuss and describe how the Communication should best be interpreted and implemented. The outcome of such an independent study would need to be launched in the European Parliament with the backing of senior parliamentarians and Commission officials.[174]

7. Establishing a chapter of the Society for Risk Analysis in Scandinavia

In the interviews that were conducted with risk-based policy makers and regulators in Scandinavia it was clear that they needed a meeting place to discuss the present developments in the risk analysis field. The Germans, for example, did not know what the Danes and the Swedes were doing in this area and *vice versa*. Similarly, because of the so called "silo" mentality there was little communication between the representatives of the Swedish Food Administration and the Swedish Chemical Agency with regard to what types of risk analyses should be used for BPA. Finally, the Finns were looking for guidance on current best practice within the risk analysis field. The establishment of a Scandinavian chapter of the SRA with an annual meeting in one of the Nordic capitals would help form some type of peer group where interested regulators, academics and stakeholders could discuss, both formally and informally, the latest issues impacting on the risk analysis field.

VI. Conclusions

The regulation of chemicals and food is never easy, particularly when regulators and policy makers are increasingly distrusted by the public[175]. It is much more complicated when chemical and food regulations become politicised. In this time of greater regulatory uncertainty, there is a need to examine the inconsistencies that are prevalent in Europe to see what can best be done to address them. It is hoped that this paper, highlighting two complex cases of BPA and Deca BDE, and by putting forward a series of policy relevant recommendations ranging from educating the public in risk assessment, to using scientific peer review of risk assessments, to promoting European-wide media guidelines, to improving the risk communication capacity and competencies of regulators in Europe, will assist in the making of more scientific and risk-based European-wide policy making.

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174 An alternative approach would be to clarify the scope and applicability of the precautionary principle by way of legislation. Indeed, there is an increasing body of case law defining the procedural and factual boundaries of having recourse to that principle. Marchant and Mossman's book, "Arbitrary and Capricious", *supra* note 172, is one such attempt in examining how the European Courts have interpreted the principle.

175 M. Hamburg, "Advancing Regulatory Science", 331 *Science* (25 February 2011), p. 987.