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Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance

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ABSTRACT

An historical framework for the analysis of the role of science in public policy is outlined and then applied to analyse a series of institutional reforms that have emerged in 8 separate institutional settings, using as examples the ways in which risks to public health and environmental conditions from food and agriculture are assessed and managed. The discussion explores the extent to which patterns of reform that have been consequent on food safety scares in the late 1990s and early years of this decade have matched the rhetorics in terms of which they were justified, and solved the problems of legitimation that they had highlighted.

1. Introduction

It is widely acknowledged by science policy analysts that a crisis of science and governance is unfolding and remains unresolved (Funtowicz and Ravetz, 1993; Jasanoff and Wynne, 1998; House of Lords, 2000; van Zwanenberg and Millstone, 2005). Old ways of conducting and representing science-based public policy-making have become scientifically and democratically unsustainable because regulatory science is increasingly often seen to be uncertain, incomplete and equivocal (Salter et al., 1988; Jasanoff, 1990) and because decision-making in conditions of scientific uncertainty is frequently acknowledged to be contestable and in practice contested (OST, 1997; European Commission, 2000b, 2001a,b, 2002b).

The crisis of science and governance has been particularly intense in relation to the safety of food products and agricultural practices. Problems in, for example, the UK, Germany, France, Japan and at the European Commission with issues such as *Bovine Spongiform Encephalopathy* (BSE or Mad Cow Disease), as well as GM foods and dioxin contamination have provoked a wave of institutional reforms, and a range of institutional experiments is under way; no two jurisdictions have structured, or are operating, their new institutions in the same way[1] (MAFF, 1998; European Commission, 2000a, 2002a; WHO, 2003; Vos and Wendler, 2006). This paper provides an analytical typology with which to describe and understand those institutional and procedural developments, an up-to-date report on their progress and a normative account of the remaining scope for further reforms with respect to the domain of food safety policy-making.[2]

2. A 3-fold typology of models of science-based policy-making

To a useful first approximation, the majority of the ways in which science-based policy-making has been organised, represented and understood can be categorised into three main groups, which are technocratic, decisionist and co-evolutionary, and there have been patterns of historical evolution between those three models that have varied geographically. The following account is therefore analytical, historical and comparative.

2.1. Technocratic models of science-based policy-making

In the USA from the 1950s to the late 1960s, and in much of Europe until the late 1990s, the dominant official narrative was a technocratic one (Habermas, 1971; Brickman et al., 1985; Ezrahi, 1990; Jasanoff, 1990, van Zwanenberg and Millstone, 2005). In

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[1] For the purposes of this discussion the term 'jurisdictions' will be used to refer not only to national governmental institutions, and international administrations such as those operating at the EU level, but also to standard setting bodies such as the Codex Alimentarius Commission (or CAC), and its advisory bodies, even though in strict legalistic terminology they may not have legislative powers. The main 'jurisdictions discussed here include the CEC, the EU, the USA, the UK, France, Germany, Japan and Argentina.

[2] The typology has previously been outlined, for example, in: Millstone et al., 2004; van Zwanenberg and Millstone, 2005; Millstone E 'Can food safety policy-making be both scientifically and democratically legitimated? If so, how?', *Journal of Agricultural and Environmental Ethics*, 2007, vol. 20, pp. 483–508. The application of the typology of models to a wide range of institutional developments is novel.

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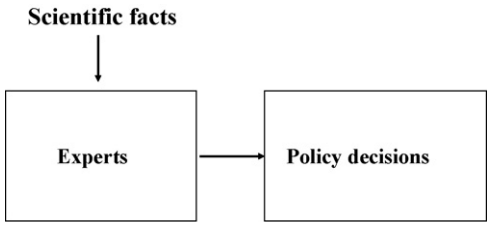

Fig. 1. The technocratic model: 'policy is based (only) on sound science'.

their purest form, technocratic models of science-based policy-making assume that scientific and technical considerations are not just necessary but also sufficient for policy decision-making. To enable them to portray scientific considerations as providing sufficient resources for policy decision-making, technocratic narratives typically make very optimistic assumptions about the progress, accuracy, adequacy and social neutrality of science. On technocratic models, policies should be decided by experts, although with the support and collaboration of what are variously called 'civil servants', '*fonctioneres*', 'public officials' or 'bureaucrats'. Consequently, on this model, the role of elected representatives and government ministers is confined firstly to recruiting the best experts, and secondly to following their advice. Technocracy implies that public administration by impartial experts should replace governance by those with particular interests because only the experts possess the relevant understanding and knowledge. The conceptual structure of the technocratic model is represented graphically in Fig. 1.

The technocratic model assumes that the relevant scientific knowledge is objective, politically neutral, readily available and sufficient. Technocratic approaches are therefore chronically vulnerable to arguments showing that the evidential base and the understanding of experts are incomplete, uncertain or equivocal. Technocratic narratives have often been officially invoked in relatively secretive governance regimes, but if and when policy-makers and their advisors are obliged to disclose the evidence upon which their judgements are based, and the reasoning by which they reached their conclusions, technocratic narratives lose much of their plausibility. In the 21st century explicit endorsements of technocratic models are rarely articulated by policy-makers or policy analysts, but whenever policies are represented as if based on, and only on, 'sound science' then implicit appeals are being made to technocratic assumptions.

In the UK, prior to the BSE crisis of 20 March 1996, ministers and senior officials repeatedly portrayed UK BSE policy as if it was based on, and only on, unproblematically sound science. For example in May 1990 during a Commons debate on BSE, Agricultural Minister Gummer suggested that: "...the first question the House must address is whether the government have any alternative but to accept the advice of the experts." (Gummer, 1990). Similarly, Prime Minister Thatcher told the post-1996 BSE Inquiry that government ministers "....were almost completely dependent on the scientists... It would have been irresponsible and perhaps even counter-productive to second guess the experts" (Thatcher, 1999).

Technocratic narratives have not entirely lost their currency in the 21st century. When challenged in the House of Commons by his recently-dismissed Environment Minister (Michael Meacher), on a question concerning policy on the authorisation of GM foods for human consumption and GM crops for cultivation, Prime Minister Blair said: "I certainly think it is important for us to take on board all the issues relating to GM food. The only thing I have said, and I say it again, is that it is important for the whole debate to the conducted on the basis of scientific evidence, not on the basis of prejudice...I would just point out to the House that the biotech industry in this country is an immensely important industry, important for the future of that industry that they recognise that the decisions the government takes are going to be based on proper scientific evidence...I do worry that there are voices here and in the rest of Europe that are not prepared to give enough consideration to the potential benefits as well as to the potential downsides of this...for the future both of our country and other countries it is important that this is conducted on proper scientific grounds" (Blair, 2003).

Blair's comments were replete with ambiguities. Firstly he asserted that all issues needed to be addressed, and that all types of considerations need to be taken into account, but then insisted that 'the whole debate' had to be conducted 'on the basis of scientific evidence', as if there was sufficient evidence on all the scientific issues, and as if all issues were essentially scientific. He asserted that decisions should not be made on the basis of prejudice, but promptly articulated his own prejudices underpinning his policy preferences. More importantly, in this context, Blair was trying to represent policy-making within the narrow confines a technocratic model, in part because he wanted to portray his government's policy as uniquely rational and unproblematically sound.

The persistence of technocratic narratives, in the face of evidence indicating that they are never true, is explicable because they enable policy-makers to represent decisions as ones for which they are not responsible, and which are also incontestable. As the UK Secretary of State for Health said to the first Chairman of the Food Standards Agency, on the occasion of their first meeting: "Professor, I want you to realise that I will never hesitate to use you as my shield" (personal communication, 7 June 2001, Gresham College, London).

