

# **The evolution of risk assessment paradigms: in theory and in practice**

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**May 2010**

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## **Abstract**

The historical evolution of theoretical representations of generic risk assessment paradigms will be reviewed, from the mid-19th century to the present day, by reference to four main types of models. Those alternative generic paradigms presuppose competing assumptions about extent and significance of uncertainties, the relationships between scientific and non-scientific considerations, and the division of responsibilities between expert advisors, public officials, elected representatives and other key stakeholders. Drawing on the example of food chemical safety policy-making in several contrasting jurisdictions and institutional settings, the evolution of policy-making institutions and practices will be characterised, and compared to the theoretical archetypes. Differences between theory and practice will be highlighted, and conclusions drawn about the conditions under which practice and theory might converge, and the likely consequences of such convergence.

## **Introduction**

The ways in which the roles of scientific expertise, evidence and advice in risk policy-making has been understood, represented and institutionalised have evolved considerably since the late 19<sup>th</sup> century. There have been several waves of reform to the institutional arrangements through which the risks putatively posed by industrial technologies have been appraised and managed. The purpose of this paper is to provide an account of the evolution of influential representations of the role of scientific knowledge and expertise in policy-making for technological risks. The discussions will focus on both analytical frameworks and institutional arrangements, to highlight how they have been understood and organised.

## **Modelling science in policy**

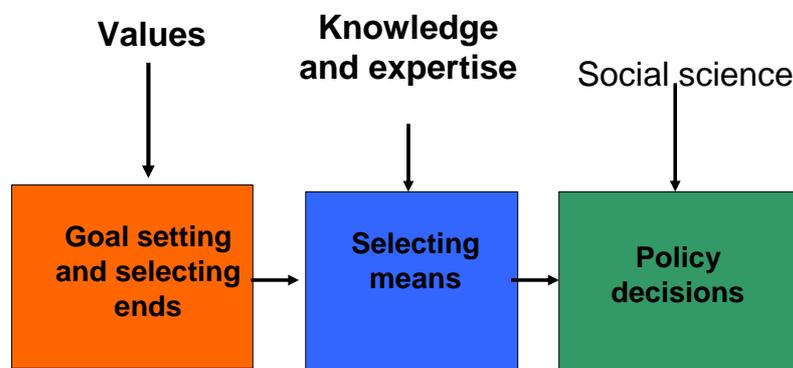
The role of science in public policy-making has been analysed and legitimated by reference to a range of ideas and models, but almost all of them have proved problematic and controversial. Many of those problems relate to how they can or do respond to uncertainties that characterise the available scientific knowledge. In discussions about food safety, and especially agricultural biotechnology, those

contests have been especially vigorous. The historical evolution of different ways of understanding the role of science in public policy will, to a first approximation, be outlined using four schematic models. The models address the general question: how can we understand the role of scientific evidence, understanding and advice in risk policy-making? The models have been used both descriptively and prescriptively, and both those types of considerations will be discussed in this paper.

### **Weberian Decisionism**

The first model dates back to the late 19<sup>th</sup> century, and the ideas developed by Max Weber and Emile Durkheim, who recognised the radical historical novelty represented by the industrial society that evolved rapidly during their lives. They argued that industrialised societies could only function with increasingly bureaucratic forms of governance, and that those societies needed and had developed new forms of organisation and administration. Weber and Durkheim were not, however, 19<sup>th</sup> century neo-Platonist; they were not advocating technocracy or governance by experts, but warning against it. In response to what they perceived as the dangers inherent in the increasing influence and power in the hands of officials and experts, they argued that the proper role of bureaucrats should be subordinated to, and accountable to, democratically elected representatives, or in the US system senior officials in the Executive Branch that should be accountable to the President and to Congress. The deliberations and judgements of bureaucrats (and by extension expert advisors) should always be framed by the goals and objectives of policies that should be set by politically-accountable representatives, rather than by unaccountable officials. Their model of the role of experts in policy-making has come to be known as a ‘decisionist’ model, because it stipulated that the deliberations and judgements of the bureaucrats should be framed by, and secondary to, prior goal-setting policy decisions. A graphic representation of this decisionist model is given below in Figure 1. To indicate the key contrast, the relative heat of politics is indicated by the use of the colour red, while blue is used to indicate the coolness often attributed to science; green is used to characterise the resultant decisions, which are portrayed as an amalgam or hybrid of politics and science.

