



Risk-assessment policies: differences across jurisdictions

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■ Preface

Risk analysis should form the foundation on which food safety policy is based in the European Union (White Paper on Food Safety, COM (1999) 719 final). The EU should base its food policy on the articulation of three primary components of risk analysis: risk assessment (scientific advice and information analysis) risk management (policy-making, regulation and control) and risk communication. Risk assessment should provide scientific advice to underpin the Commission's proposals on measures and policies that may affect the health and safety of the citizens or impact on the environment (Communication on the precautionary principle, COM(2000)1final). However, in the decision making process in the EU, other legitimate factors can also be taken into account. The definition of the scope of such legitimate factors has been debated and studied at the international level particularly in Codex Alimentarius. Examples of such other legitimate factors include environmental considerations, animal welfare, sustainable agriculture, precaution, consumers' expectations regarding product quality, the provision of information and definitions of the essential characteristics of products and their process and production methods. The role of scientific evidence and expertise and these 'other legitimate factors' in science-based risk policy-making has been the focus for considerable analysis and research for over twenty years. One key focus of those debates has been concerned with whether those 'other legitimate factors' should be taken into account 'down-stream' i.e. only after scientific risk assessments have taken place, or 'up-stream' too, i.e. in advance of the conduct of risk assessments.

This project was designed as a follow-up of a previous ESTO study (*Science in trade disputes related to potential risks: comparative case studies*, IPTS, October 2004 EUR 21301 EN) that provided detailed empirical evidence (from three disputes and six institutional settings) showing that scientific risk assessments are routinely, and perhaps invariably, conditioned by sets of prior up-stream 'framing assumptions' that determine, for example:

- which kinds of effects are deemed to be within the scope of the assessment and which are outside it,
- which kinds of evidence are included and which discounted,
- how the selected evidence is to be interpreted, and
- how much of different kinds of evidence may be necessary or sufficient to sustain different types of judgements.

That ESTO study also concluded, not just that such up-stream framing assumptions are present and active, even if they are not always explicitly acknowledged, but more importantly that they are key to understanding many of the most intractable disputes between the EU and its trading partners in the WTO, and that they are also pivotal to similar disputes within the EU.

In this context, the General Principles Committee of the WHO/FAO Codex Alimentarius Commission has articulated a new concept, namely what it terms 'risk assessment policy' to refer closely to what was explicated above, and in the mentioned ESTO report, in terms of 'upstream framing assumptions'.

Even though no statutory jurisdiction has yet explicitly articulated the concept of a 'risk assessment policy' as Codex has, several have outlined, or have bodies that have recommended elements of a risk assessment policy. There are several more-or-less fully articulated elements of what Codex refers to as 'risk assessment policy', and the study presented herewith was designed to provide a comparative map and analysis of those innovations and initiatives.

At a plenary meeting of the Codex Alimentarius Commission in Rome in July 2007 the assembled Member States adopted a policy statement to the effect that risk managers, in all national competent authorities, would provide their national risk assessment bodies with risk assessment policy guidance. That decision makes this report particularly timely.

Germany, the UK, the USA, Japan and Argentina are the 5 national jurisdictions chosen for analysis. The WHO/FAO Codex Alimentarius Commission is the pivotal organization setting baseline standards for internationally traded food and agricultural commodities, and as the source of the concept of 'risk assessment policy', was a pivotal focus of study and analysis although it is not a legal jurisdiction.

Within the EU, Germany and the UK provide a relevant contrast. In Germany, an institutional division has been created by the establishment of two separate organisations responsible for science-based risk assessments (*Bundesinstitut für Risikobewertung*) on the one hand and risk management policy-making (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*) on the other, although with little explicit attention to what Codex calls 'risk assessment policy'. In the UK, on the other hand, both risk assessment and risk management functions are located within the Food Standards Agency (FSA). The FSA has not explicitly acknowledged the concept of a 'risk assessment policy', but it has articulated something analogous in its Guidelines for Scientific Advisory Committees.

The USA has been chosen because of the importance of risk assessment policy differences between the EU and the USA, including those that were highlighted in the above-mentioned ESTO study on Science and Trade Disputes.

Argentina has been selected partly because Argentinean officials served as co-chairs (with Canada) of a working group of the Codex Committee on General Principles that drafted the working principles for risk analysis, which reported to the full Codex Committee on General Principles in April 2005. The Argentineans therefore represent the developing country that was more actively engaged in discussions of the interpretation and operationalisation of the concept of risk assessment policy than any other.

Japan is included partly because it represents a major OECD non-European country with which to contrast the risk assessment policies in the EU and USA; partly because it has recently established a new Food Safety Commission that ostensibly resembles the UK's Food Standards Agency, but which in practice is interpreting its role and remit rather differently.

The data for this study were mostly gathered during 2005 and 2006, although subsequent developments are referred to, but in less detail.

The study, coordinated by JRC, was led by Prof Erik Millstone (SPRU – Science and Technology Policy, University of Sussex) in collaboration with Dr Patrick van Zwanenberg (FLACSO, Argentina). Dr Les Levindow (Centre for Technology Strategy, Open University) was in charge of the research and interviews in USA and UK, Dr Armin Spök (IFZ - Inter-University Research Centre for Technology, Work and Culture) in Germany, Prof Hideyuki Hirakawa (Faculty for Study of Contemporary Society, Kyoto Women's University) and Makiko Matsuo (University of Tokyo, Japan) were responsible for the case studies in Japan. Dr van Zwanenberg was in charge of the study in Argentina and Erik Millstone was responsible for the study of Codex and corresponding global institutions.

■ Executive Summary

This study examined how risk assessment policies are in practice being decided and operationalised in different jurisdictions. Our starting assumption was that, where public policy-making institutions formally take responsibility for risk appraisal and decision-making, some risk assessment policy assumptions arise, even if they are not explicitly acknowledged or labelled in those terms. We found that the choice was not between having a risk assessment policy and not having one, but between being explicit and transparent about RAP judgements, or being implicit and opaque.

The topic – ‘risk assessment policy’

This project has examined food safety **risk assessment policy-making** at the global level (in the Codex Alimentarius Commission and its joint FAO/WHO expert advisory committees) in the USA, the UK, Germany, Japan and Argentina, in relation to chemical risks and to risks from GM foods and crops.¹

Aims and objectives

The aim of this project has been to enrich our understanding of the interactions between scientific and policy considerations in food safety policy-making, and of the policy implications of those interactions. The objective has been to provide detailed comparative characterisations of the ways in which scientific and policy considerations have interacted over several important food safety policy issues in the USA, the UK, Germany, Japan and Argentina and in the corresponding global institutions.

Context

The concept of a ‘risk assessment policy’ first emerged in the 1983 US National Research Council’s (NRC) report entitled *Risk Assessment in the Federal Government*, which has come to be known as the ‘Red Book’ because it was bound in a red cover.

The US NRC interpreted the concept of ‘risk assessment policy’ as referring to policy judgments that arise during risk assessments and confront risk assessors, beyond purely scientific issues. The Red Book used the expression to refer to non-scientific assumptions made by risk assessors during the course of their assessments. The authors of the Red Book understood those risk assessment policy issues as ones for which, in principle, risk managers and risk assessors could take joint responsibility and which could be embodied in agreed guidelines.

Debates about risk assessment policy type judgments have evolved significantly since then. The public policy literature increasingly recognises that scientific assessments are conditioned by various kinds of prior non-scientific ‘framing assumptions’. A recent and important example is the Codex Alimentarius Commission that since the late 1990s has been using the expression ‘risk assessment policy’ to refer to risk management considerations that frame risk assessments, and thus for which risk managers could and should take explicit responsibility.²

Codex has stipulated that:

• 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.³

¹ In this report we refer to these as ‘institutional settings’ and confine the use of the term ‘jurisdictions’ to national states that make and enforce laws.

² Codex Alimentarius Commission, *Procedural Manual*, 14th Edition, 2004, Appendix IV. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, paras 13-15, pp. 103-104

³ Codex Alimentarius Commission, *Procedural Manual*, 14th Edition, 2004, Appendix IV, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, paras 13-14, p. 103

Codex also characterises risk assessment policy as “*Documented [policy] guidelines on the choice of options and associated judgements for their application at appropriate points in the risk assessment such that the scientific integrity of the process is maintained.*”⁴

The approach

In this study, we understand the expression ‘risk assessment policy’ (or **RAP**) to refer to all those assumptions that frame and guide the conduct and content of risk assessments. We do not assume that all such judgements can necessarily be formulated as explicit policies. Nor do we assume that these are matters that should be decided either by scientists or by policy-makers on their own. We approached this study with open minds on both the question of how realistic it is to expect that any and all risk assessment policy-like judgements could be formulated as explicit policies and on the question of how realistic it is to expect policy-makers exhaustively to address any and all potentially relevant risk assessment policy issues in advance of scientific assessments commencing. Our findings indicate that some RAP issues that have remained implicit can and should be made explicit and decided in advance of commencing scientific risk assessments; and also that the importance of those RAP issues is insufficiently recognised.

The findings - three types of RAPs

Our research has shown that risk assessment policy can be understood as comprising at least **three** main types of considerations, namely **procedural**, **substantive** and **interpretative** issues. Those types of risk assessment policy issues invariably condition the ways in which risk assessments are framed, conducted and reported. They are, moreover, inter-dependent.

Procedural risk assessment policies are concerned with the responsibilities of risk assessors and the processes by which risk assessments are conducted. **Substantive** risk assessment policy issues are concerned with delineating which potential changes and effects are included within the scope of risk assessments and which are outside

their scope. **Interpretative** risk assessment policy issues are concerned with the ways in which data are interpreted. Data and documents do not interpret themselves; interpretation often involves judgements and assumptions.

The importance of RAPs

Risk assessment policy issues are important for several reasons. Often, when different risk assessors, especially in different institutional settings or national jurisdictions, reach different conclusions in their risk assessments, they do so because they are adopting distinct risk assessment policies rather than because some committees provide more or less scientific answers than others. They are, therefore, often not providing conflicting answers to common and agreed sets of questions concerning shared and agreed bodies of evidence. Often they are answering different questions because they make different risk assessment policy assumptions and are considering different sets of data. Even when the sets of questions and sets of data coincide, different risk assessment policy assumptions may entail that they interpret those data in different ways. Making a wider range of risk assessment policy issues explicit, and deciding them in transparent ways, can provide resources with which disputes can appropriately be addressed, both within and across jurisdictions.

Dynamics of change

For a variety of historical reasons, there have been pressures not only at Codex and the joint FAO/WHO expert committees, but also in the USA, in the UK, Germany and Japan to address risk assessment policy issues more explicitly and more accountably than hitherto. Similar pressures are less conspicuous in Argentina.

Procedural, substantial and interpretative risk assessment judgements are ubiquitous, in the sense that they arise in relation to any and all risk assessments in all the institutional contexts under review; and indeed in relation to all institutional contexts.

The extent to which those risk assessment policies are explicit and acknowledged varies consider-

⁴ op cit p. 46

ably. In none of the institutional settings are they entirely implicit, and in none are they entirely explicit. Over time, they have become increasingly explicit, and this trend may well continue and spread.

Partially complying with guidelines?

This study has examined the extent to which RAP decision-making has conformed to the explicit guidelines provided by Codex and by national jurisdictions. The Codex Procedural Manual stipulates that: "...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."⁵ That stipulation is not being met by Codex Committees and their joint FAO/WHO risk assessment advisory bodies. The stipulation in the Codex Procedural Manual is not being fully met in any of the five national jurisdictions under review either, but in every jurisdiction it is being partly met. There may, however, be other ways in which RAP issues can be set in publicly accountable ways, as this study illustrates.

Some risk assessment policy issues have been explicitly addressed at Codex and the joint FAO/WHO expert committees, in the USA, the UK, Germany, Japan and Argentina. Only rarely, however, are they fully acknowledged, and decided by risk managers in consultation with all relevant stakeholders in advance of the conduct of risk assessments. Only sometimes are they addressed in transparent or accountable ways.

The findings of this study indicate that, when it comes to setting and legitimating risk assessment policies, neither Codex or the joint FAO/WHO committees nor any of the five national jurisdictions is dealing with the set of risk issues we have examined in ways that are mutually consistent within particular institutional settings. All have at least some RAP guidelines, but none has comprehensive explicit guidelines covering procedural, substantive and interpretative issues.

In the USA, RAP guidance is relatively comprehensive in relation to toxicological (especially carcinogenic) risks from chemicals in the food sup-

ply, but not in relation to GM foods or crops. In the UK, Germany and Japan on the other hand, some types of RAP guidance are far more comprehensive and explicit in relation to GM foods and crops than in respect of food chemical risks.

To the extent that explicit RAP guidelines have been provided, none is being fully implemented or complied with, although in the USA the compliance of food toxicology risk assessors is more comprehensive than that found in the other institutional settings.

In each of the institutional settings, and on all of the risk issues (that they deal with), at least some aspects of the three main types of risk assessment policy issues have been explicitly addressed and decided. Frequently, however, risk assessors have decided such issues rather than risk managers. Ostensibly, scientific bodies are therefore taking policy decisions that scientific considerations alone cannot be sufficient to decide. Some risk assessment policy issues remain unacknowledged and unaccountable, with policy judgements portrayed as if they were scientific.

In Germany, the UK and Argentina numerous substantial risk assessment policy issues concerning both routine and non-threshold food chemical risk issues have been decided by scientists working as risk assessors, rather than by risk managers.

The context and ways in which GM foods and crops policies have been decided since the mid-1990s were radically different from those in which the regulatory regimes covering food additives and pesticide were developed in the 1950s and 1960s. Explicit public disputes about the breadth or narrowness of the scope of risk assessments of GM crops and foods have raged, especially in Europe and Japan, and those debates have had a profound impact on the substance and procedures of GM policy-making.

The scope of GM crop risk assessments has explicitly been widened in response to public controversies. While, initially, risk assessments focused only on direct and short-term effects, in the late 1990s in the EU and Japan their scope was broadened to include long-term and indirect effects, and in this decade to include a concern for effects, for

⁵ Codex Alimentarius Commission, *Procedural Manual*, 14th Edition, 2004, Appendix IV. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, paras 13-15, pp. 103-104

example, on non-target organisms, and in Japan to include effects on soil micro-organisms. Although changes have occurred to the scope of GM risk assessment policy in Argentina too, it has not been possible to document those changes because of a chronic lack of transparency.

In the USA the contrast across sectors is quite different. The policy dimensions of toxicological, and especially carcinogenicity, assessments are explicitly acknowledged and addressed. By contrast, GM foods have generally required no regulatory approval or risk assessment; while that policy is portrayed as based only on sound science.

In the EU, the European Food Safety Authority (EFSA) has issued some RAP guidance, for example in relation to GM foods and crops. Our findings, however, indicate divergent judgements by EFSA and some national expert committees, eg by those in the UK and Germany, and by different risk assessment bodies in both those countries.

Setting RAPs

There are already opportunities for some explicit public debates concerning the scope of risk assessments, which in this study is referred to as 'substantive' risk assessment policy-making. While some maintain that scientists should be left to decide the agenda for scientific deliberations, others argue that there may and should be more opportunities for a broad range of stakeholder groups to contribute to articulating the questions that the scientists are requested to address. That task has often previously been referred to as 'risk identification' or 'hazard identification', which sets the agenda for the subsequent deliberations of risk assessors. Within the policy literature, there are disputes between those who assert that 'risk identification' is a scientific task and others who argue that it is a risk management responsibility. Our findings suggest that it is a discussion to which risk assessors, risk managers, other stakeholders and individual citizens can helpfully contribute. Similar arguments apply to procedural and interpretative RAP issues too.

Transparency and accountability

Over recent years, policy-makers have reiterated commitments to making food-safety policy-

making more open, transparent and accountable. This trend has been especially evident in European contexts such as in the UK and Germany, and in Japan. The USA has operated with a Freedom of Information Act since the 1970s, as well as other institutional features that drive disclosure. One consequence of the sustained trend towards greater transparency and accountability has been that risk assessment policy issues of the type that remained implicit for many years in many institutional settings, are now increasingly seen for what they are.

Many aspects of the current arrangements for the organisation of risk assessments, and the interactions between risk managers and risk assessors, are confronted by challenges to their legitimacy. Some challenges arise because key risk assessment policy issues emerge at the intersection or boundary between nominally separate and independent institutions. Procedural transparency and opportunities for comparing judgements of risk assessors and risk managers, within Europe and between Europe and other international trading partners, also generate pressure on regulatory regimes to deal explicitly with all three types of RAPs.

Making risk assessment policy decisions explicit might be seen, by some risk managers, as an unwelcome extra burden, and by some risk assessors as an unwelcome intrusion into matters over which traditionally they were able to exercise autonomy and discretion. However, if risk managers took greater explicit responsibility for risk assessment policy-making they could more readily justify and sustain regulatory decisions and policy differences. They could participate in a collective exercise of comparing the risk assessment policies of different jurisdictions, thus clarifying the basis for their differences and possibly even overcoming them. Policy-making processes, and the decisions that they reach, might also achieve greater scientific and democratic legitimacy.

The ways in which risk appraisal and decision-making are decided might become more accountable if risk assessment policy issues were explicitly acknowledged to be, and treated as, policy judgements that should be decided by democratically accountable risk managers, rather than by risk assessors, and in ways that would involve a broad range of stakeholders.

■ List of abbreviations

| | |
|---------|--|
| ACNFP | The UK Advisory Committee on Novel Foods and Processes |
| ACRE | The UK Advisory Committee on Releases to the Environment |
| ADI | Acceptable Daily Intake |
| AFC | Panel on food additives, flavourings, processing aids and materials in contact with food of the European Food Safety Authority |
| AFFRC | The Japanese Agriculture, Forestry and Fisheries Research Council |
| APA | The US Administrative Procedures Act |
| BBA | The German Centre for Agriculture and Forestry |
| BfR | The German Federal Institute for Risk Assessment |
| BGA | The German Federal Health Office (<i>Bundesgesundheitsamt</i>) |
| BgVV | The German Federal Institute for Consumer Health Protection and Veterinary Medicine |
| BMD | benchmark dose |
| BMDL | benchmark dose lower confidence limit |
| BMELV | The German Federal Ministry of Food, Agriculture and Consumer Protection formerly the BMVEL |
| BMVEL | The German Federal Ministry of Consumer Protection, Food, and Agriculture, now the BMELV, established 2001 |
| BMG | The German Federal Ministry of Health formerly BMGS |
| BMR | benchmark response |
| BSE | Bovine spongiform encephalopathy (also known as Mad Cow Disease) |
| BVL | The German Federal Agency for Consumer Protection and Food Safety |
| CAC | Codex Alimentarius Commission |
| CAAEB | The Japanese Committee for the Assessment of Adverse Effects on Biodiversity |
| CCFAC | Codex Committee on Food Additives and Contaminants |
| CCRVDF | Codex Committee on Residues of Veterinary Drugs in Foods |
| CCPR | Codex Committee on Pesticide Residues |
| CoC | The UK Committee on Carcinogenicity |
| Codex | Codex Alimentarius Commission |
| CoM | The UK Committee on Mutagenicity |
| CONABIA | The Argentine advisory committee for environmental releases of GM plants |
| CoT | The UK Committee on Toxicity |
| DEFRA | The UK Department for Food Environment and Rural Affairs |
| DQA | The US Data Quality Act |
| EC | European Community |
| ECGMF | The Japanese Expert Committee for GM Foods |
| EFSA | European Food Safety Authority |
| EPA | US Environmental Protection Agency |
| ESTO | European Science and Technology Observatory |
| EU | European Union |

| | |
|--------|---|
| FAO | UN Food and Agriculture Organisation |
| FSA | the UK Food Standards Agency |
| FSC | The Japanese Food Safety Commission, established 2003 |
| FSCAB | The Japanese Food Safety and Consumer Affairs Bureau of the MAFF |
| GM | genetically modified |
| IPTS | Institute for Prospective Technological Studies |
| IRGC | The International Risk Governance Council |
| JCCU | The Japanese Consumers' Co-operative Union |
| JECFA | Joint (WHO-FAO) Expert Committee on Food Additives |
| JMPR | Joint (WHO-FAO) Meeting on Pesticides Residues |
| MAFF | The Japanese Ministry of Agriculture, Forestry and Fisheries |
| MAFF | The UK Ministry of Agriculture, Fisheries and Food, abolished in 2001 and replaced by DEFRA |
| MHLW | The Japanese Ministry of Health, Labour and Welfare |
| MoE | Margin of Exposure |
| MOE | the Japanese Ministry of Environment |
| MRL | Maximum Residue Level |
| NEL | no effect level |
| NOEL | no observed effect level |
| NOAEL | no observed adverse effect level |
| OECD | Organisation for Economic Cooperation and Development |
| OHPNDF | The Japanese Office of Health Policy on Newly Developed Foods |
| OMB | US Office of Management and Budget |
| OST | UK Office of Science and Technology |
| pH | indicator of acidity and alkalinity |
| RAP | risk assessment policy |
| RKI | Robert Koch Institute, in Germany |
| UBA | The German Federal Environmental Agency |
| UK | United Kingdom on Great Britain and Northern Ireland |
| UN | United Nations |
| USDA | United States Department of Agriculture |
| WHO | World Health Organisation |
| WTO | World Trade Organisation |
| ZKBS | The German Central Commission for Biological Safety at the BVL |

■ 1. Introduction

A recently completed comparative study for ESTO of food safety policy-making in Austria, France, the UK, the USA and the European Commission provided detailed empirical evidence showing that scientific risk assessments are routinely conditioned by sets of prior non-scientific ‘framing assumptions’ that depend on the particular social and economic context in which those deliberations take place and decisions are made.⁶

One of the most explicit official acknowledgments of the role of non-scientific framing assumptions in risk assessment science emerged in the final years of the 20th century and the early years of this decade in the deliberations of the Codex Alimentarius Commission (or Codex (or CAC) for short). Codex is a body that sets baseline food safety standards for internationally traded food and agricultural products. It is jointly convened by the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO); its members are the individual national states that belong to the UN and WHO, as well as regional jurisdictions such as the EC/EU. Codex discharges its responsibility for risk management by setting those standards in the light of advice from joint FAO/WHO expert committees that are expected to provide scientific assessments of risks.

In 2004, Codex’s Procedural Manual was revised and supplemented with explicit statements to the effect that in advance of scientific committees conducting risk assessments, they should be provided with guidance on what Codex calls ‘risk assessment policy’.

The concept of a ‘risk assessment policy’ first emerged in the 1983 US National Research Council’s report entitled *Risk Assessment in the Federal Government*, which has come to be known as the Red Book because it was bound in a red-coloured cover. In that document, the concept is introduced in the following context:

The nature of risk assessment

Regulatory actions are based on two distinct elements, risk assessment...and risk management. **Risk assessment** is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials... **Risk management** is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment...with social, economic, and political concerns to reach a decision.

Codex now defines risk assessment policy as “Documented guidelines on the choice of options and associated judgements for their application at appropriate points in the risk assessment such that the scientific integrity of the process is maintained.”⁷

The Codex Alimentarius Commission’s *Procedural Manual* refers to **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.⁸ (emphasis added)

Codex acknowledges therefore that risk assessments do not occur in a policy vacuum but in the context of prior risk assessment policy (or RAP) judgements. Codex indicated explicitly that re-

6 *Science in trade disputes related to potential risks: comparative case studies*, IPTS, October 2004; see <http://www.jrc.es/home/publications/publication.cfm?pub=1203>

7 Codex Alimentarius Commission, *Procedural Manual*, 14th Edition, 2004, p. 46

8 Codex Alimentarius Commission, *Procedural Manual*, 14th Edition, 2004, Appendix IV. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, paras 13-15, pp. 103-104

sponsibility for deciding risk assessment policy should lie with risk managers (i.e. those responsible for policy-making) and not with risk assessors. Codex also indicates that risk assessment policies should be made by risk managers in consultation with **all** other interested parties, as well as with risk assessors, and through a **transparent** process.

Even though Codex is now more explicit about the character and importance of risk assessment policies than any previous policy-making body, we propose to use the expression in a slightly wider and less dogmatic way than Codex has adopted. This is for two reasons. Firstly, in this study, we understand the expression 'risk assessment policy' to refer to all those assumptions that frame and guide the conduct and content of scientific assessments. Some of those assumptions might derive from explicit or even implicit policies, but they may also derive from legal statutes or institutional structures which are not often thought of as 'policies'. Some framing assumptions may be far more *ad hoc* than the notion of policy implies. The important point is that we do not wish from the outset to exclude particular kinds of assumptions and judgements when it is unclear, *a priori*, whether they are or could be formulated as explicit policies. Thus, for the purposes of this study we do not assume that all of the judgements that frame and guide the conduct and content of scientific assessments can necessarily be formulated as explicit policies and we approached this study with open minds on the questions of how realistic it is to expect that any and all risk assessment policy-like judgements could be formulated as explicit policies.

Secondly, the Codex Procedural Manual implies that risk assessment policies always can and should be articulated in advance of the conduct of risk assessments. We assume that while there may be considerable scope for the explicit articulation of risk assessment policies in advance of risk assessments commencing, we also assume that some risk assessment policy issues may arise during the course of risk assessment deliberation, and therefore that it may be unrealistic and unduly restrictive to suppose that they can be exhaustively specified by risk managers before risk assessment deliberations begin. We assume that risk assessors may encounter open-ended dilemmas in the scientific characterisation of risks, and that some RAP issues

may emerge in the course of their deliberation. Our approach assumes that those issues might appropriately be referred to risk managers for their guidance, without supposing that all necessary guidance can be finalised before risk assessments begin.

1.1. Research questions

The central questions upon which this research project has focused are:

What are the various types of risk assessment policies?

Can particular risk assessment policies be reliably identified, and can explicit and implicit policies be reliably differentiated and characterised?

Which risk assessment policies are being made explicit, and which remain implicit?

How are risk assessment policies being decided in practice, and how does this compare to Codex and national guidance?

How do risk assessment policies compare within and across jurisdictions and institutional settings?

One objective of this project is to identify the extent to which, and the ways in which, the guidance on risk assessment policy from Codex is being operationalised within the Codex/joint FAO/WHO system, and within several of its Member States, and to clarify whether those policies are converging or diverging.

1.2. Rationale for the project

In international trade disputes such as those concerning beef hormones and GM crops, risk assessors in different jurisdictions and institutional settings sometimes reached conflicting conclusions not because they were providing competing interpretations of shared and agreed bodies of evidence, but because they were answering different questions. Since risk assessment policy judgements are pivotal to the framing and selection of those questions, risk assessment policies should be a

⁹ Science in trade disputes related to potential risks: comparative case studies, IPTS, October 2004; see <http://www.jrc.es/home/publications/publication.cfm?pub=1203>

crucial, but hitherto neglected, focus of inquiry.⁹ An understanding of risk assessment policy-making can therefore contribute firstly to the task of explaining why particular regulatory regimes have been established and why specific risk control measures are being taken, secondly to explain how and why disputes have arisen, and thirdly to explore the conditions under which they might either escalate or be resolved. To the extent that risk assessment policies in different jurisdictions might converge, there might be fewer occasions for disputes to occur, or where they did occur, they might be addressed more appropriately and effectively.

Achieving clarity on issues of risk assessment policy might be important not only for international discussions about regulations, standards and food safety policies but also for enhancing the transparency of policy-making procedures and decisions in the domestic debates within national jurisdictions. At the European level, where the European Food Safety Authority is expected to liaise with, and coordinate, the views of 25 national competent authorities, clarity and consensus about risk assessment policy-making may be especially important.

