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# The Reconfiguration of Risk in the British State

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**Abstract**

A particularly prominent feature of contemporary politics appears to be an increasing concern with how risk, science and politics collide. To some, it reveals a political order that has become risk averse. This article challenges this view and argues that we need to appreciate the impact of the New Right on the reconfiguration of risk in politics. Influenced by a conservative view of individual responsibility and a liberal distaste for state regulation of the market, the New Right argues that risk is not to be feared, but embraced, that it should be viewed in a positive light; it stimulates both innovation and creativity. Here, the role of expert advice is to sustain the view that risks are an attendant feature of day-to-day life, that what matters is how, as individuals, we make judgements about those risks. Rather than perform the task of sustaining order through responsible government, science participates in (re)constituting order through the market. It articulates the extent to which individuals are exposed to risk, or defines more clearly where no *risk can be proven*. And if no risk can be proven, intervention cannot be warranted.

**Keywords** risk, science, regulation and the New Right

In the aftermath of the train crash at Ufton Nervet on 6 November 2004 rail chiefs were faced once again with intense public pressure to review safety. With Ladbroke Grove and Hatfield sufficiently fresh in the public mind, the *Guardian* chose an unusually forceful tone to its editorial 'An Avoidable Tragedy'; leaving no one in any doubt that it felt safety had been compromised on the altar of the free market. In circumstances such as these queues form quickly, and at the front of one that questioned the government's position was Bob Crow, general secretary of the RMT rail union, who declared that a feasibility study was urgently required: 'with the ultimate aim of removing all level crossings on the British rail network'

(*Guardian*, 8 November 2004). A few days after the crash, and with debate less charged by those inclined toward the politically bellicose, a government spokesman felt sufficiently confident to assert that there wouldn't be an independent inquiry. No one in government doubts that a tragic event took place, or that we were fortunate there were not more casualties. But, New Labour was adamant: *nothing had occurred to alter the risk assessment*.

Events such as this reveal that if there is a single word that captures the political zeitgeist, it is risk: whether the issue is genetically modified organisms, the credit crunch, a potential link between autism and the MMR jab or little red sweets and hyperactivity in children, political debate is charged with the vocabulary of risk. To those such as Beck (1992) or Giddens (1998) it confirms we have entered a new phase in modernity, a risk society in which science no longer possesses an overwhelming grip upon the public's imagination (Beck, 1992, p.10). To many, it is a persuasive argument. Indeed, among a growing cast of acolytes, David Vogel has argued that European regulation is now 'risk averse', the result of a precautionary shift that can be attributed to a 'widespread public perception of regulatory failures that have a spill-over effect: they make both public opinion more sensitive to the risks associated with new technologies' and create a gap between public expectations and policy effectiveness (Vogel, 2003; see also Farrell, 2006; Moran, 2001; Smith, 2004).

While there can be little doubt that the relationship between risk and politics has come under intense scrutiny, this article argues we must avoid being seduced by those that see risk in politics as purely a recent phenomenon or, that science has suddenly been found out, exposed before an incredulous public. In contrast to such approaches, this article argues that risk was always a central consideration of the post-war British State; it was just that it was refracted through a social democratic lens. In both the USA and Europe, politics were dominated by a view of responsible government in which judicious intervention could rid economies of the vagaries of the free market (unemployment, poverty) and engineer a just society (education, health, housing).

By the 1970s, it was a view under challenge as the New Right sought to draw our critical gaze toward excessive state intervention. For the Conservative Governments of the Thatcher/Reagan era the notion of social justice that pervades government intervention was viewed as pernicious, for not only does it deny the freedom of individuals but undermines individual responsibility: government decides what is fair, it defines just. As part of a wider critique of social democracy that sought to redefine the relationship between the state and the individual, the New Right argued that that far too much weight had been accorded to the state in deciding what is in our best interests, and far too little consideration given to the individual's capacity to decide on potential risks. It was impossible, they maintain, for the state to define an acceptable level of risk, given that it involves making a balance between competing economic and social objectives. Any pretence to the contrary, to engineer order through intervention, is economically damaging (reduces inno-

vation), inherently unjust (impacts upon choice and freedom), paternalistic and ideologically driven.

Here, the article argues that rather than perform the task of sustaining order through responsible government (the realm of the political/legal), science now participates in (re)constituting order through the market. Its role is not to *prevent* development on the grounds that a new technology, process or product *may* be risky (think GMOs), but to establish *definitively* whether a product will be detrimental to public health. It articulates the extent to which individuals are exposed to risk, thereby establishing negligence or culpability (the realm of the economic/legal).

These are important themes to the argument of this article, for once embedded within a regulatory framework the role of risk in politics shifts: intervention can be justified only once a quantifiable risk assessment has identified an ascertainable risk, not a theoretical uncertainty. This is crucial, for it anticipates that regulation involves not a lowering of the evidentiary bar, but its elevation. In turn, the role of science in decision-making becomes more important as a lack of scientific consensus offers *not* an opportunity to invoke precaution, as those such as Vogel (2003), Farrell (2006) or De Sadeleer (2002) would have us believe, but forms the basis from which to *resist* regulatory intervention. And, even in those instances where a risk is proven, intervention needs to consider whether it is appropriate: proportionate, balanced and economically justified.