**Figure 1 – Weber and Durkheim’s ‘decisionist’ model**



Weber and Durkheim argued that policy-making could be made more rational and scientific than it had been, but only partly. This decisionist model presupposes a strict and clear division of labour between what Habermas referred to as "...the objectively informed and technically schooled general staffs of the bureaucracy..." (including the experts) on the one hand and political leaders on the other. (Habermas, 1971 p. 83) Weber argued that policy-making could never be decided solely by the facts since, although the choice of 'means' may be rationalised, the choice amongst the 'ends', the objectives of policy and the underlying values remain irredeemably subjective. (M Weber, 1958, pp. 308ff)

On this type of decisionist model there are two discrete set of deliberations, and correspondingly two distinct lines of accountability. Democratically-accountable ministers or senior members of the Executive Branch should be responsible to the legislature and electorate for their choice of policy goals. Bureaucrats and experts, on the other hand, should be accountable to policy-makers for effectively pursuing the goals previously set by those policy-makers, and to other experts for the knowledge and judgements that they bring to bear in the discharge of their responsibilities. This model resonates with the Aristotelian contrast between 'ends' and 'means', and his account of 'practical reason'.

This model is exemplified, for example, in the UK in respect of the ways in which official interest rates have been set since 1998. The Chancellor of the Exchequer (or finance minister) is responsible for the politically-based judgement concerning the range within which a chosen indicator of the rate of inflation may vary, while the Monetary Policy Committee (MPC) of the Bank of England, which consists of expert economists, sets interest rates so as to try to ensure that those targets are met. In that case, moreover, the minutes of MPC meetings are published a few weeks after each meeting; and those minutes record not just that votes were taken on whether interest rates should remain unchanged, or rise or fall, but how each member of the MPC voted on each occasion. This is important in part because it provides an example of key experts explicitly acknowledging policy-relevant uncertainties. Revealing those uncertainties has not diminished public respect for, and the acceptability of, the MPC; not only has it 'not frightened the horses' it has not even de-stabilised the financial markets.

Weber anticipated that, in industrial societies, official decision-making would increasingly appeal to judgements based on ostensibly accurate observations and calculations, and that expert advisors would play increasingly important roles in decision-making in bureaucratic institutions. Industrial societies certainly did become more bureaucratic in the 19th century, but it was not until the twentieth century that scientific experts came to make more than very marginal contributions to policy-making.

The division of labour envisaged in the Weberian decisionist model was not without its difficulties. Firstly, it presupposes that officials and experts could acquire and retain comprehensive, secure and reliable knowledge, understanding and information with which to reach singular and prescriptive conclusions. In other words they could identify particular optimal solutions to complex problems. Their model has considerable difficulty accounting for how policies could be conclusively decided in

conditions where the available scientific understanding is incomplete or contested, or where the available evidence remains uncertain or equivocal. Unfortunately those characteristics are encountered in almost all risk regulatory contexts.

Secondly, in a relatively static pre-industrial society, political goal-setting might be independent of up-to-date scientific and technical knowledge, but in a rapidly changing and technologically dynamic society, those responsible for goal-setting may need a great deal of scientific and technical advice about the potential benefits and risks arising from new technologies and knowledges; without that advice, policy-makers might not even know which areas of policy need to be addressed and developed. Without scientific advice, politicians would never have known that emissions of CFCs were damaging the ozone layer or that greenhouse gases might be de-stabilising our climate. When a cloud of volcanic ash spread from southern Iceland through the atmosphere of North West Europe and the Atlantic in April 2010, the challenge to aviation did not come as a surprise to aeronautical engineers or jet engine manufacturers, but it was a complete shock to European policy-makers. In such circumstances, the division of labour between those that choose the ends of policy and those that select the means for attaining those ends becomes increasingly unrealistic. In the face of those difficulties, several influential positivists in the late 19th century posed several challenging questions namely: should experts contribute to deliberations on goal-setting as well as goal-attainment, if so how can scientists and other experts legitimately perform that role; but also: what role remains for policy-makers? Assuming a positive answer to the first of those questions, an alternative 'technocratic model' was developed, especially in France by the positivists Saint-Simon and Comte. Their approach suggested that policy could be based **on and only on** scientific expertise.

