The changing nature of communication and regulation of risk in Europe

Written and researched by
Ragnar Lofstedt, Frederic Bouder,
Jamie Wardman and Sweta Chakraborty

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About the authors
Ragnar Lofstedt is Professor of Risk Management and the Director of King's Centre for Risk Management, King's College London, UK where he teaches and conducts research on risk communication and management. Frederic Bouder is a lecturer at the Department of Governance, University of Maastricht. Jamie Wardman is lecturer at the University of Lincoln and Sweta Chakraborty is based at the Kings Centre for Risk Management, King's College London.

Contact:
Ragnar Lofstedt
Department of Geography and King's Centre for Risk Management
King's College London
Strand
London WC2R 2LS

Tel: 020 7848 1404
Email: ragnar.lofstedt@kcl.ac.uk

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Executive Summary

The regulation and communication of risk has changed significantly over the past 20 years or so, partially as a result of a number of regulatory scandals in Europe and elsewhere (Lofstedt 2004: Majone and Everson 2001; Sunstein 2005), which have led to public distrust of regulators and policy makers.

This increase in public distrust has resulted in a phasing-out of consensual-style regulation, and the emergence of a newer model of regulation based on variables including public participation, transparency, and increasingly powerful non-governmental organisations (NGOs).

This paper discusses some of the consequences of adopting this new model of regulation through a series of case studies.

Paper

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1. Introduction

Over the past ten years in many parts of Europe, and in particular in the UK, there have been moves away from the old consensual style of regulation to a new model based on transparency, public participation and social and environmental values (Lofstedt 2004; UK Strategy Unit 2002). The consensual style of regulation was used in the UK as early as1842 following the passage of the Factory Laws and has the following features (e.g. Ashby and Anderson 1981; Brickman et al 1985; Kelman 1981; Lundqvist 1980; Vogel 1986):

- It was based on consensual styles of regulation in which policy makers and industry met behind closed doors and made regulatory decisions;
- It was elitist in nature, with regulatory decisions made in consultation with a number of elite groups including heads of industry, senior regulators, and trade union representatives. These groups were seen as representing society at large.

This model of regulatory decision-making was also inherently flexible. Regulators made a point of addressing potential problems with those being regulated, whether at national and/or local level. The general public generally accepted these arrangements, and even as late as 1979 for example, only four per cent of British respondents in a survey on the public perception of regulators felt that a close collaboration between industry and the regulator was improper (Hayward and Berki 1979). At the same time there was widespread public trust of policy makers and regulators throughout Europe. The public seldom became involved in the policy-making process nor was it expected to (Ashby and Anderson 1981).

However, a number of regulatory scandals that plagued Europe at the end of the 20th century, particularly those involving Bovine Spongiform Encephalopathy (BSE), tainted blood in France and dioxins in Belgian chickens, lead to increased public distrust of authorities and industry (Lofstedt 2004 and 2005). Regulators in many parts of Europe came to the conclusion that the consensual style of regulation was flawed, or perhaps even dead (Majone and Everson 2001; see also the Dutch Scientific Council for Government Policy 2009), and that a new model was needed. This new model, developed in an ad-hoc and very much “muddling-through” fashion and arguably more advanced in some nations (such as the UK) than others (such as Sweden) has the following characteristics (European Commission 2001; Lofstedt 2004; Royal Commission for Environmental Pollution 1998; UK Strategy Unit 2002):

- It aims to be more inclusive than exclusive, encouraging greater public and stakeholder participation in the policy-making process;
- It calls for regulatory strategies to be completely open and transparent and for regulators to be accountable for any policy they propose; and

- The role of science is less important, as scientists are seen as just one of many stakeholders.

In an earlier paper one of us highlighted the possible teething problems associated with the new model of regulation. It considered whether regulators were prepared for greater transparency, whether public deliberation actually increased public trust in regulatory agencies, and whether treating scientists just like any other stakeholder led to better decision making (Lofstedt 2004). Since writing that paper it has become increasingly clear to us that not only do these teething problems remain, but that in many cases where the new model of regulation has been implemented it has led to unforeseen regulatory consequences, referred to within the UK Government as "regulatory storms" (RRAC 2008).

According to the UK Risk and Regulation Advisory Council:

"Regulatory storms are issues that engage the interest of government and attract the attention of risk entrepreneurs[1], and where a range of parties each act to raise the perception of a risk, creating the conditions for government intervention, potentially despite any opposing facts. Regulatory storms typically involve a range of individuals and groups – such as experts, special interest groups or the media – each reacting to what the next says or does, each potentially increasing the perceived size of the risk, until there is considerable pressure on government to act."

This paper is divided into three sections. In the first section we will provide evidence of how regulators have adopted the new model of regulation. In the second section we will provide a number of cases which portray the unintended regulatory consequences of adopting the new regulatory paradigm. In the final section we offer possible solutions that regulators and policy makers may wish to adopt to help better manage these consequences and assist them to make better regulatory decisions without necessarily abandoning the new model.