While orthodox technocratic narratives survived in Europe until the late 1990s, they became unsustainable in the USA during the late 1960s and early 1970s. This occurred firstly because on some occasions Congressional legislation acknowledged scientific uncertainties and provided federal agencies such as the US Food and Drug Administration (FDA) with guidance on how they should interpret and respond to such uncertainties (e.g., Delaney, 1959). Secondly, Congress introduced a Freedom of Information regime, starting in 1966 during the Vietnam War (Dobkin, 1968). That legislation was revised in 1974 and considerably strengthened in 1976 in the immediate aftermath of the Watergate Scandal (Elengold, 1980; Delbridge and Smith, 1982). The Freedom of Information Acts entailed the disclosure of sufficient information on the science used to support policy to reveal that the science was often profoundly uncertain. Consequently the USA had to develop an alternative to the technocratic model in the 1970s, whereas European countries and the European Commission have only been obliged to make similar shifts in the late 1990s and early years of this decade. With the introduction and development of Freedom of Information regimes firstly in the USA, and more recently in EU member states such as the Netherlands and the UK, though to a lesser extent in France, Germany and at the European Commission, it became increasingly difficult to represent policies as if based on, and only on sound science. The BSE saga and crises in the UK and EU torpedoed technocratic narratives below the waterline.

2.2. A 'Decisionist' alternative to the technocratic model

The challenge confronting the US authorities once Freedom of Information was legislated was, moreover, complicated by several judicial decisions, some of which had overturned regulatory decisions on the grounds that they were 'arbitrary' and 'insufficiently supported by the available scientific evidence' (MacMarthy, 1987). One of the most important court cases was a landmark judgement in the 1980 decision of the Supreme Court in Industrial Union Department, AFL-CIO v. American Petroleum Institute, also known as the 'benzene' decision. In the 1970s the Occupational Safety and Health Administration (OSHA) had lowered its standard for the maximum permitted air-borne concentration of benzene from 10 parts per

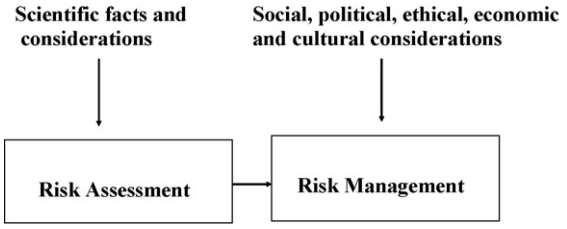

Fig. 2. Decisionism: scientific experts set goals, policy-makers select means.

million (ppm) to 1 ppm after evidence emerged indicating that occupational exposures to benzene were linked to increased rates of leukaemia. OSHA's view was not that 1 ppm was a level below which the risk was negligible or acceptably low, but rather that 1 ppm was the lowest level that was then achievable, and close to the minimum level of detection with the monitoring equipment then available.

The US Supreme Court ruled that OSHA had "...exceeded its authority by reducing permissible exposure limits to benzene at industrial worksites without making a threshold determination that a significant risk was present at the original level..." (Mounts, 1980, p. 53). The court overruled OSHA because it had failed to provide an adequate scientific case to justify the propose standard. The court introduced, moreover, a particular expression, namely a scientific 'risk assessment', arguing that the analysis on which the proposed regulation was based did not constitute such a 'risk assessment'.

Following that judgement, the US authorities adopted an innovative model of the role of science in risk policy-making, which was articulated with a new vocabulary. Science-based risk appraisal and decision-making was portrayed as a two-stage process, the first of which was called 'risk assessment' and the second of which came to be known as 'risk management'. The first of those two stages was portrayed as a purely scientific one and the second as a policy-making stage at which non-scientific considerations, such as those relating, for example, to economic, social and policy aspects of alternative policy measures could legitimately be taken into account. On this two-stage model, policy-makers (also known as 'risk managers') are informed and influenced by scientific advisors, but the scientific advisory bodies are portrayed as entirely independent of policy, and of any and all non-scientific considerations. Scientific advice was, and often still is, portrayed as emerging from a socially, politically and economically neutral space. This 'decisionist' model is represented graphically in Fig. 2.

This model is often referred to as 'decisionist' because it acknowledges that science on its own will not settle risk management policy issues, and that policy-makers need to take decisions, albeit in the light of expert advice. From the early 1970s until the early 1980s this approach was incrementally elaborated and then formalised by the US National Research Council with the 1983 publication of *Risk Assessment in the Federal Government: Managing the Process* (US NRC, 1983). Since the cover of that volume was coloured red, it became known as the **Red Book** and the resulting model is often called the **Red Book model**. The model was readily endorsed and adopted by the US government (Jasanoff, 1990). The model was subsequently elaborated with a third 'risk communication' stage, and that version became an international orthodoxy, and is represented graphically in Fig. 3.

The Red Book model diffused first from the USA to the OECD, and was then incorporated into the text of the treaties that established the World Trade Organisation (WTO) (OECD, 1993; WTO, 1994). Technocratic narratives persisted in Europe, Japan and Argentina into the 1990s, and were especially conspicuous in BSE policy statements in the UK and at the European Commission (van Zwanenberg and Millstone, 2005).

Fig. 3. The Red Book model.

The Red Book model represents current official orthodoxy in many international organisations such as the World Health Organisation (WHO), WTO, OECD, the EU and in individual jurisdictions including the USA and the majority of EU member states, but it remains conceptually bizarre. In the 19th century, when Weber and Durkheim started to theorise the role of bureaucrats and experts in the governance of modern industrial states, they insisted that the only legitimate role for officials and expert advisors was to identify the best available means for achieving goals that democratically accountable representatives had chosen. As Habermas has pointed out, the current orthodox model is bizarre because: "The dependence of the professional on the politician [as envisaged by Weber and Durkheim] reversed itself. The...[politician] becomes the mere agent of a scientific intelligentsia, which, in concrete circumstances, elaborates the objective implications and requirements of available techniques and resources as well as of optimal strategies and rules of control..." (Habermas, 1971: p. 63). Policy-makers rarely represent themselves as 'mere agents of a scientific intelligentsia', but they have not entirely lost their enthusiasm for invoking the rhetoric of 'sound science' to provide the appearance of legitimacy to policy decisions and to try to use the authority of experts to shield them from debate, scrutiny, criticisms or responsibility (van Zwanenberg and Millstone, 2005).

3. Critiquing technocratic and Red Book models

Both the technocratic and Red Book models portray scientific representations of risk (a.k.a. 'risk assessments') as if they were entirely free from all social, economic or policy influences. Numerous scholars have, however, torpedoed those models by refuting their major premise. They have provided detailed evidence showing that scientific representations of risk are routinely predicated on assumptions, which inform the scientific deliberations, but which are not themselves scientific (Jasanoff, 1987; Lewontin, 1991; Funtowicz and Ravetz, 1993; Levidow et al., 1997; Jasanoff and Wynne, 1998; Millstone et al., 1999). Historically, the superficial plausibility of technocratic and decisionist models often depended on the ability of regulatory policy-making institutions to restrict attention to relatively narrow ranges of aspects of possible risks, and to understate and conceal uncertainties and non-scientific assumptions.

For example, Jasanoff has shown how in the USA institutions such as the FDA, EPA and OSHA 'naturalise' some non-scientific risk management assumptions and judgements, while portraying their representations of risk as if they were essentially scientific. She argues persuasively that in the US context they need to do so to stabilize regulatory decisions, and to enable them to withstand judicial and legislative scrutiny (Jasanoff, 1990). While most science policy scholars have abandoned both technocratic and Red Book models of how policies are actually made, policy-makers often continue to portray science and politics as if they are being, effectively separated from each other (Jasanoff, 2005, p. 233; van Zwanenberg and Millstone, 2005, Chaps. 8 and 9).