### **Positivism and 'technocracy'**

A radically different and competing account of the role of experts in policy-making was developed by the positivists Henri de Saint-Simon and Auguste Comte; they were not warning against technocracy but enthusiastically recommending it. They made heroically optimistic assumptions about the progress, accuracy and adequacy of science and argued that public administration by impartial experts could and should replace governance by those with partial biases, ignorance and vested interests.

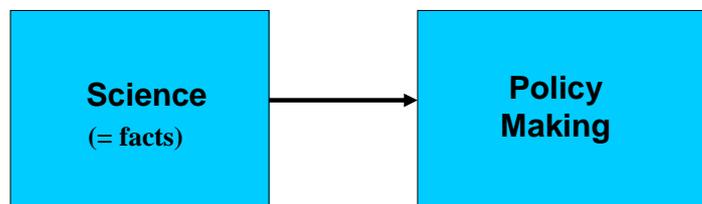
The technocratic model of policy-making, as it is widely termed, has often been encapsulated in the all-too-familiar claim that policy should be based on, and only on 'sound science'. As Peter Weingart explained: "In this 'technocratic' model...the politician becomes fully dependent on the expert. Politics is replaced by a scientifically rationalised administration." (Weingart 1999, p 154)

The assumption of technocracy, that scientific and technical considerations are not just necessary but also sufficient for policy decision-making, implies that the responsibility for policy-making can and should be allocated to scientific and technical experts; they and they alone possess the relevant knowledge and understanding. Elected representatives' and government ministers' responsibilities are confined to recruiting the best experts and to ensuring that their advice is followed.

Technocratic ideas began to acquire some currency in policy circles in the first half of the twentieth century, especially in the USA. In 1926, Leonard White wrote about the role of technical experts in the US political system, saying: “These men are not merely useful to legislators overwhelmed by the increasing flood of bills; they are simply indispensable. They are the government.” (White, 1926)

The conceptual structure of the technocratic model is given in the Figure 2. Since it is represented as all science with no politics, the text boxes are uniformly blue.

**Figure 2: the technocratic model  
policy is based (only) on sound science**



This model presupposes that the science and the facts are entirely objective and socially and politically neutral and that all the facts can readily be gathered. Technocratic narratives are therefore very vulnerable to criticisms that the evidential base and the understanding of experts are incomplete, unreliable or equivocal. Scientific uncertainty and disputes amongst the experts undermine the plausibility and credibility of the technocratic model.

Public policy-makers, such as government ministers in the UK and EU, often have claimed, and continue to claim, that policies to regulate risks are always and only based on ‘sound science’. For example, when challenged in the UK Parliament by his recently-dismissed Environment minister, on a question concerning policy on the authorisation of GM foods and crops, Tony 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...is that it is important for the whole debate to be conducted on the basis of scientific evidence, not on the basis of prejudice...I would just point out...that the biotech industry in this country is an immensely important industry...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, *Hansard* 18 June 2003)

Blair's comments were replete with ambiguities. He asserted firstly 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 all the issues were purely scientific. He insisted that decisions should not be made on the basis of prejudice, but then promptly articulated the prejudices that underpinned his policy preferences. In this context, Blair can be seen as trying to represent policy-making within the narrow confines a technocratic model, while betraying the poverty of that narrative.