2. Background

There is nothing new about the fact that the combined forces of the media, risk entrepreneurs and public pressure may influence regulators in making ineffective and often unscientific legislation. Pressure to take knee-jerk regulatory action in the face of uncertainty has been observed in many fields over the years ranging from food and animals to pharmaceuticals (Bouder 2006; Hood et al 2000; Hood et al 2001).

[1] Risk entrepreneurs are organisations whose business or focus is risk. These include the media, single issue and special interest groups, the judiciary, insurance companies, expert commentators, standard setters, academics, parliamentarians (notably select committees), and local authorities. These groups can make positive contributions to society by solving very real problems. However, they may have limited incentives to advocate a measured approach to certain risks and some make it their business to conjure up and/or exaggerate risks for reasons such as financial gain, attention seeking, power building, job security, and overzealous failure avoidance. A lack of awareness of, and challenge to, their operating practices can allow some to have a deeply unhelpful influence on societal-risk perceptions and reactions.

2.1 The new model of regulation

The new model of regulation, however, goes further. It is a direct result of a fundamental rethink of how to develop and enforce regulations that took place in many nations and trade blocks after the regulatory scandals noted in section 1 (e.g. European Commission 2001; HSE 1999; UK Strategy Unit 2002; Vos 1999). This new model is further reinforced by literature attributing the public as competent, albeit only when politically convenient (Fischhoff et al 1982).

All the tools that make up the new model of regulation have more or less one thing in common: that of de-facto decreasing the power of regulators and policy makers, while at the same time increasing the power of campaigning academics and other stakeholders who are supposed to (or claim to) represent the "public" interest. These risk entrepreneurs have either taken or been given power from the existing "old school" regulators and policy makers because they are viewed, either by the regulators themselves, the media, or the public (e.g. House of Lords 2000), as more trustworthy and honest than the old school. Indeed the calls for transparency by the media and risk entrepreneurs themselves come with the assumed observance that in many cases the old school regulators are no longer able to protect the public as a result of incompetence or because of a cosy relationship with industry (e.g.Grasseley 2007; Lofstedt 2009a and b; Psaty and Ross 2008).

2.2 The increased power of the NGOs

Hence, in recent years NGOs such as Greenpeace and Friends of the Earth have wielded increasing political power. For example, they have delayed the building of nuclear power plants in the UK through legal action, halted the offshore dumping of the oil storage buoy Brent Spar (even if it was generally seen as the best environmental option at the time by the UK Government (Lofstedt and Renn 1997), and together with certain state actors (such as Austria) ensured that genetically modified foods are neither grown commercially nor consumed by humans in most of western Europe (Jasanoff 2005). Such power is unprecedented if ones looks back to the old consensual style of regulation when many of the non-established risk entrepreneurs were either not allowed to participate or influence the regulatory process, or voluntarily chose not to be involved (Ashby and Anderson 1981; Brickman et al 1985; Kelman 1981; Lundqvist 1980; Vogel 1986).

2.3 The role of public participation

Similarly, there are increasing calls for the public to participate both in policy-making and scientific processes (UK Health and Safety Executive (HSE)1999; UK Strategy Unit 2002). For a period of six weeks between June and July 2003 for example, the UK Government spent £500,000 on a public consultation exercise to determine whether genetically modified food should be introduced into the UK. The exercise, entitled GM Nation?, showed that the majority of members of the public participating in the exercise were opposed to the introduction of GM foods. However, national public opinion polls showed that the public was largely indifferent to GM foods (Hails and Kinderlerer 2003; Horlick-Jones et al 2007; Pidgeon et al 2003), highlighting the problems of both self-selection with regard to consultation exercises, and arguably a high-jacking of the agenda by risk entrepreneurs (in this case a number of anti-GMO NGOs) (Lofstedt 1999 and 2005).

It has also been fashionable to argue for greater public participation in risk governance (van Asselt and Rijkens-Klomp 2002). These calls go back to a 2000 House of Lords report which showed that the public had lost trust in science following the BSE scare and there was now a need to regain it (House of Lords 2000). Public understanding of science exercises were set up throughout the UK, and academics who had long promoted greater public participation in policy making (Irwin 1995; Irwin and Wynne 1996; Jasanoff 1997; Wynne 1989 and 1996) used the opportunity to further argue for greater citizen participation in setting the science agenda (Wilsdon and Willis 2004; Wilsdon et al 2005) on the basis that scientists themselves do not always have the public's best interests at heart (Irwin and Michael 2003; Lidskog 2008).