Many scholars in both the sociology of science and science policy have shown that science and politics are routinely entangled in what are ostensibly and officially portrayed as if they were purely 'scientific' representations of risks. Those scholars have shown

that such representations of risk are inevitably hybrid judgements, dependent on both scientific and normative considerations. They have shown, for example, how non-scientific assumptions about what is to be counted as a risk, and what is to be discounted as, for example, an 'acceptable adaptation' inevitably influence the scope of risk assessments (Torgersen and Seifert, 2000; Levidow et al., 2000). They have shown how non-scientific assumptions about which evidence is to be included and which discounted, and about how much evidence is variously necessary and/or sufficient to sustain regulatory judgements, influence the selection and interpretation of evidence (Jasanoff and Wynne, 1998; Millstone et al., 2004). They have shown that often when different official expert advisory committees reach differing conclusions about particular products or processes this is more often because they are asking and answering different questions than because they are adopting differing interpretations of agreed-and-shared bodies of evidence (Millstone et al., 2004).

If official expert 'scientific' risk assessments are inevitably hybrid representations drawing on both scientific and normative considerations then science-based risk policy-making can only achieve political and scientific legitimacy if those scientific and evaluative considerations are more explicitly and effectively inter-related; while abandoning the discredited practice of misrepresenting them as if entirely independent. Since their interactions are unavoidable, they should be openly acknowledged and addressed accountably rather than leaving them unacknowledged and unaccountable.

Those scholars have, in effect, adopted what is often referred to as a 'co-evolutionary' model of science in policy-making (cf. van Zwanenberg and Millstone, 2005, Chap. 2). It is co-evolutionary in the sense that scientific and non-scientific considerations are portrayed as mutually inter-dependent rather than as inhabiting separate domains. If the co-evolutionary model is more realistic than its predecessors, then institutions constructed in accordance with the Red Book model may face severe difficulties.

4. The co-evolutionary model of science and policy-making

Regulatory policy analysts and sociologists of science have documented ways in which ostensibly scientific representations of risk are framed and influenced by contestable values and interests, and so have concluded that science has not provided, and cannot provide, neutral and uncontested foundations to which policy-making can be anchored. Accepting that conclusion entails abandoning both the technocratic and decisionist models and implies an alternative approach. Fig. 4 graphically represents this alternative 'co-evolutionary model'. This alternative is one that has become increasingly widely accepted by policy analysts, but less frequently by policy-makers.

The key feature of this model is that it represents specific risk assessments as located in particular contexts, which have social, economic and policy dimensions. Scientific risk assessments are, as it were, sandwiched between up-stream framing considerations and down-stream interpretative judgements. The model assumes that those contexts can affect the content, direction and outcome of those deliberations. Consequently representations of risks are portrayed as hybrid judgements constructed out of both scientific and non-scientific considerations, even if they are sometimes (or maybe even often) presented as if purely scientific.

5. Analytical summary

Those three models of the role of scientific expertise in risk policy-making provide, to a good first approximation, a set of templates in terms of which much of the evolution of institutional structures and processes can be categorised and analysed.

6. Institutional and rhetorical developments since 1996

One consequence of the BSE crises in the UK (starting in March 1996) and in Continental Europe (around the turn of the century) was to force a re-conceptualisation and an institutional re-organisation of science-based risk policy-making, especially in relation to food safety in the EU and other OECD countries. Many European policy-making systems have in recent years been reorganised along Red Book model lines, ostensibly separating 'risk assessment' from 'risk management'. EU food safety policy decisions should now be taken by risk managers in the European Commission's Directorate General for Health and Consumer Protection (DG-SANCO), acting on the advice provided in scientific 'risk assessments' provided by the European Food Safety Authority (EFSA, established in 2002) and its expert advisory panels (European Commission, 2000a, 2001a; EFSA, 2008).

An apparently similar division of labour was institutionalised in Germany when in 2001 the Ministry of Agriculture was abolished and replaced by a new Ministry for Consumer Protection, Food and Agriculture (*Bundesministerium für Verbraucherschutz, Ernährung, und Landwirtschaft* or BMVEL). The BMVEL abolished the agency that had previously been responsible for providing both scientific and policy advice on food and reorganised it into two separate bodies. The Federal Office for Consumer Protection and Food Safety (or *Bundesamt für Verbraucherschutz und Lebensmittel Sicherheit*—BVLS) is now defined as being responsible for risk management, while the Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung* or BfR) is supposed to provide scientific risk assessments and advice, but not to make policy judgements. One important difference between the reforms in the UK and the EU on the one hand and in Germany on the other is that the UK and the Commission sought to separate food safety regulation from industrial sponsorship, whereas in Germany they were re-combined, although ostensibly with consumer protection as dominant. In Japan, in 2003 a new Japanese Food Safety Commission (FSC) was established, supposedly ostensibly modelled on EFSA, institutionally to separate risk assessment (in the FSC) from risk management, which is the responsibility of the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) (FSC, 2003).

In the UK, however, despite the popularity of the Red Book model in some policy arenas (such as the Health and Safety Executive), the Food Standards Agency (FSA) was designed as a hybrid body, responsible for both scientific advice and policy decision-making. The FSA has intermittently invoked some Red Book rhetoric, but without institutionalising a formal separation of scientific from policy deliberations that other European jurisdictions have thought necessary. One reason why this has occurred is that government ministers, reflecting on the political damage caused by the mishandling of BSE, have been keen to avoid taking responsibility for contestable and contested decisions, and therefore have assigned to the FSA responsibility for almost all aspects of risk appraisal and decision-making.

Ironically, even though the contrast between 'risk assessment' and 'risk management' was most enthusiastically articulated in the USA, the US FDA is a hybrid institution, with responsibilities covering both scientific and policy aspects of risk appraisal and decision-making. On the other hand, at the global level, since the early 1990s Committees and 'Subsidiary Bodies' of the Codex Alimentarius Commission have portrayed themselves in Red Book terms, as 'risk managers' acting on the advice of joint UN Food and Agriculture Organisation and World Health Organisation expert

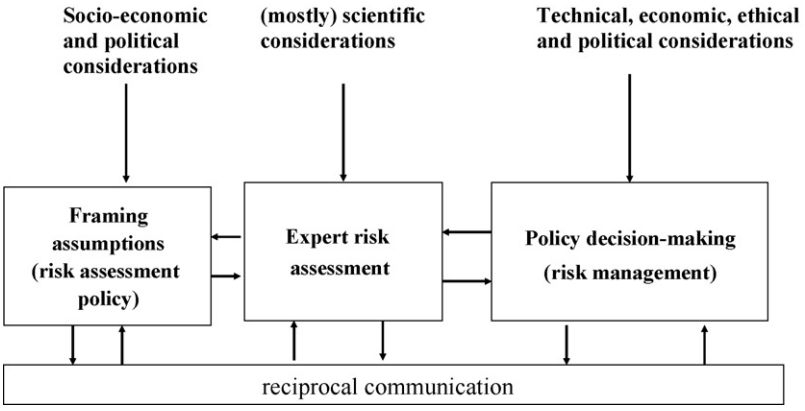

Fig. 4. A co-evolutionary model: reciprocal links between science and policy.

committees, which are portrayed as 'risk assessors'. Those risk assessment bodies include JECFA (i.e., the Joint (WHO-FAO) Expert Committee on Food Additives) (FAO/WHO, 1995) and JMPR (i.e., the Joint Meeting on Pesticides Residues) (JMPR, 2004).

7. Operationalising a co-evolutionary approach

While co-evolutionary analyses have become increasingly accepted amongst science policy scholars and sociologists of scientific knowledge, public policy institutions have been far slower in understanding the implications of co-evolutionary analyses, or they have understood them but have been reluctant to accept some or all of their implications.

In the food safety regulatory field, it has been the Codex Alimentarius Commission that has recently been in the vanguard. The CAC was jointly established in 1963 by the member states of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO); it sets food safety standards for globally traded food products. Until 1994 Codex standards were merely advisory, with no statutory force. Since the establishment of World Trade Organisation in 1995, Codex standards have been adopted as benchmarks below which importing countries can lawfully exclude products. Individual Codex member states may set higher standards than those adopted by Codex, but if challenged at a WTO Dispute, those jurisdictions would need to justify those standards as 'based on a scientific risk assessment' and as not discrimination between imported and domestically produced commodities (WTO, 1998).