The technocratic model continues to be invoked rhetorically for several reasons, but it has been torpedoed by the obvious fact that science evidence is often incomplete, equivocal and uncertain. It is repeatedly invoked because it may help to de-politicise issues and to facilitate what Hood & Rothstein have characterised as 'blame avoidance'; in other words to portray government ministers as devoid of responsibility for controversial decisions. (Hood & Rothstein, 2001) As the UK Secretary of State for Health explained to the first Chair of the newly established Food Standards Agency in their initial confidential meeting: "Professor, I want you to realise that I shall never hesitate to use you as my shield." In doing so, Frank Dobson was reproducing the approach that had characterised the ways in which UK ministers had previously defended their policies on BSE (or Mad Cow Disease).

Ministers had repeatedly claimed that they were doing what, and only what, their expert advisors recommended; even though that always a misrepresentation. From 1985 until the start of 1996 senior officials tried to ensure that ministers only received advice from scientists who would provide the kind of advice that that ministers and officials wanted to receive. (van Zwanenberg & Millstone, 2005, Ch 6) Instead of providing evidence-based policy-making they engaged in policy-based evidence-selection, while invoking technocratic narratives to conceal the underlying realities.

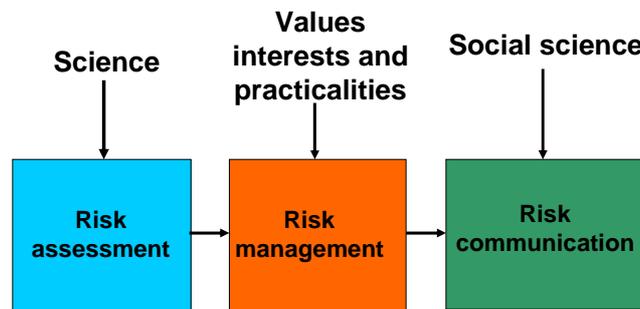
Although technocratic narratives continue to have some currency, they are torpedoed below the water-line by the uncertainties that characterise the scientific basis of policy-making. For example, the carcinogenic risks to the US population from eg saccharin are quantifiably uncertain. In the early 1980s a panel of the US National Research Council reviewed all the available evidence with a bearing of the putative carcinogenicity of saccharin, and estimated that, over the next 70 years, the number of extra cases of cancer that the prevailing average rate of saccharin consumption might range from no fewer than 0.22 to no more than 1,144,000. (US NAS 1978; Kessler 1984, p 1040, fn 26) The local impacts of climate change, or cultivating GM crops, are also uncertain and contested, although policies on such issues continue to be portrayed as if legitimated solely or primarily by reference to reliable scientific facts.

Those portrayals are always misleading, because, even if *per impossibile* all scientific uncertainties could be eliminated, scientific facts could not decide policy issues because such policies are concerned with trade-offs concerning the acceptability of risks (as well as uncertainties) in exchange for anticipated risks; facts cannot adjudicate those trade-offs because they depend on evaluative and normative judgements. Judgements about the acceptability of risks in exchange for anticipated benefits are socially variable normative value judgements; they are not purely scientific or even factual issues.

### The ‘inverted decisionist’ model or *the Red Book model*

The plausibility and sustainability of the technocratic model was undermined in the USA in the 1970s by the Freedom of Information Acts. Freedom of Information was introduced in US law for reasons that had a great deal to do with struggles between Congress and the Executive Branch over the conduct of the Vietnam War and especially the bombing of Cambodia, but it also had a huge and probably unanticipated impact on risk policy-making because the scientific uncertainties could no longer be concealed. In response to the challenges posed by that development, and judicial decisions eg in the Benzene case, a new model was developed in the USA in 1970s and early 1980s; it was formalised in 1983 by the US National Research Council in its so-called ‘Red Book’ (a.k.a. *Risk Assessment in the Federal Government: managing the process*). (US NRC, 1983) The so-called Red Book Model is an inverted form of the Weberian Decisionist Model, and is represented graphically in Figure 3, using the same colour code.