2.4 The role of transparency

The new model of regulation also calls for greater transparency. As regulators and policy makers are no longer trusted by the public and stakeholders, there is increased pressure to ensure that decision-making processes are more open. Regulators such as the UK Food Standards Agency (FSA) for example, have board meetings which are shown live on the internet via their websites, and increasingly, scientific evidence submitted to regulators and policy makers regarding a particular regulation is immediately put on a publicly-available website. This transparency has empowered critical stakeholders and NGOs (see for example Fung et al 2007) by allowing them access to information they would not have had access to in a previous era. In many cases they are using this information against policy makers and regulators. As Baroness O'Neil argues:

"Transparency requirements can benefit expert 'outsiders' by enabling them to access information about the performance of institutions and their office holders. This is particularly helpful to expert critics of government, business, and professional performance. Expert critics often have the time and ability to grasp and use information in ways that the wider public does not. Transparency is therefore particularly useful to the media and to campaigning organisations which can discover information that bears on others' performance (while they themselves are generally exempt from like transparency requirements)." (O'Neil 2006, p.88)

In addition, regulators and policy makers must be able to respond to queries, concerns and attacks resulting from these new transparency initiatives, as ignoring them could lead to public and stakeholder distrust (Lofstedt 2010) and possibly unintended regulatory consequences. In other words in this new era of transparency it is vital for the regulatory and policy bodies in question to have large and competent communications departments to handle these inquiries.

2.5 How do policy makers view the new model?

One could have expected that most regulators and policy makers would have been opposed to the various strands of the new model of regulation. In the past regulators were attracted to the role, in many cases having turned down more lucrative jobs in the private sector, because of the power and prestige of the position (Kilpatrick et al. 1964). Several studies have examined the motivation behind public sector pursuit and found that: "prestige is a

factor that influences the attractiveness of public sector jobs" (Perry and Wise 1990). As one Swedish policy maker noted:

"I work on average 12 hours a day. I am completely in love with the job I have, in particular the power that comes with it. I would be loath to either give the public a role in deciding what I should be doing, or in effect to give power to an outside watchdog-type body because there were concerns about lack of trust in our profession. In such a case I would prefer to get expert advice on how I could become a more competent and even a more powerful decision maker." (Swedish policy maker January 2009).

However, this Swedish policy maker appears to be in the minority. Many regulators and policy makers do not appear to mind greater scrutiny. As one official in the UK Food Standards Agency recently noted:

"I do not mind having the board meetings web-streamed. It means that we have to be better prepared and briefed as we realise the whole world is watching and if we are not careful we could be criticised by an outside body." (UK FSA official July 2008)

Overall in interviews and discussions we have had with regulators and policy makers throughout Europe, most appear comfortable with the tools of the new model of regulation. This is also supported by the literature which shows that government officials take the view that stakeholder engagement is necessary for regaining public trust and therefore should be encouraged as much as possible (UK Strategy Unit 2002; UK CoRWM 2006; Petts 2008). That said, in view of the political context of risk regulation, these same civil servants in our interviews recognised the reluctance of citizens to defer important decisions to institutional elites (see Laird 1989). As one civil servant noted:

"I think if we saw ourselves as 'stewards' of some risks, on behalf of the public or the environment, we would adopt a different approach. I guess this is strongly linked to trust, where the public's reaction is often saying 'I don't trust you to steward my risk?"

However, the new model of regulation not only has teething problems, but can also have serious unintended consequences. Indeed, we argue that is it is rather naïve for regulators and policy makers, in many cases influenced by risk entrepreneurs who are actively promoting greater transparency and public involvement, to accept the new model of regulation more or less as a fait accompli. In the next section we further examine risk regulation practices through a number of case studies, with a special interest in issues of transparency and risk communication, the behaviour of risk entrepreneurs, and regulatory responses to social amplification.

3. The case studies

In recent years there have been a number of examples that are instructive with regard to the challenges pertaining to risk governance in the 21st century. In this section we focus on three examples from the food and pharmaceutical fields, sectors that were particularly affected by regulatory scandals in the 1990s and the early part of this century (eg Angell 2004; Lofstedt 2007; Ratzan 1998).

3.1 Avandia

As a result of the regulatory crisis surrounding Cox-2s[2] – in particular Vioxx – in the US, the public lost trust in the medical regulator the US Food and Drug Administration (FDA) (Harris 2007 and 2008; Lofstedt 2007; Niesi 2008). The consequence of this public distrust has been the growth in the power of a number of risk entrepreneurs, most notably highly influential medical researchers such as Dr. Steven Nissen and Dr. Bruce Psaty, editors of leading medical journals (including the *Lancet* and *New England Journal of Medicine*), journalists at leading broadsheets (in particular the *New York Times*) and NGOs such as Public Citizen. The Avandia case (see Lofstedt 2009 for a full discussion) is an example of how much power these risk entrepreneurs actually have and the possible consequences of this power.