1.3. Historical context

'Risk assessment policy' in the 1983 Red Book

The concept of a 'risk assessment policy' was first articulated in the 1983 Red Book.¹⁰ In a section entitled 'The Nature of Risk Assessment' the NRC said:

Risk assessments contain some or all of the following four steps:

- Hazard identification...
- Dose-response assessment...
- Exposure assessment...
- Risk characterization...

In each step, a number of decision points... occur where risk to human health can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among possible in-

ferential bridges...we have used the term **risk assessment policy** to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions.¹¹

The NRC implied that 'both scientific judgments and policy choices' are involved in all stages of risk assessment, but that in practice scientific risk assessors have often taken responsibility for making those choices, although in principle some choices could be the joint responsibility of risk assessors and risk managers. The contemporary Codex usage of the expression is rather different; Codex uses the phrase to refer to prior policy choices that inform the conduct of risk assessments for which risk managers *can and should* take explicit and prior responsibility.

Following the upheavals in food safety policy making in European Member States in the aftermath of the UK BSE crisis of March 1996, and analogous crises in other Member States once BSE was confirmed in their cattle herds, an entire wave of new institutions was created. Policy-makers frequently insisted that the principles guiding their reforms included commitments to 'independence', 'openness', 'transparency' and 'accountability'. Similar changes also occurred in Japan, following the discovery of BSE in Japanese herds. Giving greater independence to risk assessors, and enhancing the openness with which risk assessments are conducted, and with which risk assessors and risk managers communicate with each other, has created conditions under which issues of risk assessment policy have come increasingly to be explicitly addressed, even though the term 'risk assessment policy' has only very rarely been applied to them. Against that background, this study focuses on how, in relation to food safety, RAP issues are being decided, and on comparing those decision-making processes with the template set out in the Codex Procedural Manual and in national guidance documents.

1.4. Analytical context

Prior to the BSE crises, and other food safety crises of the last ten years, the ways in which food safety policy-making, and the contributions of sci-

¹⁰ US NRC, *Risk Assessment in the Federal Government: Managing the Process*, National Research Council, Washington DC, 1983

¹¹ op cit p. 3

entific knowledge and expertise, were portrayed corresponded to two main models: a technocratic and a decisionist model.

A technocratic model

A technocratic model assumes that policy decisions about technological risks, such as those concerning food safety, can and should be based solely on scientific considerations. One indication of a technocratic approach is the claim that particular policies have been based on and only on 'sound science'. The key characteristics of the technocratic model are that it assumes, in effect, that science operates in complete independence of social, political, cultural and economic conditions, and that science provides not just a necessary, but a sufficient, basis for policy decision-making. The technocratic model is represented in Figure 1.

■ *Figure 1: The technocratic model: policy based on sound science.*



Previous research showed that the technocratic model does not, however, provide sufficient resources with which to understand international, intra-European or even domestic disputes over issues such as BSE, beef hormones, rBST and GM foods.¹² Policy differences are not simply a consequence of some jurisdictions accepting 'sound science', while all others that disagree rely on 'unsound science'. Different risk assessment bodies provide competing representations of possible risks not simply because they are providing competing answers to an agreed set of questions, but often because the questions they are addressing and answering differ significantly. They may be equally scientific, but different.

The technocratic model is not only empirically unsupported, it is also unable to explain how policy can be decided in conditions of acknowl-

edged scientific uncertainty, which cannot uniquely indicate any particular scientific, let alone policy, conclusion. The prevalence of uncertainties is increasingly hard not to acknowledge, especially when different jurisdictions are in dispute, and their disputes revolve around competing scientific conclusions.¹³

The 'decisionist' model

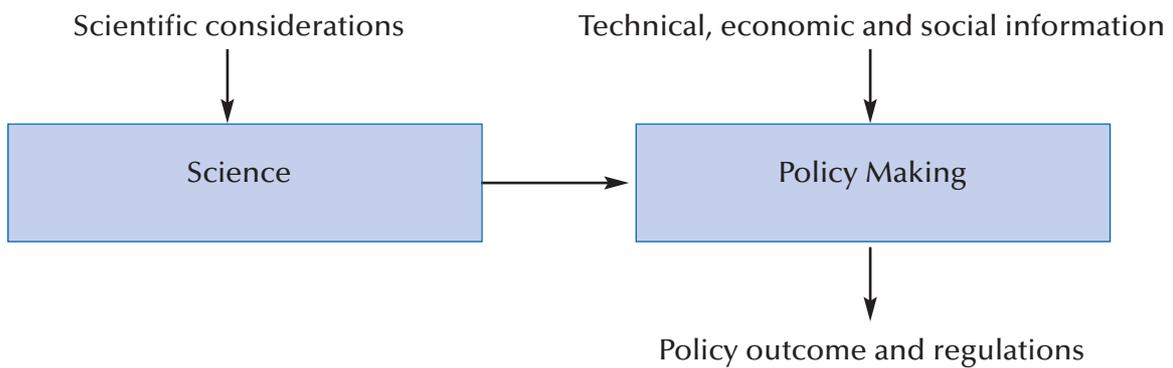
In response to the inadequacies of technocratic narratives, and the increasingly conspicuous uncertainties complicating understandings of the risks of e.g. BSE and GM foods and crops, an increasingly large portion of European jurisdictions, public policy-makers and their expert advisors now represent the processes in which they participate in terms of what is often called a '**decisionist**' model, illustrated graphically in Figure 2. This corresponds closely to what in the USA is known as the 'Red Book' model.¹⁴ Decisionism assumes that risk policy is, and should be, the product of a two-stage process, the first of which is purely scientific, often called 'risk assessment'. On this account, the scientific risk assessment is subsequently supplemented by economic, social and political considerations, which also contribute to policy decisions in a process called 'risk management'. On this model, a risk assessment should not only be prior to, but entirely independent of, any and all risk management considerations and judgements. The 'decisionist' point of view is found very widely in most of the jurisdictions we examined, and represents the prevailing contemporary orthodoxy in the USA, in Germany and Japan, as well as at the European Commission and at the FAO, WHO and Codex. Orthodoxy in those contexts often involves both the invocation of decisionist rhetorical discourse and the ostensible organisation of institutional responsibilities.

¹² E.g. P van Zwanenberg & E Millstone, *BSE: risk, science and governance*, OUP, 2005; *Science in trade disputes related to potential risks: comparative case studies*, IPTS, October 2004

¹³ See e.g. European Commission, TRANSPARENCY IN RISK ASSESSMENT CARRIED OUT BY EFSA: GUIDANCE DOCUMENT ON PROCEDURAL ASPECTS, *The EFSA Journal* (2006) 353, 1 – 16, April 2006

¹⁴ US NRC (1983) *Risk Assessment in the Federal Government: Managing the Process*, National Research Council, Washington DC

■ Figure 2: The decisionist (Red Book) model: science first, policy-making second



On this model, science influences policy-making, but policy-making does not influence scientific risk assessments. The decisionist model provides more resources with which to understand the occurrence and persistence of both domestic and international trade disputes than the technocratic model, since it can account for the fact that different groups and jurisdictions may deem different levels of risk to be acceptable; but it is not sufficiently rich fully to comprehend the nature and complexities of these disputes. Just as with the technocratic model, it remains difficult from the perspective of the decisionist model to explain why different groups of expert advisors provide incompatible risk assessments, without assuming that some or all of the competing assessments are ‘unsound’ or politically biased.

The decisionist model is nonetheless a commonplace orthodoxy in official documentation and rhetoric, both at the national and the international levels. For example, a recently issued draft joint report from the UN FAO and WHO outlining a *Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries)* presupposes a decisionist approach.¹⁵ It asserts, for example, that the proposed framework is “...based on the functional separation between risk assessment and risk management in order to ensure scientific integrity and independence, avoid confusion over the respective

roles of risk assessors and risk managers, and reduce potential conflicts of interest.¹⁶ The wholehearted endorsement of a decisionist orthodoxy on the part of FAO and WHO might seem hard to reconcile with the risk assessment policy provisions of the *Codex Procedural Manual*, but that indicates a tension between the greater willingness of the risk management body to acknowledge and take some responsibility for risk assessment policy-making compared to the reluctance of the ‘risk assessors’ to acknowledge that their risk assessments are framed by policy judgements.

The trend for governments to establish ‘independent’ agencies with responsibility for food safety policy-making has been evident in the USA, the UK, Germany, France, throughout the EU, and at the European Commission with the establishment of the European Food Safety Authority (EFSA), as well in other countries such as Japan. In the EU, Regulation 178/2002, ‘laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety’ formally set the decisionist model on a statutory basis for the EFSA.¹⁷ The creation of such agencies has often been legitimated in terms of the separation of risk assessment from risk management, although that terminology was not invoked in the UK when the Food Standards Agency was established.

¹⁵ UN FAO & WHO, *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries) - Final Draft for Public Comments*, Rome/Geneva 2006, available 27 February 2007 from http://www.fao.org/ag/agn/proscad/index_en.stm as ftp://ftp.fao.org/ag/agn/proscad/framework_en.pdf

¹⁶ op cit para 2.2 page 3

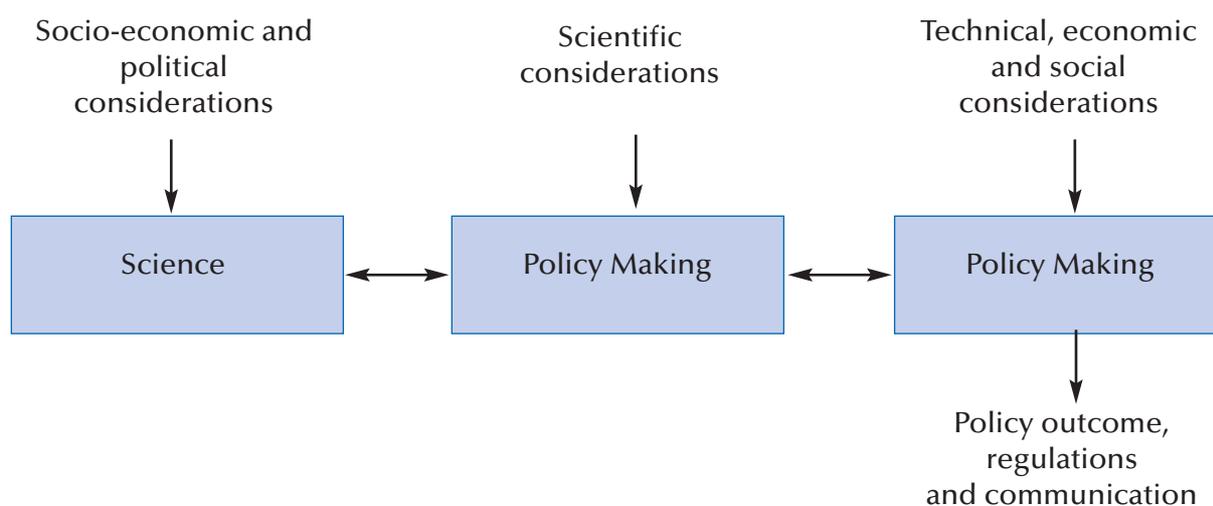
¹⁷ REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *Official Journal of the European Communities*, L 31/1-24, 1 Feb 2002, available at http://europa.eu.int/eurlex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

For the reasons set out above, we broadly share the view that underpins the introduction by Codex of the concept of risk assessment policy namely that scientific assessments of risk are framed in some important ways by their social and policy contexts. From this perspective, it is misleading to represent policy-making as divided into a purely scientific up-stream risk assessment phase followed by a down-stream risk management phase. Rather scientific risk assessments are framed by legal requirements, institutional structures, and by other social, economic and political judgements. Those up-stream judgements directly concern or indirectly influence, for example, the objectives of policy, the responsibilities of risk assessors, the effects that are deemed to be ‘risks’ or ‘adverse effects’, the evidence that is to be counted as relevant, and the ways in which data are to be interpreted and presented. They consequently con-

tribute to setting the agenda for scientists to deliberate and this explains in large part how different scientists can reach differing, but not necessarily any more or less scientific, risk assessments.

We shall adopt the vocabulary used by Codex in referring to those kinds of judgements as ‘risk assessment policy’. Moreover, we assume that the relationships between risk assessment policy and risk assessment and risk management can more appropriately be portrayed in the model given in Figure 3, representing what here is called the ‘transparent’ model. This model is not used or referred to by Codex, but it provides a fuller representation of the interactions of science and policy-making than either of the two previous models, and if our analysis is correct it accommodates, in ways that other models do not, the meaning and significance of the introduction by Codex of the concept of ‘risk assessment policy’.

■ *Figure 3: The transparent model: scientific risk assessment framed by risk assessment policy*



The distinctive feature of this ‘transparent’ model is that it not only assumes that policy decisions involve social, economic and political judgements in the context of downstream trade-offs, but it also sees scientists as operating within specific social, political, cultural and economic contexts that can affect the agendas, contents and conclusions of their risk assessments. The model does not assume that the incorporation of social, economic and political considerations into risk assessments renders them ‘un-scientific’. It assumes that risk appraisal is typically a hybrid enterprise and therefore indicates the possibility of, and scope for, addressing such considerations

more explicitly and opening them to evaluation and negotiation.

The transparent model does not entail that politics illegitimately meddles with science, but indicates rather that non-scientific considerations play a distinctive up-stream role in setting the framing assumptions that shape the ways in which risk assessments are constructed and conducted. It implies that, rather than leaving those assumptions implicit and leaving risk assessors to take responsibility for non-scientific judgements, risk managers may, and perhaps should, take responsibility for at least some of the risk assessment policy judgements

that circumscribe the scope, or at least the minimum scope, of the risk assessors' deliberations. In the terminology used by Codex, risk managers could provide their risk assessors with explicit upstream risk assessment policy (or RAP) guidance.

Although in this study we adopt the vocabulary used by Codex in referring to the kinds of judgements that frame scientific assessments as 'risk assessment policy' we do not want to imply that the division of regulatory decision-making into three discreet stages: risk assessment policy, risk assessment and risk management, as in the transparent model, is the only or best way in which regulatory decision-making should be thought about and organised. Although the majority of the institutions and jurisdictions in this study, including Codex, use the terms risk assessment and risk management, not all do. Moreover, those that do share the terminology often mean slightly different things by the terms. Thus, in adopting the useful term 'risk assessment policy' to mean the assumptions and judgements that shape the conduct and content of scientific assessments, we do not assume that the process of scientific appraisal must be called a risk assessment or that such assessments should be purely scientific and separated from risk management decisions.

1.5. Policy literature – acknowledging 'risk assessment policy' judgements

There have been some attempts, other than in the 1983 Red Book and the Codex Procedural Manual, to address risk assessment policy issues within the public policy literature, although the terminology varies. The following four examples do not attempt to provide an exhaustive catalogue of those developments, but highlight some of the main contributions, at least in the English-language literature.

1) US Presidential/Congressional Commission on Risk Assessment and Risk Management

In 1997 the issue of the policy-framing of risk assessments was addressed in the report from the *US Presidential/Congressional Commission on Risk Assessment and Risk Management*.¹⁸ That document discussed some of the ways in which non-scientific considerations frame advice from expert scientific committees in terms of their contributions to what it there variously called 'problem formulation'¹⁹ 'problem characterization'²⁰ and 'problem identification'.²¹

2) The FOSIE project

In 2003 results emerged from an EU-funded research project called Food Safety in Europe: Risk Assessment of Chemicals in the Food and Diet (or FOSIE).²² It was managed and led by senior staff at the International Life Sciences Institute (ILSI).²³ The approach adopted in the FOSIE report includes the concept of 'problem formulation', the meaning of which is close to that in the *US Presidential/Congressional Commission on Risk Assessment and Risk Management*

In relation to 'problem formulation', the authors state:

Problem formulation is the initial step in the whole risk assessment process....**The outcome of problem formulation is an analysis plan with detailed questions for the risk assessor, on which the risk characterisation process has to focus.** Ideally, **problem formulation should** be considered as an iterative process involving **dialogue with all stakeholders**, i.e. risk assessors, risk managers, manufacturers or producers, consumers, and it can develop as the risk assessment evolves... The process can be initiated by an individual outside the scientific and risk assessment community bringing a problem to

¹⁸ US Presidential/Congressional Commission on Risk Assessment and Risk Management, *Final Report Volumes 1 and 2*, 1997

¹⁹ op cit Vol. 1 p. 59

²⁰ op cit Vol. 2 p. 127

²¹ op cit Vol. 2 p. 58

²² A G Renwick et al, 'Risk characterisation of chemicals in food and diet', *Food and Chemical Toxicology*, Vol 41, 2003, pp. 1211-1271

²³ ILSI describes itself as: "...a nonprofit, worldwide foundation that seeks to improve the well-being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, and industry." (<http://www.ilsil.org/AboutILSI/> 9 November 2005) Other describe it less charitably. (S Boseley, 'Sugar industry threatens to scupper WHO', *The Guardian*, Monday April 21, 2003)

public attention... The first step to problem formulation is a planning dialogue that clarifies the management goals, the purposes and scope of the assessment... all stakeholders (from the initial producer/grower to the final consumer) bring valuable and often different perspectives to assessment planning... **Problem formulation should be as explicit as possible** and should generally **include considerations of relevance (including societal values)**... The process should undergo rigorous review by risk managers, scientific peers, and other stakeholder to ensure that **all** concerns have been addressed...²⁴ (emphases added)

That account of 'problem formulation' is substantially equivalent to our interpretation of the Codex use of the expression 'risk assessment policy'.

3) Renn et al in the Framework 6 Safe Foods project

In the context of the European Commission supported Integrated Project entitled Safe Foods²⁵, Renn et al draw heavily on the Codex General Principles, and argued that:

There should be a **functional separation** of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However it is recognized that risk analysis is an iterative process, and **interaction** between risk managers and risk assessors is **essential for practical application**.

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**. The procedure aims at ensuring that the risk assessment is

systematic, complete, unbiased and transparent. The **scope and purpose** of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.²⁶ (emphases added)

That articulation of the Codex approach in the context of a science-led, but joint natural and social science, research project suggests that a consensus has developed between natural and social scientists working at the frontier of food safety research and food safety policy research, that the concept of 'risk assessment policy' is important and relevant to both sets of perspectives.

4) The International Risk Governance Council

A report recently emerged from the International Risk Governance Council, which is a body drawn from both industrial and academic groups.²⁷ The IRGC document said:

Risk analysis

The process of decision-making on risks has been termed risk analysis. The Scientific Steering Committee of the European Commission has been defining a framework for risk analysis...risk analysis comprises risk assessment, management, monitoring and review of decisions...

The risk analysis process in this framework is *iterative*: it is continuously reviewed and adapted if needed, based on monitoring/surveillance of implemented measures and on new emerging information...The process can be conceived of as a winding stair, where each round leads to a higher level of understanding of the risks and the benefits, the views of the stakeholders and thereby the management options.

In addition, the Scientific Steering Committee identified other values, which currently are *not* incorporated in the formal risk assessment process, but which should be taken into

²⁴ A G Renwick et al, 'Risk characterisation of chemicals in food and diet', *Food and Chemical Toxicology*, Vol 41, 2003, p. 1217

²⁵ see <http://www.safefoods.nl/default.aspx>

²⁶ M Dreyer & O Renn, *SAFE FOODS WP5 - Recent activities and current status*, SafeFoods Project, Athens, October 2005

²⁷ The IRGC is a public-private partnership, based in Geneva, Switzerland, with funding sources including the governments of Switzerland, USA, the European Commission, People's Republic of China, the Zurich-based technical university ETH and the reinsurance company SwissRe.

account, such as: (i) animal welfare, (ii) sustainability, (iii) human Quality of Life parameters, (iv) risk perception, (v) ethics, and (vi) social and economical benefits. The Scientific Steering Committee has proposed a general schedule for risk analysis, which takes account of the assessment of these Quality of Life parameters....the Quality-of-Life parameters that need to be assessed...include adverse effects in humans, nutritional efficacy in humans, health protective/promotional effects in humans, environmental impact, ecological impact (farming, fishery, industry), occupational health issues in farming and industry, associated animal welfare issues, connected local and global sustainability issues, economical impact assessment, ethical issues and consumer perception issues.²⁸

IRGC explicitly refers to the 'identification of concerns' and 'formulation of risk management questions' [...of risk assessors], as well as: 'Establishment of risk assessment policies for conduct of the risk assessments'. The IRGC portrays RAP issues as including the 'formulation of risk management questions' and 'identification of a food safety problem' and 'establishment of risk assessment policies for conduct of the risk assessments'. The first and second of those expressions correspond to what we term substantive RAP, while the third corresponds to what we term procedural and interpretative RAP. This also provided evidence of a growing recognition of the existence and importance of risk assessment policy-making, although the IRGC refers to RAP issues only in generic terms, rather than in terms that are concrete and specific.

1.6. Risk assessment policy and Codex Member States

The Codex Alimentarius Commission's policy-making system is, to a first approximation, comprised of the sum of the individual jurisdictions represented and participating at Codex meetings.

That might be thought to imply that the explicit obligation on risk managers to provide risk assessment policy guidance to risk assessors had not only been accepted by Codex, but also that it had been fully and formally accepted and endorsed by all Codex Member States, i.e. the membership of the WHO and the UN-FAO. The position is slightly complicated, however, and in flux.

At a meeting of the Codex General Principles Committee held in Paris in April 2005, Member States failed to agree a text that would have stipulated that each of them should also be subject to the same injunctions as all Codex risk management bodies.²⁹ Subsequently, however, a meeting of a Working Group of the Codex Committee on General Principles, on Working Principles for Food Safety, which met in Brussels in September 2006, unanimously agreed a draft document setting out **Working Principles for Risk Analysis for Food Safety for Application for Governments**.³⁰ That text included references to 'risk assessment policy', using very similar wording to that in the Codex Procedural Manual, namely:

- 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.³¹

At a plenary meeting of the Codex Alimentarius Commission in Rome in July 2007, the assembled Member States adopted a policy statement to the effect that risk managers in all national competent authorities would provide their national risk assessment bodies with risk assessment policy guidance.³² In the context of that decision, it is par-

²⁸ <http://www.irgc.org/>

²⁹ *Report of the Twenty-Second Session of the Codex Committee on General Principles, to Codex Rome July 2005, ALINORM 05/28/33a*

³⁰ *Report of the Working Group on Working Principles for Risk Analysis for Food Safety, Brussels, 26-28 September 2006*

³¹ Op cit Appendix III, pp 26-27

³² see <http://www.codexalimentarius.net/web/archives.jsp?lang=en>

ticularly important to understand and compare the ways in which risk assessment policies have been articulated, interpreted and implemented within global institutions and across national jurisdictions. Once national jurisdictions start to implement the recent agreement, and compare and contrast their individual risk assessment policies, this may cause Codex risk management bodies to reflect on their own policies, and to explore the extent to which the separate approaches of Codex member states can be reconciled at the global level.

Our starting assumption was that, where public policy-making institutions formally take responsibility for risk appraisal and decision-making, some risk assessment policy assumptions arise, even if they are not explicitly acknowledged or labelled in those terms. We found that the choice was not between having a risk assessment policy and not having one, but between being explicit and transparent about RAP judgements, or being implicit and opaque.

■ 2. Materials and methods

2.1. General Approach

The approach adopted in this research was as follows. Firstly, a review of the rather limited general literature on risk assessment policy was conducted and secondly documents published by the respective risk managers and risk assessors, with responsibility for each of the case studies and each of the six institutional settings, and some contributions from the wider policy community, were gathered and scrutinised for explicit statements of risk assessment policy, and for comments that indirectly imply assumptions about risk assessment policies.³³ From that analysis, a set of interim hypotheses was developed concerning what the official risk assessment policies might be, and where and how they may have been decided. Those interim hypotheses were then triangulated against information obtained through a set of semi-structured interviews with key participants, including those identified as ‘risk assessors’ and ‘risk managers’, in each of the relevant institutional settings. On the basis of those findings, individual reports were written on each of the institutional settings. The aim was to document the location and substance of risk assessment policy-making in relation to the case studies. In the concluding stage, a comparative analysis was developed exploring the implications of the extent of divergence and convergence in risk assessment policies that the case studies revealed.

In analysing risk assessment policies in and across six different institutional settings we have had to be careful to ensure that those analyses and comparisons were meaningful given a rather diverse range of institutions, legal traditions and practices. As several academic studies of comparative regulation have indicated, the ways in which risk appraisal and decision-making are organised and practiced in different jurisdictions vary, sometimes quite markedly, because those practices are shaped in important ways by the laws, institutional and administrative cultures specific to each juris-

diction.³⁴ That variance extends to the ways in which the scientific aspects of policy decision-making are organised, practiced and portrayed. For example, the distinction between ‘risk assessment’ and ‘risk management’ originated and took on a particular meaning in the USA. Other jurisdictions have shared the terminology, but the meaning of the distinction cannot be presumed to be identical. Furthermore, not all jurisdictions make the same distinction between risk assessment and risk management. To take another example, the notion of what constitutes an accountable process of risk decision-making will be understood in different ways across jurisdictions, given different legal, political and regulatory cultures, even though many of the core aspects of what contributes to and detracts from accountable decision-making will be shared. Thus, despite such variations, meaningful comparative analyses can be made but care is required in interpreting differences and imposing concepts that are not necessarily universally shared.

Our findings indicate that risk assessment policy can be understood as comprising at least three main types of considerations, namely **substantive**, **interpretative** and **procedural** issues. **Substantive** risk assessment policy issues are concerned with delineating which kinds of potential changes, effects and evidence are included within risk assessments and which are outside their scope. **Interpretative** risk assessment policy issues are concerned with the ways in which data are interpreted. This includes issues such as the inference principles used to extrapolate carcinogenic risks from test animals to human populations, and the relative importance of seeking to identify and take account of possible false negatives and false positives. **Procedural** risk assessment policies are concerned with the responsibilities of risk assessors and the processes by which risk assessments are conducted. They cover all institutional issues, such as those concerning the recruitment and inde-

³³ Not all cases were, or could be, covered in all six settings. For example, the joint FAO/WHO expert committees have not conducted risk assessments of GM foods or crops.

³⁴ S Jasanoff, *Designs on Nature: science and democracy in Europe and the United States*, Princeton University Press, 2005

pendence of experts, the extent of openness and transparency and the ways in which the responsibilities of scientists and policy-makers are coupled together. Our analytical discussion of the case studies and institutional settings is organised in terms of those three types of RAPs.

2.2. Case Studies

Four case studies were chosen. The first two concern different aspects of GM crop safety: agro-environmental risks and human food-borne risks. Both aspects of GM crop safety constitute rich cases for identifying, and appreciating the importance of risk assessment policies because in all jurisdictions the chosen approaches to assessing the safety of GM crops and GM foods are in a state of flux. The remaining two case studies concern two aspects of public health risks from food chemicals: food chemical risks where toxicological dose thresholds are known or assumed to exist and chemical risks for which no dose threshold is presumed. Compared to GM crop safety, there is much less debate and dispute over the regulation of chemicals in the food supply. Nevertheless, similar types of risk assessment policy issues arise and these have been pertinent to regulatory decision making for many decades.

The four case studies were selected because they illustrate well the kinds of food safety topics, and the range of substantive, interpretative and procedural risk assessment policy issues that individual jurisdictions and multilateral organisations such as Codex have to cope with. The intention of this report is not to provide a detailed or definitive analysis of risk assessment policy for each case, or to compare each case across different jurisdictions. Rather it is to illustrate the variety of ways, and some of the general differences, in how several jurisdictions have handled risk assessment policy issues in the area of food safety.