**Figure 3 – The *Red Book* ‘decisionist’ model**



A distinctive feature of this model is that it portrays scientific and political deliberations as if they took place in separate compartments. Scientific deliberations constituting risk assessments are represented as if they occur in a complete political vacuum. While risk management policy-making is informed by, and based on, a scientific risk assessment **the arrow is uni-directional, left to right**. Science is portrayed as influencing policy-making, but supposedly policy-making and political considerations do not influence the science. On some accounts policy-making deliberations only commence once scientific experts have completed their deliberations and made their determinations, so policy-making could not have influenced the science.

While technocratic models and narratives survived in Europe into the late 1990s, the BSE crises in the UK in 1996, and at the turn of the century in many continental European countries provoked a wave of institutional reforms, many of which have been based on the Red Book model. This model has become the official orthodoxy not just in the USA and EU, but also at the WTO. The presumed division of labour between scientific experts, who are on everyone’s side because they are on no-one’s side, and the policy-makers may be superficially plausible, and commonly invoked, but it is problematic both conceptually and empirically.

Conceptually that model is bizarre because when it is benchmarked against the contrast between ‘ends’ and ‘means’, it can only be interpreted as implying that scientific experts can take responsibility for identifying and selecting the ends and goals of policy, while policy-makers are confined the selecting the means by which those goals should be achieved. That interpretation of the supposed division of labour is profoundly counter-intuitive and conceptually bizarre.

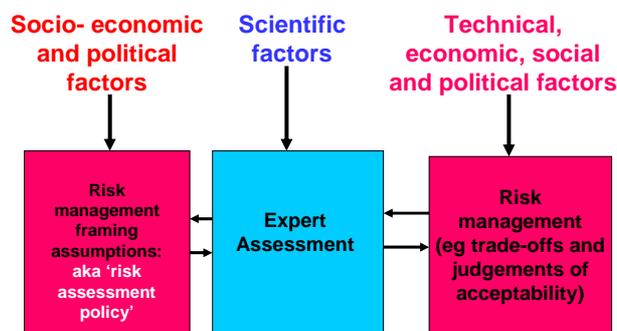
### The co-dynamic model

Empirical evidence has, moreover, torpedoed the Red Book model below the waterline. The kinds of scientific uncertainties that undermined the technocratic model are no less fatal to the Red Book model, but that is not the only source of its problems. A substantial body of science policy research, regulatory studies research, and work by sociologists of scientific knowledge has demonstrated that scientific deliberations on risks in policy-making contexts never operate in a policy vacuum.

Scientific considerations on their own can never select or explain the choice of questions that scientific experts address, the range of evidence they deem relevant, or their chosen benchmarks indicating how much of which kinds of evidence are deemed necessary or sufficient for recommendations to permit, restrict or ban particular products or processes; those judgements invariably depend on prior socially variable framing assumptions. Those framing assumptions are issues on which scientific advisors can have no particular authority; their expertise cannot legitimate the choice of up-stream assumptions that frame the deliberations and advice from expert advisory bodies. They are irredeemably evaluative, and in a democracy it should be electorally-accountable policy-makers, ie members of the Legislature or Executive Branch, or in European systems government ministers, who should take explicit responsibility for the framing assumptions that set of agenda for the experts’ deliberations.

The conceptual and analytic lessons of those studies and findings can be embodied in one further model of science in policy, which in this context is termed the ‘co-dynamic model’. A graphic representation of this model is provided in Figure 4.

**Figure 4 - the co-dynamic model:**  
reciprocal links between **science** and **policy**



This model has several distinctive features. Firstly, instead of attempting to portray scientific deliberations as if they took place in a policy vacuum, the existence and importance of that policy context is acknowledged explicitly. The institutional and practical implications of that acknowledgement is that such issues should be addressed by institutions and through processes that are legitimate because they are democratically accountable, that is to say taken by individuals and organisations that are democratically accountable for those decisions. Secondly, scientific deliberations are understood as ‘sandwiched’ between two sets of policy deliberations: one up-stream and one down-stream. The down-stream risk management decisions can be understood, as in the Red Book model above, as the adjudication of trade-offs between anticipated risks and benefits. The Red Book model correctly highlighted the importance of those considerations, and the nature of those down-stream decisions, but it failed to acknowledge the critical contribution that high-level up-stream framing assumptions also make. Thirdly, the arrows of communicative exchange between the expert risk assessors and both the up-stream and down-stream risk management policy makers are bi-directional. That means, for example, that while expert advisors and risk assessors may have contributions to make to deliberations on the chosen up-stream assumptions that frame their deliberations, responsibility for setting those up-stream assumptions lies with risk managers rather than with risk assessors.