The drug Rosiglitazone, under the trademark Avandia, is a Type 2 diabetes drug manufactured by the UK-based pharmaceutical company Glaxo Smith Kline (GSK). Avandia effectively lowers blood-sugar levels in type-2 diagnosed diabetics, thereby preventing long-term complications of the disease. High blood sugar affects nearly every part of the body and can cause blindness, kidney failure, heart attack and stroke. The US FDA approved the use of Avandia to control blood-sugar levels in 1997 and until May 2007 it was being taken by two million people worldwide including a million Americans. In May 2007, Nissen and Wolski published an article based on a meta analysis in the *New England Journal of Medicine*, which showed that of the 42 clinical trials analysed, diabetic patients taking Avandia experienced 43 per cent more heart attacks than those not taking the drug (Nissen and Wolski 2007). Although the Nissen and Wolski article was not an "outlier", as GSK and FDA unpublished meta analyses had shown trends in a similar direction (von Eschenbach 2007), because the results were published in an article in a leading medical journal, they led to massive media coverage causing a drop in GSK's share price and a fall in Avandia prescriptions. For example, between publication of the Nissen and Wolski article in May 2007 and February 2008, when GSK posted its full year results, GSK's share price fell from £14.64 to £10.78, with company executives blaming the Avandia scare for wiping off a billion dollars in profits over 2007 (Jack 2008).

More problematically, the Avandia scare led many diabetics to halt their medical treatments. Prior to the NEJM article one million Avandia prescriptions were being written each month. By September 2007, Avandia prescriptions in the US had decreased by 60 per cent to 436,000 a month. In the same period, Avandia's main competitor, a drug called Actos, only increased by an additional 100,000 prescriptions a month leaving almost 500,000 prescriptions unaccounted for (Saul 2007). During the entire six month episode, media headlines were dominated by Nissen and his other medical research colleagues as along with Congress, which had decided to investigate the case.

There were a number of key trigger factors in the Avandia episode. Firstly it is a widely-used diabetes drug, used by millions of patients on a daily basis. Hence there is a "scale" issue. Regulators and the public are much more worried about products that can affect large

[2] Cox-2 inhibitors are part of a class of drugs that reduce pain inflammation as effectively as older medicines (so called non steroidal anti-inflammatory drugs-NSAIDS) but which lessen the risk of gastric bleeding.

numbers of people (Burgess 2004). Secondly, the initial meta analysis was carried out by a widely-respected and trusted neutral third party, lending credibility to the results (Slovic 1993). Thirdly, there was a political timing issue. In 2007 the US Congress would conduct its five-yearly review of the FDA under the so-called PDUFA (Prescription Drug User Fee Act) Programme. The review had a particularly strong focus on the post-marketing division as a number of reports, most notably those of the US Government Accountability Office (GA) and the Institute of Medicine (IOM), had advocated strengthening this division following high profile safety cases such as Vioxx (IOM 2006). Fourthly, Nissen shared preliminary data with politicians who were in the middle of a Congressional investigation of the FDA. In short there were a number of trigger factors that would ensure that any media story would be amplified (Kasperson et al 1988; Pidgeon et al 2003). To make matters worse, politicians promoting reform of the FDA knew about the forthcoming Avandia article while the FDA was unaware of the study until the day it was published.

Avandia is an example of how transparency (here in the form of clinical trial data) can further empower the risk entrepreneurs and cause an unintended regulatory consequence. Since 2004, leading medical journals including the *New England Journal of Medicine* have come to an agreement that they will no longer publish articles on clinical trials unless those carrying out the studies (in many cases big pharma) publicly register the tests on recognised websites (such as www.ClinicalTrials.gov). In addition lawsuits have also forced big pharma to become more transparent. For example, GSK put all its drug-trials data on a publicly-available website in September 2004 after the settlement of a lawsuit regarding the antidepressant Paxil with the then New York attorney general Eliot Spitzer (Meier 2004). This increase in transparency in the pharmaceutical sector has strengthened the hand of risk entrepreneurs active in this area, as they have been able to accumulate information that was previously not available to them. This is how Nissen and Wolski were able to complete their meta analysis on Avandia.

3.2 Azo dyes

Communicating risks and benefits in the UK in the post BSE era has never been easy. The public has lost much of its trust in regulators (although there are signs that this may be increasing again (FSA 2009)) and as a result does not listen to or believe regulators. In many cases this has led to a policy vacuum which has been quickly filled by risk entrepreneurs. This was seen, for example, with the 2005/06 aspartame controversy (see section 3.3 below) which received significantly more headlines in the UK than any other country apart from Italy (Lofstedt 2008), and with the 2007 scare regarding azo dyes, which involved campaigning academics, media journalists acting as lobbyists, and pressure groups. The scare in effect started when the UK Food Standards Authority (FSA) commissioned Professor Jim Stevenson and his group at the University of Southampton to conduct a study to show whether there was a link between the consumption of six artificial colours and a preservative and hyperactivity in children (for a full review of this case study see Lofstedt 2009). This was in effect a follow up study of the Isle of Wight project which purported to show a link (Bateman et al 2004), but which was considered by the FSA's scientific advisory body, the Committee of Toxicity (COT), to be fundamentally flawed in that the link was only witnessed by parents and not by independent observers (COT 2001).