Since 1995, with the enhanced role of Codex standards within the WTO regime, regulatory convergence and divergence has become increasingly important. Codex has struggled to set agreed common standards given the differences amongst the competing standards of various member states. Under these conditions, and given the collisions amongst the risk assessments and regulatory standards of competing Codex and WTO member states, it is perhaps not surprising that explicit attention has been given by Codex to up-stream framing assumptions that contribute to the construction of competing risk assessments. Codex is the first major public policy institution explicitly to acknowledged that scientists' assessments of food safety risks are framed by prior up-stream framing assumptions, which Codex calls 'risk assessment policy'.

The Codex Alimentarius Commission characterises '**Risk Assessment Policy**' in the following terms:

- Determination of risk assessment policy should be included as a specific component of risk management.
- Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.
- The mandate given by risk managers to risk assessors should be as clear as possible.
- Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options (CAC, 2003, Appendix IV, paras. 13–16).

The introduction of those provisions in the early years of the 21st century represented an important innovation. Codex introduced a novel obligation on its risk management committees (also known in Codex-speak as 'subsidiary bodies') to articulate risk assessment policies, and in recent years several Codex Committee have been struggling with that challenge.

The implications of these developments may be quite profound although their significance is not yet widely appreciated. Their importance has been hugely reinforced by the fact that at the July 2007 plenary meeting of the Codex Alimentarius Commission, the text on the ***Working Principles for Risk Analysis for Food Safety for Application by Governments*** was formally adopted (CAC, 2007, p. 9, paras. 56–60). Under the provisions of that agreement, all Codex member states and regional jurisdictions like the EC have accepted an obligation on their domestic risk managers to provide their risk assessors with explicit risk assessment policies prior to the start of the deliberations of those risk assessors. The text the Codex member states adopted on 'risk assessment policy' is identical to that in the *Codex Procedural Manual*, cited above (CCGP, 2007, Appendix VIII, paras. 16–19, p. 62). It is just possible that all these regulatory institutions and their expert advisors are 'sleepwalking into the light'; or perhaps they realise the full implications of the step they have taken?

Whether member states realise it or not, they have, at least implicitly acknowledged that scientific representations of risks cannot be fully separated from risk policy-making, although their separate contributions can nonetheless be duly acknowledged and legitimated, bearing in mind that the mechanisms of scientific and democratic legitimation differ significantly. Irrespective of whether Codex member states fully appreciate the fact, they have implicitly repudiated the **Red Book** model, by adopting a text that contradicts that model.

In the face of those ambiguities and destabilising conditions, it is worth examining the extent and direction of risk assessment policy-making in practice at the global level (i.e., in relation to Codex, its subsidiary bodies and their joint FAO–WHO expert advisory committees) and also in relation to the new institutional structures at the European Commission and in differing national settings. The remainder of this paper therefore reviews key aspects of the changing rhetorics, institutional structures and processes to be found

in the global institutions, EU institutions, and those in the USA, the UK, France, Germany, Japan and Argentina. That selection of institutional settings is self-evidently not exhaustive or representative, but it does reveal fascinating patterns and contrasts. The following discussion draws on data compiled from seven separate studies; which collectively covered a far wider range of institutional settings and jurisdiction from which this selection has been made.[3] For brevity the abbreviations 'RAP' will be used to refer to 'risk assessment policy' and 'RAPs' to refer to 'risk assessment policies'.

8. Rhetorical orthodoxies, institutional structures and practices

Not surprisingly, the practice of representing the overall process of risk appraisal and decision-making as a two stage Red Book-type process has its longest history in the USA. Americans coined the vocabulary of differentiating 'risk assessment' from 'risk management', and they were the first to adopt it; they also promulgated its diffusion. In the late 1980s and early 1990s, in the context of the negotiations for the Uruguay GATT round, the Red Book model was written into the text of the agreements that lead to the creation of the World Trade Organisation (or WTO).

A fact rarely appreciated is that domestically the US Federal government has interpreted the Red Book model differently from the way in which it has encouraged other jurisdictions to interpret it. Domestic US regulatory agencies, such as the FDA and EPA, are hybrid institutions containing within them responsibility for both 'risk assessment' and 'risk management'; as the text of the Red Book actually recommended. Of the other jurisdictions discussed here, only the UK and Argentina are operating mono-institutional systems. In the UK, the FSA is a hybrid institution including both scientific and policy functions and responsibilities, but without any invocation, except very occasionally and *en passant*, of Red Book labels of 'risk assessment' and 'risk management'.

The creation of the UK FSA was intended to mark the separation of regulation from industrial sponsorship, rather than science from policy (MAFF, 1998). The implicit model underlying the UK government's approach was that once responsibility for regulation was separated from responsibility for sponsoring the economic welfare of farmers and the food industry, the separation of science from politics would either occur automatically, or it would become evident that science and policy-making always had been separated, even if that fact was not widely recognised (cf. Packer, 2006). In practice, scientific representations of food-borne risks in MAFF were exquisitely sensitive to their political context (van Zwanenberg and Millstone, 2005).

In the UK, under the new post-MAFF regime, the Board of the FSA is, in effect, the policy-making body. Members of the Board are appointed by ministers; they (unlike ministers) are not directly accountable to Parliament. The 1998 White Paper entitled *The Food Standards Agency: A Force for Change* implied that the FSA would be an NDPB (or 'non departmental public body') that would provide advice to ministers who would take policy decisions in the light of that advice; which would have been consistent with orthodox interpretations of the Red Book model. By the time draft legislation was published in January 1999, the FSA had mutated into an NMDP (or non-ministerial departmental body). That subtle change of terminology concealed a substantial change in the location of responsibility for policy decision-making. The FSA became, and remains, a non-ministerial policy-making body; it is in practice acting to shield ministers from responsibility for food safety policy as well as attempting to protect consumers. The first chair of the FSA Board was an Oxford Professor of Zoology; what better way could there have been to imply that the FSA was essentially a scientific body from which policy emerges. The spirit of technocracy still stalks the corridors of Whitehall because it helps ministers to engage in what Hood and Rothstein term 'blame avoidance' (Hood and Rothstein, 2001).

The Argentinean regime is archaic and anomalous because the participants in the regulatory system routinely portray their activities in old-fashioned technocratic terms. Argentinean decisions are officially portrayed as based on, and only on, science. GM crop and food policy-making bodies in Argentina hold their meetings in closed sessions, and they do not publish the evidence by reference to which they made their decisions. Under those conditions it is difficult to compare their rhetoric with actual practice. Since, however, the 'expert' discussions routinely include representatives of the companies whose products are under consideration, it is unlikely that non-scientific considerations play no part in their deliberations.

9. 'Two-Body' solutions

At the global level, since the 1990s, Codex and its Subsidiary Bodies have been responsible for what is explicitly label as 'risk management', while responsibility of 'risk assessment' is explicitly ascribed to separate institutions for which the WHO and UN FAO are jointly responsible. Those expert advisory committees, such as JECFA and JMPR, are described by Codex, and by the WHO and FAO, and by themselves, as 'scientific risk assessors'. Since 2003 Codex has, however, stipulated 'risk assessment policy-making' as one indispensable element in risk management; but that modifies the 'two body' solution because risk managers are supposed to provide their risk assessors with explicit RAP guidance, **in advance** of the conduct of particular risk assessments, consequently science and politics mutually influence each other, and it is no longer possible to pretend that while science influences policy-making, policy-making in no way influenced science.