The article is divided into four sections. The first section explores briefly the manner in which expert advice was refracted through the political architecture of the British State under social democracy and raises doubt about whether political decisions were ever underpinned by scientific certainty. The second section examines the reconfiguration of risk under the influence of the New Right and how this can be traced through prominent international bodies such as the Organisation for Economic Co-operation and Development (OECD), World Trade Organization (WTO) and the Codex Alimentarius Commission. This process is by no means inevitable or universal; individual nation states may experience common pressures, but different institutional and cultural environments ensure that as risk is refracted through this global administrative architecture variations occur. The third section addresses regulatory reform in two key areas, food safety and blood: chosen specifically because they are examples of policy scarred by a crisis that spurred (allegedly) precautionary action. The final section addresses the reconfiguration of risk in the British State from the 1980s onward, where risk analysis has featured prominently in moves to reduce the regulatory burden upon business.

## **Risk and Regulation under the Interventionist State: The Imprimatur of the Public**

To many political observers the welfare state represented a decisive victory for the political forces of the labour movement, a vindication of the positive sum

reformism of social democracy. Indeed, the Keynesian vision that underpinned this project provided the tantalizing prospect of an electoral mandate, a succession of economic tools for interventionist government and, in areas of social policy, a political argument to reduce (but not necessarily remove) the vagaries of the free market (Pierson, 1991, p. 27).

In its qualification of the free market Keynes' work found a ringing endorsement in the work of those such as Titmuss, who rejected the narrow interpretation of choice in welfare to be found in the liberal economic thinking. Titmuss' fervent opposition to the unfettered forces of the free market was expressed most cogently in his promotion of a blood supply system based not on the 'professional donors from skid row denizens' to be found in the USA, but on a system involving free donations. His advocacy of this system carried force because it would improve not just the 'choice of all' in welfare, but confirm that altruism and solidarity could form the basis for *efficient* state intervention (Titmuss, 1967, pp. 37–8). Socialism, for Titmuss, was about community as well as equality, and it was important to recognize our contribution to that community. It was a political climate in which risk was central to policy, for intervention could be considered legitimate if it reduced the risks to health, welfare and employment without imposing an excessive burden upon the free market.

If we are to understand how risk was refracted through the architecture of the British State, ensuring that it garnered the imprimatur of the public, we need also to recognize that the British political system is designed to reproduce strong governments, where referenda occur rarely, and only to reconcile substantial policy differences in government. It is a political tradition underpinned by the idea that a responsible government is one willing to take strong and decisive action and underscored by a view that 'government knows best' (Marsh et al., 2001). Here, ministers place value upon expert advice largely because it carries weight, reassuring the public because it is not: 'tarnished with the political shenanigans of government' (Philips and Ferguson-Smith, 2000, p. 36).

In practice, the distinction between the objective pronouncements of science and the subjective interpretation of politics are often blurred. Advice given to a minister might be affected by an expert's understanding of the minister's current thinking and, while an opportunity for debate meant that a particular *line* could be challenged, once a firm decision had been made at ministerial level: 'it would have been very unusual to have advised ministers to think again, unless there was a factor which they had clearly not been able to take into account ...' (Philips and Ferguson-Smith, 2000, p. 14).

While the relationship between ministers, civil servants and experts provided a political context in which advice was shaped, the communication of that information, whether to Parliament or the public, was also important in the construction of policy. As the Conservative MP Stephen Dorrell has pointed out, once a minister had taken a certain line, public officials would be expected to follow suit. Consequently, officials often proposed: 'less than we might have done if we had

thought the minister shared our perception of the seriousness of the situation ... there is no point whatsoever in putting advice forward which has very little chance of being accepted' (Philips and Ferguson-Smith, 2000, p. 10). We need also to acknowledge that policies do not evolve in a vacuum; they require consideration of statements made by ministers, either in opposition or office. It is hardly surprising therefore that civil servants should very quickly take into account a minister's relationship with the public and public relations.

If the manner in which expert advice was refracted through the political architecture of the British State raises doubt about whether decisions were ever underpinned by *scientific certainty*, the nature of the regulatory principles adopted during this period provide further grounds for caution. During the 1970s, much of the legislation drafted operated with an assessment of risk that involved regulatory principles that endorsed different views. The Health and Safety at Work Act (1974) contained the principle ALARP: that any risk must be reduced to as low as reasonably practicable. In the licensing of medicines, or the assessment of food additives, the preference was to adopt NOAEL: No observable adverse effects level.

It was not simply that a plethora of regulatory principles existed, each with a subtle but nonetheless discernibly, different slant on risk. Rather, they were premised upon the realisation that science was *incomplete*, that a government's defence would need to be: 'bolstered by regulations that were soundly based in law, were *reasonable* themselves, were *consistent* and had been subject to *reasonable consultation*' (Philips and Ferguson-Smith, 2000, p. 36, emphasis added). Remarkable though it may seem, political debate has been distorted by a view of risk in politics that has assumed difficulty to lie in the ability of government to cope with inconclusive science (see Smith, 2004; Vogel, 2003). Such a view blatantly fails to recognize that in its regulation of the market the post-war interventionist state was always keenly aware of the incomplete nature of scientific knowledge and that *risk* was central to policy making environs.