2.3. Institutional settings

Each case study will be examined across some, but not all, of the six institutional settings (the Codex Alimentarius Commission and its joint FAO/WHO expert committees, the UK, Germany, the USA, Japan and Argentina). This is partly because not all of the jurisdictions have developed distinct policy regimes in relation to each case

study. For example, Codex has no role in relation to the agro-environmental aspects of GM crops whilst the USA has effectively deregulated GM foods. Another rationale for limiting the number of case study/institutional setting combinations is that the principle purpose of our analysis is not to provide an exhaustive account of actual practices or an analysis of any single jurisdiction. Rather it is to provide an illustration of the variety of different ways in which different jurisdictions are thus far managing risk assessment policy-type issues

As we outline below, the six institutional settings manage the business of risk appraisal in quite different ways, partly reflecting each jurisdiction's political and administrative culture, although there are many similarities too. In several of the settings those practices are undergoing considerable change. These differences, similarities and changes are especially important for procedural risk assessment policies.

In three of those institutional settings, namely the UK, Germany and Japan, food safety policy-making institutions have recently been restructured and reformed, largely as a consequence of BSE and in some cases other food policy crises. In the UK and Japan this has involved the separation, at least partially, of food safety responsibilities from agriculture and food industry sponsorship, as well as the creation of new institutions with responsibilities for food safety. In Germany, by contrast, those distinct responsibilities were combined so that agriculture, food safety and consumer protection policy, previously separate, are now in a single ministry. Germany and Japan also responded to the ways in which the BSE saga unfolded domestically by attempting institutionally to separate the functions of risk assessment from risk management. The UK, on the other hand, combines risk assessment and risk management within a single institution (the Food Standards Agency or FSA), although partially independent expert committees provide a substantial part of the scientific assessment.

In the remaining settings, namely the USA, Argentina and at Codex and the joint FAO/WHO committees, the structure and mandate of food safety policy-making institutions has continued unchanged for several decades. Those jurisdictions have not, however, faced the same kinds of crises over BSE and/or agricultural biotechnology that occurred in Europe and Japan. At the international level Codex/FAO/WHO has long had separate in-

stitutions for risk assessment and risk management policy-making whilst in the USA and Argentina those functions have long been combined within, or overseen by, single agencies or departments.

Argentina is the only institutional setting in which no distinction is made between risk assessment and risk management. Instead, there exists the kind of technocratic regime, common until relatively recently in many other jurisdictions, in which all of risk appraisal and policy decision-making is represented as (and organised as if it were) entirely technical in nature. The remaining five institutional settings all invoke a general distinction between risk assessment and risk management, although this is sometimes articulated abstractly rather than organised in practice. Although the language of risk assessment and risk management is widespread, no two jurisdictions are interpreting and operationalising the contrast in the same way.

The next sub-section provides a brief comparative summary of the institutional settings and their roles in relation to the assessment and management of risk. Some generalised similarities and differences are highlighted. Those differences reflect different political and administrative cultures and traditions, as well as varying responses to the threats and challenges posed by contemporary food policy regulation.

Codex

The Codex Alimentarius Commission (or Codex for short) was established in the 1950s, as a joint initiative of the UN Food and Agriculture Organisation (founded in 1945) and the World Health Organisation (founded in 1948).³⁵ Until the establishment of the World Trade Organisation (WTO) in 1994, Codex standards had no statutory force under any legislation, national or international. One of the elements of the treaty under which the WTO was created is the agreement on Sanitary and Phytosanitary Standards (or SPS agreement).³⁶ Under its provision, Codex standards are defined as providing a minimum benchmark of food safety for internationally traded foodstuffs. Any WTO Member State can lawfully exclude products that fail to comply with Codex standards, but Member States can only law-

fully exclude products that comply with Codex standards if their regulatory measures are based upon a scientific risk assessment.³⁷

Codex is organised into Committees, which are known in Codex terminology as ‘Subsidiary Bodies’; and the three upon which this study concentrates are the Codex Committee on Food Additives and Contaminants (CCFAC), the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) – both of which receive risk assessment advice from JECFA (Joint (WHO-FAO) Expert Committee on Food Additives – and the Codex Committee on Pesticide Residues (CCPR) – that receives advice from JMPR (the Joint Meeting on Pesticides Residues).

Codex has responsibility for risk management and standard setting for food additives and contaminants but a far more limited role in respect of GM food safety and no role at all in relation to agro-environmental aspects of GM crops. On GM foods, Codex has only set out some general principles and guidelines for risk assessment but has not become involved in assessing specific foodstuffs. Since the environmental impact of GM plants will vary as a function of the different ecosystems into which they might be introduced, it would be unrealistic to imagine a centralised global body, such as Codex, providing generally applicable assessments of the agro-environmental risks posed by cultivating particular GM varieties.

Within the Codex system, risk assessment and risk management functions are ostensibly located in separate institutions and treated as distinct activities. Codex’s key policy responsibilities in respect of standard setting for food additives and pesticides, lie, respectively, with the Codex Committee on Food Additives and Contaminants (CCFAC) and the Codex Committee on Pesticide Residues (CCPR), which consists of representatives from member governments plus observers, who are largely from industrial firms and trade associations.

Risk assessments, and recommended standards for pesticides residues in traded food commodities are provided by the FAO/WHO’s Joint Meeting on Pesticide Residues (JMPR). The FAO/WHO’s Joint Expert Committee on Food Ad-

³⁵ See History of Codex at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/008/y7867e/y7867e00.htm

³⁶ Available at: http://www.wto.org/English/tratop_e/spse/spse.htm

³⁷ WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Article 5.1

ditives (JECFA) provides risk assessments of food additives and contaminants, primarily in terms of quantitative estimates of ‘acceptable daily intakes’ or ADIs. Standards for levels of use of additives in particular categories of food products are set by CCFAC, rather than by JECFA. JECFA and JMPR are expert scientific advisory committees comprising scientists drawn from professional scientists working in public and private institutions. JECFA and JMPR are institutionally separate from Codex, even though providing advice to Codex has become their main function. They have their own secretariats, provided jointly by the WHO and FAO, rather than by Codex or its Committees.

UK

Food safety policy-making in the UK had traditionally been the responsibility of the Ministry of Agriculture, Fisheries and Food (MAFF), which was also responsible for sponsoring the food and farming industries. In 2000, in the wake of the BSE debacle, the UK Government separated food safety responsibilities from agricultural and industrial sponsorship by creating the Food Standards Agency (FSA). This was followed in 2001 by the abolition of MAFF and its replacement with the Department for Environment, Food and Rural Affairs (DEFRA).

De facto responsibility for both the risk assessment and risk management components of food safety policy-making in the UK (including GM food and food chemicals) now rest with the Board of the FSA, although *de jure* Department of Health ministers can over-ride the ‘advice’ of the FSA. Environmental releases of GM crops had been the responsibility of the Department of the Environment’s Biotechnology Unit. Since 2001 those responsibilities have passed to DEFRA.

Although risk assessment and management functions are combined within the FSA (for GM food and food chemicals) and DEFRA (for GM plants), expert advisory committees, often comprising mostly non-governmental employees, play significant roles conducting, what are in effect, risk assessments, although they are rarely so labelled. FSA, DEFRA and other Ministerial departments nevertheless provide secretariats to those commit-

tees and technical support including providing initial assessments of the assembled evidence.

The principal committees for our case studies are the Advisory Committee on Novel Foods and Processes (ACNFP) in relation to GM foods, the Advisory Committee on Releases to the Environment (ACRE) for GM plants, and in relation to food additives the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (CoT – and its sub-committees - the Committee on Carcinogenicity (CoC) and the Committee on Mutagenicity (CoM). ACNFP and ACRE consist of members drawn from universities and public sector research organisations whilst the CoT, CoC and CoM also have members drawn from the private sector.

The expert committees sometimes represent what they provide as ‘risk assessments’. It is much rarer, however, for officials engaged in scientific aspects of appraisal to characterise their activities as ‘risk assessment’. Rather, much of what takes place within the Food Standards Agency is a hybrid scientific/policy activity with no clear demarcation between scientific and policy aspects of the FSA’s responsibilities.

UK legislation and regulation (and for Germany too) in relation to both food chemicals and GM crops and foods, is subordinate to EU legislation and regulations. However, national governments within the EU retain reserve powers that allow them to ban or restrict products that are already approved at an EU-wide level, but only under certain conditions. Consequently UK and other European national regulatory systems of regulation have not entirely been displaced by European level decision-making.

Germany

Germany also restructured its food safety policy-making system in the wake of the BSE saga. Rather than separating agriculture and food safety responsibilities, however, as in the UK, those responsibilities were combined under the German reforms. In January 2001, agriculture, food safety and consumer protection policy, previously: separate, were combined in one powerful ministry the Federal Ministry of Consumer Protection, Food, and Agriculture (BMVEL).³⁸

³⁸ Recently renamed as Federal Ministry of Food, Agriculture and Consumer Protection (BMELV).

When the new BMVEL was created, the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV), which had previously been responsible for the assessment and management of most categories of food and consumer products, was added to the portfolio of BMVEL and then subsequently split into two new institutions: the Federal Institute for Risk Assessment (BfR) and the Federal Agency for Consumer Protection and Food Safety (BVL). This change was represented as institutionally separating risk assessment (in BfR) from risk management (by BVL).³⁹

The situation is, however, more complex for GMOs where not just the BfR performs risk assessments but so do at least four additional institutions: 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. There is also some inconsistency between the planned institutional demarcation and what happens in practice. In some policy fields, such as for GM crops and foods, the separation between risk assessment and risk management was only partially implemented. RKI and BfN are not subordinate to the BMVEL/BMELV and were therefore not included in the institutional reforms. They remain hybrid institutions, with both risk assessment and management responsibilities. As the nominal risk manager, the BVL not only has its own scientific advisory committee, the ZKBS, but also set up its own in-house risk assessment expertise, which was deemed essential for risk managers.⁴⁰ Risk assessment conclusions on GMOs delivered by the BfR, BBA, RKI, BfN and the ZKBS are then considered in relation to BVL's own risk assessment judgements. The procedures and conclusions of BVL risk assessments, however, remain opaque, even to other risk assessment institutions.

Japan

As in Germany and the UK, Japan has sought to reform food safety policy-making as a consequence of BSE and other food safety crises. In July

2003 the new Japanese Food Safety Commission (FSC) was established in order to institutionally 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).

For GM foods, risk assessments are conducted by the Expert Committee for GM Foods (ECGMF) of the FSC, while risk management is carried out by the Office of Health Policy on Newly Developed Foods (OHPNDF) of the Pharmaceutical and Food Safety Bureau (PHSB) of the MHLW.

For GM crops, risk assessments are the responsibility of the Committee for the Assessment of Adverse Effects on Biodiversity (CAAEB) whose secretariat is the Biotechnology Safety Division of the Agriculture, Forestry and Fisheries Research Council (AFFRC) of the MAFF and the Wildlife Division of the Nature Conservation Bureau (NCB) of Ministry of Environment (MOE). The committee was newly established in 2004 as functionally and organizationally separated from risk management body, namely the Food Safety and Consumer Affairs Bureau (FSCAB) of the MAFF.

USA

Food safety policy-making in the USA is primarily the responsibility of the Food and Drug Administration (FDA) whose structure and mandate have remained largely unchanged. The FDA's Center for Food Safety and Applied Nutrition is responsible for policy on food additives and contaminants. The FDA is also responsible for GM food regulation but in practice has declined formally to regulate those products. GM crops are the responsibility of the US Department of Agriculture (USDA) whilst the Environmental Protection Agency regulates all plant pesticides (which include Bt toxins). In practice, the USDA has deregulated GM crops and therefore only the EPA has active regulatory oversight for GM plants, or rather those that have pesticidal properties.

³⁹ Eventually, three areas - animal medicines, animal diseases and plant protection products - were exempted from the separation of risk assessment and risk management: according to some interviewees there was strong political resistance in each case to the separation of risk assessment and risk management. In the former case BMG, the competent authority for animal medicines, insisted on having only one contact instead of two if risk assessment and risk management would be separated. In the second case, geographical reasons also probably apply - as Bundesforschungsanstalt für Viruskrankheiten der Tiere is located on an island which is considered a safe place to deal with animal diseases.

⁴⁰ Despite its role as the risk manager, senior managers portray the BVL as a scientific institution.

The EPA and FDA are responsible for both risk assessment and risk management. Those two functions are nevertheless treated separately; within each Agency there are two categories of staff, designated as either risk assessors or risk managers. Both Agencies have external advisory committees, comprised of scientists drawn from public sector research organisations and universities (the Scientific Advisory Panel in the case of the EPA's Office of Pesticide Programs and the Food Advisory Committee for the FDA's Center for Food Safety and Applied Nutrition). The role of those committees is not to produce risk assessments but rather to peer review, and comment on, risk assessments that have been produced by Agency staff.

Argentina

Argentina is the world's second largest producer of GM crops and so far the technology has not attracted the sorts of controversies that have beset European countries. Consequently, the regulatory regimes have not been forced to try and accommodate domestic tensions either over GMOs, or food safety policy more generally and, like the USA, Argentina has not been under pressure to reform food safety policy-making. The Argentinean risk regulatory regimes are also less well resourced than the equivalent regimes in wealthier OECD countries.

Policy responsibility for GM plant and food regulation falls to single agencies within the Secretariat of Agriculture, Livestock, Fisheries, and Food. These are the National Advisory Commission on Agricultural Biotechnology, for GM plants, and the National Agrifood Health and Quality Service for GM foods. In both cases the Secretary of Agriculture is formally responsible for taking regulatory decisions although in practice the agencies provide prescriptive advice that is almost always followed. Food additive regulation is the responsibility of the National Food Institute in the Ministry of Health and Environment.

In the case of both GM crops and GM foods, expert committees are responsible both for conducting assessments of risk and making risk management judgements. That distinction between risk assessment and risk management, or between scientific and policy aspects of risk decision-making is, not generally used in the Argentinean regime, which instead portrays the entire risk appraisal and

decision-making process as a purely technical one. There is, in fact, no discreet set of activities that the Argentinean regulatory system represents as risk management. Rather what other jurisdictions take to be risk management activities are either ignored in official discourse, or seen as a technical matter (such as the conditions attached to approval) or are not conceptually distinguished from risk assessment (such as issues of risk acceptability). Unlike the USA and UK, the expert committees comprise not only experts from universities and other public sector research organisations but also government officials and individuals from the principal industrial trade associations. For food additives, Argentina does not routinely undertake risk assessments, relying largely on the standards provided by Codex and other regulatory authorities in OECD countries.

In the following discussion of our empirical findings, the sequence in which the various institutional settings are discussed varies. The specific order in which they are reviewed in relation to particular topics has been chosen to reflect either the dominance of particular approaches or the recent introduction of interesting innovations. The order is intended to be analytically informative rather than mechanically repetitive.

■ 3. EXPLICIT Formal risk assessment policies

What kinds of risk assessment policies have been articulated and how have they been established?

The analysis presented in this section begins by describing which kinds of formal risk assessment policies have been established in the six institutional settings (in relation to the four case studies) and the ways in which those policies have been established. Those policies are rarely referred to as a ‘risk assessment policy’ but they are nevertheless explicitly recognised as policy guidance to risk assessors. In some cases the policies that have been explicit have been procedural while others have been substantive and/or interpretative. Procedural risk assessment policies generally cover an entire jurisdiction, or an area of broad policy, and as such tend to derive from relatively high-level policy officers and must subsequently be interpreted by risk managers and/or risk assessors in specific policy domains. Substantive/interpretative risk assessment policies, on the other hand tend, by their nature, to be applicable only within specific policy domains only and as such usually originate with either the risk assessors and/or risk managers within the relevant area of policy.

That discussion will then be followed in Section 4 by a more detailed scrutiny of the contents of the policies themselves, beginning with various procedural aspects of risk assessment policy and then in Section 5 various substantive and interpretative aspects. The discussion in Section 6 then focuses on the extent to which we can identify implicit risk assessment policies in the six institutional settings. Section 7 provides an account of how some policy practices compare with the policy ambitions set out by Codex and the five jurisdictions. Section 8 provides a brief summary and conclusion.

Codex

While national food safety crises have provoked considerable institutional changes, such as

those in the USA in the 1970s and in Europe in the late 1990s and in the early years of the first decade of the 21st century, Codex institutions have remained remarkably unperturbed. Ironically, that structural inertia at Codex has been combined with conceptual innovations. It is Codex, rather than any of the national jurisdictions, that explicitly recognised that risk assessments are routinely framed by prior upstream judgments and Codex explicitly committed its risk management decision-makers to providing ‘risk assessment policy’ guidance to risk assessors in the joint FAO/WHO expert advisory committees; even though those FAO/WHO committees have rarely acknowledged that they need, or should be guided by, risk assessment policy framing guidance from Codex subsidiary bodies.⁴¹

The phrase ‘risk assessment policy’ appears to have been introduced, accepted and adopted in response to calls from Member States and the Codex subsidiary bodies (comprised of representatives of Member States) to make its procedures and those of its expert advisory committees more transparent. Some Member States assumed that risk assessment policy guidance would be primarily or even entirely procedural, while others, including the USA, understood that some substantive guidance might also be essential.

The inclusion in the Codex Procedural Manual of an explicit formalised obligation from Codex to its ‘subsidiary bodies’ such as CCFAC, CCPR and CCRVDF potentially transforms the relationships between risk assessors and risk managers. If risk managers are obliged to provide a risk assessment policy framework to risk assessors, then the latter are under an obligation to conduct their deliberations in accordance with that guidance. Technocratic and decisionist portrayals of the relationship between science and policy lose their plausibility, and a fresh approach to representing risk assessment and risk management is required and new forms of accountability may be required.

⁴¹ Codex Alimentarius Commission, Procedural Manual, 14th Edition, 2004, Section III, paras 13-16, pages 102-103

In the early years of this decade, the CCFAC, CCPR and CCRVDF developed a varied set of RAP proposals, intended to operationalise the provisions of the Codex *Procedural Manual*, that JECFA and JMPR then rejected; and rejected quite abruptly. Over a period of five years, lengthy, complex and discreet negotiations resulted in a series of agreed compromises between those three Codex Committees on the one hand and JECFA and JMPR on the other.

The initial proposals

A draft risk assessment policy was first produced by CCRVDF for JECFA in July 2001 although the document was referred to as ‘risk analysis principles and methodologies’.⁴² The following month a draft *Risk Assessment Policy Statement for the Interaction Between CCFAC and JECFA* was circulated for discussion.⁴³ In December 2001 the CCPR published a document, which like the CCRVDF, referred to draft risk analysis principles rather than risk assessment policy.

All three drafts contained some procedural guidance, while the CCRVDF document also provided some substantive and interpretative guidance. The procedural guidance referred primarily to requirements that the committees should be independent, that uncertainties and assumptions be made explicit, and included a requirement from CCPR to JMPR stipulating that the risk assessors should provide risk managers with scientific comments on a range of pre-defined risk management options.

The CCRVDF’s substantive and interpretative guidance included indications about what was to count as a benchmark of acceptable risk, about the kinds of metabolic changes, following use of veterinary drugs, that should or should not be the focus of JECFA’s attention, as well as guidance concerning the use a safety factor of 100 to calculate ADIs from NOELS (or ‘no observed effect levels’) in animal studies. CCRVDF indicated that it took the view that deciding the value of different safety

factors was a task to which risk managers should contribute, although the 2001 document observed that: “It is odd that CCRVDF has never addressed this important matter and issued the necessary guidance to JECFA.”⁴⁴ CCRVDF also portrayed risk assessment, which is JECFA’s explicitly responsibility, as a four-step science-based process (comprising hazard identification, hazard characterization, exposure assessment and risk characterization).⁴⁵

By 2005 the CCFAC document had been discussed, modified, agreed by JECFA and by the full Codex Commission, and incorporated into the Codex *Procedural Manual*. There it is listed as ‘risk analysis principles’, despite the *Procedural Manual* stipulating that what the risk managers should set is a ‘risk assessment policy’, and despite the first draft being known as a ‘risk assessment policy’. CCFAC and JECFA agreed on referring to ‘risk analysis principles’ apparently because neither JECFA nor most members of CCFAC chose to acknowledge that these were issues of ‘policy’, since that would entail that they could legitimately be politically contested. The CCPR document is due to be forwarded for adoption to the Codex Commission in 2007. The CCRVDF document, on the other hand, the most detailed of the three and the only one to include explicit substantive and interpretative guidance, was discussed by JECFA in February 2004; but when JECFA did so, the draft was comprehensively rejected.

JECFA rejects the CCRVDF proposals

JECFA’s rejection of the CCRVDF draft proposals stated:

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 Annex I of the above mentioned draft **discussion paper in its current form requires substantial revision**, which should consider the following issues:

⁴² *Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods*, CX/RVDF 01/9 July 2001

⁴³ Codex Alimentarius Commission, Request for Comment on the Proposed Risk Assessment Policy Statement for the Interaction Between CCFAC and JECFA, CL 2002?_FAC_2002; NB this document is not available on the WorldWideWeb, and cannot be located on the CODEX Website.

⁴⁴ *Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods*, CX/RVDF 01/9 July 2001, p 10 para 53

⁴⁵ op. cit. para 11

- 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 Expert Committee is an independent scientific body that provides advice not only to Codex but also directly to FAO and WHO and to member countries. The risk assessment policy needs to recognize these related but independent roles of the Committee.
- The Committee noted that similar activities are on-going in other Codex Committees (e.g. CCFAC, CCFH, CCPR) and therefore strongly recommends that every effort should be made to harmonise these activities.

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.⁴⁶ (emphases added)

JECFA's February 2004 response to CCRVDF was remarkably undiplomatic in its choice of words. It not only rejected the specific suggestions from CCRVDF, it implicitly repudiated the provisions and premises of the *Codex Procedural Manual*. JECFA explicitly rejected both the form and the content of the guidance that CCRVDF had provided. JECFA did not contest the suggestion that risk assessment consisted of four steps, but insisted that it was for JECFA to decide how those steps were conducted. 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 a risk assessment. JECFA was, in effect, claiming that it was for risk assessors and not risk managers to decide JECFA's rules and standards of procedure and interpretation.

JECFA's response to CCRVDF was noteworthy in several respects. Firstly, while CCRVDF had referred to the role of 'other legitimate factors', to inform the risk assessment policy that it was articulating,⁴⁷ JECFA never referred to those factors, as if they were entirely tangential to JECFA's deliberations and CCRVDF's proposals. Secondly, the *Codex Procedural Manual* does not say that risk assessors can veto the policy guidance provided by risk managers, such as CCRVDF. JECFA's response reads like an attempted veto. Thirdly, the wording of the JECFA response is curiously long-term for a body that has no sustained membership. As Crossley explained (in his report to FAO & WHO entitled *Review of the working procedures of the Joint FAO/WHO Meeting on Pesticides Residues*) the JMPR is an *ad hoc* body that exists for only two weeks of the year (and the same can be said for JECFA too).⁴⁸ Since that JECFA meeting had rejected the guidance provided by CCRVDF, it is unclear why the CCRVDF risk managers did not subsequently request JECFA's FAO/WHO Secretariat only to select for JECFA membership those who would accept the risk assessment policy guid-

⁴⁶ JECFA 62nd Meeting February 2004, Summary report at: <http://www.who.int/ipcs/food/jecfa/summaries/en/Summary62.pdf>

⁴⁷ Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods, CX/RVDF 01/9 July 2001, para 56

⁴⁸ S J Crossley, *Review of the working procedures of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR)*, WHO & FAO, Rome February 2002, page 5

ance that CCRVDF had provided. CCRVDF did not however pursue that option.

Subsequently a less than transparent process of negotiations took place and the positions of both CCRVDF and JECFA shifted noticeably. At a meeting in May 2006, CCRVDF agreed a text that represented a compromise between the two initial positions, but a relatively dilute compromise that omits any reference to issues that have been and remain contentious.⁴⁹ Issues omitted from the eventually agreed text include 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.

Although the CCRVDF document, like the one produced by CCFAC, provides what it terms 'risk analysis principles' rather than 'risk assessment policy', it does refer to risk assessment policy in the context of the discussion of Risk Analysis Principles, and it does so when setting out the risk management responsibilities of CCRVDF. The first element of risk management is referred to as 'preliminary risk management activities'.⁵⁰ Preliminary risk management activities are then portrayed as firstly including: 'establishment of risk assessment policy for the conduct of risk assessments'.⁵¹

The next paragraph states: "The responsibilities of CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in **Risk Assessment Policy** for the Setting of MRLs in Food, established by the Codex Alimentarius Commission."⁵² (emphasis added) In other words, CCRVDF and JECFA have agreed that there can and should be a 'risk assessment policy', but only in respect of JECFA's responsibility for proposing MRLs; not otherwise.

When MRLs are set, they make specific reference to recommended maximum levels of par-

ticular compounds in specific categories of foods. That contrasts with ADIs, which refer solely to the compounds, and not to the foodstuffs that may contain the residues. Setting MRLs therefore involves making judgements about how permitted residues can be apportioned across different categories of foodstuffs, in ways that should ensure that ADIs are not, or only rarely, exceeded. Setting, or proposing, MRLs can therefore depend on industrial considerations that need not arise in relation to ADIs. It is therefore understandable that JECFA and CCRVDF might acknowledge risk assessment policy assumptions are involved in setting MRLs, even if they do not acknowledge any involvement of such issues in setting ADIs.

The CCRVDF document also says: "After approval by the [CAC] of the priority list of veterinary drugs as new work, the CCRVDF forwards it to the JECFA with the qualitative preliminary risk profile as well as **specific guidance on the CCRVDF risk assessment request**."⁵³ (emphasis added) The characteristics of that 'specific guidance...on the risk assessment request' remain unclear, but one plausible interpretation is that rather than providing general risk assessment policy guidance to JECFA, CCRVDF envisages providing a multiplicity of individual risk assessment policies in connection with particular requests and compounds.

CCRVDF indicated procedurally that, when reporting the results of its deliberations JECFA should provide reports that "...clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided."⁵⁴ Moreover CCRVDF indicates that: "JECFA should, if necessary, propose different risk management options...[and]...should present, in its report, different risk management options for CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options."⁵⁵

⁴⁹ ALINORM 06/29/31, Report of the Sixteenth Session Of The Codex Committee on Residues of Veterinary Drugs in Foods, Cancun, Mexico, May 2006, to the CODEX ALIMENTARIUS COMMISSION, Twenty-ninth Session, July 2006, Appendix VIII

⁵⁰ ALINORM 06/29/31, Appendix VIII, page 89, para 8

⁵¹ op cit p. 90 Section 3.1 para 10

⁵² op. cit. p. 90 para 11

⁵³ op cit p 91 para 19

⁵⁴ op cit p. 91 para 20

⁵⁵ op cit p. 91 para 23, cf p 94 para 2(c)

To summarise, despite the explicit requirement from Codex to CCFAC, CCRVDF and CCPR to provide JECFA and JMPR with RAP guidance, that requirement is not being fully met. That failure has come about in part because of a refusal on the part of JECFA and JMPR to accept the RAP guidance initially developed for them. Instead the risk management committees have drafted, and in the case of CCFAC finalised, a text called 'Principles of Risk Analysis' that constitute an attempted retreat to a Red Book decisionist division of labour, with no recognition that scientific representations of risk depend on prior non-scientific assumptions about what states of affairs or changes are to be counted as risks, and which others are to be discounted. Instead they attempt simply to portray JECFA and JMPR as conducting purely scientific risk assessments without relying on any non-scientific assumptions or considerations (eg 'other legitimate factors'), with Codex committees as acting on information from JECFA and JMPR but with no reciprocal input or guidance. The CCFAC, CCPR and CCRVDF texts do however invoke the concept of independence of risk assessors, but without explaining of whom or what they should be independent; they also acknowledge some uncertainties and assumptions. Such guidance as is provided is primarily procedural; substantive risk assessment policies remain implicit. When discussing debates about the relationship between science and policy-making on GM crops and foods in the USA, Jasanoff said that some were trying: "...to return to an imagined prelapsarian state...by rebuilding the walls between science and politics..."⁵⁶ That description could apply equally well to the compromise agreed between CCFAC and JECFA.