### **The Codex Alimentarius Commission’s attempt to operationalise a co-dynamic model**

As a consequence of processes that have yet to be explained, one globally-pivotal international organization, namely the Codex Alimentarius Commission has in effect adopted a variant of the co-dynamic model. The Codex Alimentarius, which was formed in 1963 from the joint membership of the World Health Organisation and the United Nations Food and Agriculture Organisation, is an inter-governmental body with a remit to set food safety standards for internationally-traded commodities. Until the WTO was activated in 1994, Codex standards had only been advisory; they had had no statutory force. Under the WTO regime, Codex standards set legal global minimum standards for internationally traded food products. All countries can lawfully refuse to accept imports from WTO member states that fail to meet Codex standards, but disputes can arise when importers refuse to accept products that meet Codex standards but not the national standards of the potential importer.

The text of the Sanitary and Phytosanitary Agreement, which was couched in orthodox Red Book terms, was widely interpreted as implying that an agreed scientific risk assessment could provide a sound scientific basis for globally agreed uniform standards. (Millstone & van Zwanenberg 2003) By the early years of this century however, Codex effectively abandoned the Red Book model in favour of a co-dynamic model, which was embodied by the introduction of an important conceptual innovation. Codex introduced and coined the expression ‘risk assessment policy’, and used it to refer to what in this discussion has previously been referred to as ‘up-stream framing assumptions’.

### **Risk Assessment Policy – a pivotal variable**

The Codex Alimentarius Commission’s *Procedural Manual* 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 2003 represented an important innovation. Codex introduced a new obligation on each of its risk management committees (also known in Codex-speak as ‘subsidiary bodies’), they were supposed to articulate risk assessment policies, although several Codex Committee have been struggling with that challenge. (Millstone 2009)

The implications of these developments may be quite profound although their significance is not yet widely appreciated. Their importance was substantially 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)

Detailed analyses of multiple policy issues have indicated that at least three distinct types of up-stream framing assumptions can be differentiated and characterised. (Millstone et al 2008; Millstone 2009) They have been characterised as: **substantive**, **procedural** and **interpretative** risk assessment policies.

**Substantive** risk assessment policies 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 relevant and 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? When the risks from mobile telephones handsets are assessed, should they be confined to thermal effects or should they also include electro-magnetic effects? When the risks of cultivating GM crops are assessed should the scope be confined to short term and direct effects or should they also include long-term and indirect effects? When the risks from pesticides are assessed, should they be assessed one at a time, or should possible effects of mixtures also be assessed? When the risks from pharmaceutical products are assessed, should they be assessed individually, or should interactions between combinations of drugs also be assessed?

**Procedural** risk assessment policies 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? Should risk assessors be allowed to have conflicts of interest, and is it sufficient that those be declared? If so should that declaration be just to the secretariat of the panel, to other panel members or to the general public?

**Interpretative** risk assessment policies 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? How much of which kinds of data are to be deemed necessary and/or sufficient to support recommendations to permit, forbid or restrict some product or process?

### **Paradigms and Institutional Practices: cross-regime comparisons**

Not only have theorists, policy-makers and expert advisors drawn in various ways from that repertoire of models, and sub-variants of them, in particular jurisdictions and institutional settings, the ways in which institutional structures and processes have been organised have evolved. While they have evolved, they have not converged on one agreed template.