The lexicon of the skilled and experienced legal draftsman was replete with concepts such as reasonable, acceptable and tolerable, not because these terms were evasive (although often they are), but because ministers, civil servants and experts recognized the imperative to consult widely with vested interest groups in order to offset the potential for a legal challenge. If we refuse to acknowledge that public servants operated within boundaries set by conflicting expert advice, and that the science was often inconclusive, we cannot begin to understand how decisions were taken, or the importance of risk within the formation of policy.

## Risk and the New Right

In Europe and the USA, the political landscape of the 1980s differed markedly to that of the 1960s. The positive glow of post-war economic growth had subsided, to be replaced with pessimism in political circles about escalating public sector debt, increasing inflation and rising long-term unemployment. Under the leadership of

Margaret Thatcher, Helmut Kohl and Ronald Reagan, Conservative Governments extolled the virtues of competition and individual responsibility. Though far from a consistent or coherent project, this political agenda influenced profoundly the role of risk in politics in both the USA and Europe.

Much of the intellectual resource for this new conservatism came from Hayek's damning critique of socialism, where his antipathy rested on the fact that two of its core principles, altruism and solidarity, provide significant obstacles to sustained economic growth. Perturbed by the fact that even anti-socialists regard such concepts as virtuous, Hayek asserted that altruism extends only to the needs of *known other people* and that in an extended order, its practice is impossible. In contrast to the interventionist vision of Keynes, Hayek proposed that the morality of the Great Society was one constructed upon individual freedom and responsibility, a limited state and a reduction in the power of the trade unions. He rejected constructivist rationalism; that institutions and action could be based upon reason. Knowledge was, in his opinion, imperfect, dispersed, fragmented and decentralized and therefore central planning was flawed because it assumes a central authority can somehow collect knowledge and construct a more perfect market (Gamble, 1996, p. 68).

Not surprisingly, the notion of social justice that pervades the Keynesian Welfare State was viewed as pernicious, for not only does it deny the freedom of individuals (the state 'decides' what is fair, it defines what is just), but undermines individual responsibility. For the New Right, risk should be viewed in a positive light, for it stimulates innovation and creativity: it should be embraced, not feared. It was a set of political ideas that would inform significantly the reform of risk in politics in both the USA and Europe, manifest in the separation of risk assessment from its management and a corresponding elevation in the role of science so that it defines more clearly both the need and extent of regulatory intervention. New regulatory principles also emerged, which sought to achieve a balance between environmental protection and other, valued social objectives such as economic growth, employment or innovation.

From the late 1970s the impact of Federal regulation in American politics had become an increasingly controversial issue. Conservative lobby groups (such as the National Rifle Association) balked at the level of regulation to materialize from a sustained period of environmental legislation in the 1970s.<sup>1</sup> Much of this legislation, and subsequent regulatory action, drew upon emerging scientific disciplines – toxicology, epidemiology and environmental monitoring that raised new issues for administrative conduct: the relevance and integrity of the science, the competence of those charged with evaluating such evidence and the role of the courts in overseeing the way in which regulatory agencies operated (Merrill, 2003, pp. 1–5; see also Breyer, 1993, pp. 14–24).

There was, as Epstein observes, significant consternation at the manner in which regulatory science was presented. While the United States Food and Drugs Administration (USFDA) harnessed the authority of science in support of policy

preferences, it was not science in any ordinary sense, but a hybrid activity that combined elements of scientific evidence and reasoning with large doses of social and political judgement (Epstein, 1996, p. 277; see Breyer, 1993, pp. 49–50). To business and trade associations such intervention was unpalatable, based as it was on either ‘junk science’ (science that cannot provide certainty with regard to causal explanation) or from a predefined agenda that chose to ignore competing scientific interpretations (Hornstein, 2003).

Determined to reduce the regulatory burden on industry the Reagan Administration initiated reforms in the Office of Management and Budget (OMB) and introduced the Executive Order (12291), intended to reduce the autonomy of Federal agencies and ensure that decisions were subject to cost-benefit analysis. It also introduced the Ritter Bill, which required a government-wide programme of research on quantitative and comparative risk analysis. While these had been tools used by agencies, their use was extended after the Supreme Court’s ruling in *Industrial Union Department v American Petroleum Institute*, which challenged successfully the Occupational Safety and Health Administration’s (OSHA) decision to reduce work place exposure to airborne benzene without undertaking a risk analysis.

In a response to the increasingly controversial role of science in decision-making Congress requested the National Academy of Sciences to assess future options. The outcome, the National Research Council’s (1983) influential report *Risk Assessment in Federal Government: Managing the Process* (generally referred to as the Red Book) was the first, tentative step in reform of Federal regulation. Though it fell short of recommending a formal separation between risk assessment and its management, it recognized that risk assessment should be promoted as a rational mechanism for evaluating scientific knowledge regarding potential hazards to human health or the environment and that, in the light of this assessment risk management would weigh policy alternatives and select appropriate controls. However, it did not dissipate the controversy surrounding Federal agency regulation that became increasingly the focus of challenge through the courts.

To some, it seemed sufficient that judges insist that scientific evidence was ventilated with interested parties (Merrill, 2003). To others, more was expected of the courts; judges should be versed in the underlying science to assess an agency’s competence. The findings of *Daubert v Merrell Dow Pharmaceuticals inc* (1993), a landmark case, would decide in favour of the latter, as the Supreme Court assigned a gate-keeper role to Federal judges hearing cases that involved expert testimony. Following *Daubert*, trial judges would be required to familiarize themselves with the science underpinning testimony; to assess whether it was sufficiently sound and that scientific data was sufficiently robust to justify the expert’s scientific conclusions (Raul and Dwyer, 2003).