In the autumn of 2006 an FAO/WHO draft report was circulated to Codex Member States that was entitled *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries) - Final Draft*

for *Public Comments*. The text included a proposal for "...the provision of explicit documentation of **all procedures, policies and practices**."⁵⁷ (emphasis added) That wording was included in the definitive version that was published in 2007.⁵⁸ If the procedures of all WHO/FAO food safety and nutrition scientific advisory committees were to be explicitly documented, that would substantially contribute to making some procedural aspects of risk assessment policy-making more transparent and potentially accountable. The foreword to that document claims that the report "...describes the principles, practices and procedures currently applied by FAO and WHO for the provision of scientific advice..."⁵⁹ but since for example JECFA and JMPR reports do not "...include explicit recognition of any uncertainty either in the current state of knowledge or in the adequacy of the available data"⁶⁰ the *Framework for the Provision of Scientific Advice on Food Safety and Nutrition* seem in places to be more aspirational than *reportage* (as is evident from the discussion of JECFA's assessment of neotame reviewed in Section 6 of this document, starting on page 73).

The *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition* that was published by WHO and FAO in 2007 represents a significant change from the *status quo ante* because it includes in an Annex a more comprehensive list of documents that provide JECFA and JMPR (as well as the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment and the Joint FAO/WHO Expert Meetings on Pesticide Specifications) with procedural risk assessment policy guidance than had ever previously been published.⁶¹ The question of the extent to which those documents report traditional practices or represent aspirational benchmarks yet to be achieved is beyond the scope of this study but represents an occasion for subsequent research.

⁵⁶ S Jasanoff, *Designs on Nature - Science and Democracy in Europe and the United States*. Princeton: Princeton University Press, 2005, p. 233

⁵⁷ UN FAO & WHO, *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries) - Final Draft for Public Comments*, Rome/Geneva 2006, p. 9, available 27 February 2007 from http://www.fao.org/ag/agn/proscad/index_en.stm as ftp://ftp.fao.org/ag/agn/proscad/framework_en.pdf

⁵⁸ *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition*, WHO/FAO, 2007, available at ftp://ftp.fao.org/ag/agn/proscad/Proscad_Framework_Final_E.pdf

⁵⁹ Op cit p. vi

⁶⁰ Op cit p. 4 para 2.1

⁶¹ Op cit Annex B pp 28-39

USA

In the USA a variety of explicit risk assessment policies, both procedural and substantive, have been established by regulatory agencies and Congress. Even where specific risk assessment policy guidance does not exist, there are several legal statutes, some long-standing, 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 avoid or anticipate 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 proposed rules 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.⁶²

More recently, in 2001, the US Congress passed The Data Quality Act (or DQA), albeit without discussion or debate.⁶³ Weiss described the DQA as the 'nemesis of regulation', while Graham (who was then the head of the OMB Office of Information and Regulatory Affairs) portrayed it as a means of ensuring that the federal government sticks to 'sound science'.⁶⁴ The DQA obliges the Director of the OMB and other federal agencies to: "...provide policy and procedural guidance to Federal agencies for ensuring and maximising the quality, objectivity, utility, and integrity of information..." Irrespective of the contest over the political significance of the DQA, it is evident that the DQA imposes procedural obligations on US government

regulatory agencies such as the FDA and EPA to provide some interpretative RAP guidance to their risk assessors.

Regulatory decisions 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, under a 'formal adjudication' procedure, the courts may overturn any decision not supported by 'substantial evidence'. In making such a judgement, courts may review any of the evidence cited, by drawing on expert witnesses.⁶⁵ This threat of litigation has provided a strong incentive for agencies to adopt consultative procedures, as well as to formalise and routinise 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 assumptions, including inherent extra-scientific and/or non-scientific judgements. According to the US National Research Council's 1983 Red Book 'a single risk-assessment method may not be sufficient' because there may not be only one right way of assessing risks, and so the choice of appropriate assumptions requires interactions between risk assessors and risk managers.⁶⁶ According to subsequent guidance from the US National Research Council in 1997, risk assessors should evaluate the weight of evidence that supports different assumptions or conclusions.⁶⁷ In effect, legislation such as the APA and DQA set procedural risk assessment policy, which in turn generates pressures for some substantive risk assessment issues to be made more explicit that was previously, or would otherwise be, the case; ongoing debates about those issues are thereby engendered.⁶⁸ Most regulatory rule-making processes are regulated by specific statutes that in part provide some substantive RAP guidance on which risks are to be controlled. Since the

⁶² Brickman R, Jasanoff S, Ilgen T, *Controlling chemicals: the politics of regulation in Europe and the US*, Cornell University Press, 1985, p. 88

⁶³ Data Quality Act, Section 515 of the Consolidated Appropriations Act, 2001, Pub.L. 106-554; available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ554.106

⁶⁴ R Weiss, 'Data Quality Law is nemesis of regulation', *Washington Post*, 16 Aug. 2004, p A1

⁶⁵ Brickman R, Jasanoff S, Ilgen T, *Controlling chemicals: the politics of regulation in Europe and the US*, Cornell University Press, 1985, p. 53

⁶⁶ US NRC., 1983, *Risk Assessment in the Federal Government: Managing the Process*, National Research Council, Washington DC, p. 40

⁶⁷ US NRC, 1997, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington, DC: National Academy Press

⁶⁸ There is no single up-to-date authoritative version of US procedural risk assessment policy, although important reference points have been provided by the US National Research Council in 1983 and 1996, the US RC, 1997 and OMB, 2006. US National Research Council, *Understanding risk: Informing decisions in a democratic society*, National Academy Press, Washington, DC, 1997

1980s numerous judicial rulings have obliged agencies to justify regulatory initiatives through risk assessments, especially in quantitative terms, to show that their decisions are not 'arbitrary'; regulatory agencies have internalized those rulings, especially through a reluctance to restrict or delay products.

In addition to the procedural features of US risk assessment policy, stipulated or engendered by statutes, the US authorities have published a series of documents on data requirements for chemicals in food under the title of *Toxicological Principles for the Safety Assessment of Food Ingredients*; the first edition emerged in 1983 and has subsequently been through at least six revisions.⁶⁹ That document, also often referred to as the *FDA Red Book* (as opposed to the US NRC 1983 'Red Book', cf Figure 2, on page 14), provides detailed guidance concerning minimum toxicological data requirements and the ways in which the FDA normally interprets toxicological data, introducing what are referred to as 'default assumptions'. The US Environmental Protection Agency (EPA) has published guidance of a similar type, in respect of putative carcinogens.⁷⁰ To that extent, and in those ways, the US government risk managers are providing some explicit substantive risk assessment policy guidance to risk assessors.

The inference guidelines emerged initially from risk managers but have been, and are, produced through relatively extensive processes of consultation not just with risk assessors but also a wide variety of stakeholders, though the types of stakeholders and nature of involvement varies across sectors. For food toxicology, for example, drafts of the FDA's Red Book have been reviewed by the chemical industry before being finalised and later revised.

There is extensive and detailed guidance on toxicological data requirements for food chemicals, whereas for GM crops no similar guidance has been formalised or codified. In relation to

some GM crops, such as Bt maize, the EPA has indicated some data requirements in specific cases, but that has not been formalised or generalised.

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 judgments 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.⁷¹ 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.

UK

In the UK, in the aftermath of the BSE crisis of March 1996, the Food Standards Agency (FSA) and Office of Science and Technology (OST - headed by the government's Chief Scientific Advisor) have provided explicit procedural risk assessment policy guidance to expert advisory committees, the details of which are provided in subsequent sections.⁷² Those explicit risk assessment policies are almost entirely procedural rather than substantive or interpretative.

The FSA subsequently published in April 2002 a review of the conduct of its scientific advisory committees; its conclusions and recommendation also provided detailed procedural guidance.⁷³ 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 invites interpretation as procedural RAP guidance of the sort called for by the Codex Procedural Manual. The FSA's advice was also developed in open consulta-

⁶⁹ U.S. Food and Drug Administration, *Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food*, (also known as FDA Redbook I), FDA Bureau of Foods 1982; and revisions in 1993, July 2000; Updated October 2001, November 2003, April 2004, February 2006; available at <http://www.cfsan.fda.gov/~redbook/red-toca.html#ftn1>

⁷⁰ US EPA (1996) Proposed guidelines for carcinogenic risk assessment, *Federal Register* 61(79): 17960-18011

⁷¹ S Jasanoff, *The Fifth Branch: science advisors as policy makers*, Harvard University Press, 1990

⁷² OST (2005) *Scientific Analysis in Policy Making*. London: Office of Science and Technology [revision of OST, Scientific Advice and Policy Making, 2000]

⁷³ Food Standards Agency, 2002, *Report on the Review of Scientific Committees*, 15 April 2002, available from <http://www.food.gov.uk/news/newsarchive/58746>

tion with a wide range of stakeholders, unlike the earlier Office of Science and Technology guidance that had no such involvement, except for an opportunity for submitting written comments after the document had been published.

Substantive RAP guidance emerged, for example, when the Committee on Toxicity's subcommittee on Carcinogenicity and the Department of Health published guidance on toxicological data requirements, as well as some guidance on how toxicological data would be interpreted.⁷⁴ In that case, RAP guidance emerged prior to the BSE crisis of March 1996.

In relation to GM crops and foods, ACRE (the Advisory Committee on Releases to the Environment) and DEFRA (the Department for Food and Rural Affairs) have jointly published guidance documents on substantive risk assessment criteria for GM crops, complementing EU-level guidance.⁷⁵ Those elements of substantive RAP, unlike the more general and higher level procedural guidance, have been issued by expert advisory bodies, along with their host departments. In practice such substantive RAP represents the result of joint discussions between risk assessors and risk managers. For example, for GM crops, "...[risk assessment] criteria evolve in a two-way iterative process between advisors and regulators."⁷⁶

The substantive RAP guidance is usually put out for consultation whilst in draft form. This was the case, for example, with the CoT's guidance documents on data requirements and data interpretation.⁷⁷ For GM crops, the 1998 DEFRA decision to extend risk assessment to include the impact of herbicides on farmland biodiversity involved open consultations with a wide range of stakeholders. For GM foods, reference has been

made to European Guidance since 1997, which in turn was set in consultation with all Member States and some stakeholders. The ACNFP also holds open public meetings, approximately once a year, to discuss difficult or new issues and that committee has also included an informal 'public' representative.

Germany

Some procedural risk assessment policy guidance has been published by the new key German risk assessment body, the BfR (although the German authorities do not use the expression 'risk assessment policy', or its German equivalent).⁷⁸ That guidance was developed by BfR staff, i.e. by risk assessors rather than by risk managers or some combination of the two, and then presented to risk managers at BVL, in effect as a *fait accompli*. Stakeholders were almost entirely excluded from establishing that procedural risk assessment policy guidance. General stakeholder involvement at BfR is understood as something that happens after finalising an assessment,⁷⁹ and does not include influencing or involvement in the risk assessment question or process. Occasionally very generic risk assessments of novel or broader issues, such as nanotechnology, are reviewed, and on those rare occasions stakeholders may be invited to participate in a carefully circumscribed deliberative process.

Following the shift of GMO risk assessment responsibilities from the German Federal Environmental Agency (UBA) to the BfN, conflicts between BVL and BfN emerged on contrasting approaches to risk assessment and differences over the conclusions that could be drawn. The response of the Ministry was to impose an Inter-

⁷⁴ COC (1991) *Guidance for the Evaluation of Chemicals for Carcinogenicity*; COC (2004) *Guidance on a Strategy for the Risk Assessment of Chemical Carcinogens* available at <http://www.advisorybodies.doh.gov.uk/coc/guideline04.pdf>

⁷⁵ ACRE & DEFRA (1999) *Commercial Use of GM Crops in the UK: Potential Wider Impact on Farmland Wildlife*; ACRE & DEFRA (2001) *Risk Assessment for Release and Marketing of GMOs in the EU*

⁷⁶ pers. comm. Senior DEFRA official, 2006

⁷⁷ Committee on Toxicity, Draft report of the Working Group on Variation and Uncertainty in Toxicology, Wednesday 12 April 2006 COC (2004) *Guidance on a Strategy for the Risk Assessment of Chemical Carcinogens*; COM (2000) *Guidance on a Strategy for Testing of Chemicals for Mutagenicity*

⁷⁸ BfR 2005: *Guidance Document – The Format for Health Assessment Documents*

⁷⁹ "risk communication work of the Federal Institute is to be understood as an ongoing and interactive process of opening up its assessment work and results to the general public, scientists and other involved or interested circles. Differing views can be presented in the course of this dialogue. [...] another goal of the dialogue should be to determine whether there are differences in the way in which the participants in the dialogue perceive, assess and handle risks. Knowledge and consideration of different values and standards on which this assessment is based, make two things possible: the reaching of a consensus on action options and the identification of dissent. In this way, it will be possible to furnish the responsible offices with the foundations for their decisions on risk management." (BfR on risk communication, <http://www.bfr.bund.de/cd/1834>).

gency Agreement (*Verwaltungs vereinbarung*) providing a procedure to resolve such disagreements, without consulting external stakeholders. The agreement stipulates that, in the event that such differences can not be resolved, the final opinion that the BVL will submit to the EFSA, or to other parties, should include statements of minority opinions.

The German authorities have not explicitly articulated any substantive guidance concerning the scope or limits of the risks to be assessed, and German risk assessors are therefore guided only by EU and other international guidance documents and their own judgements, customs and practices. There are, moreover, inter-institutional differences in the extent to which those guidance documents are acknowledged. For example, the BfN emphasises the guidance on environmental risk assessments provided by the Annexes of Directive 2001/18/EC and Commission Guidance Note while the BfR and the RKI more frequently refer to the EFSA guidance document.⁸⁰ In common with all EU Member States, risk assessors of GM crops and foods in Germany are also covered by guidance from EFSA concerning the minimum scope of risk assessments as well as some aspects of procedures.

Argentina

In Argentina, the authorities have provided no explicit procedural or substantive 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, both of which involve representatives of the regulated industrial sector. Although those members are appointed as experts, rather than as for-

mal representatives of the industrial sector, that process nevertheless 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 Argentina, once a plant GMO has been field tested, the applicant can request that the crop be approved for unconfined, usually large-scale, planting. This procedure, known as ‘flexibilization’, is the second stage of the environmental evaluation and is required prior to full commercial clearance. Resolution 39/03 states that the purpose of the assessment: ‘...aims at determining that the environmental impact of the released GMPO will not significantly differ from that of its non-modified counterpart.’⁸¹ That provides some guidance as to what assessors should do, but the document is quite vague; it does not explain how the term ‘significant’ should be interpreted, nor which environmental impacts should be assessed, nor what kind of agricultural system should provide the comparator for the non-modified counterpart. As RAP guidance goes, it is rather open-ended.

Japan

In Japan, several substantive as well as procedural RAP guidance documents setting out data requirements and data collection methods have been published for legally-mandated risk assessments of GM foods and crops. For GM foods, the principal document is *Standards for the Safety Assessment of Genetically Modified Foods (Seeds Plants)*.⁸² For GM crops, procedural guidance documents include *the Guidance on Implementation of Assessment of Adverse Effects on Biological Diversity of Type 1 Use of Living Modified Organ-*

⁸⁰ COUNCIL DECISION, of 3 October 2002, establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, (2002/811/EC) http://ec.europa.eu/environment/biotechnology/pdf/dec2002_811.pdf; EFSA (2004): European Food Safety Authority: Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. 8 November 2004. The EFSA Journal 99, 1–94.

⁸¹ SAGPyA (2004) Revision of Argentina’s National Biosafety Framework, (Revisión Del Marco Nacional Sobre Bioseguridad En Argentina) UNEP-GEF PROJECT, Sagpya – UNEP – GEF – GF/2716-02-4406, Secretariat of Agriculture, Livestock, Fisheries and Food, Buenos Aires. Available at: <http://www.unep.ch/biosafety/development/Countryreports/ARNBFENVol1.pdf>

⁸² Food Safety Commission Japan. Standards for the Safety Assessment of Genetically Modified Foods (Seeds Plants), Food Safety Commission Decision, 29 January 2004. Along with this one, several documents have been published for assessment of cross-bred GM plants, GM-derived food additives, and feeds and feed additives.

isms⁸³ and the *Application of Approval for the Production and Distribution of GMOs under the Jurisdiction of Minister of Agriculture, Forestry and Fisheries*.⁸⁴ Those guidance documents were issued in early 2000's and replaced previous guidelines.⁸⁵ As in UK, these 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.⁸⁶

In the case of GM foods, these elements of risk assessment policy emerged primarily from the risk assessors, namely the Expert Committee for Genetically Modified Foods (ECGMF) of the FSC. The documents were developed by risk assessors, based on the previous Japanese guideline and relevant international documents (including *the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* of Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology), while also taking account of some public comments.

On the other hand, in the case of GM crops, new RAP guidance documents were developed in the context of adapting legislation to enable the

Japanese government to implement the Cartagena Protocol on Biodiversity. In order to draft those documents relevant ministries, such as the Ministry of Environment (MOE), Ministry of Agriculture, Forestry and Fisheries (MAFF), created their own *ad hoc* advisory committees to consider the new regulatory framework. Among others, MOE's committee outlined substantive RAP issues, concerning the scope and data requirements of risk assessment. Through the deliberations of those committees, and also taking account of the public comments on the draft, these ministries finalised guidance documents as well as a new domestic law to ratify the Cartagena Protocol.

In this *ad hoc* process, however, the advisory committees included not just 'scientists' but also those concerned with broader issues of risk management, their membership included natural scientists, social scientists and stakeholders' representatives. At that stage, moreover, the institutional separation between risk assessors and risk managers had not yet been introduced. It was only after all the guidance documents had been finalized, that the Committee for the Assessment of Adverse Effects on Biodiversity (CAAEB), as an independent risk assessment body for GM crops, was established.

⁸³ Ministry of Environment Japan et al. *Guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 Use of Living Modified Organisms*, Ministry of Environment (MOE), Ministry of Finance (MOF), Ministry of Education, Culture, Sports, Science and Technology (MEXT), Ministry of Health, Labour and Welfare (MHLW), Ministry of Economy, Trade and Industry (METI), Ministry of Agriculture, Forestry and Fisheries (MAFF): http://www.bch.biodic.go.jp/download/en_law/en_assessment_guidance.doc

⁸⁴ Director-General of the Food Safety and Consumers Bureau of MAFF et al. *The Application of Approval for the Production and Distribution of GMOs under the Jurisdiction of Minister of Agriculture, Forestry and Fisheries*, Notification of the Food Safety and Consumers Bureau of Ministry of Agriculture, Forestry and Fisheries (MAFF), No.15-5839; Notification of Director-General of Nature Conservation Bureau of Ministry of Environment (MOE), No.040209002, 9 February 2004.

⁸⁵ Ministry of Health and Welfare (MHW). *Procedure of Application for Safety Assessment on Foods and Food Additives Produced by Recombinant DNA Techniques* (MHW Announcement No.233, 1 May 2000: abolished on 30 June 2003); Ministry of Agriculture, Forestry and Fisheries (MAFF). *Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries* (April 1989: abolished on 18 February 2004).

⁸⁶ For Japanese risk managers, 'risk assessment policy' means more specific guidance to be set out for each case of appraisal and includes concrete information regarding what risk managers want to achieve in their management and relevant designations to risk assessors. The operation of risk assessment policy in this sense is still under development.

■ 4. Procedural aspects of risk assessment policies

This section focuses on more specific questions concerning procedural RAPs: that is, guidance about the processes by which risk assessors are expected to perform their scientific assessments. This discussion covers several issues, such as the way in which scientific assessments should be reported, the relationship between risk assessors and managers, the recruitment and selection of experts and the involvement of broader stakeholders in the assessment process. Both this and the subsequent section are structured by issue, rather than by jurisdiction. This is because the main purpose is to highlight the diverse national approaches to each aspect of RAP, rather than to explain and compare national systems.

Main cross-sectoral and cross-jurisdictional differences

More explicit procedural risk assessment policy guidance has been provided at the global and national levels than either substantive or interpretative RAP guidance.

The USA has numerous statutes that opportunities for litigation, judicial review of Agency decision-making, and judicial case law has explicitly contributed to many aspects of US procedural RAP. In the UK and at Codex, some explicit and detailed procedural guidance has been published, relatively recently, the full implementation of which would constitute a marked shift from traditional practices. Implementation so far remains patchy. By comparison with Codex and the UK, Germany and Japan have recently provided somewhat less comprehensive procedural guidance, concerning for example clarification of uncertainties and interpretative assumptions. No procedural guidance has been provided in Argentina.

Much of the procedural RAP is generic and applies across several sectors. Some countries especially Japan and Germany have some institutional- and sectoral-specific RAP guidance. Procedural guidelines in Germany apply only to some risk assessment bodies not all, and they differ markedly amongst them.

In all the jurisdictions, including the global institutions, except Argentina at least some statements have been published concerning the independence of risk assessors from risk managers, and in some cases from other stakeholders too. Often, what is meant by independence, or indeed what it is that risk assessors are supposed to be independent of, is not clarified. ‘Independence’ sometimes refers to freedom for risk assessors from having the content and/or conclusions of their risk assessments determined by risk managers. On other occasions ‘independence’ is interpreted as a freedom from influence on the scope of risk assessments. In some jurisdictions, risk assessments often result from close discussions between those nominally labelled as ‘risk assessors’ and ‘risk managers’, whose inter-dependencies may not always be transparent. In several jurisdictions, the supposed ‘independence’ of risk assessors is portrayed as guaranteeing scientific integrity.

In Japan, the UK and sometimes in Germany and the USA, but not in Argentina or in the global institutions, official statements have said that risk assessors should not make risk management judgements. In practice, risk assessors in all jurisdictions make at least some risk management judgements, although almost invariably they have done so implicitly rather than explicitly. Published RAP guidance documents often invite risk assessors to advise on selected risk management options. Sometimes advice from risk assessors pre-empts decisions about risk management, while in others risk managers portray their decisions as if they were based solely upon scientific assessments of risks. Key ambiguities concern 1) which kinds of risk management issues risk assessors should avoid, 2) how those issues should be articulated and 3) how the boundary between risk assessors and risk managers should be delineated.

Risk assessors in Codex, the UK, and in some respects in Germany and the USA, but not in Japan or Argentina, have been told to be explicit about scientific uncertainties, although without much detail about which kinds of uncertainties should be made explicit. In practice, the risk assessors that

we have reviewed were only rarely explicit about uncertainties, although some uncertainties are implicit in requests for further data. Risk assessors normally only draw attention to those uncertainties that can be addressed using currently available methods, although occasionally more intractable uncertainties are highlighted.

CCFAC and the UK have told their advisors to make **any/all** assumptions explicit, but in practice only some have been made explicit; many remain implicit and unacknowledged. In Japan there is a requirement to clarify the grounds for judgements in GM crop assessments but in practice only some of those grounds have been made explicit. No similar guidance has been set out in either Germany or Argentina.

The US system has long been subject to an explicit Freedom of Information regime that covers risk assessments, the process by which those assessments were conducted, as well as much of the scientific and technological data on which the assessments are based. The provisions of the UK Freedom of Information Act are more restrictive than those in the USA, though some expert advisory committees hold many of their meetings in public. Proposed guidelines for the FAO/WHO committees envisage continuing with current practice of holding only closed meetings and allowing sponsors to decide whether or not their data enter the public domain. In Argentina almost no information is disclosed by the regulatory authorities.

Over recent years, especially in European contexts such as the UK and Germany, and in Japan too, policy-makers have reiterated commitments to making food safety policy deliberations more open and accountable. In Germany, however, data are usually not disclosed; and the outcomes of some risk assessments remain confidential. In relation to GM foods and crops, German risk assessment procedures are opaque and all meetings are closed.

Opportunities for public and stakeholder involvement in risk assessment have long been extensive in the USA. In Japan there are mechanisms for public and stakeholder comments on draft risk assessments; public meetings are also sometimes held at an early stage in relation to generic issues.

In the UK there are a few formal opportunities for stakeholder and public comments on risk assessment issues. At meetings of the CoT, and its sub-committees, observers may comment but not until after the committee's conclusions have been finalised. In Germany policy-makers have made rhetorical statements about such opportunities but little has been done to facilitate stakeholder engagement in the course of decision-making. The FAO/WHO advisory committees do not explicitly include stakeholder involvement. In Argentina expert advisory committees include members from the industries whose products are being assessed, but other stakeholder groups are excluded.

The UK FSA recently published the report of a joint project with the Royal Society which included the proposal to: "...consult stakeholders and the public (where appropriate) on the framing of questions to be put to expert scientific advisory committees."⁸⁷ If that procedural change were to occur in the UK it would represent a distinct innovation by making substantive risk assessment policy-making more inclusive and transparent.

In the USA, official substantive and interpretative risk assessment policies have long been explicit in relation to food chemical risks, especially carcinogenic risks. Almost no substantive or interpretative RAP guidance has been provided in relation to GM food, for which approval has not routinely been required in the USA. In relation to GM crops, modified to express an insecticide such as Bt, the EPA set a clear policy in the mid-1990s to include impacts on insect resistance in the scope of its official risk assessments. For non-target harm, by contrast, scoping RAP assumptions have been not codified, but have emerged on a case-by-case basis. In Germany and Japan official substantive and interpretative RAPs have not been explicitly articulated in relation to food chemical risks. In Japan, on the other hand in relation to GM foods and crops, some explicit substantive RAP guidance documents have been published. UK and Germany risk assessors routinely refer to official EU guidance, in relation to both food chemicals and GM foods and crops. Those EU documents include some explicit substantive and interpretative RAPs. At the FAO/WHO committees and in Argentina substantive and interpretative

⁸⁷ CoT paper TOX/2006/12, available at <http://www.food.gov.uk/science/ouradvisors/toxicity/cotmeets/cot2006/cotmeeting060328/cotmeeting060328agenda>

RAPs have been conspicuous by their absence, except for minimum data requirements.

All the jurisdictions, as well as the joint FAO/WHO committees, accept unpublished data, but some of them, including the USA, the UK, Germany and Japan, but not either Argentina or the FAO/WHO committees, subsequently place some of the submitted data in the public domain.

The independence of risk assessors: Have explicit assertions been made that risk assessors should be independent of risk managers? In which other ways is the ‘independence’ of risk assessors being interpreted?

In all five jurisdictions, and at the global level, several official statements have been published concerning the ‘independence’ of risk assessors from risk managers and in some cases from other stakeholders too. Often, however, what is actually meant by independence, or indeed what and/or whom it is that risk assessors are supposed to be independent of, is not clearly articulated. Independence sometimes seems to refer to freedom for risk assessors from having the content, or at least the representation of the content, of their assessments shaped, or biased, by political and other non-scientific criteria. The assumption is often, though not always, that all such intrusions on scientific criteria for conducting risk assessments are unwarranted. This is one of the senses in which independence is used in several jurisdictions.

At least two mechanisms to try to ensure such independence can be found. One aspires to ensure the scientific credibility of assessments through mechanisms such as peer review (as in the USA), or by emphasising the fact that assessors are professionally qualified (as in Argentina). In others, independence is portrayed as an institutional rather than individual achievement, based for example on criteria for selecting experts, by reference to their occupational locations (eg academia and public sector institutions) as well as their relevant expertise, or by requiring expert advisors with conflicting institutional or personal interests to excuse themselves from certain deliberations. In

others it may involve locating scientists and policy-makers in different buildings under different forms of institutional management and control.