In practice, I interpret the range of institutional structures currently in operation to regulate food safety as if they were a set of simultaneous real-time experiments. None of the institutional structures I will discuss has yet reached equilibrium, they all remain in a state of flux, but the results of this real-time experiment have only just started to be assessed and interpreted. The jurisdictions and institutional settings that will be referred to in this paper include: the USA, the UK, Argentina, Japan, the European Union, Germany, France and CODEX. This discussion draws on several previous research projects in which I have been engaged. The comments on individual settings are necessarily brief and incomplete, but they are intended to highlight key structural features, and comparisons to the models set out above.

### **Food safety policy-making in the USA**

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. The US FDA and EPA, and other similar bodies have often provided a narrative according to which ‘risk assessment’ and ‘risk management’ are separated by ‘Chinese Wall’; they take place within a single institution, but that institution is internally sub-divided into risk assessors and risk managers, where the former have substantial autonomy. 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’.

### **Food safety policy-making in the UK**

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 & 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 been redefined as 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 Board of the FSA is charged with responsibility for making policy decisions; the role of ministers barely even amounts to providing a 'rubber stamp' to the FSA's decisions. 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 ghost of technocracy still stalks the corridors of Whitehall because it helps ministers to engage in what Hood and Rothstein term 'blame avoidance'. (Hood & Rothstein 2001)

### **Food safety policy-making in the Argentina**

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.

### **Food safety policy-making at CODEX**

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 & Vendlar eds 2006; Millstone et al forthcoming)

### **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.

### **Food safety policy-making at 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 (ie 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). 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.

### **Food safety policy-making in 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 & 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.

### **Food safety policy-making in 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.

### **Food safety policy-making in 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 apparently shared interpretations of Red Book narratives.

### **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 invariably illusory. In each jurisdiction or institutional setting 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 risk assessment policy issues.

### **Conclusions and Implications**

My research, and that of my colleagues, has indicated that in all the institutions under discussion, some aspects of risk assessment policies have been explicitly articulated in respect of some risk domains, but no jurisdiction had addressed them explicitly and comprehensively. (Millstone et al 2008; Millstone 2009) Furthermore, within each jurisdiction, risk assessment policies are not consistent when comparing across different sets of risks and hazards, and when comparing across particular types of risks and hazards, there is no consistency between the jurisdictions. Moreover, in most jurisdictions and in respect of most types of risks and hazards, risk assessment policies are being decided by expert risk assessors rather than democratically accountable representatives.

Furthermore, international trade disputes about the regulation of technological risks, such as food additives, pesticides, pharmaceuticals or GM crops more frequently arise as a consequence of the assumption of divergent risk assessment policies than because divergent interpretations are provided to shared and agreed bodies of evidence. If on the other hand, risk managers in each of the jurisdictions were to take explicit responsibility for risk assessment policy guidance to their risk assessors, and if risk

assessors were to follow that guidance, or to provide acceptable explanations of particular occasions when those provisions were not fully complied with, then risk regulatory policies might become increasingly legitimate, both scientifically and democratically. Finally, if the risk managers of those contending jurisdictions were to explicitly negotiate with each other to see if they could reach a consensus about a shared set of risk assessment policies, then the frequency and severity of international disputes could be substantially diminished.

Once the role and importance of those dimensions of risk assessment policies are acknowledged, it becomes relatively straightforward to analyze and explain when and why regulatory policies have, or have not, converged. The available evidence indicates that in the majority of cases when different jurisdictions adopt different regulatory standards, for example over food safety or the cultivation of GM crops, because they are adopting different risk assessment policies. There have long been unresolved differences between the ways in which risk assessments of cultivating GM crops have been framed in North America and in Europe. More recently, it has become undeniable that there are differences amongst EU Member States over similar sets of issues. Each jurisdiction can legitimately decide for itself what the **scope** of official risk assessment should be. The scope of those deliberations has, in practice, been in flux in many jurisdictions; nothing resembling equilibrium has been achieved. Overall, however, the scope of official risk assessments of GM crops has been especially narrow in the USA, although it has widened marginally, especially since evidence of putative risks to that iconic species, the Monarch Butterfly, emerged in 1999. The scope of official risk assessments has long been wider in Europe than in North America, but since the late 1990s it has become increasingly obvious different EU Member States were making different assumptions about the scope of their official risk assessments, especially of the cultivation of GM crops.