In a conservative political environment in which the calls for the shackles on business to be removed were incessant, two other reforms complemented *Daubert*: the Shelby Amendment (1998) and the Data Quality Act (2000). The intention was

to improve peer review and provide checks on research of poor quality. Thus, the Shelby Amendment allows regulatory participants access to data underlying studies funded by Federal money, while the Data Quality Act requires agencies to respond to petitions lodged by interested parties for the correction of information, placing them in the role of peer reviewer. Taken together, the 'good science reforms' in the USA do not simply qualify the actions of Federal Agencies but seek to redefine the role of science and risk in regulation. Under political administrations that favour deregulation, agencies are under direction to ensure that their science is not only of high quality, but also of sufficient magnitude or quantity to justify regulation (Wagner, 2003).

It would be remiss to ignore the extent to which this political agenda has permeated influential international bodies and how, in turn, this has shaped the manner in which risk is refracted through national polities. Here, those such as Kingsbury et al. (2005a,b) observe that a global administrative space has emerged, populated by a variety of international institutions and transnational networks that are increasingly significant. These networks and committees have eschewed the development of law, proffering the adoption of procedural principles, codes of practice and norms: transparency, harmonization and equivalence in order to prevent delay or arbitrary decisions. It is important to realise that these transnational networks (OECD, WTO, CODEX) are not directly subject to control by national governments and that, while the principles used are not formally binding, trade agreements give substantial incentives to conform, restricting the regulatory menu available to governments (Kingsbury et al., 2005b, p. 17; Levidow et al., 2007). Of more import to the arguments of this article, these networks have been crucial in promulgating principles that endorse the reconfiguration of risk, nowhere more evident than in the case of GM regulation.

During the early 1980s the USA identified the Biotech industry as a crucial engine of future economic growth and was determined that it would not be smothered in a regulatory straitjacket. The USFDA's early decisions on GM were framed with this in mind, adamant that regulation should avoid being seduced by irrational fears about a cutting-edge technology. Opting to appraise GM in terms of the similarities these products had with their conventional counterparts, the USFDA ruled that there was no need to introduce new standards: these were products that could be Generally Regard as Safe (GRAS), and therefore safety lay at the doorstep of the Biotech industry. It was a view endorsed by the OECD, which adopted the term substantial equivalence, emphasizing once again the similarities of GM and conventional products, reducing the possibility of different regulatory standards emerging (and therefore barriers to free trade) (OECD, 1993, p.13).

Initially, the EU adopted a different regulatory approach, a line that emphasized the differences, rather than similarities, between GM and conventional products. Here, regulatory concern focused on the process (by which GM products were generated) rather than the final outcome (product). However, the publication of

the OECD's report, *Safety Evaluation of Foods Derived by Modern Biotechnology*, influenced the EU's decision to revise significantly its legislation on GM (see Levidow and Carr, 2007).

The regulation of GM shows that global procedural principles declared through these transnational networks are increasingly important in shaping regulation at the level of individual states (Cassese, 2005). It also confirms that (any) intervention is balanced and proportionate, acknowledging the value of competing objectives: technological innovation, growth and free trade. Further regulation can be justified only on the grounds of a risk assessment that adheres to internationally recognized standards, confirming the reconfiguration of risk in this global administrative space.

## **Risk and European Regulation: Food Safety and Blood**

From the early 1990s, the EU moved progressively away from the style of regulation where legislation is binding. Both the Single European Act and the Maastricht Treaty accentuated this move, reflected in a preference for framework Directives, soft law and voluntary codes of practice (Lowe and Ward, 1998, p.18). Few would doubt that the EU's complicated decision-making process contributed to this shift in thinking: a failure to provide a sound scientific basis to policy was often exacerbated by a tendency to invoke the principle of subsidiarity if the autonomy of Member States was threatened, ensuring that legislation was compromised (Heritier, 1996). As the Commission became increasingly preoccupied with costs and practicalities, British pragmatism was elevated at the expense of continental abstraction, revealed in the emergence of two new regulatory principles: the Best Available Technology Not Entailing Excessive Cost (BATNEEC) and Proportionality.

BATNEEC has a crucial role in the Integrated Pollution Prevention and Control Directive and shapes the role of environmental protection agencies (EPAs), where a licence (to produce, but also to pollute) is granted according to whether it achieves a balance between environmental benefit and financial cost. It has been complemented by the principle of Proportionality, which requires that any action should consider balance, necessity and suitability and was generally taken to mean not using a 'sledgehammer to crack a nut'. It was adopted to assess whether national regulations impact inordinately on the free movement of goods (see Rothstein, 2004). Principles such as Proportionality or BATNEEC reveal a concern not only to reduce regulatory intervention but also involve a risk assessment that accords value to other objectives, such as wealth creation, international competitiveness and technological innovation. They also qualify significantly the rhetorical assurances of precaution in much of the EU's regulatory discourse.

This is not a view endorsed universally. Indeed, those such as Vogel maintain that the political fall out from the BSE crisis has made policy makers 'more comprehensive and risk averse', even in 'areas where these policies adversely affect the

financial interests of important industries' (Vogel, 2003). I do not wish to downplay the political significance of the BSE crisis as a catalyst for change. Indeed, elsewhere I have argued that a succession of food safety scares, the most prominent and expensive of which was BSE, prompted widespread demands for reform (Taylor and Millar, 2002, 2004).