Codex and WHO/FAO bodies

At the international level, JECFA and JMPR are supposed to be independent of national governments; and occasionally interviewees claimed that they were independent of risk managers in Codex too. Indeed when JECFA rejected the proposed risk assessment policy from CCRVDF, it did so in part by asserting its independence from Codex risk managers. Members of JECFA and JMPR can be, and some often are, industrial consultants; although there are now some requirements for disclosures.

More specific assertions, or rather proposals, about independence have also been made in the draft and final risk assessment policies drawn up by CCFAC and CCRVDF.

CCFAC

A key passage in the first draft of the 2002 CCFAC document refers to conflicts of interest:

JECFA should ensure the independence of its scientific experts from conflicts of interest by ensuring that the selection of experts and advisors to JECFA is conducted in a transparent manner and any commercial interests of its scientific experts are declared.⁸⁸

Those provisions represented a challenge to traditional procedures. JECFA’s secretariat has requested self-nominations from scientific experts, but the ways in which experts are selected remain opaque. At a full meeting of CCFAC, in March 2002 a version of the draft paper was discussed, but it had been significantly diluted.⁸⁹ On the issue of recruitment, selection and independence of members of JECFA from commercial interests, the revised text just said: “JECFA will select scientific experts on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.”⁹⁰ No reference was then made by JECFA

⁸⁸ Codex Alimentarius Commission, Request for Comment on the Proposed Risk Assessment Policy Statement for the Interaction Between CCFAC and JECFA, CL 2002?-FAC_2002, page 4 para 15

⁸⁹ Report of 34th Session of CCFAC, ALINORM 03/12, April 2002 see www.codexalimentarius.net/download/report/28/Al03_12e.pdf

⁹⁰ op. cit. p. 124 para u

to declarations of conflicts of interest, even less to public declarations of conflicts of interest, though since 2006 brief comments on declarations of interests have been included in JECFA reports⁹¹. The term 'independence' was used, without any indication of that from which risk assessors should be independent.

Since 2006 candidates for committee membership should disclose potential conflicts of interest to the WHO/FAO secretariat,⁹² and since then JECFA reports have started to include explicit statements on the absence or presence of conflicts of interest.⁹³ Recent reports suggest that sometimes committee members who have declared a conflict of interest are required to leave the room or remain silent when topics related to their declared interests are discussed.⁹⁴

CCRVDf

The CCRVDf document states:

Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved....⁹⁵

That passage does not say that scientists should be selected in a transparent manner, just that they are. The document also asserts that "JECFA is...responsible for providing independent scientific advice" but no clarity is provided concerning independence from whom or what. As re-

cently as March 2006, JECFA had commented on the draft "Overall it is not clear if the document is describing current procedures, or is describing a way of working that should be achieved in the future."⁹⁶ If it was unclear to JECFA, then it is even less clear to outside observers. Neither JECFA nor CCRVDf then commented on the issue of independence of JECFA from commercial interests; although since 2006 declarations of potential conflicts of interest have been required and reported.⁹⁷

USA

In the USA, the independence of risk assessors (i.e. staff at the FDA and EPA), or rather the independence of their products – the risk assessments – tends to be associated with peer review, rather than as a function of the institutional relationships between risk assessors and risk managers, or between Agency staff and other institutions. As the US Risk Commission has pointed out: "The integrity of a risk assessment is best assured if it is carried out or peer-reviewed independently, for example, by scientists at regulatory agencies, universities and research institutions."⁹⁸ Risk assessors are portrayed as separate, or separable, from policy-making in the US system through assurances of scientific quality, or as the US Office of Management and Budget implies, by virtue of the fact that risk assessment would ideally follow the quality norms of a scientific experiment, such that "...independent reanalysis of the original or supporting data using the same methods would generate similar analytical results."⁹⁹

⁹¹ See eg Evaluation of certain veterinary drug residues in food (Sixty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives) WHO Technical Report Series, No. 939,2006; Evaluation of certain food additives and contaminants (Sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 940, 2007

⁹² Cf: FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries), Rome/Geneva, 2006 para 5.4

⁹³ See eg Evaluation of certain veterinary drug residues in food (Sixty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives) WHO Technical Report Series, No. 939,2006; Evaluation of certain food additives and contaminants (Sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 940, 2007

⁹⁴ Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods, CX/RVDF 01/9 July 2001 p 89 para 7

⁹⁵ Report of 66th Meeting of JECFA, JECFA/66/SC 2006 available at http://whqlibdoc.who.int/publications/2006/9241209399_eng.pdf

⁹⁶ See eg Evaluation of certain veterinary drug residues in food (Sixty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives), WHO Technical Report Series, No. 939,2006; Evaluation of certain food additives and contaminants (Sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 940, 2007

⁹⁷ US Risk Commission, Vol. 1, 1997: 25

⁹⁸ Office of Management and Budget, *Proposed Risk Assessment Bulletin*, March 2006, p. 16

⁹⁹ OST (2005) *Scientific Analysis in Policy Making*. London: Office of Science and Technology [revision of *Scientific Advice and Policy Making*, 2000], p. 7

UK

In the UK, general guidance from the government's Office of Science and Technology places some emphasis on the independence of risk assessors, or rather that fraction of risk assessors who operate as expert advisors, from decision-making and from political considerations. It states that: "Experts should not be expected to take into account potential political reaction to their findings before presenting them."¹⁰⁰ That advice almost certainly reflects experience of BSE regulation in which, with hindsight, expert committees underplayed or misrepresented their assessments of potential risk in order to match their assessment of the political contingencies of policy-making at that time.¹⁰¹

The OST does acknowledge that risk assessors are not entirely independent from risk managers as regards the remit of their deliberations or the kinds of policy options that they should comment on; rather it asks that such choices be made explicit and not confused with scientific decisions. To that extent, the OST guidance to scientific advisory committees acknowledges that their functions and judgements are hybrids of scientific and policy considerations. For food safety specifically, official guidance also emphasises a need for 'independent expert committees', without clarifying from whom or what those committees should be independent.

The OST (recently renamed the Office of Science and Innovation or OSI) also stipulated that all material interests should be disclosed, but that departments may conclude that a conflict of interest will not likely 'undermine the credibility and independence of the advice'.¹⁰² In practice, the relevance of this particular piece of generic advice varies greatly across committees. With respect to GM crops, when the Advisory Committee on Releases to the Environment was reorganised in 1998, there was an explicit policy decision to exclude all potential candidates based in industry or in NGOs. The Food Standards Agency has set a similar policy in relation to the Advisory Committee on Novel Foods and Processes, which still has

a public representative, (appointed as an expert, currently an academic social scientist) as well as members with active relevant commercial interests.¹⁰³ For chemical toxicity there is no general commitment to independence from commercial interests, just declarations of interests.

Germany

In Germany the independence of the BfR, responsible for food risk assessments, is stipulated by statute and includes independence to conduct its own risk communication activities, to set its research agenda, and to manage its own budget. Risk assessors at BfR are also supposed to be independent of risk management considerations. As one civil servant put it, the BfR should pursue their tasks "...even if these tasks are costly and might bring some problematic results out into the open."¹⁰⁴ Claims of independence have not been made for other official institutions with responsibility for risk assessment such as the UBA, BfN and RKI, which are involved in assessing risks from eg pesticides and/or GMOs. Those institutions remain under 'professional supervision' by their respective ministries.

Japan

In Japan, GM risk assessors are said to be 'independent' in three senses: of risk management organizations, of industrial promotion and of interest parties. An example of explicit assertions of the first sense is found in *The Annual Report on Food, Agriculture and Rural Areas in Japan FY 2002* that was published after BSE crisis in 2001:

In the past food safety administration, functions of risk assessment and risk management had not been differentiated in the area of agriculture, forestry, fisheries and others. However, since this new organization [i.e. Food Safety Commission] is required to produce results of objective, scientific risk assessment, independence and competence must be ensured.

¹⁰⁰ Phillips, Bridgeman J & Ferguson-Smith M (2000) *The BSE Inquiry: Report: evidence and supporting papers of the Inquiry into the emergence and identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (vCJD) and the action taken in response to it up to 20 March 1996*, The Stationery Office, London

¹⁰¹ OST (2005) *Scientific Analysis in Policy Making*. London: Office of Science and Technology, p. 5

¹⁰² See <http://www.acnfp.gov.uk/acnfpmembership/acnfpmembersint> as of 22 November 2006

¹⁰³ Interview pers. comm.2005

¹⁰⁴ BSE Investigation Committee. *The Report of BSE Investigation Committee, BSE Investigation Committee*, 2 April, 2002.

An example of a second interpretation of independence first appeared in the 2002 report of the *ad hoc* advisory body set up in response to the BSE crisis.¹⁰⁵ Pointing out the problem of not differentiating 'risk assessment' from 'risk management', it claimed that:

"Radical reform of the *status quo* of Japan is needed. A characteristic common to the recent reform of food safety administrative organizations of EU, France and Germany is that they established independent risk assessment organizations. In particular, separation and independence from organisations responsible for industrial promotion is indispensable."

To achieve effective independence from considerations of industrial promotion, an institutional separation between risk management and industrial promotion was also invoked. This emphasis reflected an acknowledgement that, in the past food, safety policy had often been dominated by business concerns, with responsibility for both sets of considerations located in a single section of the Ministry of Agriculture, Forestry and Fisheries. A break with traditional arrangements was institutionalised when MAFF established the Food Safety and Consumer Affairs Bureau as an independent food safety section.

The third sense of independence was evident in statements asserting that the members of Food Safety Commission (FSC) should only be drawn from scientific experts to ensure scientific objectivity, and the 'purity' of risk assessments. For example, according to a report of the Japanese Consumers' Co-operative Union (JCCU), when it asked the Preparatory Office for the Food Safety Commission to include representatives of consumers and industry to the members of FSC, the Preparatory Office replied as follows:

"We think that the role of Commission is to conduct scientific risk assessment and that it is the place for scientific discussion by experts. 'Representative of ...' is the position of stakeholders and it is undesirable that scientific assessments are influenced by interests. In this

sense, we plan to add an 'expert on consumers' attitude and behaviour' to the members of FSC."¹⁰⁶

This interpretation of independence was embodied in FSC's 2003 decision 'Regarding the Conduct of Research and Deliberation of Food Safety Commission'.¹⁰⁷ It stipulated that committee members have to declare their interests and leave the meeting if, for example, they were an author of an application or contributor to a dossier submitted by an applicant.

Argentina

In Argentina, no explicit assertions have been made about the independence of those responsible for performing assessments of risk. In private, interviewees stressed, however, that there was no external pressure, for example, from ministers, on the hybrid risk assessment/risk management activities performed by the relevant committees and agencies for GM plants and GM foods.

In an analogous way to the USA, there is an implicit assumption that since Argentinean risk assessment activities are nominally purely scientific judgments then they are by definition independent of non-scientific considerations. For example, the Argentine advisory committee for environmental releases of GM plants (known as CONABIA) contains several representatives from the life sciences industry who are represented as performing their duties as technically qualified individuals rather than as representatives of the sectors that employ them. As the Agriculture Ministry puts it "...the main characteristic [of CONABIA] is that its operational proceedings are based on exclusively technical considerations..."¹⁰⁸

Are risk assessors asked not to make risk management judgements? What happens in practice?

The remit of risk assessors, in relation to risk managers, and in particular how the boundary be-

¹⁰⁵ Japanese Consumers' Co-operative Union. "Report of Public Meetings with Preparatory Office for Food Safety Commission", Web CO-OP, December 2002 [in Japanese]: http://www.jccu.coop/web_magazine/back_number/web_2002_12/1tokusyu/index0.html

¹⁰⁶ Food Safety Commission Japan. "Regarding the Conduct of Research and Deliberation of Food Safety Commission", Food Safety Commission Japan Decision, 2 October 2003 (amended on 13 November 2003).

¹⁰⁷ SAGPyA, 2004, 35

¹⁰⁸ US EPA (2006) *Environmental risk assessment for modified Cry3A Bt protein for MIR604 corn*

tween what risk assessors are seen as responsible for, and what risk managers are supposed to do, is an important variable. Most jurisdictions that articulate risk policy-making in accordance with either decisionist or transparent models (cf Figures 2 and 3 above pp. 14-15) make statements implying that risk assessors should not make risk management judgements.

There are many different kinds of risk management judgements, some relatively obvious 'downstream' issues, such as whether or not to grant approval to a product. Other risk management issues are less obvious, and some RAP issues arise 'upstream', for example concerning particular assumptions about what to count as 'harm' or 'good manufacturing practice'. There will probably always be at least some risk management judgements that are, in effect, made by or assumed by risk assessors. One key issue concerns: which kinds of risk management decisions risk assessors should avoid taking? That might be more appropriate than stipulating that risk assessors should never make any assumptions about risk management, but few jurisdictions are set out to locate the boundary, and interdependency between risk assessors and risk managers at such a level of detail.

An important distinction is sometimes drawn between risk assessors deciding regulatory issue on the one hand, and risk assessors commenting on potentially relevant risk management options, judgements and decisions on the other. Those alternatives are clearly different; the latter can perhaps best be understood as scientists helping to clarify the kinds of decisions that risk managers are expected to take, while in the former case their might be portrayed as prejudging decisions that risk managers would otherwise be expected to take.

USA

In the USA, EPA risk assessors have sometimes commented on risk management issues about Bt crops when providing advice, as have advisors from the EPA's Scientific Advisory Panel. Thus, for

non-target harm, EPA assessors have proposed monitoring requirements in parallel with commercial use, for example proposing a three-year study "...to evaluate insecticidal protein degradation, accumulation and persistence in a variety of soil types."¹⁰⁹ As a rationale, the agency cited methodological limitations of the available studies, but nevertheless risk assessors were then advising on a risk management issue. In part this example illustrates the difficulty of separating risk issues into components that are unambiguously scientific and those that are clearly policy-related.

UK

UK RAP guidance from the Food Standards Agency to its scientific advisory committee notes that: "While committees are not responsible for risk management, it may often be appropriate to ask them for scientific advice on options for risk management."¹¹⁰ As noted above, such a practice, if followed, ought to inform risk managers as they make policy decisions rather than making those decisions for them; in those conditions, risk assessors would not be taking responsibility for risk management decisions. Less clear, however, might be a practice in which risk assessors comment on risk management issues, without formally taking responsibility for them, but where those comments are not confined to indicating what is known and not known about the risks associated with those management options, but become instead actively prescriptive.

Risk assessors sometimes specify or assume conditions under which their advice would apply, but this is not so much a risk management judgement as an acknowledgment that risk assessments are rarely about determinately controlled phenomenon, but rather about risks that in practice depend on a variety of factors that in the real world are conditional and contingent on broader political, institutional and social processes. Thus, for example, risk assessment advice in relation to the impact on biodiversity of certain GM crops was contingent upon implicit assumptions, for example that farmers will spray

¹⁰⁹ FSA, 2005: 26

¹¹⁰ *FAO/WHO draft framework for the provision of scientific advice on food safety and nutrition*, Rome/Geneva, 2006, p 4; *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition*, WHO/FAO, 2007, available at http://ftp.fao.org/ag/agn/proscad/Proscad_Framework_Final_E.pdf

their GM crops in the ways that occurred during the Farm Scale Evaluations, and not in significantly different ways. For imports of GM rape-seed into the UK, ACRE proposed a requirement for monitoring to deal with the possibility of 'seed spillage', which implies that ACRE sometimes chose to assess a relatively broad set of risk, taking into account both herbicide use and issues of segregation.

Codex

At the international level, the FAO/WHO expert committees do not formally make risk management decisions, those are supposed to be taken by Codex Committees. The risk assessors do make risk management judgements, however, for example in setting ADIs, or 'acceptable daily intakes'. ADIs are the standard concept in terms of which the results of animal toxicology tests are interpreted for regulatory purposes of consumer protection. Although the concept of an ADI superficially resembles a scientific concept, since it is frequently applied quantitatively and measured in units of milligrams of dose per kilogramme of body weight of the recipient, its application involves judgements of 'acceptability'. Ascribing an ADI to a compound is an evaluative judgement about levels of exposure at which risks are acceptably low; decisions to use ADIs, and the ways in which they are used, involve issues of risk assessment policy. For example, it is a matter of policy to choose just to set ADIs for entire human populations or whether also to set additional ADIs for sub-populations, such as children, infants or immuno-suppressed individuals who may be more susceptible to chemical risks than an average healthy adult. The 2006 draft *WHO/FAO framework for the provision of scientific advice on food safety and nutrition* assumed that setting ADIs is a purely scientific judgement, and so too did the definitive 2007 version of that document, but that remains a problematic assumption.¹¹¹

CCPR has provided itself and JMPR with some procedural guidance to the effects that: "When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option."¹¹² That implies that, when asked by CCPR, JMPR should provide conditional rather than prescriptive advice which might, if followed, help risk managers exercise their judgements.

Japan

In Japan there is a shared acknowledgement that GM food risk assessors are not to take responsibility for risk management judgements, and they have restricted themselves to producing scientific conclusions of risk assessment. In fact, the distinction between risk assessment and risk management has been often invoked in the deliberations of the Expert Committee for GM foods (ECGMF). A typical example is the case of Bt10 maize, where risk managers asked the ECGMF to evaluate the validity of setting a provisional permissible standard for contamination of human foods and animal feedstuff with Bt10. In response, an expert on the ECGMF insisted that such decisions should be taken by risk managers not by risk assessors.

On the other hand, in other FSC committees such as those for chemical contaminants, pesticides and food additives, risk assessors are asked to take responsibility for setting ADIs, which involve evaluative judgments that should be under the responsibility of risk managers. In addition, the Food Safety Basic Law stipulates that the FSC shall take charge of making recommendations in relation to risk management.¹¹³

In relation to GM crops, making risk management judgements is, in principle, not the responsibility of risk assessors in the CAAEB, but they also sometimes give prescriptive advice on monitoring when faced with uncertainties. The

¹¹¹ PROPOSED DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES, Appendix 1 of *RISK ANALYSIS POLICIES USED BY THE COMMITTEE IN ESTABLISHING MRLS FOR PESTICIDES*, CX/PR 05/37/8, March 2005, para 17

¹¹² The Article 23 (3) of the Food Safety Basic Law stipulates that the FSC shall take charge of making "recommendations to related ministers through the Prime Minister about policies to be implemented for ensuring food safety on the basis of the results of the assessment of the effect of food on health, which was conducted in accordance with the provisions of the preceding item".
Director-General of the Food Safety and Consumers Bureau of MAFF et al, cf footnote 80

¹¹³ BfR 2005, Guidance for Health Assessment Documents, p. 11

explicit guideline, *the Application of Approval for the Production and Distribution of GMOs under the Jurisdiction of Minister of Agriculture, Forestry and Fisheries*, stipulates that risk assessors can request applicants to submit a monitoring plan when necessary.¹¹⁴ In fact, the CAAEB requested monitoring for several varieties of Bt maize including MON810, MON863, MON810 x MON863.

Germany

Risk assessors at the German Federal Institute for Risk Assessment (BfR) are supposed not to consider risk management issues in their deliberations, based on advice issued from the BfR itself. However, that advice suggests that the BfR may indicate the scope for possible regulatory actions, including targets, strategies and options, although it should not constrain the BVL (Federal Agency for Consumer Protection and Food Safety) "...to a single set of measures unless there is an urgent need to do so."¹¹⁵ In other words the BVL should be able to choose between various risk management options even if the BfR had made risk management policy judgements concerning the range of options that were available. One interviewee noted that when the links between the BfR and BVL were being designed it was envisaged that risk assessors could not only make requests for further data, and decisions about when a risk assessment was complete, but that they should fulfil several functions that are often considered part of the remit of risk managers; such as recommendations about monitoring and proposals on whether or not to authorise particular products.

Argentina

In Argentina there is no requirement on the part of risk assessors to avoid taking risk management decisions. In practice, the committees that provide assessments of GM crops and foods are formally responsible for both scientific and policy aspects of decision-making, although as noted previously no explicit distinction is made between those two roles. Nominally, the committees do not

make formal decisions about approval, however. That role is taken by ministers acting on the advice of the committees but it is rare for Ministers not to follow that advice.

To what extent have risk assessors been asked to be explicit about scientific uncertainties, and how explicit are they in practice? Consistently or selectively?

The question of the extent to which risk assessors have been asked to be, and are being, explicit about uncertainties is especially important, partly because if key uncertainties are not made explicit risk managers are unlikely to be able to appreciate the relative fragility or robustness of scientific assessments. Consequently they may not appreciate the scope for exercising precaution. There are, however, so many different sources and types of uncertainties that it would almost certainly be impossible to be explicit about all uncertainties. In practice, as some commentators have pointed out, expert advisors may only emphasise the types of uncertainties that current research methods could readily allow them to address, but not to the more complex, subtle or challenging ones. Advisors and regulatory institutions can also be selective in other ways about the kinds of uncertainties that are acknowledged; for example, by being explicit about those uncertainties that have been resolved (as well as those that could readily be resolved) while not being explicit about qualifications to an overall judgement, or by acknowledging only those uncertainties that provide a rationale for not doing what a policy institution doesn't choose to do.

Despite those complexities, policy guidance about uncertainties rarely moves beyond general statements about making uncertainties explicit; although not all jurisdictions provide such guidance. In our study, risk assessors and/or expert advisors in the UK, Germany and in Codex have been asked to be explicit about scientific uncertainties, although without any further qualification, but not in Japan or Argentina. In practice, however, risk assessors have fallen considerably short of formal expectations.

¹¹⁴ www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf

¹¹⁵ Carrington, C. and Bolger, P.M. (1998) 'Uncertainty and risk assessment', *Human and Ecological Risk Assessment* 4(2): 253-57

USA

In March 2006 the US Federal government's Office of Management and Budget issued a *Proposed Risk Assessment Bulletin*.¹¹⁶ In what it calls 'new technical guidance on risk assessments' the OMB proposed that all risk assessment bodies should be obliged to acknowledge all uncertainties, while also seeking to quantify the extent of those uncertainties. Indeed, in practice, US risk assessors tend to focus on quantifiable rather than unquantifiable uncertainties. As two FDA risk assessors put it in 1998: "It is necessary to quantify uncertainties to convey them to the risk manager".¹¹⁷

UK

In the UK, guidelines for expert committees have emerged as a specific response to the BSE crisis, in the wake of which it became clear, amongst other things, that risk assessments had sometimes failed to draw attention to key uncertainties and had often depended upon implicit assumptions about risk management.¹¹⁸ In response, official guidance now requires an explicit account of uncertainty. Thus, the OST stated in 2000 that: "Departments should ensure that levels of uncertainty are explicitly identified and communicated directly in plain language to decision makers."¹¹⁹ The FSA Board has also stated that, for expert committees, an audit trail, "...showing how the committee reached its decisions..." will be required.¹²⁰ It adds 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."¹²¹ In practice, however, advisors rarely make explicit statements about scientific 'uncertainty', and not when mak-

ing safety claims, which are typically unqualified and unconditional.

Requests for additional data, especially when advisors are not yet ready to give advice, imply judgements about uncertainty, though without necessarily or always indicating the stakes involved, e.g. specific risks to be clarified and specific criteria for data that could clarify them. For GM crop cultivation, committee advice on risk-management measures sometimes explains uncertainties that warrant RM measures; but sometimes the rationale remains ambiguous, e.g. as a means to gain extra information for longer-term assessments of risks.

The FSA guidance also stipulated that: "Chairs of advisory committees ...[should ensure]...that **no view is ignored or overlooked**, and that **unorthodox and contrary scientific views are considered**...[and should ensure] that the proceedings of the committee, if necessary including minority opinions, are properly documented...so that there is **a clear audit trail showing how the committee reached its decisions**...We recommend that committee decisions should include an **explanation of where differences of opinions have arisen** during discussions and why conclusions have been reached, even if alternative opinions were expressed. They should also explain **any assumptions and uncertainties** that are inherent in their conclusions..."¹²² (emphases added) That guidance is not, however, yet being fully complied with.

Germany

In Germany, the BfR's own guidance requires that its risk assessors acknowledge certain uncertainties explicitly and indicate how they influence results of risk assessments. It states, for example, that uncertainties should be acknowledged 'where there is discernable lack of knowledge' and 'where

¹¹⁶ Phillips, Bridgeman J & Ferguson-Smith M (2000) *The BSE Inquiry: Report: evidence and supporting papers of the Inquiry into the emergence and identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (vCJD) and the action taken in response to it up to 20 March 1996*, The Stationery Office, London; E Millstone and P van Zwanenberg, 'The politics of expert advice: lessons from the early history of the BSE saga', *Science and Public Policy*, Vol. 28, No. 2, April 2001, pp. 99-112

¹¹⁷ OST (2005) *Scientific Analysis in Policy Making*. London: Office of Science and Technology, p. 7

¹¹⁸ FSA (2002) Report on the Review of Scientific Committees. London: Food Standards Agency, p. 22

¹¹⁹ op. cit. p. 25

¹²⁰ op. cit. paras 88-89

¹²¹ BfR 2002: Updating the risk assessment of acrylamide in foods. Opinion of BfR of 28 November 2002, BgVV - Expert talks on the occurrence of acrylamide in foods; available at <http://www.bfr.bund.de/cms5w/sixcms/detail.php/1425>

¹²² ibid

any necessary quality requirements have been ignored in studies' and that risk assessments should report on 'the extent of inadequacy of data submitted to the BfR' and 'the gaps in knowledge which may arise as a result'. In practice, however, it appears that uncertainties are only rarely and selectively made explicit. For non-threshold toxicology, BfR opinions acknowledge some uncertainties that could be overcome by further work, e.g. in the case of acrylamide, and statements by BgVV/BfR with respect to data on dietary intakes.¹²³ Uncertainties have also been acknowledged with respect to genotoxic carcinogens in general, as regards extrapolation from high doses to low doses.¹²³

For GMOs, the BfN highlights uncertainties but other groups of risk assessors do not even mention the word uncertainty.¹²³ The BfN's numerous requests for further information, including additional testing, are in some cases explicitly justified by reference to uncertainties, but for the most part the BfN is implicitly drawing on uncertainties that cannot be accommodated by the particular designs, approaches or results of tests conducted.

Codex

Within Codex, guidance given to JECFA and JMPR by the Codex Committees on Food Additives and Pesticides (in the form of draft risk assessment policies) did refer to uncertainties. For example, the CCFAC draft proposed that:

"In its risk assessments, JECFA will communicate to CCFAC the level and type of uncertainty, where the uncertainty arose during the risk assessment process, and the impact of the uncertainty... A clear understanding of the level of uncertainty associated with the risk assessment is essential for

ensuring transparent, science-based risk management decisions."¹²⁶

At the subsequent full meeting of CCFAC, in March 2002, a version of that draft paper was discussed, but it had been significantly diluted.¹²⁷ In relation to 'uncertainties' the revised CCFAC draft said: "JECFA will communicate to CCFAC the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA will provide CCFAC a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment... JECFA will communicate to CCFAC the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties."¹²⁸ That passage does not say that JECFA should draw attention to any and all uncertainties. On the contrary it could be interpreted as implying that uncertainties should be highlighted only if their magnitude can be quantitatively estimated. In practice, JECFA has however continued to report only a few uncertainties, and to do so unevenly and inconsistently.¹²⁹

The draft 2006 *FAO/WHO framework for the provision of scientific advice on food safety and nutrition* asserted that the FAO/WHO defined scientific advice, of the sort the FAO and WHO presumed to be routinely received from eg JECFA and JMPR, was advice that "...include[s] explicit recognition of **any** uncertainty either in the current state of knowledge or in the adequacy of the available data."¹³⁰ (emphasis added) That wording was also included in the definitive 2007 version of that document.¹³¹ The evidence reported in this document implies that explicit recognition is given to only relatively few of the uncertainties.