With the adoption of a discursive binary differentiation of 'risk assessment' from 'risk management' at the global level, at the European Commission, in France, Germany and Japan, explicit and deliberate decisions have been taken to create separate pairs of institutions, with one of the pair labelled as responsible for 'risk assessment', having a scientific mandate, and the other labelled as having responsibility for 'risk management' policy decisions (Vos and Wendler, 2006; Millstone et al., 2006). In the 1980s US officials at the FDA and EPA used to talk about institutional sub-divisions and constructing 'Chinese walls' within those institutions effectively to separate assessment from management, but that rhetorical practice has become increasingly conspicuous by its absence (Millstone et al., 2006). Hajer has argued that forms of discourse gain power and authority if and when they are translated into institutional arrangements (Hajer, 1995, p. 61). The contrast between the USA and others suggests that Hajer's model may be correct in some but not all cases.

10. Variable institutional geometries

Even though the European Commission, France, Germany and Japan have all adopted Red Book terminology and rhetoric, no two have interpreted and institutionalised it in the same way.

[3] Project, *Building a common data base on scientific research and public decision on TSEs in Europe*, Commission Contract PL 976057; CJD Risk Project, *Public perceptions of BSE and CJD risk in Europe, their interplay with media, policy initiatives and surveillance issues. Drawing the lessons for information policy*, Contract PL 987028; ESTO Project on Science in trade disputes related to potential risks: comparative case studies; ESTO Project on Risk-assessment policies: differences across jurisdictions; EC Framework 6 *SafeFoods* Integrated Project; the EC Framework 6 PorGrow project on Obesity Policy in the EU—evaluating the options.

10.1. The EU

The European Commission issued a White Paper in 2000 proposing the institutional reorganisation of food safety policy-making, with a proposal to create a European Food Authority as a risk assessment body that would report to (i.e., advise) the European Commission in its role as 'risk manager' (European Commission, 2000a). After lengthy negotiations with member state governments, selected stakeholder groups and the European Parliament, a decision was taken stipulating that from 2004 EU food safety policy-making would be decided by the Directorate General (or DG) for Health and Consumer Protection (DG-SANCO) of the European Commission, acting on the advice and risk assessments provided by a new and separate body called the European Food Safety Authority (EFSA).[4] At the Commission, responsibility for food safety policy had previously been located in the DG with responsibility for industry, and later in the DG with responsibility for the 'internal market'. Relocating it to DG-SANCO represented a decision to separate responsibility for regulating the food industry from sponsorship of that sector, a change intended to resemble that which had occurred in the UK with the establishment of the FSA.

10.2. France

The French reform process involved the introduction of an explicit institutional separation of the functions of 'risk assessment' from 'risk management', which was officially portrayed as coinciding with the separation of science from politics. The official narrative was that they had not always previously been properly or clearly distinguished (Hirsch et al., 1996). The *Agence Française de la Sécurité Sanitaire des Aliments* (AFSSA) was established in 1999 with responsibility primarily for risk assessment, with ministers having responsibility for risk management. In relation to veterinary medicines, however and for historical reasons, AFSSA is responsible for both the risk assessment and risk management. In all other relevant policy domains, however, AFSSA is supposed to give science-based advice, but not to decide policy.

AFSSA is, moreover, not only accountable to the Ministry of Health, but also to the ministries of Agriculture and of Consumer Affairs. Opportunities for tensions between AFSSA's responsibilities for food safety and the Ministry of Agriculture's responsibility for the economic welfare of French farmers. In the context of the UK-French dispute in the early years of this decade about possible exports of British beef to France, ministers applied political pressure to AFSSA when the agency failed to provide ministers with the advice they preferred to receive. Ministers wanted to be told that there was sufficient evidence to maintain a prohibition on the import of beef from the UK, while AFSSA concluded in 2003 that there too much uncertainty for it to make a comparative safety judgement as between beef from the UK and French domestic beef, once BSE had emerged in France (van Zwanenberg and Millstone, 2005, p. 271). The issue of 'risk assessment policy' guidance from risk managers to risk assessors has yet to be systematically addressed in France, but conflicts over the intersection of science and politics suggest that RAP issues are ones that will not go away. There is no evidence indicating that RAP issues, known in French as *L'établissement d'une politique d'appréciation des risques pour effectuer des évaluations de risques*, have been explicitly addressed in the relationship between AFSSA and French government ministries.

10.3. Germany

In January 2001, after BSE emerged in German cattle herds, the new Ministry for Consumer Protection, Food and Agriculture (or BMVEL) was established. The remit of that ministry is noteworthy because it embodies a quite different strategy from that adopted in the UK and at the European Commission. The approach adopted in Germany was to integrate responsibility for consumer protection with responsibility for promoting farming and food industry interests, although ostensibly subordinating food and agricultural policy to the primary objective of consumer protection. Separating 'science' from 'policy-making' was the dominant priority in Germany.

The arrangements in Germany differ from those in the UK, France and at the European Commission. The institutional structure in Germany formally presumes a clear separation between scientific 'risk assessment' and 'risk management'. Unlike the position in France, however, responsibility for risk management is not assigned to a government ministry and ministers, but to an arms length risk management policy-making institution namely the *Bundesamt für Verbraucherschutz und Lebensmittel Sicherheit* (BVLS) that will be expected to provide ministers with policy recommendations, in ways that resemble the role of the FSA in the UK. In effect it provides ministers with the freedom to decide which issues they will leave to the BVLS and those for which they will take responsibility.

In Germany, in relation to GM foods and crops the position is however rather more complex. In practice the BfR is not the only official risk assessment body, four additional official institutions also provide assessments of some aspects of possible risks. They include: the Federal Biological Research Centre for Agriculture and Forestry (BBA), the Federal Agency for Nature Conservation (BfN), the Robert Koch Institute (RKI) and the Central Commission for Biological Safety (ZKBS) at BVL; and each is in effect deciding its own risk assessment policies. The issue of 'risk assessment policy' guidance from risk managers to risk assessors has yet to be systematically addressed in Germany, though conflicts amongst those five risk assessment bodies and between the BfR, the BVLS and ministers over the interactions between science and politics suggest that RAP issues are ones that will not go away.

10.4. Japan

As in Germany, Japan reformed its food safety policy-making institutions as a consequence of the emergence of cases of BSE in its domestic herds. In July 2003 a Japanese Food Safety Commission (FSC) was established in order institutionally to separate risk assessment (in the FSC) from risk management, for which the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries (MAFF) are responsible. The issue of 'risk assessment policy' guidance from risk managers to risk assessors has yet to be systematically addressed in Japan, especially because Japanese ministries expect the FSC to provide not just scientific advice, but also policy recommendations. Japanese ministers are in effect trying to use the FSC to reinstate technocratic accounts of policy-making.

The contrasts between the institutional structures reviewed above indicate that a wide range of different tactics have been adopted, as the various jurisdictions endeavour to provide either political or scientific legitimacy, or both, to their food safety regulatory systems. No two institutional structures are the same, even those that are ostensibly based upon Red Book narratives.

[4] The inclusion of the word 'safety' in the organisation's title was at the insistence of the European Parliament, because a majority of MEPs were opposed to giving that body any responsibility for nutrition policy.

11. Reality rarely coincides with Red Book rhetoric or with Codex provisions

In all those jurisdictions, however, the realities do not match the rhetorics. The alleged separation of science from all policy considerations is illusory. In each jurisdiction some 'risk management' policy issues are being decided by scientific advisory bodies, typically but not invariably acting as 'risk assessors'. Those decisions concern both down-stream issues such as the acceptability of risk and uncertainties, as well as some important up-stream RAP issues.

How scientific and policy-making issues are in practice entangled can be illuminated by focussing on the issue of where and how RAP issues are being decided. To distil the main characteristics of those patterns, **three** main types of up-stream RAP framing assumptions will be differentiated, namely those concerning **substantive, procedural** and **interpretative** issues, although they are also often inter-dependent (Millstone et al., 2006).