There can be little doubt that the breadth of political support clamouring for change presented a convincing political argument for the replacement of a myriad of confusing legislative arrangements with a single authority to provide a coordinated, integrated and fully transparent approach to food safety. However, the reforms bear an uncanny resemblance to the choices taken in environmental protection where the thrust of change hinged on a new, elevated role for science and a reorientation in regulatory responsibilities, the trajectory of which required consideration of the internal political dynamics of the EU, where ceding autonomy to Member States in this politically charged sector would have to be balanced with the overriding desire not to curtail an extension in the free market. Reform was also shaped crucially by the European Union's need to consider fully the implications of international agreements negotiated under the auspices of the WTO, where the Codex Alimentarius Commission had been pushing for decisions to be based on objective, quantifiable risk analyses, a move designed specifically to reduce instances where precaution could be invoked, raising the possibility of trade disputes not founded upon sound scientific principles.

Formed in 1962 by the Food and Agriculture Organisation (FAO) and the World Health Organization (WHO), Codex developed further its international reference status on standards, which ultimately mean scientific justification is required for control measures that diverge from internationally agreed relevant standards. The agreement on Sanitary and Phytosanitary measures (SPS) operates in tandem with the agreement on Technical Barriers to Trade (TBT) and, while they recognize the sovereign right of states to provide the level of protection deemed appropriate, these measures must recognize the need to avoid constructing impediments to free trade. Although European and American models employ different rhetoric, they take broadly similar *deferential* approaches to the review of science-based risk regulatory measures. Thus, as Peel observes, the WTO 'continually returns to a position that gives a privileged role to science ... in determining the proper scope of risk regulation' (Peel, 2004, p. 3; see also Cassese, 2005). These are important themes to our understanding of how risk has been reconfigured in the area of food safety, revealed eloquently in the recent furore that broke out over research that linked food additives in sweets with hyperactivity in (some) children (McCann et al., 2007).

Keen to allay public concern, Diane Beckford, Head of Toxicology at the UK Food Standards Agency (FSA) appeared on Channel 4 news to explain the agency's position. Channel 4's anchor, Jon Snow, began the interview with a polite enquiry: 'If children without behavioural problems had been affected by the additives, should the FSA not consider banning these things?' Beckford's reaction

was instructive: She pointed out that the research *also* showed that ‘a significant number of ordinary children ... *did not* react, so we can’t say *all* children will react’ (emphasis added). Snow countered that: ‘... if the research shows that a significant number with no predisposition react in this way ... that’s a serious problem, isn’t it?’

Adopting a more conspiratorial tone, and altering his line of questioning, Snow queried whether the agency was ‘trying to dismiss this research’. Beckford insisted this was not the case, and that ‘It was very important research, we consider it is very important for ... a ban to take place at the *European level* ... because foods are *transported freely, traded freely* ... that’s why we’ve alerted the European Food Safety Agency’ (emphasis added). What started out as an engagement with the ‘findings of science’, presumably to assist in our understanding of the role and impact of artificial additives, had suddenly morphed into a wider discussion of how foods are ‘transported and traded freely’. Without wishing to sound glib, or downplay the importance of this issue, the white lab coat appears to have been replaced by the grey suit of management speak.

Following the publication of McCann et al.’s research in *The Lancet* (2007), the European Commission asked the European Food Safety Authority (EFSA) to assess the results, taking into account, if possible, other available scientific literature. On foot of the Commission’s edict, the Food Additives panel issued a scientific opinion that observed some, *but not all*, earlier studies (2002–5) had reported effects of food colours on child behaviour. While the panel conceded that McCann et al. provided ‘*limited* evidence that the synthetic colours and sodium benzoate had a small and statistically significant effect on activity, and attention in some children, the effects were not observed in *all* age groups and were not *consistent* for the two mixtures’. Moreover, it noted that the findings were *only* relevant for ‘specific individuals within the population, showing sensitivity to food additives in general or to food colours specifically’ (EFSA, 2008, p. 3). It was not possible, the panel maintained, to assess the prevalence of sensitivity in the general population, and reliable data on sensitivity to individual additives was not available. The clinical significance was ‘unclear’, and it was not *known* ‘whether these small alterations in attention and activity would interfere with schoolwork and intellectual functioning’ (EFSA, 2008, p. 3).

The panel identified further problems in the research that were, not surprisingly, largely methodological: the limited consistency of the results with respect to age and gender, the type of observer (parent, teacher or independent observer); the *unknown* clinical relevance of the novel metric; the fact that the study had not been designed to identify the effects of individual additives; a lack of information on dose response and finally (though not a methodological issue) the lack of a biologically plausible mechanism for induction of behavioural effects from consumption of food additives (EFSA, 2008).

My apologies for all the italics, I am trying to convey the extent to which the EFSA’s risk analysis identifies uncertainty, ensuring that weaknesses in statisti-

cal rigour or a lack of scientific consensus, offers not an opportunity to invoke precaution, but forms the basis from which to resist regulatory intervention. It anticipates not *a lowering of the evidentiary bar*, but its elevation. Of more import is the extent to which it reveals the separation of risk assessment (EU) level from its management (Member State level), confirming the elevation of science in decision-making and the UKFSA's deference to the EFSA. Indeed, precaution is now more accurately understood as a tool of risk management; a temporary measure pending further scientific information and considered only after a quantifiable risk assessment has dealt with an ascertainable risk, not a theoretical uncertainty.