¹²³ The BfN provides risk assessment advice to the BVL with a particular focus on risk to the environment including higher animals.

¹²⁴ Codex Alimentarius Commission, *Request for Comment on the Proposed Risk Assessment Policy Statement for the Interaction Between CCFAC and JECFA, CL 2002?_FAC_2002* page 6 para 28

¹²⁵ Report of 34th Session of CCFAC, ALINORM 03/12, April 2002 see www.codexalimentarius.net/download/report/28/Al03_12e.pdf

¹²⁶ op. cit. p. 125 paras dd-ee

¹²⁷ See discussion on Neotame later in this document; JECFA, *Food Additive Series*, 54, 2004

¹²⁸ *FAO/WHO framework for the provision of scientific advice on food safety and nutrition* 2006, p. 3

¹²⁹ *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition*, WHO/FAO, 2007, available at [ftp://ftp.fao.org/ag/agn/proscad/Proscad_Framework_Final_E.pdf](http://ftp.fao.org/ag/agn/proscad/Proscad_Framework_Final_E.pdf)

¹³⁰ According to applicant's dossiers, there is a possibility that Cry35 broadens the holes that Cry34 created on intestinal cells of target insects. Basic questions were 1) what the causal mechanism of this synergy is and 2) whether this synergy is unique to this specific combination of proteins. Risk assessors were afraid that unless the synergetic behaviour of Cry35Ab1 is specific to its combination with Cry34Ab1, it might cause adverse effects on human health.

¹³¹ Committee for the Assessment of Adverse Effects on Biodiversity, *Minute of 5th Meeting of General Committee of Committee for the Assessment of Adverse Effects on Biodiversity*, 28 May 2004, p. 7

Japan

In Japan in relation to GM foods, as well as most other food safety issues, risk assessors have not been asked to be explicit about scientific uncertainties, but in practice published minutes of the ECGMF indicate that risk assessors have held extensive discussions about various uncertainties and repeatedly requested additional data from applicants. One example is the case of a Coleoptera-resistant and glufosinate-tolerant maize. It took six ECGMF meetings, from June 2004 to August 2005, to finalize its assessment. One of persistent issues was the uncertainty about the mechanism of synergistic action of two proteins, Cry34Ab1 and Cry35Ab1, which are produced by the inserted genes.¹³² Following lengthy deliberations, exchange of opinions between the ECGMF and the Du Pont and the submission of new data, an initial conjecture was rejected and replaced by a new plausible explanation that the target insect (western corn root worm) has specific receptors for Cry34Ab1 and Cry35Ab1. The ECGMF accepted that account and concluded that the product did not pose a risk to human health.

In spite of extensive arguments and deliberations, Japanese risk assessors have rarely described uncertainties in their final assessment reports. This is largely because they share a tacit convention that they should produce clear-cut conclusions indicating that products are either safe or not safe, after resolving all relevant uncertainties. Only occasionally would they conclude that they couldn't resolve some uncertainties and report them to risk managers who can take them into consideration. In the case of Bt10, the ECGMF concluded in its final report that it was difficult to complete risk assessment because it couldn't resolve uncertainties in terms of fragmentation and relocation of inserted genes and the determination of DNA sequence of those genes and their neighbourhood.

Also for GM crops, risk assessors have not been required to be explicit about uncertainties, but there is a tacit convention in the Crops Subcommittee of the CAAEB that its conclusions should be based on unanimity among its members.¹³³ To this end, where there are uncertainties, the committee tries to resolve them and reach consensus by collecting additional scientific information from the applicants or other sources. If the committee cannot resolve the issues, it notifies the General Committee of that uncertainty. The same applies to the General Committee, where several of uncertainties have been scrutinized and sometimes publicly reported to risk managers so that they could consider taking precautionary measures. The most repeatedly cited uncertainties concern the possibility of 1) horizontal gene transfer by viruses when the transferred DNAs derived from a viral source 2) adverse effects of Bt toxin on soil organisms when GM plant residues are incorporated into soils and 3) evolution of Bt-resistant pests. For all of those uncertainties, additional information and monitoring has been requested of the applicants.

Although uncertainty is often an important issue for the risk assessors of GM crops and the evolution of discussions is publicly accessible through the committee minutes, not all uncertainties are deemed to deserve special attention. Some speculative uncertainties are discounted as not requiring an immediate response, but as grounds for passive precautionary measures such as monitoring and preparing emergency preventive plans.¹³⁴ In addition, more tacitly, scientific advisors distinguish between 'what it would be nice to know' and 'what we need to know'.¹³⁵

Argentina

In Argentina, too, risk assessors have not received any guidance on how uncertainties should

¹³² An example for highly speculative uncertainty is the possibility of adverse effects of Bt toxin on non-target species whose ecological behaviour, or existence as such, is unknown or little known.

¹³³ When a member of the General Committee of CAAEB raised a question about the possibility of cross breeding between GM Erect-leaved semidwarf rice (Ø OsBR11, *Oryza sativa* L.) and wild plants belonging not to genus *Oryza* but to the same family as *Oryza* (i.e. Gramineae), another member claimed as follows: "It is often claimed in scientific argument that we need to distinguish between 'nice to know' and 'need to know'. Even if it is nice to know about that information from the point of view of biodiversity, it doesn't mean, from past experience, that it is indispensable for evaluating effects on biodiversity. Therefore, I think, while it is reasonable that we take it into consideration because it is nice to know, it is a logical leap that we have to confirm its safety beyond the knowledge we have accumulated so much about *Oryza*". See: Committee for the Assessment of Adverse Effects on Biodiversity "Minute of 3th Meeting of General Committee of Committee for the Assessment of Adverse Effects on Biodiversity", 15 March 2004, p.16.

¹³⁴ Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants, CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups, in *Codex Alimentarius Procedural Manual*, para 35

¹³⁵ *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition*, WHO/FAO, 2007, p 22 para 6.1

be reported and handled in risk assessments. Since, however, risk assessors sometimes ask for further data, this constitutes evidence that at least some data gaps and/or uncertainties are recognised. However, as almost nothing is published by the regulatory regime about the outcome of risk assessments we do not know how explicit risk assessors are about uncertainties in practice.

To what extent have risk assessors been asked to be explicit about the scientific and other assumptions by reference to which data are interpreted, and how explicit are they being in practice?

The focus of this section concerns the extent to which risk assessors have been told by risk managers to be explicit about assumptions by reference to which data are interpreted. These assumptions may be concerned, for example, with scientists' understandings about which changes count as 'harm', and when cause-effect relationships are indicated and established, i.e. how much of which kinds of evidence is variously necessary to indicate such links and sufficient to establish a causal connection. The assumptions may concern when and how to extrapolate from experimental models, such as laboratory animals or computer models of the structure and activity of chemicals, to likely effects on humans or agricultural animals. Other types of assumptions might be less scientific, and be concerned for example with how agricultural employees handle, prepare and apply pesticides. They might also concern the range of policy options available to, and deemed appropriate by, risk managers.

Codex

Prior to drafting a risk assessment policy, Codex did not require that its expert committees make explicit any of their assumptions, scientific or otherwise. The draft RAPs, however, marked a significant change. The CCFAC document on Risk Analysis Principles says "JECFA should communicate to CCFAC the basis for **all assumptions** used in its risk assessments including default assumptions

used to account for uncertainties."¹³⁶ (emphasis added) That provision did not however survive the subsequent process of amendment. Nonetheless the 2007 WHO/FAO *Framework for the Provision of Scientific Advice on Food Safety and Nutrition* does contain guidance indicating that reports of all expert bodies should include: "...an explanation of the reliability of the data and *assumptions* made (and their impact on uncertainty)..."¹³⁷

UK

In the wake of the BSE debacle, official guidance is quite clear about the need for assumptions that influence the interpretation of data to be made explicit by expert advisors. Thus, the FSA requires that: "Chairs of advisory committees ... [should ensure]...that no view is ignored or overlooked, and that unorthodox and contrary scientific views are considered...[and should ensure] that the proceedings of the committee, if necessary including minority opinions, are properly documented...so that there is **a clear audit trail showing how the committee reached its decisions**...We recommend that committee decisions should include an **explanation of where differences of opinions have arisen** during discussions and why conclusions have been reached, even if alternative opinions were expressed. They should also explain **any assumptions** and uncertainties that are inherent in their conclusions..."¹³⁸ (emphases added) Despite those requirements, however, the practices of ACRE, ACNFP and CoT do not match those guidelines, insofar as they rarely explain assumptions that might be tested or reviewed later.

USA

Regardless of specific guidance for risk assessment, scientific assumptions tend to become explicit through statutory procedures and/or anticipation of legal challenge, as noted previously in section 3.1. For example, explicit default assumptions for carcinogenicity assessments have been devised so that regulatory agencies can claim that they are not being 'arbitrary' in their treatment of particular chemicals.

¹³⁶ op cit paras 88-89

¹³⁷ BfR 2005: Guidance Document – The Format for Health Assessment Documents, p. 7.

¹³⁸ No explicit guidance on uncertainty has been provided to BBA, RKI, BfN.

Germany

BfR generic guidance does not explicitly mention assumptions but provides guidance that can be interpreted as covering assumptions. Risk assessments should report "...where any opposing scientific views that may be relevant have been presented and where different interpretations in international assessment systems, e.g. of rules for classification and labelling, may influence the results."¹³⁹

BfR practice in GMO risk assessment has not however complied with that guidance, neither do other institutions involved in risk assessments specify their assumptions.¹⁴⁰ Only very general assumptions for genotoxic carcinogens are made explicit by risk assessors.¹⁴¹ For example, when mentioning that in relation to suspected genotoxic carcinogens no threshold can be assumed and therefore the application of ALARA will be the only available approach.

Japan

In Japan, with regard to GM foods, there is no definite stipulation demanding risk assessors to be explicit about their assumptions, but in practice some of data requirements virtually require the applicants and risk assessors at the Food Safety Commission to clarify some of the assumptions on which they base their risk estimates and judgements. An interesting example concerns assumptions about estimating the daily intakes of proteins expressed by the inserted genes. The minutes of ECGMF committee's meetings indicate that the acceptability of those assumptions have been frequently discussed by those risk assessors.

On the other hand, with the environmental risk/safety of cultivating GM crops, while the term 'assumptions' is not used, there is a generic stipulation in guidance document requiring risk assessors to record and clarify the grounds for their judgements.¹⁴² Additionally, some of data requirements, such as those concerning productivity

of harmful substances, explicitly require clarifying the assumptions on which estimates of the likelihood of adverse effects on biodiversity are based. In connection with those matters, each risk assessment report has included an account of the relevant assumptions used to model and estimate the maximum distance of pollen flow.

Argentina

Argentinean policy officials have not made any formal demands on their expert advisors with respect to making assumptions explicit. In practice the extent to which any such assumptions are in fact made clear is unknown because the advice provided by expert advisors to the Argentinean government is not publicly available.

Transparency and relations to stakeholders

The final aspect of procedural risk assessment policy concerns transparency and relations with stakeholders. Transparency can variously refer to the risk assessment itself, the process by which that risk assessment was produced, and the data upon which the assessment was based. Transparency is important not least because moves to greater transparency often entail that issues of substance get raised and critically addressed, where previously they might have remained implicit and unnoticed, especially by those outside of the regulatory regime. Thus procedural change may contribute to substantive and interpretative changes.

USA

The USA has operated with a Freedom of Information Act since the 1970s. That regime involves the disclosure not just of risk assessments, but the process by which those assessments were conducted, as well as much of the scientific and technological data on which the assessments are based. Opportunities for public and stakeholder involvement in risk assessment have also long been extensive in the USA.

¹³⁹ e.g. BfR 2002b: Updating the risk assessment of acrylamide in foods. Opinion of BfR of 28 November 2002; , BfR 2003d: Assessment of acrylamide intake from foods containing high acrylamide levels in Germany. Abbreviated version of a BfR study from 15 July 2003.

¹⁴⁰ Japan MOE et al. The Guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 Use of Living Modified Organisms, p.6: http://www.bch.biodic.go.jp/download/en_law/en_assessment_guidance.doc

¹⁴¹ Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods, CX/RVDF 01/9 July 2001 ftp://ftp.fao.org/codex/ccrvdf13/rv01_09e.pdf Appendix IX, p 94 para 3

¹⁴² Food Standards Agency, 2002, Report on the Review of Scientific Committees, paras 64-65

Codex

A key provision in CCRVDF's proposed guidance to JECFA referred to what was there called 'Data Protection' saying: "Considering the importance of intellectual property in the context of data submission for scientific evaluation, JECFA has established procedures to cover the confidentiality of certain data submitted. These procedures enable the sponsor to declare which data...[are]...to be considered as confidential. The procedure includes a formal consultation with the sponsor."¹⁴³ No such provision is included in the CCFAC guidance to JECFA or in the CCPR's guidance to JMPR. This text from CCRVDF indicates that commercial and industrial sponsors have the freedom to decide which of their data will remain confidential, and which may enter the public domain. It is not clear how that provision can be reconciled with commitments to transparency. The FAO/WHO advisory committees do not explicitly include stakeholder involvement.

UK

In the UK in recent years, policy-makers have made commitments to making food-safety policy-making more open, transparent and accountable. For example, the FSA have said that: "...data used as the basis for risk assessments and other committee opinions should be made freely available, within the constraints of confidentiality...at as early a stage in the process as possible... Whenever time permits committees should issue a draft opinion for public consultation before offering their final advice."¹⁴⁴

On the crucial issue of 'confidentiality' the FSA recommends: "...that each committee should have clear guidelines to define what material can justifiably be regarded as confidential..."¹⁴⁵ It is not clear why the FSA Board recommended that each advisory committee should decide for itself which data it will treat as confidential rather than observing an agency-wide policy of full disclosure in the public interest.

Some expert advisory committees in the UK now hold many of their meetings in public. Other than those open meetings, however, there are few formal opportunities for stakeholder and public comments on risk assessment issues. The UK FSA recently published the report of a joint project with the Royal Society which included the proposal to: "...consult stakeholders and the public (where appropriate) on the framing of questions to be put to expert scientific advisory committees"¹⁴⁶ If that procedural change were to occur in the UK it would represent a distinct innovation.

Japan

In Japanese food safety policy-making, transparency and stakeholders involvement has been considerably enhanced in recent years. It occurred partly because of serious decline of public trust in food safety governance caused by the BSE crisis of 2001 and partly because of overall governmental reforms since the late 1990's. In the process of the developing RAP guidance documents for both GM foods and crops, there were formal mechanisms for providing some transparency and public/stakeholders involvement. In developing the guidance documents for assessing the risks of GM foods, committee meetings were open to the public and public comments were invited on draft documents via the FSC's websites and other means. Public meetings were also held prior to and during the deliberation. The approach was similar during the preparation of guidance documents for assessing the risks of cultivating GM crops, except that public/stakeholders meetings were not held. Instead, some stakeholders' representatives were included in the advisory committees which drafted the guidance documents.

In the routine operation of risk assessment of GM foods and crops, all minutes of the committee meetings and risk assessment reports, as well as all the guidance documents, are publicly available on the website of the Food Safety Commission (for GM foods) or the Japan Biosafety Clearing House (for GM crops), with the exception for confidentiality of

¹⁴³ op. cit. para 68

¹⁴⁴ CoT paper TOX/2006/12, available at <http://www.food.gov.uk/science/ouradvisors/toxicity/cotmeets/cot2006/cotmeeting060328/cotmeeting060328agenda>

¹⁴⁵ See BfR's self portrayal on its website at: <http://www.bfr.bund.de/cd/572>

¹⁴⁶ <http://www.bfr.bund.de/cd/1834>

sections concerning data deemed to be 'private intellectual property'. On the other hand, as regards disclosing data used in risk assessments of GM foods and crops, the summary results of tests are recorded in the assessment report while raw data remain confidential. Lists of sources, including published and non-published documents, are attached to the official assessment reports on GM crops, but they are often omitted, for reasons of 'confidentiality' from subsequently published official reports. As for the public/stakeholders involvement, public comments are routinely invited on draft risk assessment reports for each item of appraisal for both GM foods and crops. In addition, open public and stakeholders meetings are sometimes held in relation to more generic issues concerning GM food risk assessment. In 2000, a consensus conference on GM foods and crops was also held by the Ministry of Agriculture, Forestry and Fisheries.

Argentina

In Argentina the regulatory authorities disclose almost no information. The expert advisory committee for GM crops includes members from the industries whose products are being assessed, but other stakeholder groups are excluded. Those members are, however, officially included as 'suitably qualified experts' rather than as 'representatives of particular interests'. The committee on GM foods also contains members from the industries whose products are being assessed but also a slightly broader range of stakeholders including a representative of a consumer organisation.

Germany

As in the UK, German policy-makers have in principle made commitments to making food-safety policy-making more open, transparent and accountable than was previously the case. According to the BfR "[a]ssessments are to be presented in a transparent and comprehensible manner to the general public, scientists and other involved or interested circles. The assessment results will, in principle, be made publicly accessible whilst maintaining the confidentiality of protected

data."¹⁴⁷ The BfR suggests that not only will risk assessments be publicly available but that the process of producing those assessments will involve stakeholders and will itself be transparent. It has portrayed risk communication as an "...interactive process of opening up its assessment work and results to the general public, scientists and other involved or interested circles."¹⁴⁸ Despite those commitments, in practice, at least for GMO regulation, things are rather different. The German process of GMO risk assessment is at almost no stage transparent to outsiders. The official German comments issued by the BVL to the EFSA, and the comments of the five authorities including the ZKBS, have never yet been made public, and almost no information is publicly available on the assessment process itself. The only way to access documents is to make a formal request under the German *Umweltinformationsgesetz*, but access may not be granted if the documents are used in a process that is still not completed or if they require the prior consent of other involved authorities.¹⁴⁹ Stakeholder involvement in GM risk assessment is rare in practice.¹⁵⁰ In one case Greenpeace Germany sued the BVL to obtain access to the full-text of a study and succeeded; BVL had initially refused access because the applicant deemed the study as 'confidential'. According to interviewees, in no case has the BVL or other authorities actively sought the involvement of wider non-industrial stakeholders. Contacts with industry are of course established in cases where the application was submitted to Germany. In the food toxicology arena, there are in practice, by contrast, somewhat greater levels of transparency and opportunities for stakeholder involvement. Risk assessments by BfR are made public, including preliminary assessments. These risk assessment opinions are, however, rather brief and apparently directed to a stakeholder community. They do not provide full technical and scientific details and do not provide indications of the scientific basis upon which assessments were produced. Although risk communication is usually portrayed by BfR as a bi-directional process, in practice stakeholders have so far largely been involved at the very end of the risk assessment process.

¹⁴⁷ The latter conclusions are partly based on personal experiences made by co-author (AS) when trying to access the documents.

¹⁴⁸ - with the possible exception of public/political pressure as in the case of the debate on the whole-food toxicity study of maize MON863

¹⁴⁹ The Frenchman René Truhaut was awarded the Legion d'Honneur, recognising his claim as 'father of the ADI'.

¹⁵⁰ *Procedural Manual of the Codex Alimentarius Commission 15th Edition*, FAO, Rome, 2005, p. 109 para 8, footnote 31

■ 5. Substantive and Interpretative Aspects of Risk Assessment Policy

Summary

Main cross-sectoral and cross-jurisdictional differences

In the USA some aspects of official substantive and interpretative risk assessment policies have long been made explicit in relation to food chemical risks, especially carcinogenic risks. Almost no substantive or interpretative RAP guidance has been provided in relation to GM foods, for which official approval has not routinely been required in the USA. In relation to GM crops, the EPA set a clear risk assessment policy in the mid-1990s to include insect resistance in the scope of official assessments of GM crops modified to have insecticidal properties. On the other hand, for risks of harming non-target species, no scoping RAP assumptions have been codified, although they have emerged on a case-by-case basis. In Germany and Japan official substantive and interpretative RAPs have not been explicitly articulated in relation to food chemical risks. In Japan, on the other hand in relation to GM foods and crops, some explicit substantive RAP guidance documents have been published. UK and German risk assessors routinely refer to official EU guidance, in relation to both food chemicals and GM foods and crops, which includes some explicit substantive and interpretative RAPs. At the FAO/WHO committees and in Argentina substantive and interpretative RAPs have been conspicuous by their absence, except for minimum data requirements.

Substantive RAPs

Following the food safety crises of the last 10 years in the EU and Japan, there have been pressures to make more explicit substantive RAP assumptions concerning the risks posed by GM foods and crops. In the early and mid-1990s the scope of European risk assessments of GM foods were primarily focussed on the potential toxicity of newly and deliberately introduced proteins, whereas more recently their scope was widened to include unintended effects of genetic modifications. In the early and mid-

1990s risk assessments of GM crops focused primarily on short-term and direct effects; more recently their scope has been explicitly widened to include long-term and indirect effects, and, for Bt crops, effects on a wider range of non-target organisms. In some cases official guidance was modified to formalise changed practices, in others the practices changed in response to the revised guidance. For herbicide tolerant crops, their scope now includes effects of commercial cultivation on farmland biodiversity, while those issues were not included even in the late 20th century. Since 2002, EU guidance for assessing the risks of cultivating GM crops has implied that their scope could include effects on soil micro-organisms, although in practice that option has not always been exercised. In Japan, the scope of risk assessments for GM crops had already included possible effects on soil micro-organisms since 1990s and, since 2000, it has been widened to include non-target effects of Bt crops. Effects on farmland biodiversity are increasingly deemed to be significant in Japan even though they are not explicitly referred to in the official guidance documents. From 2001 to 2005 in Japan, in response to the proposal made by the consensus conference on GM crops in 2000, several national laboratories jointly carried out monitoring survey on the effects of long-term cultivation of GM crops on farmland as well as natural biodiversity.

In relation to food chemical risks, some substantive RAP guidance has been provided in the form of minimum data requirements, while the USA has issued more extensive and detailed substantive guidance. At the joint FAO/WHO level, the CCRVDF initially drafted RAP guidelines for JECFA according to which several particular metabolic changes, following the use of veterinary drugs, would have been specifically included in JECFA's assessments; but JECFA refused to accept any such specific substantive guidance. CCFAC's guidance to JECFA does instruct the committee to focus on toxicological considerations, but provides no indication that any other considerations, such as public health nutrition, could be relevant. In the USA risk assessors are also explicitly instructed to take account of anticipated benefits when evaluating risks.

Interpretative risk assessment policies

Some interpretative RAP guidance has been published in five of the six institutional settings covered by this study, the exception is Argentina. In none of the institutional settings has interpretative RAPs been uniform or comprehensive; they are patchy and evolving.

Setting ADIs is one dominant orthodox way of interpreting toxicity data for policy purposes. The concept of an 'ADI' was invented in Europe¹⁵¹, but officially embraced first in the USA and then by the joint FAO/WHO committees and by Japan. ADIs have only rarely been set in the UK and Germany; never in Argentina. At the global level, both the risk assessment committees and the risk management bodies portray ADIs (and in ARfDs too) as if they were purely scientific risk assessment judgements rather than as evaluative judgements concerning the 'acceptability' of risks. Judgements of acceptability are evaluative rather than technical judgements, and so might be deemed appropriate to risk managers rather than scientists. The decision, on JMPR's part, to set some ARfDs represents a recent change in its interpretative RAP; which constitutes another example of scientific risk assessors choosing their own RAPs without reference or accountability to risk managers, let alone all other stakeholders.

Generalised interpretative RAPs for routine toxicology is provided by the standardised procedure for setting ADIs. In recent years, both risk managers (eg CCFAC and CCPR) and risk assessors (JECFA and JMPR) agreed that supplementary RAPs need to be articulated concerning how data on genotoxic carcinogenicity should be interpreted for policy purposes, since ADIs assume thresholds below which risks are vanishingly slight. Extensive and detailed proposals have emerged, and are being implemented, but the interpretative guidance was developed by the risk assessors and delivered to the risk managers, rather than the other way round. The US FDA has published guidelines for interpretation data on genotoxic carcinogenicity, e.g. using linear extrapolations from high to low doses, which are rather different from those adopted by JECFA and JMPR.

In recent years, the body of official interpretative RAP guidance has been extended and supplemented, especially in the UK and Germany (and in many EU countries too) as well as in Japan, with official emphasis on the importance of risk assessors paying explicit attention to scientific uncertainties and drawing risk managers' attention to policy-relevant uncertainties. The acknowledgement by risk assessors of uncertainties, and the explicit treatment of those uncertainties that are acknowledged is, however, very uneven and inconsistent across sectors and institutions. In Germany, where several bodies play a role in assessing the possible risks from GM crops and foods, some bodies such as the BfN draw attention to uncertainties that other German risk assessors do not highlight. In Japan, guidance documents do not explicitly refer to the notion of scientific uncertainty, but there are several specifications indicating substantively how to address and interpret uncertainties in the risk assessment of GM food and crops. The Argentineans have not provided any explicit guidance concerning the interpretation of uncertainties.

In relation to the interpretation of uncertainties, in the USA and at JECFA and JMPR there has been a longstanding practice of setting ADIs, by dividing 'no effect levels' (or NELs) in animal studies (or 'no observed effects levels' (NOELs) or 'no observed adverse effects levels' (NOAELs)) by a 'safety factor'.¹⁵² Sometimes those factors have been portrayed as taking account of the possibility that humans may be more sensitive to toxic effects than laboratory animals. On other occasions those factors have been represented as 'uncertainty factors', implying some acknowledgement of systemic uncertainties in extrapolating from laboratory animals to human consumers.

5.1. Explicit scoping judgements

This section focuses on the question of the extent to which explicit decisions have been made concerning the scope of risk assessments and/or changes to the scoping of risk assessments.

Prior to March 1996, there were almost no public debates about the scope of risk assessments

¹⁵¹ op cit, p. 109 para 8, footnote 31

¹⁵² op cit p. 109 para 13

of GM foods and crops, as there had been few such debates concerning the scope of assessments of the risks posed by chemicals in the food supply such as additives, pesticides, contaminants or veterinary pharmaceuticals. Since 1996 public debates on the scope of risk assessments on GM foods and crops have been explicitly conducted, and consequently some overt decisions have been taken to change their scope, and to do so by widening them to cover issues that either were not addressed, or that were addressed only partially and tangentially. While GM food and crop policy-making was recently transformed, at least in Europe and Japan, the same is less true for policy-making of routine food chemical risks. In relation to risks posed by genotoxic carcinogens, there have been some explicit changes in procedural and interpretative risk assessment policies, but not on substantive scoping issues.

Codex and joint FAO/WHO expert committees

The CCRVDF endeavoured to provide some substantive RAP guidance to JECFA by indicating in some detail which metabolic changes, following the use of veterinary drugs, should (and should not) be the focus of JECFA's attention. JECFA responded, however, by vetoing any such guidance, asserting that those were matters that risk assessors and not risk managers should decide.

CCFAC's *Risk Analysis Principles* asserted in 2005 that: "CCFAC shall base its risk management recommendations...on JECFA's risk assessments, including safety assessments, of food additives, naturally occurring toxicants, and contaminants in food."¹⁵³ The introduction of the term 'safety assessment' constituted a linguistic innovation, but that text otherwise represented an endorsement of the procedural *status quo*. Since the discussion was framed in terms of NOELs and ADIs, it implied that risk and safety assessments should just address toxicological issues, without any reference to nutrition or other aspects of human health such as interaction with pharmaceutical products. It also

implied that the issue of selecting safety factors is not one on which risk managers should have a view or provide any input.¹⁵⁴ CCFAC was enjoined to attend to those uncertainties to which JECFA draws attention, but not otherwise to be concerned with possible uncertainties.