The Southampton study tested two different cocktails with a placebo on two groups of school children aged three and eight to nine. The first cocktail used in the Southampton study was the same one used in the Isle of Wight study. A second cocktail contained food colourings more in line with the ones presently available (and not containing tartrazine which had been phased out as a food colouring). Researchers concluded that the children taking the first cocktail containing tartrazine were less well behaved than those taking a placebo, but there was less clarity with the second cocktail (ie that not containing tartrazine). The behaviour of the eight to nine year olds was significantly affected according to the statistical methodology used by the authors, while that of the three year olds was not (McCann et al 2007).

The FSA received the final report from Professor Stevenson in February 2007 which was immediately sent out for independent peer review to the COT. In May the same year, prior to publication, the Southampton study became front page news with the title in the *Guardian* newspaper: "New fears over additives in children's food". A source at the University of Southampton leaked the results of the research, which validated the earlier Isle of Wight findings to the industry magazine *The Grocer* (Lawrence 2007). Because of the leak and the media coverage it received, the FSA was forewarned that there would be significant media coverage once the Southampton article was published.

The FSA's outreach strategy before and after publication of the Southampton study (September 2007) was to take the communication initiative before it was seized by pressure groups so as not to unnecessarily alarm the public. As a result, the FSA informed industry about the results of the article two days before the publication embargo (6th September), and on 5th September 2007 held a press conference at the FSA headquarters with Professor Jim Stevenson attending. The initial stance of the FSA was to put forward a scientific message regarding the findings. For example, the Chief Scientist, Dr. Andrew Wadge at the FSA noted:

"We have revised our advice to consumers; if a child shows signs of hyperactivity or ADHD [Attention Deficit Hyperactivity Disorder], then eliminating the colours used in the Southampton study from their diet might have some beneficial effects. If parents are concerned about any additives they should remember that, by law, food additives must be listed on the label so they can make the choice to avoid the product if they want to." (Wadge in Smithers 2007).

The FSA's guarded and more scientific response was immediately attacked by a number of risk entrepreneurs for not going far enough. They said that the food colourings used in the Southampton study should be legally banned. The FSA said it could not unilaterally ban additives as the UK is part of the European Union, but sent the Southampton study to the European Food Safety Authority (EFSA) for an expert opinion. Terrence Collis, Director of Communications at the FSA, defended the decision and argued:
"This is a proportionate response. To ban all additives would scare many parents and let's be clear, these additives are not poisoning children." (Collis in Wallop 2007)

Two vocal academic risk entrepeneurs found this stance unacceptable and tried to put pressure on the FSA by sending open letters to the board of the FSA asking it to implement a unilateral ban of the six colourings (e.g. Millstone and Lang 2007) but this was rejected by the board.

The EFSA's scientific opinion was published on 7th March 2008, noting that the Southampton study "provided limited evidence that the mixtures or additives tested had a small effect on the activity and attention of some children" (EFSA 2008), and concluding that the UK study could not be used as a basis for changing the acceptable daily intake (ADI) of the respective food colours and the preservative sodium benzoate. The EFSA's opinion was immediately attacked by risk enterpreneurs who said that it showed that the FSA did not properly design the Southampton research project (Poulter 2008).

In September 2007 Dame Deidre Hutton, then chair of the FSA, promised to raise the Southampton study once again after the scientific opinion from the EFSA had been received. She kept this promise and the food additives and hyperactivity issue was re-tabled when the FSA board met on 10th April 2008. Just prior to the board meeting Stevenson and his colleagues at Southampton produced a rebuttal to the EFSA's scientific opinion. This compared children's exposures to azo dyes with the state of knowledge about lead and IQ in children evaluated in the early 1980s, noting that effect sizes between high and low lead groups were similar to the effect sizes obtained in their study of food additives and hence this was enough justification for immediate action (Stevenson et al 2008). This rebuttal was socially amplified by the media (Kasperson et al 1988) and used by the new regulators to put pressure on the board to change their opinion. At the board meeting following presentations from both the EFSA and COT, the FSA decided to push for a voluntary ban of the six dyes with Dame Hutton arguing:

"If one puts consumers first, which is our duty, we must recognise that these colours are not necessary and it would be sensible to have them removed from all foods." (Clarke 2008).