1. **Substantive** RAPs are concerned with delineating which potential changes and effects are to be included within the scope of risk assessments and which are outside their scope, and which kinds of evidence are admissible and which are not. For example, when the risks posed by food additives are considered do they focus solely on toxicological issues or should they be extended also to consider possible impacts on public health nutrition?
2. **Procedural** RAPs are concerned with the processes by which risk assessments are conducted and reported. For example, should risk assessment deliberations be conducted in open or closed meetings, and how should risk assessors respond to uncertainties?
3. **Interpretative** RAPs are concerned with the ways in which data are interpreted. Data and documents do not interpret themselves; interpretation often involves judgements and assumptions. For example, are laboratory rodents treated as good or as poor models for the effects of chemicals on humans—and for all types of lesions at all sites, or only for some?

The following discussion will highlight key examples where risk managers either have, or have tried to, take responsibility for some of those risk assessment policy issues. In all other cases it follows that in practice RAP risk management judgements are in practice being made by expert scientific advisory bodies, the majority of which are labelled as 'risk assessors'.

12. A Codex saga

The most diligent attempts to establish risk assessment policies have taken place within the Codex system, since the Codex *Procedural Manual* set out that obligation in 2003 (CAC, 2003). A particularly illuminating example is provided by the efforts of the Codex Committee on Residues of Veterinary Drugs in Foods (or CCRVDF) to provide RAP guidance to the Joint (WHO-FAO) Expert Committee on Food Additives (JECFA). In July 2001, CCRVDF prepared a draft risk assessment policy document for JECFA; although that text was referred to as 'risk analysis principles and methodologies' rather than "risk assessment policy" (CCRVDF, 2001[5]).

The CCRVDF document provided some substantive, procedural and interpretative guidance to JECFA. The procedural guidance required the committee to be 'independent' (without clarifying of what they should be independent) and stipulated that 'uncertainties and assumptions' should be acknowledged. The substantive and interpretative guidance included stipulations about what should count as a benchmark of acceptable risk, about the kinds of metabolic changes (following the administration of veterinary drugs), that should and should not be the focus of JECFA's attention, as well as instructions to use a safety factor of 100 to calculate 'acceptable daily intakes' (or ADIs) from 'no observed effect levels' (or NOELS) in animal studies. CCRVDF also portrayed risk assessment, which is JECFA's explicit responsibility, in an orthodox fashion, as a four-stage science-based process comprising: hazard identification, hazard characterization, exposure assessment, and risk characterization (CCRVDF, 2001, para 11).

The CCRVDF document was discussed by risk assessors at JECFA in February 2004; and their response was a comprehensive rejection. JECFA said:

"Although the Committee recognised the value of a risk assessment policy, it was concerned that **the current draft document to CCRVDF was not adequate due to serious flaws in structure and content**. . .the Committee agreed that. . .the above mentioned draft **discussion paper in its current form requires substantial revision**, which should consider the following issues:

- A risk assessment policy should provide a general policy framework for the work of risk assessors and not describe the details of the four steps of the risk assessment process.
- The roles and responsibilities of risk assessors and risk managers need to be clearly defined, recognizing the independence and transparency of the risk assessment process.
- The development of risk assessment guidelines is an inherent part of the corresponding scientific work which needs to be accomplished by risk assessors. . .
- The Committee recommended that a risk assessment policy (principles and processes) should include at least the following elements:
- Objectives of a risk assessment
  Responsibilities of risk manager and risk assessor in the process of problem formulation
  Need and mechanisms for effective dialogue between risk manager and risk assessor
  Core principles to conduct a risk assessment (e.g. scientific soundness, transparency, etc.)
  Inputs to the risk assessment (e.g. sources of data, *confidentiality,* etc.)
  Outputs of the risk assessment (form and detail, including request for different risk management options and their consequences)
  Level of protection to be provided by the risk assessment.
- The Committee welcomed the opportunity to comment on the current document; the Joint Secretariat is asked to continue the discussion with CCRVDF and to consider the possibility of consulting members of JECFA before the next meeting of the Committee in a written procedure. A close co-ordination with other ongoing activities is also desirable" (JECFA, 2004) (emphases added).

JECFA's response to CCRVDF was strikingly undiplomatic. JECFA not only rejected the specific suggestions from CCRVDF, it implicitly repudiated the provisions and implications of the Codex *Procedural Manual*. JECFA rejected both the form and the content of the guidance that CCRVDF had provided. JECFA did not contest the idea that risk assessment consisted of four steps, but insisted that it was for JECFA to decide what those steps were and how they were operationalised. JECFA insisted in effect that it was not for CCRVDF, or any other Codex Committees for that matter, to tell JECFA how it should conduct its risk assessments. JECFA implied that it was for risk assessors and not risk managers to decide JECFA's rules and standards of procedure and interpretation.

The response from JECFA was remarkable in several respects. Firstly, the Codex *Procedural Manual* does not suggest that risk

[5] Subsequently the custom has been to interpret 'risk analysis principles' as including but not being exhausted by 'risk assessment policy'.

assessors can veto RAP guidance provided by risk managers; but JECFA's response constituted an attempted veto. Secondly, the wording of the JECFA response is curiously long-term for a body that has no sustained membership. As Crossley has explained, JECFA (like its pesticides counterpart the Joint FAO/WHO Meeting on Pesticide Residues) is an *ad hoc* body that exists for only a few weeks of the year (Crossley, 2002, p. 5). Since that particular JECFA meeting had rejected the guidance provided by CCRVDF, it is was not clear why the CCRVDF did not instruct JECFA's FAO/WHO Secretariat only to invite to JECFA meetings those who would accept the guidance that CCRVDF had provided. CCRVDF did not pursue that option, for reasons that have never been explained.

Subsequently, an opaque process of negotiation occurred and CCRVDF's position shifted noticeably. In May 2006 CCRVDF agreed a compromise text, but a tame compromise that omitted any reference to the contested issues (CCRVDF, 2006). Omitted issues included, for example, discussion of which metabolic changes should (and should not) be the focus of JECFA's attention, the use of data from laboratory animals as a basis for extrapolations to humans, or circumstances when evidence of adverse effects in laboratory animals may be discounted. JECFA also said nothing about how it would or should respond to uncertainty. The 'risk assessors' implied in effect that if risk assessment policy decisions needed to be taken, it would be they, not risk managers, who would take them.

13. Developments in other jurisdictions

In the EU, it has been in relation to GM crops and foods that risk managers have had occasion to be particularly explicit about several procedural RAP issues. For contingent historical reasons European policy-makers have been obliged to deal explicitly with contested aspects of policy-making in relation to GM crops and foods. As a result European institutions have provided some explicit **substantive** and **procedural** RAP guidance to risk assessors, although little or no **interpretative** guidance.

13.1. Substantive RAPs

The **substantive** issues have been concerned with what kinds of changes and effects should be included with, and excluded from, official risk assessments. In the USA, throughout the 1990s, risk assessments of the environmental impacts of the commercial cultivation of genetically modified crops deemed as **adverse** environmental effects only those changes that would harm the commercial prospects of US farmers; all others were discounted (House of Lords, 1998). In Europe, on the other hand, under the provision of a Directive issued in 1990, the scope of official risk assessments of GM crops included effects on flora and fauna that could disrupt both agricultural and non-agricultural environments (EC, 1990). Subsequently the scope of scientific deliberations in both jurisdictions was widened in response to pressure from environmental and scientific groups. In the EU the scope was explicitly widened to include not just direct and short-term effects but also some indirect and long-term effects. Those changes were explicitly articulated by the European Parliament when replacing Directive 90/220 with Directive 2001/18 (EC, 2001).