In 2004 CCPR provided JMPR with some RAP guidance that was, in part, substantive, procedural and interpretative, without fully acknowledging the types of guidance provided, when it said: "JMPR provides CCPR with science-based risk assessments...that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate."¹⁵⁵ The advice to set not just ADIs but also some ARfD constitutes a recognition (jointly by CCPR and JMPR) that some acute adverse effects occur in some particularly sensitive sub-groups at levels of exposure below the ADIs, and consequently that for such compounds ADIs on their own are insufficient.¹⁵⁶ The judgement that ADIs should be supplemented with at least some ARfDs represents a clear shift in substantive and interpretative risk assessment policies.

UK

In relation to assessing the risks from GM crops and foods, the replacement of Directive 90/220 with Directive 2001/18 constituted an explicit change in substantive and interpretative RAPs in all EU Member States. Since 2001 the European Commission has issued explicit guidance as to the minimum scope of such assessments; risk assessors in Germany, the UK and other Member States explicitly and routinely cite that guidance. The criteria by which risks are assessed were explicitly extended by EU Ministers in 1998 and then incorporated into the 2001 Directive. Under the provisions of Directive 90/220, risk assessors were required in effect only to assess direct and short-term risks from the introduction of GM crops, but under 2001/18 they were also required to consider

¹⁵³ Report Of The Thirty-Eighth Session Of The Codex Committee On Pesticide Residues, Alinorm 06/29/24, p 68 para 21

¹⁵⁴ JMPR, Pesticide residues in food—2004, FAO Plant Production and Protection Paper. No 178, 2004, http://www.fao.org/ag/agp/agpp/pesticide/jmpr/pm_jmpr.htm, Section 2.1 Guidance on the establishment of acute reference doses

¹⁵⁵ CoT paper TOX/2006/12, available at <http://www.food.gov.uk/science/ouradvisors/toxicity/cotmeets/cot2006/cotmeeting060328/cotmeeting060328agenda>

¹⁵⁶ BfR 2005: Guidance Document – The Format for Health Assessment Documents

indirect and long-term risks. Subsequently, the UK authorities have elaborated that guidance and those criteria specifying when changes to ecological parameters are to be deemed to constitute 'environmental harm', although the criteria were developed by risk assessors in ACRE rather than by risk managers.

For the products of agricultural biotechnology, EU legislation also explicitly precludes risk assessors from taking putative 'benefits' into account when the risks are assessed. The European Commission's *Communication on Precaution* indicates that while 'benefits' may be taken into account, account should be taken of them by risk managers rather than by risk assessors, and that they should do so when making comparisons with alternatives that may pose relatively less risk, rather than as a counterpoint to putative risks of particular products.

Unlike the domain of GM foods and crops, the scope of risk assessments of food additives, pesticides, contaminants and veterinary medicines was not directly or explicitly affected by the BSE crises of the late 1990s. The structures and organisation of the institutions through which they are assessed have changed, and there have also been changes in the procedural and interpretative RAP guidance for those institutions. But the scope of the assessments of those food chemicals has remained largely insulated from, and consequently unchanged by, public policy debates.

In September 2005, a meeting was jointly convened by the UK's Food Standards Agency (FSA) and the Royal Society of London (RS) on *Social Science Insights for Risk Assessment*.¹⁵⁷ The report from that meeting to the CoT stated that:

...principles were identified, which may enable more effective risk assessment, and related management and communications processes...include[ing]...

- consult stakeholders and the public (where appropriate) on the framing of questions to be put to expert scientific advisory committees;
- acknowledge assumptions and uncertainty in risk assessment..."

Those comments constitute a re-iteration of the FSA's previously published procedural guidance, but the instruction to 'consult...on the framing of questions' represents a more explicit acknowledgement of the importance of substantive RAP issues than had previously emerged from the FSA.

During a meeting held at the FSA by the Committee on Toxicity on 28 March 2006, the CoT discussed that FSA/RS report. The discussion revealed a tension between a suggestion that the principles set out in the FSA/RS document were already implicit in the long-standing practices of the CoT, and therefore that the explicit articulation of that doctrine had no implications for the CoT other than maintaining the *status quo*, and on the other hand an acknowledgement that following some or all of the principles agreed between the FSA and the Royal Society would imply radical changes to the ways in which the CoT and its sub-committees operated. Consultation, on the part of the FSA, with a broad range of stakeholders and the public on the framing of questions to be put to expert scientific advisory committees has yet to take place.

Germany

The BfR has developed its own guidance document on health assessments, but it provides no guidance on how to deal with benefits; the focus is on the assessment of risks.¹⁵⁸ The BfR indicated that on occasions, it might be appropriate for risk assessors to assess benefits, for example if health claims are made. BfR says that if possible benefits are considered they should be assessed and reported in a similar way to risks. BfR also proposed considering "...whether the health benefits claimed for the population or individual groups if weighed against the risks are justifiable".¹⁵⁹ In practice, benefits are normally not considered by BfR risk assessors; they are deemed to be the responsibility of risk managers.

Whether benefit assessment can and should be included in risk assessments appeared as a novel and contested issue at the BfR. Some argued that there are cases where risks and benefits

¹⁵⁷ op cit p. 10

¹⁵⁸ pers. comm. with senior risk assessor

¹⁵⁹ The level of in-depth assessment might however be different.

are to be assessed along the same dimensions, e.g. nutrients and possible overdose of nutrients. A recent BfR workshop discussed risk-benefit analyses around such issues.¹⁶⁰ Others contest the validity of conducting benefit assessments within risk assessments. In principle the BVL, which together with Federal Ministries (BMVEL/BMELV), serves as the risk managing institution for food safety policy, can consider other legitimate factors such as possible benefits. In relation to policies specifically on GM crops and foods, however, BVL denies that potential benefits are taken into account. Similarly, GMO risk assessors are expected not to consider benefits, even if possible benefits are reported in the dossiers under consideration.

In relation to GM crops and food policy, German legislation does not limit the scope of the deliberations of the risk assessors. The official German risk assessment bodies do not agree about how the scope of their deliberations should be circumscribed. Consequently, some variables are assessed by all the authorities involved (including molecular characterisation, compositional analysis, substantial equivalence and whole food toxicity studies¹⁶¹), others by many but not all (e.g. environmental monitoring). Some institutions address issues that seem to be beyond the scope of their remit. For instance, BfN sometimes comments on issues of allergenicity, and the RKI comments on environmental risks; while BVL (perhaps assisted by ZKBS) tries to cover all aspects.

Japan

In Japan, the government has provided some explicit substantive scoping risk assessment policy guidance in relation to GM crops and foods, while general data requirements provide some im-

PLICIT scoping guidance. For GM crops, the scope of assessments covers biological effects on natural biodiversity but excludes effects that may be economically and/or agronomically significant to farmers, such as effects on non-GM conventional crops¹⁶².

The principal guidance document, *Guidance on the Implementation of Assessment of Adverse Effects on Biological Diversity of Type 1 Use of Living Modified Organisms*, stipulates that the scope of risk assessments of GM crops should include possible risks of cross-breeding with wild plants, the risks of competition with wild plants, the possibility of the release of harmful substances, and specifies data requirements under 3 main headings and 15 sub-headings.¹⁶³ Among others, the risk of cross-breeding is a new element introduced by the 2004 Guidance. A supplementary document, *the Application of Approval for the Production and Distribution of GMOs under the Jurisdiction of Minister of Agriculture, Forestry and Fisheries*, provides detailed specifications of issues of scope, data requirements and data-collection methods. Possible impacts on soil micro-organisms are also to be evaluated under the category of 'production of harmful substances'.¹⁶⁴ In addition, though not explicitly stipulated in these official documents, non-target harm of Bt toxin through pollen flow had been routinely evaluated in accordance with MAFF's announcement of March 2000, prior to the establishment of current guidance documents.¹⁶⁵ The net effect of those explicit and implicit provisions is to require Japanese risk assessors to assess the full range of risks that were being addressed, for example, in the USA and in the EU, but also to add two extra items, namely the impact on soil micro-organisms and effects of stacked genes.

¹⁶⁰ Effects on non-GM conventional crops were covered by a legally non-mandatory guideline of the Ministry of Agriculture, Forestry and Fisheries, The Guideline for Experimental Cultivation of Living Modified Organisms approved for Type 1 Use (notified on 24 February 2004).

¹⁶¹ Guidance on Implementation of Assessment of Adverse Effects on Biological Diversity of Type 1 Use of Living Modified Organisms, Article 3 and Table 1, 2 and 4.

¹⁶² In fact, evaluation of the impact on soil micro-organisms has been carried out since 1990s under the former guideline of MAFF, namely the Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries.

¹⁶³ Secretariat of the Agriculture, Forestry and Fisheries Research Council (AFFRC). "Safety Assurance of Insect-resistant GM Maize", 14 March 2000. Possibility of evolution of Bt-resistance of target insects is also a serious concern for Japanese risk assessors, though the assessment of this effect has not actually been conducted so far.

¹⁶⁴ Op cit., Table 3.

¹⁶⁵ Food Safety Commission Japan. *The Concept of Safety Assessment of the Food Derived from Breeding Recombinant DNA Plants*, Food Safety Commission Decision, 29 January 2004

The Guidance also sets out procedures for 'item-by-item Assessment of Adverse Effects on Biological Diversity'. That Guidance specifies following four procedural steps and assessment methods for each item.¹⁶⁶

Step 1: Identification of wildlife likely to be affected

Step 2: Evaluation of concrete details of adverse effect

Step 3: Evaluation of likelihood of adverse effect

Step 4: Judgment of existence of Adverse Effect on Biological Diversity.

In relation to GM foods, the scope of risk assessments is stipulated by *the Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)*, which stipulates assessments of allergenic effects and effects of antibiotic resistance genes. Adverse health effects caused by changes of major nutrients, nutritional adverse effects of long-term consumption, unintended adverse effects, and effects of pesticide residues should also be considered. However, a risk assessment of nutritional changes is required only if 'safety' cannot be confirmed by means of routine compositional analysis, for example when the composition of nutrients is significantly modified so as to improve nutritional values.

The same applies to toxicological effects. Tests of acute toxicity, sub-acute toxicity, chronic toxicity, reproductive effects, mutagenicity, carcinogenicity, intestinal toxicity, immunotoxicity and neurotoxicity are not mandatory but required only if deemed necessary. So far, acute toxicity tests have been conducted voluntarily by applicants (e.g. Du Pont's Bt maize DAS-59122-7, Monsanto's Bt-herbicide tolerant maize MON88017), while sub-acute toxicity was requested by the FSC for DAS-59122-7. On the other hand, the novel explicit procedural stipulation for the assessment of so-called 'further strains', including varieties with stacked genes, is a

distinctive feature of current Japanese regulation of GM foods that is not matched in the USA or the EU, nor in previous Japanese practice.¹⁶⁷

In Japan, any consideration of benefits is deemed to be outside the scope of risk assessments of both GM foods and crops. Although not mentioned explicitly in any official documents, risk assessors and managers agree that consideration of possible 'benefits' falls under the responsibilities of risk managers. For example, in the process of drafting *the Standards for the Safety Assessment* for GM foods at the ECGMF of FSC, one of its members posed a question about whether to include consideration of benefits of GM foods (e.g. high-oleic soybean, vitamin-A enhanced rice, etc.) in a risk assessment. In response the FSC secretariat indicated that consideration of utility and effectiveness is the business of risk managers.¹⁶⁸ Similarly, for GM crops, a discussion considered whether benefits of Bt maize should be taken into account, but it was agreed that such matters were relevant to risk managers but not risk assessors. At the 4th meeting of General Committee of the CAAEB, the chairperson of the Crops Subcommittee, who is also a member of the General Committee, stated that: "...while it is a matter of course to compare risk and benefit, Japanese rule is not designed to do so".¹⁶⁹

USA

In the USA, very little in the way of explicit RAP guidance on the framing of risk assessments of GM foods and crops is available. The reliance by the FDA on an interpretation of the concept of 'substantial equivalence', which assumes that comparisons of data from chemical analyses can be sufficient to establish the substantial equivalence of a GM food with its non-GM counterparts, and that ascribing 'substantial equivalence' provide sufficient grounds to conclude that further assessments of risk or tests are unnecessary, entails that few formal official GM-food risk assessments

¹⁶⁶ Food Safety Commission Japan. "Minute of 2nd meeting of Expert Committee for GM Foods", 19 November 2003, p.27. Under the former guideline before establishment of FSC and introduction of RA/RM separation, benefit was explicitly argued in the case of high oleic soybean.

¹⁶⁷ Committee for the Assessment of Adverse Effects on Biodiversity. "Minute of 4th Meeting of General Committee of Committee for the Assessment of Adverse Effects on Biodiversity", 16 May 2004, p.36.

¹⁶⁸ Gaylor, D., Bolger, P.M., and Schwetz, B. (1998) 'US FDA perspective of the inclusion of effects at low-level exposures in safety and risk assessment', *Environmental Health Perspectives* 106, supplement 1: 391-94

¹⁶⁹ USDA Foreign Agricultural Service, 2005 Argentina Biotechnology Annual 2005, GAIN Report Number: AR5033

have been conducted in the USA, and no formal guidance has stipulated their minimum scope.

For the environmental risks of Bt insecticidal crops, some substantive RAP guidance has been elaborated through specific cases. Unlike the other countries in this study, a benefits' assessment was also included, because Bt toxins fall under US pesticide legislation, which obliges the EPA to balance risks against benefits. For Bt crops, environmental benefits were initially taken for granted, but more recently such claims have been challenged and eventually downplayed.

The FDA's toxicological assessments of food chemicals consider only direct product risks, i.e. testable characteristics; they do not include indirect effects on overall diet or on nutritional public health. On the other hand, proposals to restrict and/or ban food ingredients or products, and thereby to reduce risks, are judged against potential losses of nutritional benefits. Little in the way of systematic evidence is required indicating that such benefits would be lost; they tend rather to be assumed.

The FDA's legislative basis, the Food Drugs and Cosmetics Act, allows a consideration of benefits when assessing risks from foods containing environmental contaminants, but (under the provisions of the Delaney amendment) it precludes such consideration for food additives suspected of being carcinogenic.¹⁷⁰

In the USA, where the FDA and EPA are hybrid institutions, responsible for both risk assessment and risk management, it is not possible to identify precisely the fractions of those agencies that are, and that are not, responsible for taking account of the potential benefits that potentially risky products and processes might provide. The EPA's legislative framework directs the EPA to balance judgements of the risks of GM crops against the benefits they are expected to provide. In routine policy-making in respect of food additives and contaminants, US risk assessors have a long-standing practice of considering anticipated benefits when assessing, not so much the magnitude of particular risks, but their acceptability. When fed relatively high doses of the preservative sodium nitrite

(as well as sodium nitrate and potassium nitrite – E249-E252) laboratory rats showed measurable dose-related increases in the incidence of malignant tumours. The FDA's response was to argue that the benefits provided by the use of those compounds, in terms of reducing the risk of acute bacterial food poisoning from pathogenic micro-organisms, substantially outweighs any relatively modest long-term risks that the compounds might pose. Ceasing to use those preservatives would cause greater mortality and morbidity than their continued use.

When evidence emerged, indicating that when fed even moderate doses of saccharin, especially over two generations, rats showed dose-related increases in the incidence of bladder cancer in males, and the FDA proposed to ban the use of saccharin under provisions of the Delaney amendment, Congress passed legislation obliging the FDA not to ban it but merely to require warning labels, arguing that the benefits of saccharin consumption outweighed the risks. In that case, elected representatives in Congress took explicit political responsibility for providing the FDA with risk management policy guidance, to the effect that risks were to be assessed in the context of judgements concerning benefits too. The evidence suggests that the FDA has subsequently acted in conformity with the guidance that Congress provided.

Argentina

In Argentina, no explicit guidance on the scoping of risk assessments is provided, but data requirements provide some very limited implicit scoping guidance. Benefits do not explicitly form part of risk assessments of GM foods or crops. However, not only do the Argentinean authorities conduct assessments of risks to domestic consumers from the introduction of GM crops and foods, they also include, in the scope of their considerations, possible economic risks to export markets. Those risks to markets access are assessed by a separate part of the agriculture department; GM plants are normally only approved for domestic cultivation if they have previously been approved for sale in major export markets. Recently, the Ar-

¹⁷⁰ Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods, CX/RVDF 01/9 July 2001 [ftp://ftp.fao.org/codex/ccrvdf13/rv01_09e.pdf](http://ftp.fao.org/codex/ccrvdf13/rv01_09e.pdf), paras 26-28

gentine Secretary of Agriculture approved a variety of herbicide tolerant maize for commercialisation, before the EU granted import authorization, but that was the first time such a decision had been taken.¹⁷¹

Which explicit judgements have guided policy on which kinds of evidence to include in risk assessments, and which to exclude or discount?

Within the EU, and under the provisions of EU legislation and EFSA Guidance documents, data requirements and some criteria of assessment for GM crops and food indicate the minimum kinds of data that must be provided. Those provisions stipulate not only the types of studies from which data are required, but also their minimum duration. For pesticides and additives, there are some standard data requirements, but there are no comparable general data requirements for contaminants; they do not have any explicit sponsors.

No general statements have even been published by either CCFAC or by JECFA indicating how much information, and of which kind, is necessary and/or sufficient for judgements to accept, restrict or reject the proposed use of particular food additives. Risk assessment policy assumptions of that type are, and always have been, implicit. They have never been explicitly articulated, but can be derived inferentially by scrutinising institutional practices.

At the global level, both JECFA and JMPR routinely accept evidence that has not been published in peer-reviewed journals, and then allow that evidence to remain unpublished indefinitely. On this issue, the practices in the UK, Germany, Japan and Argentina were, for many years, indistinguishable from those of JECFA and JMPR. Recently, more scientific evidence has entered the public domain because of decisions by the British and Japanese risk management authorities.

Since the provisions of the US Freedom of Information Act were strengthened in 1976, following the Watergate Scandal, almost all the toxicological data by reference to which food additives and pesticides have been approved in the USA have been, in principle at any rate, in the

public domain, as they are in several Scandinavian countries. Despite this fact, JECFA, JMPR continue to accept and rely on unpublished data, and data from unpublished studies.

Academic peer review is supposed to provide a degree of quality control over papers in scientific journals. Some policy-makers therefore rely primarily on evidence from scientific studies that have been published in peer-reviewed journals. Risk assessors in the UK, Germany, Japan and Argentina accept unpublished data and studies, and until recently all acquiesced in keeping the evidence out of the public domain (in whole or in part). Not even in the USA are they all available as electronic files on the internet.

No explicit decision rules have been set out in Argentina, by expert advisors or policy-makers, concerning which data to require and which not to require, or to discount. Decisions on those matters have been taken, but how they were taken is not publicly accountable, although representatives of industrial applicants typically attend meetings at which their applications are considered. When considering whether or not to require long-term monitoring for GM plants, for example, the decision rule may therefore be explicitly indicated to the applicant, but not to the general public.

Have risk assessors been provided with, or themselves published, any default assumptions about the interpretation of data for policy?

Risk assessments are routinely portrayed as evidence-based, and they often are based on evidence, but evidence does not interpret itself. Particular bodies of data can and often do legitimately admit a range of alternative scientific interpretations concerning public and environmental health, and groups of experts can differ on the issue of what to count as relevant evidence. While contrasting risk assessments may be equally scientific, they are not necessarily equally precautionary; some may be significantly more or less precautionary than others.

For example, the approach adopted in the USA, that many aspects of GM crops and foods that the Europeans and Japanese deem worthy of risk as-

¹⁷¹ op. cit. para 16

assessments, do not require such assessments is in that respect less precautionary than the European and Japanese approaches. On the other hand, the approach of the US authorities to suspected carcinogens in the food supply may well have been significantly more precautionary than the approaches adopted in Europe or by the global FAO/WHO risk assessors. The focus of the discussion in this section concerns the extent to which interpretations of data are framed by explicit RAP guidance, and if not whether implicit interpretative risk assessment policies can be identified, and characterised by reference to notions of precaution.

USA

The US authorities have published guidance documents setting out the default assumptions with which they interpret carcinogenicity data, but similar forms of guidance have not been developed for other toxicological 'end points'. The USA was the first major jurisdiction to issue explicit 'procedural' risk assessment policy, in relation to the interpretation of evidence of carcinogenicity. The guidance has changed over time, but those changes have been explicit, with an audit trail of the changes online. Key assumptions were both made explicit in official documents, and explained in journal articles by US government officials.

The changing US approach to genotoxic carcinogens

During the 1970s and into the early 1980s, the US government started to show greater precaution in relation to food-borne chemical carcinogens than it had previously. The FDA began to assume, more or less explicitly, that all carcinogenic agents should be classified and assessed as if they were non-threshold agents unless there was evidence indicating that a threshold mechanism accounted for the carcinogenic effects of compounds. The basis for the new policy was not that *all* carcinogens were believed to act in a non-threshold manner, but rather that even if some mechanisms of carcinogenesis involve thresholds, in practice scientists could not reliably determine where those thresholds were located. The FDA's policy was to exercise precaution; it was deemed

prudent to act as if no threshold existed unless, in particular cases, there were good grounds for supposing otherwise. Since ADIs presume a threshold, the default RAP guidance was that risk assessors should not routinely assign an ADI to carcinogens. In practice, by the mid-1980s, the US authorities had modified that approach.

The 1958 Delaney amendment stated that: "...no additive shall be deemed safe if it is found to induce cancer when ingested by man or animal." In that context Congressional legislation explicitly provided US risk managers with RAP guidance on how to regulate known or suspected carcinogens. The passage of that amendment posed significant problems for the FDA and subsequently for the EPA. For example, saccharin was shown in 1976 to be an animal carcinogen, but there were high levels of commercial and congressional support for its continued use; and FDA risk managers assumed that artificial sweeteners were essential for diabetics and helpful for weight control. In response, the US authorities introduced quantitative mathematical modelling with which to try to extrapolate from high doses given to laboratory animals to low doses to which consumers were, or might realistically be, exposed. The revised policy meant not always banning additives or pesticides that were carcinogenic in a laboratory study, but restricting consumption sufficiently so that residual risks were deemed acceptably slight. In particular, US risk managers and risk assessors adopted as a conventional benchmark of acceptability, an indication that an additional lifetime risk of developing cancer would not exceed one chance in a million; such levels came to be referred to as 'virtually safe' doses. The Delaney amendment has never been formally repealed, but it is not consistently implemented.

Codex

When CCRVDF proposed to JECFA that it could use a default safety factor of 100 to 'calculate' (rather than to 'estimate') ADIs from NOELs, it was providing some explicit interpretative RAP guidance, which moreover amounted to little more than codifying routine practice.¹⁷² Nonetheless, JECFA vetoed that guidance. CCRVDF also pro-

¹⁷² op. cit. paras 24

posed that JECFA should treat laboratory animals as providing a basis for extrapolation to humans, and indicated circumstances when some evidence of adverse effects in laboratory animals should be discounted.¹⁷³ CCRVDF indicated (procedurally, substantively and interpretatively) that decisions, about what is to count as a benchmark of an acceptable level of risk, is one for which CCRVDF, rather than JECFA, should be responsible.¹⁷⁴ Whether that meant that CCRVDF and not JECFA should set ADIs, or whether JECFA should continue to set ADIs but only by acting in accordance with guidance from CCRVDF (and presumably CCFAF too) remains unclear. Since JECFA vetoed the draft, and CCRVDF responded with a fundamentally different type of document, that has yet to be clarified.

Risk assessment policy in relation to non-threshold toxicological effects

In recent years regulatory toxicologists have been asked to assess the risks of an increasing number of compounds, primarily contaminants, for which the rules for setting ADIs cannot readily apply. In cases like acrylamide, evidence suggests that they might not only be carcinogens but also genotoxic compounds, and therefore that even one molecule may be sufficient to initiate a tumour, therefore there may be no threshold greater than zero below which risks can be assumed to be negligible. If no threshold can be identified, estimated or assumed, there is a conspicuous need for some alternative to the ADI.

JECFA's approach

For many years JECFA's approach (in contrast to that of the US FDA and EPA) was to allocate ADIs to compounds that had been shown to be rodent carcinogens, as long as they were deemed 'non-genotoxic'. At JECFA and JMPR the long-standing practice was to assume that carcinogens act with threshold-limited mechanisms unless there was clear evidence of genotoxicity. That policy has not been explicitly embodied in formal published documents, but it was in practice the

implicit rule of thumb. For genotoxic carcinogenic contaminants, JECFA's advice was that the ALARA approach should be adopted, i.e. risk managers should aim to reduce exposures to 'as low as reasonably achievable'.

In 2005 JECFA acknowledged that 'ALARA' was insufficient. That was partly because improved analytical and testing methods meant that ever more genotoxic carcinogens were being detected in foods. Some risk managers also indicated that ALARA-type advice could not provide them with a way of prioritising efforts to reduce exposures as between different genotoxic carcinogenic compounds.

Innovating four regulatory concepts

In response, a set of four new regulatory concepts was invented and adopted by JECFA. If the risks from genotoxic carcinogens cannot be measured on a cardinal scale, their relative risks might be ranked on an ordinal scale. JECFA introduced what it terms the 'benchmark response' (or BMR) and the 'benchmark dose' (or BMD). The BMD is defined as a dose that generates a chosen level of measurable benchmark carcinogenic response or 'BMR'. JECFA selected as its BMR a 10% increased incidence of tumours in test animals compared with the controls. JECFA proposed that, the 'lower confidence limit' of the BMD (termed a 'BMDL', or 'benchmark dose lower confidence limit') could and should be used to rank genotoxic carcinogens in terms of their potency. JECFA proposed that the BMDL, together with exposure data, could be used to calculate a 'Margin of Exposure', or 'MoE'. The MoE is defined as the ratio of the BMDL to estimated exposure to the compound. MoEs could be used to prioritize different contaminants, as well as providing a basis for judgements about how far exposure should be reduced.

UK

In the UK, there has been little in the way of explicit guidance about the interpretation of toxicological data. In the UK there has been a process

¹⁷³ DoH (1991) *Guidelines for the Evaluation of Chemicals for Carcinogenicity*. Report on Health and Social Subjects No. 42. Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. HMSO, London

¹⁷⁴ Secretariat of the Agriculture, Forestry and Fisheries Research Council of MAFF (2000) "On the safety assurance of the insect-resistant maize", 14 March 2000

built on examples and precedent, with slow incremental adjustments at the margin. Patterns of data interpretation have been far more matters of ‘case law’ rather than of ‘statute law’. Customary practice in UK toxicological risk assessments was to treat any adverse effects that occur in ways that were not monotonically dose-related and/or at levels above the conventional benchmark of statistical significance (of there being less than a one chance in 20 of the phenomenon not being a random artefact) as being effectively zero and discountable, when testing chemicals on samples of 50 male and 50 female rodents, at ‘low, medium and high’ doses alongside a control group of 50 animals per sex. In that respect, the approach adopted in the UK has been significantly less precautionary than that in the USA.

Historically, British committees have chosen not to use, even hypothetically, mathematical extrapolation models; as an FDA official put it ‘the Brits always try to stay out of the numbers game’. The Committee on Carcinogenicity has argued against using quantitative models on the grounds that they depend on numerous approximations and assumptions that cannot be validated. The problem is not that there are no mathematical models, but rather that there are too many, and that there are no conclusive grounds for selecting one rather than another. The Department of Health’s expert Committee on Carcinogenicity explicitly stipulated (in 1991), in a similar way to the US agencies, that not only genotoxic carcinogens, but also non-genotoxic carcinogens for which no mechanism has been established, should be assumed to have no threshold of entirely safe exposure.¹⁷⁵ The approach by the mid-1990s in the UK was to ban the use of genotoxic carcinogens as food additives or pesticides and to reduce levels of contaminants ‘as low as is reasonably achievable’.