This revised stance by the FSA went against its own scientific evidence and that provided by the EFSA. This new precautionary stance taken by the FSA was seen as a victory for the new regulators with Richard Watts of the campaign group Sustain arguing:
"The FSA had little choice other than take this step as soon as they received evidence that these additives were about as harmful to children as leaded petrol." (Clarke 2008)

The outcome of this unilateral precautionary action, caused by the regulatory storm driven by risk entrepreneurs, aside from giving more power to the entrepreneurs themselves, is unclear. But it is likely that it will unnecessarily increase public concern regarding colourings, preservatives and dyes as previous research has shown that making decisions based on a precautionary basis can lead to more public concern about the product in question (Barnett et al 2006 and 2007; Wiedemann and Schutz 2005; Wiedemann et al 2007) rather than less.

3.3 Aspartame

The 2005/06 aspartame controversy is an example of a regulatory storm driven by a media-savvy risk entrepreneur (Ramazzini) with significant economic consequences for the producers of the product (see Lofstedt 2008 for a detailed discussion).

Aspartame is a high-intensity sweetener marketed under brands such as Equal, Nutrasweet and Canderel and has been added to dry food and soft drink products since the early 1980s. It was first discovered by the US-based chemical company G.D.Searle in 1965, but was not approved for use in foods until the early 1980s because of possible cancer-related concerns. Today aspartame remains a highly controversial sweetener, although peer-reviewed scientific studies to date indicate that aspartame is safe – that is no evidence for harm has been found – to consume as an artificial sweetener (e.g. European Commission 2002).

In 2005, the European Foundation of Oncology and Environmental Sciences, more commonly referred to as the Ramazzini Foundation, published an initial study noting that aspartame causes cancer in rats. The publication of the Ramazzini study took the world by storm as it was a scientific 'outlier', going against most of the previous studies in the area.

Once Dr.Soffritti (the lead researcher involved) and his colleagues at the Foundation completed their initial research on the aspartame-cancer link, they implemented a multi-pronged communication strategy. Firstly, prior to the initial results being published in their own in-house journal, they gave a number of presentations regarding the results to regulators and universities in Europe and North America. In July 2005 the Foundation held a press conference publicising the initial findings, which had now been published in its in-house journal, the *European Journal of Oncology*. The paper with "in press" was made available on the day of the press conference and was published on Ramazzini's website. The press release, and a statement by the International Sweeteners Association (ISA) challenging the findings, was picked up by the Italian National Press Agency (ANSA) and rapidly spread across the continent. Key articles appeared in the UK press including BBC News Online, the *Daily Mail*, the *Daily Express* and the *Guardian* newspapers, referring to the press release and ISA statement with headlines such as the *Daily Mail's* "Sweeteners link to cancer denied" and the *Guardian's* "Fresh fears raised about aspartame: manufacturers dispute study into lab rats sweetener." And the controversy did not end with the press conference. In September 2005 Ramazzini researchers once again presented their results, this time at their own scientific conference in Bologna entitled "*Framing the Future in Light of the Past: Living in a chemical world*" which was attended by academics from Europe and North America. And on 17th November 2005 the Foundation issued a press release announcing that its latest paper on the aspartame-cancer link had been published online in the peer-reviewed journal *Environmental Health Perspectives*.

Meanwhile, the European Food Safety Authority (EFSA) was urgently trying to begin its risk assessment on aspartame using primary data from the Ramazzini Foundation. The EFSA initially requested this information in June 2005 following publication of the data in the *European Journal of Oncology*, and Herman Koeter (then acting director of EFSA) requested it again when he attended the institute's September 2005 symposium, but no data was forthcoming. To put more pressure on the Foundation, the EFSA issued an unprecedented

press release on 29th November 2005 urging the institute to send the Authority this data (EFSA 2005a). On 15th December 2005 the Foundation sent both the Italian Ministry of Health and the EFSA a 900-page report with some of the data. On 19th December the EFSA acknowledged that the data had been received and that it would begin its scientific risk assessment (EFSA 2005b). Crucially, however, the report did not contain any of the 34,000 slides that the institute had made and on which key results of the study were based. When Koeter and scientists across the world asked for this data from Ramazzini the official response was:

"…we do not think it is appropriate for slides to be reviewed on data that has already been published. It's 34,000 slides and eight years work. Dr.Soffritti is not open to a third party reading a small subset of slides and issuing an opinion on the study." (Kathy Knowles, quoted in Lovett 2006).

In mid December 2005 the controversy took on a political dimension. The UK Liberal MP Roger Williams held an adjournment debate in the House of Commons on aspartame concluding that the substance should be banned just like the red food dye Sudan 1. He cited the Ramazzini Foundation's study as the new "monumental" study that should have "set alarm bells ringing in health departments around the world." (Williams 2005) and claimed:

"There is compelling and reliable evidence for this carcinogenic substance to be banned from the UK food and drinks market" (Williams 2005).