## Risk and the Blood Directive

The hepatitis C/HIV crises that devastated haemophiliac populations across Europe cast a dark shadow over the integrity of European Community's blood systems and brought in its wake tribunals, litigation and compensation payouts on a scale not seen since the Thalidomide controversy. Here, those such as Farrell have argued that these scandals provided a touchstone through which 'public distrust of those in public authority was revealed' and that 'policy makers' ultimate point of reference' would be that which was politically acceptable, over and above what was considered by experts to be scientifically reasonable' (Farrell, 2005, p.145; see also Feldman and Bayer, 1999, p. 7). In stark contrast, this article suggests that reform in blood regulation follows a path strikingly similar to that of environmental and food regulation.

In the aftermath of the blood scandals, the issues of voluntary donation and self-sufficiency were never far from the centre of debate. To those such as the European Blood Alliance (EBA) and the European Plasma Fractionation Association (the not-for-profit sector), the issue was simple and clear cut: voluntary donation contributed significantly to blood safety. It was a view also endorsed by the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) of the Health and Consumer Protection Directorate, which pointed out that while testing had improved it was essential to *avoid* inducement for donors: voluntary, non-remunerated donations had the lowest residual risk, offering a higher margin of safety (SCMPMD, 2000, p.5).

With substantial interests in the lucrative European market, the Plasma Protein Therapeutics Association (PPTA) reacted with alarm to calls for voluntary donation to be made mandatory, arguing that it was simply trade protectionism by another name, designed to maintain voluntary or state monopolies. The real issues were safety and supply and subsidising the not-for-profit sector was contrary to the principles of the EC Treaty.

Drawing upon its experience in pharmaceutical regulation over three decades the EU's Blood Directive attempted to surf the tension between restoring confidence in blood supplies without compromising the drive toward developing inno-

vative technologies in a free market. In pharmaceutical regulation, the EU initially introduced the Committee for Proprietary Medicinal Products (CPMP, 1975) and a system for licensing medicines based on mutual recognition (see Oraz et al., 1992; Majone, 2003; Vogel 1998). However, drug approval times lengthened, rather than shortened, as Member States were allowed ‘too much autonomy’, enabling them to raise time-consuming and ‘unnecessary questions’ about applications (Lewis and Abraham, 2001, p. 63). In order to dispel the qualms of industry, the EU introduced the European Medicines Evaluation Agency (EMA), a body that would centralize the administration of drug licensing and, more importantly, ensure that decisions from CPMP were *binding*. It was reform that would have a significant bearing upon blood regulation.

Though the Blood Directive suggests that Member States encourage voluntary donation as far as possible, it was not made a requirement and, while Member States are free to impose more stringent protective measures, including the prohibition or restriction of imports of blood and blood components, these have to be justified on the grounds of a threat to public health and *must* recognize both international protocols and the free movement of products. Crucially, it would have to be ratified by the EMA (Hervey and McHale, 2005, p. 247).

In contrast to the SCMPMD the EMA’s CPMP argued that any move to mandate voluntary donation would create supply difficulties for many EU States and that, while those from high-risk categories in the past had contributed to infection, debate about safety had moved on: these were risk factors now largely removed by rigorous screening and/or viral inactivation. While a risk from a pathogen, including those of unknown nature could not be absolutely excluded, the application of these complementary measures meant that there was *no evidence* that paid donations increased the risk of viral transmission. Safety had improved considerably with new standards that favoured repeat donors (lower risk than first time donors) and inventory holds that allowed donations to be removed if the donor later tested positive.

In its defence of this position the CPMP noted that even if paid donation (in theory) impacted on safety, voluntary donation was not a panacea, for as the example of the UK had shown, a reliance upon a single supplier could have disastrous consequences in the event of a plant shutdown or an outbreak of nv Creutzfeldt Jacob Disease (nvCJD) (CPMP, 2002). As the Blood Directive was unveiled, it confirmed that commercial fractionators had been successful in resisting moves to mandate the twin pillars of voluntary donation and self-sufficiency: the best way to improve safety, they argued, was to cut costs, reduce regulatory burdens, ensure open competition and increase customer choice. Any moves to mandate voluntary donation and self-sufficiency could not be sustained on scientific grounds and were simply residues of an era obsessed with social engineering.

In both food and blood regulation, the precautionary mandate associated with a regime that is risk averse appears to be missing: a lack of scientific consensus on risk offers not an opportunity to invoke precaution, but forms the basis from which

to resist regulatory intervention. The reconfiguration of risk is there for all to see: the separation of risk assessment from its management, an elevated role for sound science that defines both the *need* and *extent* of intervention and an insistence that the political autonomy of Member States should not compromise the drive toward free markets.<sup>2</sup>

## Risk and the British State

Conservative Governments in the 1980s and early 1990s were intent on reducing public expenditure and, where possible, allow full reign to the entrepreneurial spirit. Initially, this found expression in a programme of privatization and moves to both liberalise and deregulate markets. In such a political climate the British Government became increasingly interested in the role of risk in politics and whether it would be possible to reduce government responsibility, releasing further the private sector from the burden of unnecessary regulation.