For example, policy on the scope of such assessments in the UK has been relatively stable, and relatively narrow, by comparison to continental EU Member States. French policy has been less stable and conspicuously volatile, while Austrian risk assessment policy has remained resolutely stable, and exceptionally broad. In the UK for example, assessments normally consider how the environmental impact of cultivating GM crops might compare to the cultivation of conventional high-input agriculture. Austria, which has more organic farms than the rest of the EU added together, instead asks its risk assessors how the impact of cultivating GM crops compares to the impact of an organic counterpart. In such cases we find that risk assessment determinations differ not because different groups of experts are providing competing interpretations of shared bodies of evidence, or because some are delivering 'sound science' and others are 'unsound', but because they are answering different questions.

The co-dynamic model has been offered not as a final and complete account, but as providing a richer repertoire with which to understand policy-making processes, practices and outcomes than any of its predecessors. It can moreover serve several purposes. Firstly, it can help to explain why and where regulatory disputes have arisen, but secondly it can enable us to identify the conditions under which convergence might be attainable. If, but only if, risk managers across multiple jurisdictions can make key dimensions of their risk assessment policies explicit, they could readily identify areas of agreement and negotiate over their differences.

Thirdly, the model indicates a set of structural and procedural conditions under which science-based regulatory policy-making process can become both **democratically** and **scientifically legitimate**. Meeting those conditions would, moreover not only enhance the domestic legitimacy of policy regimes, they would also render them ‘WTO-proof’. Risk assessment policies are therefore pivotal to understanding the role of science in policy-making, the causes of regulatory trade disputes, and the conditions under which regulatory diversity can be sustainable and those under which regulatory convergence might be enhanced.

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This section summarizes the theory, principles, and methods of risk assessment epidemiology for studying exposure-disease relationships. The two essential components of risk assessment are a measure of exposure and a measure of disease occurrence. A demiology is to base models on radiobiological principles and theories of carcinogenesis to the fullest extent possible, keeping in mind statistical limitations imposed by the quantity and quality of data available for model fitting. Biologically based and empirically derived mathematical models for risk are discussed in the next two sections. Risk management Australian style “ theory vs. practice. Paper presented at Project Management Institute Annual Seminars & Symposium, Nashville, TN. Newtown Square, PA: Project Management Institute. Assessment criteria in the literature tend to focus on the process objectives (e.g., time, cost, quality) whilst ignoring consideration of whether the risk event might affect the operation of the project's product. “ Scope of Risk Management”Where the focus of the risk management workshop in upon the identification of the all possible risks and not detailed risk analysis or treatment strategies, then it is possible to generate a large number of risks. This was the context for the project A in which 319 risks were identified in one day. Introduction The Risk Assessment Process Develop Assessment Criteria Assess Risks Assess Risk Interactions Prioritize Risks Putting It into Practice About COSO About the Authors. Thought Leadership in ERM | Risk Assessment in Practice | iii. Page. 1 2 3 8 12 14 18 19 19. www.coso.org. w w w . c o s o . o r g. Thought Leadership in ERM | Risk Assessment in Practice | 1. Introduction. Value is a function of risk and return. Some entities define impact scales for opportunities as well as risks. www.coso.org. 4 | Risk Assessment in Practice | Thought Leadership in ERM. Illustrative Impact Scale. Rating Descriptor. Risk Assessment Paradigms. June 2014. DOI: 10.1002/9781118910030.ch3. The development of QMRA has its origins from the chemical risk framework associated with environmental pollution. This chapter addresses the evolution of the National Academy of Sciences chemical risk assessment approach, ecological risk assessment, and finally the QMRA framework. It presents an overview of the various methodologies used in QMRA as developed by the World Health Organization (WHO), Environmental Protection Agency (EPA), and food industry addressing water and food safety. The focus of risk assessment for waterborne disease is now on defining the specifics of the watershed and com