The then Public Health Minister Caroline Flint responded in the House of Commons by saying that she took the issue very seriously and would look at the new data, but noted that the UK expert Committee on Toxicity (COT) had reviewed the Ramazzini Foundation's research on aspartame and had not been convinced by its interpretations (Flint 2005).

The adjournment debate led to media amplification in the UK press. The front page of the *Daily Express*, for example, had the headline "Cancer is linked to sweetener – Risk in 6000 food and drink products" and quoted Williams and the Italian (Ramazzini) study. On page 7 of the *Guardian* on the same day the headline ran: "Safety of artificial sweetener called into question by MP". These strongly worded headlines led to public concern as to whether aspartame should be consumed as a sweetener.

From November 2005 to May 2006 Ramazzini's two papers were in the public domain, but journalists, scientists and other stakeholders were waiting for the EFSA's opinion on the research. Newspaper articles were written on the Ramazzini findings without the EFSA being able to comment on them. However, at the end of April 2006 the EFSA's analysis was complete and on 5th May 2006, it held a press conference with a webcast in Rome summarising its scientific opinion of the aspartame report and put a lengthy opinion on the EFSA website. The EFSA panel concluded that a number of cancers were irrelevant (kidney, ureter and bladder) as they were specific to rats and not to humans; and the increase in cancers were unrelated to the aspartame treatment. The panel concluded that based on all of the available data to date there was no reason to "further review the previous scientific opinion on the safety of aspartame…"

The EFSA press conference received significant press coverage – for example a headline in the *Daily Mail* ran: "Sweetener cleared from cancer link" – but by this time, the damage had already been done. The Ramazzini articles had led to a 40% fall in the consumption of table-top aspartame in countries like France, which continue to the present day.

4. Recommendations

These three case studies appear to show that the new model of regulation may have teething problems that can lead to detrimental effects for society, be it patient safety, unnecessary market restrictions and economic losses, or more risky replacement products. That said, in this post-trust era it will be difficult to move back to the consensual style of regulation even though some policy makers would clearly welcome this (e.g. Taverne 2005). Rather what is needed now is for regulators and policy makers to benefit from some of the theoretical insights that can be derived from decades of risk research. In this final section we put forward some suggestions which regulators and policy makers may wish to consider.

4.1 Improving risk communication capacity and competences

Distrusted regulators and policy makers are generally poor communicators of risk. Firstly, they are often too slow to communicate, in more cases than not being held back by the vast bureaucratic machinery that makes up most government departments. By being slow in their communication strategy officials spend more time fire-fighting and engaging in reactive risk communication. The problem with this is that reactive risk communication destroys public trust whereas proactive risk communication gains public trust (Fischhoff 1995; NRC 1989 and 1996). In contrast, many new regulators or risk entrepreneurs are 'well-oiled' public relations machines that excel in courting media attention and framing public opinion, debate and controversy, and by being fast and nimble they can consistently engage in proactive risk communication attuned to the demands of a 24-hour news cycle.

Secondly, the same government officials need to improve their communication skills and understanding. Risk communication failures can typically occur either from a narrow appreciation of the risk communication problem at hand, or from an inability to execute responsive risk communication competently and efficiently once a problem has been recognised (Fischhoff 1995). Many officials have not been trained in communication skills and often find it difficult to put over the clear and concise messages needed for the modern media. This problem is not helped by an over reliance on public relations consultants who tend to have only a surface understanding of the nuanced workings of risk-communication processes in advanced liberal democracies. This can hinder the ability of officials to appropriately match communication strategies to the context of communication problems, which can vary according to both the characteristics of the risk and the social dynamics of the situation at hand (Klinke and Renn 2004; Lofstedt 2005; Wardman 2008). To address this problem, regulators and policy makers could be encouraged to attend risk communication courses for continuing professionals such as the one that is given every summer at Harvard University.

4.2 Understand the limits of transparency

Although transparency has been widely promoted as the key tool to regain public trust (European Commission 2001; UK Strategy Unit 2002), policy makers and regulators need to

realise that transparency is not problem free (O'Neil 2006). Was it in society's interest, for example, to put all the clinical trials associated with Avandia on a publicly-available website? It is true that there should be some form of proper policing of clinical studies so that not only the positive ones get published (e.g. Niesi 2008), but complete transparency may be a step too far. More than 500,000 American Avandia patients stopped taking the drug as a result of the 2007 New England Journal of Medicine publication. As Steven Galson, the previous director of the Center for Drug Evaluation and Research (CDER) at the FDA argued:

"I would be very concerned about the wholesale posting of thousands of clinical trials leading to mass confusion." (Galson in Meier 2007)

This is something that Senator Davis of Virginia agrees with:

"People get very confused when this stuff gets out in the media and it gets very unfiltered." (Davis 2007, p.52)

In addition as noted previously, transparency benefits the sophisticated new regulators more than the public itself, and regulators and policy makers should now debate what the right level of transparency is: What is the balance between what is needed to gain public trust in the policy-making process and what will weaken regulators and policy makers still further and arguably lead to greater public distrust?