The first significant public airing of risk in politics occurred at the Sizewell B Inquiry into Central Electricity Generating Board's (CEGB) decision to opt for the controversial Pressurized Water Reactor (PWR). As the Inquiry unfolded it revealed the propensity for major projects to be the subject of risk analysis, an obscure area of science dominated by mathematical modelling that had assumed an increasing hold on policy makers, discernible in the burgeoning field of research that sought to justify and expand its use (see O'Riordan et al., 1988).<sup>3</sup>

In an attempt to grapple with some of the difficulties of risk analysis the Chairman of the Sizewell B Inquiry, Sir Frank Layfield, criticized terms such as *acceptable risk* because they failed to reflect the importance of the problem and the reluctance individuals show toward hazardous activities (Hood et al., 1992, p. 93). The term *tolerable risk*, he suggested, might better reflect the true seriousness of the question, prompting the UK's Health and Safety Executive (HSE) to argue that 'tolerability does not mean acceptability. It refers to the willingness to live with a risk to *secure certain benefits* and in the confidence that it is being properly controlled' (Hood et al., 1992, p. 93, emphasis added).

A succession of White Papers during the early 1990s reveal how the British State struggled to reconfigure the role of risk in politics that would bear fruition in the Deregulation Initiative, which questioned the need for complex regulations that impacted detrimentally upon business, prompting the establishment in 1991 of the Inter-Departmental Group on Risk Assessment (ILGRA), to produce guidance on risk assessment with a view to achieving greater consistency.

ILGRA had followed publication of the Treasury's *Economic Appraisal in Central Government*, the first in a series of documents that sought to adopt risk analysis for capital spending projects, as well as provide 'structured thinking' for other policy options. Following closely in its footsteps, the Department of the Environment (1992) published its *Policy Appraisal and the Environment: A Guide for Government Departments*. By the mid-1990s, the UK Treasury was of the

opinion that it was a mistake to regulate against *all* risks and that regulation must be seen to be balanced and appropriate.

Drawing upon the legacy of its Conservative predecessors, New Labour has sought to locate a role for risk analysis in attempts to reduce the regulatory burden upon industry that has emerged forcefully in a succession of reports that include the *Modernising Government, Review of the Regulatory Reform Act 2001* (2005), *Regulation: Less is More, Reducing Burdens, Improving Outcomes* (2005) and *Reducing Administrative Burdens: Effective Inspection and Enforcement* (Hampton Report, 2005).

Influenced by administrative reform in Holland, *Less is More* recommended that government adopt a 'one in, one out' approach to regulation that would force departments to seek a balance between introducing new regulations and remove existing ones. Risk assessment was identified as an important tool and *risk profiling*, an innovative way in which regulators could incentivise performance. Citing the Environment Agency's Operator Pollution Risk Assessment (OPRA) in support of its argument, *Less is More* argued that the frequency of inspections could be reduced and that previous 'good form' rewarded with a reduction in compliance assessment (earned autonomy) (*Less is More*, 2005, p.60).

The Hampton report flagged the need for regulators to appreciate more fully the conflict to arise between prosperity and protection. It surveyed a wide tranche of regulators, assessing the impact of inspections, demands for information and enforcement on business. It noted that, where demands for data were concerned, requests did not differentiate on risk and yet, had they done so, low-risk firms would need to provide less information, reducing their administrative burden. Hampton also revealed that while three quarters of regulators used some form of risk assessment, fewer than half used this to reduce enforcement activity on high performing businesses and, even where it was used, patterns of enforcement did not alter. Indeed, only 25 of 36 regulators included some element of earned autonomy, where good performers were visited less often, or had less onerous reporting requirements (Hampton, 2005, pp. 26–8).

The National Audit Office's study of the Environment Agency's OPRA scheme reveals the potential for glaring inconsistencies to emerge: it is required to visit licensed waste sites at least quarterly ... and yet, some low-risk sites are inspected even more often; *a pet cemetery ... had been inspected eight times a year!* (Hampton, 2005, p. 4, emphasis added). As the National Audit Office's study shows, when a comprehensive risk assessment was used, inspections were reduced from 125,000 to 84,000. It was by no means an isolated case. In 2002/3 local authority trading standard officers inspected 60 per cent of high risk premises in Great Britain (35,000 inspections), yet inspected 10 per cent of businesses classified as a low-risk (72,000). The Hampton report concluded that in parts of the regulatory system inspection was higher than necessary to achieve outcomes and that it is not just that unnecessary inspections are made, but that necessary inspections may not be carried out (Hampton, 2005, pp. 4–5). Not surprisingly, it was confident that if used con-

sistently, risk analysis should reduce the need for inspections on less risky business and identify those enterprises that require more or less inspection.

Keen to display his enthusiasm for such reform, and to expand the role for risk analysis into a wider range of public policy, Gordon Brown confirmed New Labour's commitment to remove the operating and financial review (OFR), which required stock market listed companies to provide a written account of corporate governance, social values, ethical policies and the impact of their businesses on the environment and society. Adamant that New Labour would not insist on the 'gold-plating' of regulations emanating from Brussels, he assured business that only those industries that pose a risk would be required to undertake such tasks. Echoing this sentiment, Tony Blair implored the Financial Services Authority to consider regulation that: 'inhibited efficient business by perfectly respectable companies'. Regulators, he believed, should make decisions based upon risk, so that rather than regulate equally across a particular sector, they should examine only those companies that pose a threat to consumers (*Times*, 7 June 2005).