When evidence emerged in the USA in 1999 indicating that the cultivation of GM crops might adversely affect emblematic species such as the Monarch butterfly, the US authorities widened the scope of their deliberations about the possible environmental effects of cultivating such crops (Losey et al., 1999; Jasanoff, 2000; Levidow and Carr, 2000). In those contexts, the scope of US risk assessments was also widened by risk managers and in the EU by a combination of risk managers and the European Parliament, in response to newly emerging evidence and changing patterns of public concern.

By contrast, the location of responsibility for possible changes to the scope of risk assessments for food chemicals remains unclear across all the jurisdictions under review. The acceptability of the usage of particular food additives is routinely decided on a case-by-case basis, i.e., one compound at a time, and by reference to their industrial utility and toxicological considerations; but other factors could also enter the frame. For example, emulsifiers are used to suspend oils and fats in aqueous solutions, and *vice versa* (Whitehurst, 2004). In recent decades, the quantities of emulsifiers used in the food supply have risen markedly, and so too has the fat content of consumers' diets. Leatherhead Food International estimated that between 2001 and 2004 the world market for emulsifiers grew by 3–4% per annum (Leatherhead Food International, 2005, p. 181). The incidence of obesity in all industrialised countries is also rising rapidly, so if the use of emulsifiers was more tightly restricted, that might make a significant contribution to combating the obesity epidemic. When risk assessors at JECFA, at EFSA or any of the national counterparts assesses the risk from emulsifiers, they maintain their long-standing practice of confining their attention narrowly to toxicological issues, and specifically to the toxicological effects of individual compounds. While emulsifiers may well be toxicologically innocuous, they may nonetheless be exerting a significant and collective adverse impact on public health nutrition, but that issue is currently outside the scope of official risk assessment in all the jurisdictions under considerations. It remains moreover unclear where a decision to extend the scope to include impacts on public health nutrition could be taken. Since they are scoping RAP issues, those decisions are matters of public policy rather than scientific judgments, but neither risk assessors nor risk managers have started to come to grips with such issues, nor are there conspicuous procedures by which that could happen. Explicit responsibility is being taken for some RAP issues, while many others remain implicit and unacknowledged, and no-one is taking responsibility for them.

13.2. Procedural RAPs

While many issues of substantive RAP have been, and remain, implicit, procedural RAP issues have in many contexts been address more explicitly. In the USA a variety of explicit RAPs, both procedural and substantive, have been established by regulatory agencies and Congress. Even where specific RAP guidance does not exist, there are legal statutes that guide and restrict the procedures with which US risk assessors can frame their assessments and gather, select and interpret data. At least some of the key assumptions that frame and underpin risk assessments become explicit in US institutions and procedures, partly as a consequence of the requirements of US statutes but also attempts on the part of regulatory agencies to anticipate or avoid legal challenges.

For example, the US Administrative Procedures Act 1946 imposes constraints on agencies' regulatory discretion by stipulating mandatory consultation procedures. Regulatory agencies must give advance notice of draft regulations as well as opportunities for comments by interested parties. This requirement has generated adjudicatory procedures with broad scope for participation, often testing evidence in adversarial hearings (Brickman et al., 1985). More recently, in 2001, Congress passed *The Data Quality Act* (or DQA), albeit without much debate (US Congress, 2001). The DQA imposed procedural obligations on US government regulatory agencies such as the FDA and EPA to provide some procedural RAP guidance to their risk assessors. It was, however, also widely interpreted as an attempt to impose a de-regulatory and an anti-regulatory agenda, because it set relatively high evidential standards before regulatory measures may be introduced (Weiss, 2004).

Regulatory decisions in the USA are also routinely subject to judicial review, and the courts may overturn decisions deemed 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law'. Moreover the courts may overturn any decision not supported by 'substantial evidence'. In making such a judgement, courts may review the evidence cited and by drawing on expert witnesses. This threat of litigation has provided a strong incentive for agencies to adopt consultative procedures, as well as to formalise risk assessment methods that can be defended in adversarial judicial contexts. Under those conditions, risk assessment guidance has emphasised and made explicit the role of several assumptions, including inherent extra-scientific and/or non-scientific judgements.

As Jasanoff has shown in her analysis of the role of expert scientific advisors in US risk policy-making regimes, there is a tendency in the USA for both risk assessors and risk managers to portray many of their key risk assessment policy judgements as if they were fundamentally scientific. The purpose of so doing may, as Jasanoff suggests, be to try to insulate those sensitive issues from Judicial or Congressional scrutiny (Jasanoff, 1990). That tactic can also be interpreted as an attempt to invoke a decisionist Red Book model, so that risk assessments can be portrayed as emerging from a policy-free zone.

A curious feature of the US system, that contrasts sharply with the EU and Japan, is that while US risk managers have provided extensive and detailed substantive, procedural and interpretative guidance on toxicological risks from food chemicals, for GM foods and crops no similar guidance has been formalised or codified. In relation to some GM crops, however such as Bt maize, the EPA has indicated some data requirements in specific cases, but that has not been formalised or generalised.

In the aftermath of the BSE crises the European Commission issued a raft of documents stipulating the procedures that should be followed by European risk assessors. In 2002 at least 5 separate documents emerged from the Commission intended to improve regulation and governance. They were

1. Communication from the Commission towards a reinforced culture of consultation and dialogue: general principles and minimum standards for consultation of interested parties by the Commission, COM (2002) 704
2. Communication from the Commission on the collection and use of expertise by the Commission: principles and guidelines, COM (2002) 713
3. Communication of the Commission on impact assessment, COM (2002) 276
4. Communication from the Commission action plan simplifying and improving the regulatory environment COM (2002) 278
5. Communication from the Commission The operating framework for the European Regulatory Agencies COM (2002) 718 and those had been proceeded by the European Commission's Communication on the Precautionary Principle COM (2000).

The detailed provisions in those documents are beyond the scope of this discussion but suffice it to say that, in part they provide some procedural guidance to expert risk assessment bodies that advise Commission-based policy-makers. In other words, they represent examples where Commission risk management policy-makers have provided some explicit up-stream procedural RAP guidance, although without labelling it in those terms, and without consulting all interested parties. Moreover, they persist is trying to portray their 'risk assessors' and 'risk assessments' as entirely independent of all policy-making considerations.

In other cases, however, some procedural RAP guidance to EU risk assessors has also been published by a group of risk assessors, namely the European Commission's Scientific Steering Committee, which issued its '*First report on the harmonisation of risk assessment procedures*' in 2000. In that case, the procedural RAP guidance came to subordinate risk assessors from more senior risk assessors rather than from risk managers.

In the UK, in the aftermath of the BSE crisis of March 1996, the Office of Science and Technology (OST—headed by the government's Chief Scientific Advisor) provided explicit procedural RAP guidance to expert advisory committees (OST, 1997, 2000, 2005). In April 2002, the FSA published a review of the conduct of its scientific advisory committees; its conclusions and recommendation also provided detailed procedural guidance (FSA, 2002). That guidance covered, for example, issues of data confidentiality and openness, and the treatment of scientific uncertainties, assumptions and unorthodox scientific views. It was not referred to by the FSA as 'risk assessment policy' but it did provide generic advice to any and all committees in advance of their appraisal of particular risks, and so constitutes some upstream procedural RAP guidance. The FSA's advice was also developed in open prior consultation with a wide range of stakeholders, unlike the earlier OST guidance.

The FSA guidelines stipulate that its expert committees should routinely provide an audit trail: "...showing how the committee reached its decisions..." (FSA, 2002, p. 22). This document also stipulates that: "When reporting outcomes, committees should make explicit the level and type of uncertainty (both limitations on the quality of the available data and lack of knowledge) associated with their advice... Where significant uncertainty exists, committees should advise on the steps that might be taken to reduce this in future" (FSA, 2002, p. 25). In practice, however, FSA expert committees rarely make explicit statements about scientific 'uncertainty', especially not when making safety claims, which are usually unqualified and unconditional. When discounting evidence of possible adverse effects, however, possible uncertainties are enthusiastically highlighted (CoC, 2006). Uncertainties concerning possible false negatives are never highlighted.