4.3 Media guidelines

Citizens are not stupid and there is no need to "educate" them in the fashion that many policy makers seem to believe (Taverne 2005). Rather many public outcries or alarms that are prevalent in today's world are perpetuated by undue media attention and amplification of risks which could be better and more responsibly communicated. This is exemplified by the mishandling of the Measles, Mumps and Rubella (MMR) vaccine scare in the UK (Goldacre 2008; Horton 2004), the communication of the Y2k or the Millenium computer bug (Davies 2008) and other scientific uncertainties (Friedman et al 1999). Effective media risk communication in such cases is often undermined by poor handling of science which can, for example, result from impatience. As the former CEO of GSK Jean-Pierre Garnier notes:

"My wish for media is to be more sophisticated when they report scientific news. Debates now are being thrown into the public domain before scientists have given their opinion." (Quoted in Barriaux 2008, p.31)

On the other hand when scientists are consulted they are often pitted against each other, or against impassioned citizens and campaign activists in the name of proportionality, regardless of their scientific credentials. This leads to scientific pluralism (Jasanoff 1997) and in many cases either a confused public (Is farmed salmon safe to eat?) or further distrust of science (for an example concerning acrylamide see Lofstedt 2003). One way of addressing poor communication would be through the development of reporting guidelines, similar to those agreed by the BBC in 2003 (Harrabin et al 2003), that would help journalists to become more attuned to communication pitfalls (for a discussion see Lofstedt 2009b). More science-media forums to encourage greater critical dialogue between scientists and journalists, such as those promoted by the European Science Forum, could also be used. Had media guidelines been in place and implemented by print and broadcast journalists at

the time of the azo dyes and Avandia controversies, it is less likely that these would have led to regulatory storms.

4.4 Constructive deliberation

As part of a democratic society public deliberation is healthy and should be encouraged (Barber 1984; Renn et al 1995). But it does not offer a panacea and could be better targeted and better used by policy makers and regulators. One tool that could be promoted is the International Risk Governance Council's risk governance model (IRGC 2005) which calls for the inclusion of social context, recognising that the public, stakeholders, and regulators perceive risks differently (e.g.Slovic 1987 and 2000) and that such differences in risk perceptions are not reducible to a 'knowledge deficit' on the part of non-experts (Irwin and Wynne 1996; Wynne 1989, 1996). With the categorisation of risk-related knowledge, the IRGC framework recognises that not all risks are the same. Some are better understood than others: potential negative consequences are obvious, applied values are non-controversial and uncertainties can be captured in probability distributions. Other risks are inherently uncertain, complex and or ambiguous. These risks should be treated differently and should involve pubic deliberation at some times but not at others (IRGC 2005; Renn and Walker 2008).

4.5 Scientific peer review of risk assessments used for regulations

One possible way of promoting higher quality science-based decision making in this era of unintended regulatory consequences would be to help ensure that the risk assessments and other underlying scientific arguments used as the foundations for many regulations in the health and environment spheres are based on some form of external scientific peer review. Such a peer review could be based on the US Office of Information and Regulatory Affairs (OIRA) Office of Management and Budget (OMB) 2006 somewhat controversial Risk Assessment Bulletin that had as an objective to:
"enhance the technical quality and objectivity of risk assessments prepared by federal agencies." (OIRA 2006)

The then Administrator of the OIRA, Professor John Graham, was concerned about the varying quality of the risk assessments used in the development of regulations and felt that by having a peer review system in place, the overall practice of risk assessment could be improved. The US National Academy of Sciences, which was asked to review the proposed bulletin, had a number of concerns, most notably that a set of principles rather than legally binding guidance should be put forward in order to ensure de-facto control of the Agency's risk assessments by the White House Office of the President (US NRC 2007). But the idea may be worth introducing to Europe, as long as risk assessment guidelines are developed in tandem with a number of key regulatory agencies in order for them to have some ownership of the project and are not merely dictated to by a central oversight authority.

5. Conclusions

This paper has provided some insights into the challenges of risk governance in the post-trust era, demonstrating that there are no simple formulas to resolve the teething problems of the new model of regulation. In particular the emergence of this new model marks a battleground between risk entrepreneurs on the one hand and distrusted official authorities

on the other. At present the risk entrepreneurs have increased their influence due in no small part to their superior communications skills. However, as highlighted by the cases above, citizens have not always been the benefactors of this increased influence. If official authorities are to counteract these trends for the better they need to become more competent communicators of risk and encourage the development of media guidelines and constructive deliberation. This paper can be seen as an effort to outline a number of areas for improvement that policy makers and regulators may want to address in the future.

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