## Conclusion

While there can be little doubt that the relationship between risk and politics has come under scrutiny, this article has argued that we need to avoid being seduced by those that suggest risk in politics is a purely recent phenomenon or, that science has suddenly been 'found out', exposed before an incredulous public. It is a view that palpably fails to recognize that risk was always a central consideration in the regulatory principles developed by the post-war British State and that politicians (and civil servants) were aware that expert advice was rarely absolute, subject to conflicting interpretation and that it was important to consult those with a vested interest in order to allay the possibility of any legal challenge.

However, it is not just that those such as Beck, Vogel or Smith underestimate the role of risk under the auspices of the interventionist state. Rather, they neglect sufficient consideration of the impact of the New Right on the role of risk in politics, which has ensured that our critical gaze be drawn firmly toward the inexorable growth of the state, where a deluge in state responsibility impinges upon the individual's capacity to decide on risk. In the vernacular of the New Right, far too much weight has been accorded to the role of the state in deciding what is in our best interests, and far too little consideration given to the individual's capacity to decide on risk. It maintains that it is impossible for the state to decide what is an acceptable level of risk: there are simply too many conflicting and competing variables (economic, technological and social) to consider for a balance to be achieved.

In such a scenario, the role of expert advice is to sustain the view that risks are an attendant feature of day to day life, that what matters is how, as individuals, we make judgements about those risks. Rather than perform the task of sustaining order through responsible government, science now participates in (re)constituting

order through the market. It articulates the extent to which individuals are exposed to risk, or defines more clearly where no *risk can be proven*. The role of science should not be to *prevent* development on the grounds that a new technology, process or product *may* be risky, but to establish *definitively* whether a product will be detrimental to public health, thereby establishing negligence or culpability (think Thalidomide). These are technologies that may be contentious, possibly risky, but grounds for regulation must be founded upon a *proven risk*. The objective of a risk analysis is not to prevent development at all costs, but establish *how* a risk is to be *managed*, an exercise that seeks to achieve a balance between the potential costs of regulating against risk, with other valued social objectives such as economic growth and employment.

The role of risk in politics (both nationally and internationally) is reconfigured, for science no longer underscores the regulation of the market through the state (the realm of the political/legal) but assists in the reconstruction of individual citizens as consumers of both products and their attendant risks (the realm of the economic/legal – producer/consumer). Here, New Labour has drawn upon the legacy of its Conservative predecessors where the appeal of an elevated role for risk analysis in public policy rests on the fact that it is no longer reserved for those areas in which science reigns, for it has assumed a Smithsonian dimension: risk is to be viewed in a positive light, stimulating innovation and creativity. In this new guise, risk can be employed to define more clearly where intervention (management) *cannot* be justified across vast tracts of public policy: a programme of reform where primacy, though not exclusivity, is afforded to risk assessment, because some form of risk management is still required in a free market.

## Notes

1. The most notable were the Clean Air Act (1963), the Occupational Safety and Health Act (1970), the Clean Water Act (1972), amendments to the Federal Pesticide Law (1972) the Toxic Substances Control Act (1976) and the Resource Conservation and Recovery Act (1976).
2. Much of the argument presented here sits comfortably with Moran's (2001) work on rise of the regulatory state, most notably his recognition of: a shift in regulatory responsibilities as the interventionist state was challenged by the New Right; the reform of self-regulation and the rise of new regulatory agencies concerned with issues about risk and safety. Differences emerge, however, on his *tentative* acceptance of Beck's risk society as a contributory force behind the rise of the regulatory state and his assertion that much of regulatory innovation is about managing risk (interventionist in leaning). Although he recognizes that any 'objective rise' in risk 'may be debatable' it appears Beck's idea of a risk society captures a concern with new 'catastrophic, unknowable' risks that individuals can do little to safeguard against (Moran, 2001, p. 29). However, I would suggest that the role of science has been reconfigured, elevated as part of a sustained attempt to reduce intervention (management). Without accepting Beck's ideas, these are arguments that sit easily with other elements of his analysis: the impact of the EU,

the audit explosion, scandals. I would add influential international bodies such as WTO, Codex, etc.

3. The use of risk analysis has been subject to extensive criticism from political scientists for its tendency to underestimate or downplay implementation deficits because it assumes a rational transfer (and acceptance) of knowledge. Little room is given for competing views, conflicts of opinion or differences about how change is received (O’Riordan et al., 1988, p.14: see also Douglas, 1994; Wynne, 1996). A further problem lies in the use of comparison in fine-tuning, and yet with highly complex technologies, such as nuclear power, we simply do not know. We have no experience to draw upon, an omission dramatically revealed at the Sizewell B Inquiry where the project Director of the PWR at Three Mile Island was asked if he ‘had any comparable experience?’. His response, which provoked laughter in the audience, was ‘No. (not) until after the accident’ (O’Riordan et al., 1988, p. 182).

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### Government Publications

- Reducing Administrative Burdens: Effective Inspection and Enforcement (Hampton Report (2005)
- Regulation: Less is More, Reducing Burdens, Improving Outcomes (2005)
- Review of the Regulatory Reform Act, 2001 (2005)
- Setting Safety Standards, HM Treasury (1996)

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