Some procedural RAP guidance has been published by the new German risk assessment body, the BfR rather than by risk managers (although the German authorities do not use the expression 'risk assessment policy', or its German equivalent). That guidance was developed by BfR staff, and then presented to risk managers at BVL, in effect as a *fait accompli*. Stakeholders and interested parties were almost entirely excluded from establishing that procedural risk assessment policy guidance. In general, stakeholder involvement is understood by the BfR as something that happens after finalising an assessment, and does not include influencing or involvement in the risk assessment question or process (BfR, 2005a,b).

In Argentina, the authorities have provided no explicit procedural RAP guidance to their expert advisory committees. Some implicit substantive guidelines are available since the minimum data requirements for a risk assessment of either GM plants or GM foods have been published. Those data requirements were drawn up and endorsed by the relevant technical committees, which involve representatives of the regulated industrial sector. Although those members are appointed as experts, rather than as formal representatives of the industrial sector, that process allows representatives of that stakeholder category to participate in risk assessment policy-making, while other stakeholder groups, except government departments and public sector research organisations, are not represented on the expert committees. It is not clear, given the lack of transparency, whether or not applicants in practice meet those data requirements.

In Japan, several procedural RAP guidance documents setting out data collection methods have been published for legally-mandated risk assessments of GM foods and crops by the Food Safety Commission, i.e., by risk assessors rather than risk managers. For GM foods, the principal document is *Standards for the Safety Assessment of Genetically Modified Foods* (*Seeds Plants*) (FSC, 2004). For GM crops,

however, procedural guidance documents have been published by risk managers, including *Guidance on Implementation of Assessment of Adverse Effects on Biological Diversity of Type 1 Use of Living Modified Organisms* and *the Application of Approval for the Production and Distribution of GMOs under the Jurisdiction of Minister of Agriculture, Forestry and Fisheries* (MAFF Japan, 2004; MoE, undated). Those documents are not referred to as 'risk assessment policy', but they do provide risk assessors with specifications indicating substantively which types of risks should be assessed; and they also provide some procedural guidance.

13.3. Interpretative RAPs

There have been several contexts and occasions in which risk managers have provided their risk assessors with some explicit guidance on how the evidence to be considered should be interpreted. The passage of the Delaney Amendment by the US Congress imposed some constraints on the exercise of the discretion of the FDA (Delaney, 1959). Subsequently detailed guidance has been provided from time to time to FDA risk assessors on how animal toxicological data should be interpreted in respect of humans, which has included stipulations that estimated added lifetime risks of less than 1 in a million can be deemed sufficiently slight to be socially acceptable (US Federal Register, 1987). Guidance on how to deal with some uncertainties has also been provided, which typically asks the experts to estimate the magnitudes of the uncertainties that confront them.

At the global level, the Codex subsidiary bodies have provided no interpretative RAP guidance, or perhaps it would be better to say that in so far as they have done so, they have provided interpretative RAP guidance in homeopathic doses. The policy of using ADIs has been adopted by the risk assessment bodies, but those decisions have subsequently been accepted and endorsed by risk managers.

In the UK, the FSA has not provided interpretative RAP guidance to its advisory committees, over and above that implied by the procedural guidance discussed above. Similar comments apply also to France, Germany, Japan and Argentina, from which it follows that in all those contexts decisions about interpretative RAP issues have been, and are being, decided by expert advisory committees that function as risk assessors rather than by policy-makers acting as risk managers. Consequently, the supposed separation of scientific deliberations from policy considerations is marked more frequently in the breach than in the observance.

Those few examples highlight the main respects in which explicit responsibility has, so far, been taken for risk assessment policies. In almost all other respects, and across all those jurisdictions and regulatory domains, RAP decisions have remained implicit, and have in effect been taken by expert advisors, frequently but not invariably labelled as 'risk assessors'; consequently they have not been decided by risk managers who should be responsible for those judgements. They have been taken in unacknowledged and unaccountable ways that are inconsistent with the provisions of the Codex Procedural Manual to which Codex member states committed themselves in July 2007. Consequently, while extensive reforms have taken place, institutional structures, procedures and rhetorics have yet to reach stable and sustainable states.

14. Summary and conclusion

In the USA, at the global and European levels, in France, Germany and Japan Red Book rhetoric is frequently encountered, but the practices never match the rhetorics. In numerous ways and contexts, risk management policy decisions that science alone cannot determine are being taken by expert scientific advisory bodies that are characterised as 'risk assessors'. Those occasions include, but are not exhausted by, examples of risk assessors choosing their own risk assessment policies, without reference either to risk managers or to what Codex terms 'all other interested parties'.

The orthodox Red Book rhetoric was predicated on the premise that distinguishing 'risk assessment' from 'risk management' went hand-in-hand with separating responsibility for regulatory policy-making from policies for industrial support and sponsorship, and separating science from politics.

The more recent rhetoric, embodied in the texts of Codex agreements, referring to 'risk assessment policy' – for both Codex itself and for all the member states contradict the Red Book model's premise that, while science can influence policy-making, policy-making in no way influences the science of risk assessment.

Current practices, in both the post BSE-crises reformed institutions (in the UK, EU, France, Germany and Japan) and in the unreformed jurisdictions (at the global level, in the USA and Argentina) are frequently inconsistent with both the Red Book model and the co-evolutionary model, which is presupposed by the text of agreements referring to the responsibilities of risk managers to provide risk assessors with 'risk-assessment policy' guidance.

The evidence indicates that, when it comes to setting and legitimating risk assessment policies, neither Codex and the joint FAO/WHO committees nor the European Commission and EFSA, nor any of the national jurisdictions and institutions under discussion are dealing with risk assessment policy issues in ways that are mutually consistent across policy fields within those institutional settings.

All jurisdictions have explicitly articulated at least some risk assessment policy guidelines, but none has comprehensive explicit guidelines covering procedural, substantive and interpretative issues. To the extent that explicit risk assessment guidelines have been provided by risk managers, none is being fully implemented or complied with, although in the USA rates of compliance are greater than those found in the other institutional settings.

In each of the institutional settings, and on all of the risk topics (that they deal with), at least some aspects of the three main types of risk assessment policy issues have been explicitly addressed and decided; although they have almost never been characterised as 'risk assessment policy'. Science is not being separated from policy issues, frequently, risk assessors have decided RAP issues. In effect, therefore, scientific bodies are taking numerous pivotal policy decisions that scientific considerations alone cannot decide. Numerous pivotal risk assessment policy issues remain officially unacknowledged and therefore unaccountable, while in practice policy judgements are misleadingly portrayed as if they were purely scientific. That may be the *status quo*, but those conditions may be increasingly unsustainable.

The adoption of the commitments for risk managers to take explicit responsibility for 'risk assessment policy' issues has coincided with unprecedented commitments to increasing openness with evidence and transparency of processes. If the commitments to openness are kept, the conditions will have been created in which promises for risk managers to provide their risk assessors with explicit RAP guidance will be difficult to avoid.

The process that began at Codex, with the introduction of the concept of 'risk assessment policy' as a responsibility for risk managers to provide their risk assessors with up-stream guidance, and which had nominally spread to all Codex member states, has the potential radically to perturb the institutional, procedural and rhetorical *status quo*. If it does so then further institutional and procedural reforms will be implemented, in ways that may well reflect the co-evolutionary model.

If a future wave of regulatory reform were to transform food safety policy-making institutions and procedures, in ways that allow the full implementation of the Codex provisions relating to RAP guidance, where RAP issues were decided **in advance** of risk assessment, **in consultation with** risk assessors and **all** other

interested parties, in processes that are **systematic, complete, unbiased and transparent** then the conditions may be in place for this set of science-based risk policy decision-making processes to become both scientifically and democratically legitimate; the process is under way, but there is still a long way to go.

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