In the UK, only two main sets of default assumptions have been explicitly set out, and they emerged from toxicology advisory bodies not risk managers. The committees have indicated that they will not routinely use linear models to extrapolate from adverse effects at high doses to estimate effects at lower doses. Risk assessors are, in effect, expected to exercise discretion and take account of chemical and biological evidence and knowl-

edge, thereby making more informed judgements. The one exception to that rule is that advisors have been told to interpret data concerning compounds that appear to exert carcinogenic action via a genotoxic mechanism, as indicated with data from *in vivo* studies, by assuming a non-threshold dose-response relationship, such as a linear model.

The approach adopted by the UK has differed in several key respects from that of the USA. In practice, in the UK the CoT, and its sub-committees, has occasionally exempted suspect carcinogens from those default assumptions, by reference to hypotheses about mechanisms of action that may, for example, occur at high but not at low doses. Typically (though implicitly) those committees assumed that almost all toxicological mechanisms are not just dose-related but also dose-limited. Genotoxic carcinogens have become the only category of toxic agents assumed to accomplish their effects through processes with no threshold, but the UK CoT has not yet endorsed the innovations outlined above recently introduced by JECFA. In that respect too, the approach adopted in the UK has been significantly less precautionary than that proposed by JECFA and JMPR.

Germany

BfR risk assessors have explicitly articulated some of their default assumptions concerning risk assessments of contaminants. In cases where there is evidence of carcinogenicity, but without evidence of genotoxic activity, the BfR assumes that there is a threshold and that an ADI can be set. On the other hand, for carcinogens believed or known to act through genotoxic mechanisms, the assumption is that there is no threshold and therefore ADIs are not appropriate. Instead, the BfR invokes recommends reducing exposure to the maximum extent that can reasonably be achieved, but leaves it to BVL risk managers to decide what, in those contexts, is reasonable.

GM food and crops

No formal guidance on the interpretation of data has been published in the USA by either risk assessors or risk managers for GM crops as a

¹⁷⁵ Bolger, P.M. and Carrington, C. (2005) ‘Food safety and toxicology’, in *Encyclopedia of Toxicology*, 2nd Edition, p. Wexler et al eds, Elsevier, 2005, p. 360, see http://www.elsevier.com/wps/find/bookdescription.cws_home/704200/description#description

whole, or for categories of GM crops such as those expressing Bt. In particular cases, however, risk assessors have provided some account of how data were interpreted. Risk assessors have also acknowledged some methodological uncertainties about how to investigate effects of Bt toxin on non-target organisms. The 'indicator species', upon which the risk assessors have required tests to be conducted, evolved during the late 1990s. That constituted at least an implicit recognition of some uncertainty, which can be interpreted as a shift from a relatively less to a relatively more precautionary approach.

In the UK, on the issue of antibiotic resistance marker genes, the ACNFP refers to its own specific guidance indicating that GM foods should not contain genes coding for antibiotics that play a significant role in human medical therapy. On the other hand, in the UK for GM foods, no general guidance has been published by either risk assessors or risk managers on the interpretation of data. As in the USA, however, the ACNFP sometimes provides some explanations of how, in particular cases, data were interpreted. In Japan, no official guidance on the interpretation of data has been published for GM foods and crops. But, as in the USA, the method of indicator species has been also used to evaluate non-target effects of Bt toxin since the MAFF distributed a press release in March 2000 that specified the procedure of the evaluation.¹⁷⁴ As mentioned above, this implies that risk assessors recognise some uncertainties and can take a precautionary approach to them. In Germany and Argentina no explicit documents have been issued indicating default assumptions for data interpretation by risk assessors of GM crops and foods.

Have risk assessors been provided with, or themselves articulated, any default procedural assumptions about the interpretation of uncertainties for policy?

Global institutions

In the context of its treatment of chemical toxicology, JECFA has established the practice of setting ADIs by dividing NOELs (or sometimes

NOAELs) with a numerical parameter that is sometimes referred to as a 'safety factor' (or SF) and at others as an 'uncertainty factor'. That practice has been explicitly set out in a document by both JECFA and CCFA. Beyond that, JECFA has not explicated any general rules about acknowledging or responding to uncertainties. When asking for more data, JECFA implicitly acknowledges that it faces significant uncertainties. In the USA, FDA staff have acknowledged that 'safety factors' may themselves be uncertain, but neither JECFA nor JMPR acknowledged that.¹⁷⁷

USA

When the US Congress introduced the DeLaney Amendment, it did so because it recognised that there were considerable uncertainties in extrapolating the effects on humans from laboratory animal data. Subsequently, the FDA has provided risk assessors with explicit guidance about particular kinds of scientific uncertainties, and how to respond to them. US regulatory culture is one in which, when faced by uncertainties, the reaction is to try to quantify the uncertainties, or to use quantitative tools despite the imprecision in data and their interpretations. Procedural risk assessment policy concerning the risks of possible carcinogens has been extensively and explicitly set out, usually by groups comprising both risk assessors and risk managers.

While chemical carcinogenesis has been a focus of risk assessment and risk management in the USA, similar levels of attention have not been devoted to regulating the products and processes of agricultural biotechnology; on the contrary they are widely assumed to be safe and subject to far less detailed scrutiny than chemicals. The knowledge of their likely interactions with human and environmental health are officially characterised in the USA as well understood and not complicated by uncertainties. In the absence of any acknowledgement of uncertainties, there has been no perceived need to articulate policies about uncertainties. In the USA official food toxicology risk assessors at the FDA represent themselves as routinely making conservative assumptions in response to uncertainties. They sometimes explicitly

¹⁷⁶ Gaylor et al., 1997: 310

¹⁷⁷ US RC, Vol 2, 1997: 90 ??

acknowledged uncertainty in extrapolating from animal studies, and tried estimating the scale of those uncertainties.¹⁷⁸ Official US guidance explicitly discusses the complex issue of ‘conservative default assumptions’, ostensibly so that practitioners can clarify and justify their choices.¹⁷⁹

Germany

In **Germany**, the BfN sometimes refers to the precautionary principle, and uses it when interpreting available data. For example, it has done so in relation to Bt11 maize when recommending minimum separation distances of GM crops from ecologically sensitive areas, to diminish risks to non-target organisms.¹⁸⁰ The BfN explicitly acknowledges uncertainties, and has adopted explicit routines for responding to them. The BfN has also drawn attention to evidence of statistically significant differences in compositional analyses between GM foods and their non-GM counterparts, and evidence from feeding trials, as indicating important scientific uncertainties. The BfN has also argued that particular forms of post-release monitoring should be required, which also implicitly acknowledges uncertainties. The other federal German institutions (such as the RKI and the BVL) with responsibility for assessing the risks of GM crops and foods refer less frequently to precaution or to uncertainties. The BfR has issued its own default guidance on the application of precaution and sees its role as identifying relevant uncertainties that might provide the occasion for a possible exercise of precaution, while assigning to the BVL responsibility for deciding whether or not, and how, to implement precaution.¹⁸¹ For non-threshold toxicity no explicit guidance has been provided by risk managers. Nevertheless, the BfR apparently ‘inherited’ some risk assessment approaches from the former BgVV. For example, in relation to a known or suspected genotoxic carcinogen, no threshold can be assumed and ‘ALARA’ is the routine approach to risk mitigation. Since EFSA was established, German authorities have often accepted EFSA judgements without conducting their

own assessment. Some German officials indicated, however, that a BfR assessment of, for example, dichlorvos might have been more precautionary than that delivered by EFSA.

UK

In the **UK**, for GM food and crops, members of the ACNFP and ACRE say that they adopt ‘conservative’ assumptions when there are relevant uncertainties, but no formal official documents stipulate such an approach. In practice, in the late 1990s, expert advisors acknowledged that important uncertainties remained concerning the potential consequences of consuming foods that had been modified with antibiotic resistance marker (or ARM) genes. They were uncertain whether ARMs could transfer to microbial pathogens in the human gut, or in the digestive tracks of agricultural livestock. Rather than waiting until the uncertainties were diminished, their advice was that, in respect of some types of especially important antibiotics that medical practice could not afford to lose, it would be better not to use those ARMs in GM foods. Risk managers accepted that advice, and it has also been endorsed by EU authorities. Subsequently, some other uncertainties have been acknowledged, mainly those that could be significantly reduced by relatively modest further studies.

Japan

In Japan, for GM food and crops, the guidance documents do not explicitly refer to the notion of scientific uncertainty, but there are several specifications indicating substantively how to address and interpret uncertainties. For example, in relation to GM crops, a document provides a stipulation that allows risk assessors to request the applicants to submit plans of monitoring and emergency preventive actions¹⁸², which constitutes a default procedural assumption about how to address the uncertainty. In practice, risk assessors have requested monitoring for several varieties of

¹⁷⁸ BfN comments on Directive 2001/18/EC dossiers of maize Bt11 and maize 1507.

¹⁷⁹ BfR 2005: *Guidance Document – The Format for Health Assessment Documents*

¹⁸⁰ Director-General of the Food Safety and Consumers Bureau of MAFF et al. *The Application of Approval for the Production and Distribution of GMOs under the Jurisdiction of Minister of Agriculture, Forestry and Fisheries*, pp.3-4.

¹⁸¹ Subsequently WHO Food Additives Series 54 was published in 2006

¹⁸² Millstone, E, ‘Aspartame: the litmus test for the FSA and the EFSA’, *The Food Magazine*, Issue 73, Apr. 2006. pp. 8-9

Bt maize, taking into account uncertainties in the evaluation of non-target effects of Bt toxin.

A second example is the specification of the evaluation method for the effects of Bt toxin on non-target insects in farmland soil, which was developed by risk assessors in the CCAEB. In this case, risk assessors recognized the uncertainty in the survivability of Bt protein in soil. Based on this recognition, the CCAEB adopted a conservative, or precautionary, assumption that Bt protein could remain active in soil for several weeks or months, much longer than previously assumed.

In relation to GM foods, risk assessors are provided with no explicit guidance about the interpretation of uncertainties, but they have made some default assumptions concerning uncertainties. For example, in the deliberation about α -Amylase LE399 (Novozymes Japan Co., Ltd), a food additive derived from GM microbes, there had been an extensive discussion whether to assume the possible widest range of use of the additive or particular usage designated by the applicants. The problem was that the additive could be used in other ways than assumed by risk assessors and, if so, it might pose additional risks that have not been evaluated. In order to address such an uncertainty, risk assessors have so far worked out an agreement that they should presuppose the possible widest range of use of the additive, which implies that they have made a conservative assumption in relation to uncertainties. In **Argentina**, no RAP guidance has been published in connection with identifying or handling uncertainties.

■ 6. Implicit aspects of risk assessment policies

Section summary

The discussion in Section 5 indicated the extent to which interpretative risk assessment policies have been made explicit. This section explores, by contrast, the extent to which, and the ways in which, implicit RAPs can be inferred and characterised. The ease with which implicit RAPs or risk assessment policy-type judgements can be identified depends to a large extent on the extent to which empirical evidence is publicly available in each institutional setting. In those cases where the documentary evidence on scientific assessments of risks is sparse it can be difficult to identify RAP-like judgements because the methods of identifying implicit RAP-like judgements require careful scrutiny and reconstruction of scientific assessments and decision-making. Furthermore, unless we scrutinise a large representative sample of scientific assessments within any one jurisdiction it can be difficult to establish whether any such identified RAP-like judgements are deployed consistently across different products – and thus constitute an implicit ‘policy’ – or whether all we can identify are the *ad hoc* judgements made by an individual assessor or assessment team, and which might vary as between different products or assessors.

Implicit procedural RAPs have been previously reviewed above in the context of the discussion of procedural practices and how those practices compare with explicit procedural guidance. Substantive risk assessment policies have often limited the focus of attention to sub-sets of possible considerations, although those exclusions typically remain implicit. The sub-sets that are included have widened in recent years, in relation to GM crops and foods, but not in relation to chemical risks. Another important aspect of substantive RAP concerns judgements about including, excluding or discounting certain types of evidence; those judgements vary within and between institutional settings. Statements about the scope of risk assessments are more explicit about what is included than about what is excluded. The

risks that are excluded can often only be inferred, and comparing assessments prepared in different institutional settings can facilitate those inferences.

Interpretative RAPs interact with judgements about the scope of risk assessments and data requirements. They have often also involved distinctly asymmetric approaches to dealing with possible false positives and false negatives. In several cases we found evidence that risk assessors have discounted evidence of possible adverse effects by reference to hypotheses about, for example, modes of action, even where those mechanistic hypotheses were not supported by specific evidence showing the hypothesis to be well-founded. On the other hand, risk assessors rarely take systematic steps to avoid possible false negatives, even when the test methods provided conspicuously poor models of real life conditions.

Implicit assumptions that have been guiding the interpretation of data have been crucial to determining the conclusions of many risk assessments, therefore if the request from risk managers to risk assessors to make all their interpretative assumptions explicit were implemented it would make the underlying reasoning far more transparent than has hitherto been the case.

To the extent that risk assessment policies have been implicit rather than explicit, can we identify what they are or have been?

At the global level

A recently published full report from JECFA’s discussions on food additives (JECFA Food Additives Series 52) emerged in 2004. The evaluations contained in that volume constituted, at the time of writing, an up-to-date sample of its work.¹⁸³ The prevailing implicit risk assessment policy adopted by JECFA (in 2004) can be illustrated by reference to a comprehensive food additive risk assessment; it concerns a novel synthetic sweetener called **Neotame** –Nutrasweet’s follow-up dipeptide

¹⁸³ JECFA, *Food Additive Series*, 54, 2004, p. 124

methyl ester to aspartame. The toxicological monograph from JECFA on neotame cited 69 reports, every one of them unpublished.

Neotame: substantive RAP - which studies were reported?

Against the background of an unresolved and acrimonious debate (from the early 1970s until the present day) about the safety and acceptability of neotame's parent compound (aspartame¹⁸⁴), a wider range of studies was conducted on neotame than had been conducted on aspartame at the stage when it was first approved by JECFA.

When JECFA met in 2003 "The absorption, distribution, metabolism and excretion of neotame have been studied in mice, rats, dogs, rabbits and humans." Studies were reported under 17 headings. Seven of the first nine categories were routine 20 years ago, while requirements for studies of reproductive toxicity and developmental toxicity had been increasingly common since the mid-1990s. The scope of the appraisal of neotame was as wide as for any other new additive, although its scope did not extend to tests for endocrine disrupting effects. Some data on 'tolerance' of single doses and repeated doses were reported for small groups of healthy adults.

As usual, short-term tests served as 'range-finding' studies to set dose levels for longer-term studies. During those short-term tests, it was evident that, at even relatively moderate doses, the rate at which laboratory animals consumed food and gained weight diminished, when compared with animals in the control groups. One question therefore was whether those failures to ingest food and gain weight at the anticipated rates were 'toxic effects' or merely problems of 'unpalatability'. 'Palatability' is one of the categories under which data were reported, and it will be discussed below.

Discounting positive evidence of neotame toxicity

At several points, JECFA referred to some evidence of adverse effects. On each occasion, JECFA

characterised the phenomena as 'sporadic' or 'relatively low level', and discounted those symptoms and evidence, as if they had not occurred or were unimportant. JECFA treated levels of consumption below which evidence of adverse effects had occurred, as if they provided a demonstrable 'no observed effect level'. Several inconvenient or unwelcome observations were treated as if they had not been observed. An alternative, and equally scientific but more precautionary, way of interpreting those data could have been to request more detailed studies of those adverse effects. A decision of that sort is a matter of procedural and interpretative risk assessment policy concerning how uncertain evidence is to be interpreted.

In the context of a discussion of the results from a 3-month study of 'tolerance' of repeated dosing with neotame with 144 healthy human adults, JECFA said:

"...82 persons reported at least one adverse reaction during the study. Most of these were determined to be of mild or moderate severity, and were reported in all three treatment groups, with no dose-response relationship or statistically significant differences between groups. Headache was the most common adverse experience, occurring in 16, 15 and 13 persons at 0, 0.5 and 1.5 mg/kg bw per day, respectively. There were no serious adverse reactions during treatment.

There were no treatment-related changes throughout the study in pulse rate, blood pressure, respiratory rate, temperature, body weight, ophthalmological or haematological parameters. The sporadic changes observed in clinical chemistry parameters were not considered to be of biological significance or to be treatment-related.

On the basis of the results of this study, neotame was well tolerated at a dose of up to 1.5 mg/kg bw per day for 91 days, with no treatment-related adverse effects."¹⁸⁵

JECFA implicitly made several risk assessment policy assumptions. 82 out of 144 of the people in the two treatment groups reported "...at least one adverse reaction..." but JECFA provides no information on how many symptoms were reported by dif-

¹⁸⁴ Pardridge W. M., (1988), 'Phenylalanine Transport at the Human Blood-Brain Barrier', Chapter 5 of *Dietary Phenylalanine and Brain Function*, Wurtman R.J. & Ritter-Walker E. (eds.), Birkhaeuser, Boston, 1988

¹⁸⁵ JECFA, Food Additive Series, 54, 2004, pp. 98-99

ferent fractions of the sample. Some of those 82 experimental subjects may have reported several or many symptoms, but such information is not provided by JECFA. JECFA did not say whether or not those in the control group reported similar symptoms; that assumption remains implicit. The most commonly reported symptom was headaches. This may be important because, amongst consumers who have reported suspected adverse effects from aspartame (from which neotame is derived), severe headaches have been the most frequently reported adverse effect.¹⁸⁶ The absence of statistically significant dose-response relationships, cited by JECFA, is inconclusive. If all the individuals who were intolerant of neotame responded even at the lower of the two doses, then similar effects would have occurred in both test groups, and therefore the effects would not be ‘dose-related’. But that does not entail that the reported adverse effects were ‘sporadic’ or discountable. Without data in the public domain, it is not possible to be sure. JECFA was making RAP interpretative assumptions, but neither their use nor their adoption was transparent or precautionary.

JECFA stated that “[t]here were no serious adverse reactions during treatment...” but not how the distinction between ‘serious’ effects and those deemed not to be serious was drawn, nor who drew it. JECFA did not indicate whether the subjects participating in the study thought the effects were serious.

In relation to a short-term ‘range-finding’ 13-week mouse study of neotame, using 20 male and 20 female mice, JECFA said:

“In females, **haematology revealed small significant decreases in mean corpuscular volume** at 4000 and 8000 mg/kg bw per day, but these were within the historical reference range and not considered to be toxicologically significant. There were **slight but significant increases in absolute liver weights** at 8000 mg/kg bw per day **in both sexes** and slight but significant increases in relative liver weights in females at 4000 and 8000 mg/kg bw per day. These changes were generally within the ranges for historical controls and were not accompanied by microscopic changes. There were no treatment-related gross pathological

changes. Histopathological examination revealed a slight **increase in chronic inflammation of the kidney in both sexes**, but no dose–response was evident. The NOEL was 1000 mg/kg bw per day on the basis of changes in relative liver weight.”¹⁸⁷ (Emphases added)

If those adverse effects on haematology and liver weights were ‘significant’ in the formal statistical sense of there being less than 1 chance in 20 of having occurred randomly, in samples of just 20 mice, those changes must have occurred with conspicuous frequency. JECFA does not however report that frequency. JECFA said “...changes were generally within the ranges for historical controls...” but not how they compared to concurrent controls. The choice of comparing test groups to concurrent controls or to average historical controls (or to both) is an issue of interpretative risk assessment policy, and one that was implicitly being made by neotame’s corporate sponsors and by JECFA, but not by risk managers. JECFA discounted apparently positive evidence of toxicity as if it had been shown to be a false positive.

Similarly in the context of a discussion of a short-term study on dogs, JECFA said:

“The absolute weight of the liver was increased by 18% in males in week 12 at 1200/2000 mg/kg bw per day, and by 12–23% in females at 600 mg/kg bw per day. There was a significant increase in relative liver weight (to body weight) at 1200/2000 mg/kg bw per day in males (49% more than controls) and in females at doses of >600 mg/kg bw per day (27–35%). Absolute spleen weight was decreased in males in all groups (15–43%), and spleen weights were increased in females at 200 and 1200/2000 mg/kg bw per day only, although **none of these changes were statistically significant.**”¹⁸⁸ (emphasis added)

Given, however, that the experiment involved as few as 6 dogs per sex per dose level, the changes would have had to have been both severe and ubiquitous to satisfy the standard requirement for statistical significance.

¹⁸⁶ JECFA, Food Additive Series, 54, 2004, p. 103

¹⁸⁷ JECFA, Food Additive Series, 54, 2004, p. 107

¹⁸⁸ CoT Minutes, page 6 para 25

Neotame and weight change: toxicity or 'unpalatability'?

During the course of its discussion JECFA identified 18 separate studies in which laboratory animals treated with neotame exhibited absolute or relative body weight loss, and changes to organ weights. The effect occurred remarkably consistently. The lowest reported level of exposure at which that effect occurred was 30 mg/kg bw in a 14-day rat feeding study in groups of 10 male and 10 female rats per dose level. Nonetheless, at the conclusion of its assessment, JECFA deemed 200 mg/kg bw per day as the 'no observed effect level' (or NOEL), on the basis of the 1-year dog study. It was not that weight loss was not observed at lower levels of exposure, or that the weight changes were not 'effects'. It was an observed effect that JECFA categorised as one that did not count.

JECFA said that the weight changes were not toxic effects. Rather, the animals found the dosed feed unpalatable and therefore consumed less of it, implying that neotame did not make them ill, they just preferred to eat less if their diets contained it. JECFA did not deny that the animals did not thrive on the diets containing neotame, but discounted that effect by invoking a previously unstated interpretative assumption: that weight changes on their own, or symptoms that can be attributed to weight loss, can be discounted.¹⁸⁹

A possible false negative

JECFA repeatedly discounted evidence of putative adverse effects of neotame as if they could reliably be categorised as 'false positives', but was relatively forgiving when it came to possible false negatives. For example, studies on the degradation products of neotame included tests in what JECFA described as: "...mock beverages containing phosphate- and citrate-buffered solutions simulating formulations used in commercial cola soft drinks (pH 2.8 and 3.2), lemon-lime soft drink (pH 3.8) and root beer soft drink (pH 4.5)...These conditions simulated typical commercial, as well as extreme, storage conditions for beverages..." Since commercial cola products frequently contain high levels of caramels and often contain high levels of caffeine, the absence of tests on those more real-

istic mixtures is puzzling. Using insufficiently realistic 'mock beverages' could have generated false negatives, but JECFA did not request further studies on actual beverage formulations or more realistic models.

Summary

JECFA's assessment of the risks of neotame relied upon numerous implicit interpretative risk assessment policies. One key assumption illustrates an inversion of what was supposed to be happening under what is called a 'positive list' system. When 'positive list systems' were introduced in the 1960s and 1970s, the claim was that instead of food chemicals being assumed safe until proven harmful, they would be assumed risky until proven safe. JECFA's practice, however, has implicitly shifted to the contrary interpretative perspective. Evidence from studies suggesting no adverse effects were taken at face value, while evidence from studies suggesting that there might be adverse effects were subject to a far more critical examination, to see if there might be any grounds for discounting the evidence. Furthermore, several of those decisions to discount evidence of adverse effects, were based on hypotheses for which no supporting evidence was adduced.

Implicit routine toxicology risk assessment policies in the UK

From the 1960s until the European Food Safety Authority was established in 2002, the UK's CoT conducted scientific reviews of evidence of risk and safety of food additives. The CoT, however, disclosed far less than JECFA did by way of information or interpretations. Since 2003, when the AFC (or Panel on food additives, flavourings, processing aids and materials in contact with food) of the European Food Safety Authority was established, the CoT has not conducted a detailed comprehensive review of any food additives. Its food-related work has focused on contaminants and 'materials in contact with foods', such as wrapping and packaging. Since the CoT has not recently published any assessments of the toxicological risks from food additives, it is not possible to document its contemporary practices.

¹⁸⁹ It might not be a coincidence that the individual who uttered that remark acts as a paid consultant to a set of chemical companies.

On the other hand, since the implementation of the FSA's procedural guidance for scientific advisory committees, the CoT (and its subcommittees) has held (almost all of) its meetings in public. At a CoT meeting held in London on 28 March 2006, and in the context of a discussion of evidence indicating that a group of compounds might exert a carcinogenic effect in human consumers, a member of the committee said: "We [i.e. the members of CoT] have a particular responsibility to seek and to avoid false positives."¹⁹⁰ When that remark was made, none of the other committee members commented on, or contested; none suggested that avoiding false negatives was equally, or at least as, important.¹⁹¹

Germany

The institutional structure in Germany, and its risk appraisal and decision-making on GM crops and foods, is complex, opaque and problematic. Some implicit risk assessment policy judgements have, however, emerged from the interactions between the various institutions. Formally, only the BfR and the BBA are designated as a 'risk assessment body', but other institutions such as the RKI, the BfN (for GM foods and crops) and the UBA (for pesticides) are in effect hybrid institutions that, amongst other things, contribute to assessing the risks of GM crops and foods. The BVL is ostensibly the institution responsible for risk management, but it also conducts its own risk assessments of GM foods and crops. The BVL does not, and never has, provided any explicit risk assessment guidance to risk assessors or to hybrid bodies in advance of risk assessment; nor have ministers in the German government. The BVL does not see itself as empowered to provide RAP guidance.

The division of labour amongst the institutions, or lack of it, is complex and heterogeneous. Some questions are addressed and assessed by all of the participating institutions (e.g. molecular characterisation, compositional analysis, substantial equivalence, whole food toxicity studies¹⁹²),

while others such as the issue of post-release monitoring are assessed by several institutions. Some institutions discuss issues that seem conspicuously outside the scope of their remits. For example, the BfN sometimes comments on issues of allergenicity to consumers, while the RKI comments on environmental risk issues. The BVL sees its role as taking account of all of the possible risks on which the other participating institutions report. Each of the German bodies is implicitly making their own substantive RAP decisions.

Our interview evidence indicated that the interactions amongst different federal German institutions have been vigorous, and our knowledge of what happened is inferential, since the exchanges have not taken place, nor been recorded in the public domain. Protracted processes of negotiation appear to have taken place, the results of which only entered the public domain once agreed positions have been reached and delivered to EFSA or DG-SANCO. Available evidence suggests that the BVL's view is the one that tends to prevail.

The BfN has apparently been the institution that has interpreted the evidence and uncertainties in particularly precautionary ways. For example, in case of stacked events the BfN recommended that additional tests should be conducted on the resulting crop (including whole food toxicity tests, full molecular characterisation and investigation into genetic stability). The BVL, RKI and BfR, on the other hand, did not consider any additional tests to be necessary. With the dossiers evaluated since 2003 in Germany, the BVL, RKI and BfR interpreted the data as providing no indication of unintended effects. The BfN however often reported statistical significant differences, such as marked differences in levels of protein expression, for example in relation to GM Maize.¹⁹³

The BVL, RKI and BfR use the concept of 'substantial equivalence', and interpret it as providing a framework with which to assess the nutritional and toxicological consequences of consuming GM food, but only the BfN interprets it as including

¹⁹⁰ The level of in-depth assessment might however be different.

¹⁹¹ 2 The compositional analysis shows a substantial number of statistical differences between Mon863xMon810 and the control lines (Total comparisons 290; 71 significant differences with Mon846; 59 significant differences with Mon863; 122 significant differences with Mon810; 142 significant differences with commercial lines)." (BfN 2005, Notification EFSA/GMO/DE/2004/03 of the transformed application for Mon863 x Mon810 maize feed and food products in accordance with regulation (EC) 1829/2003

¹⁹² e.g. RKI comments on 1829/2003 dossiers of Cotton 281 and MON863xNK603

¹⁹³ Food Safety Commission Japan. *The Concept of Safety Assessment of the Food Derived from Breeding Recombinant DNA Plants*, Food Safety Commission Decision, 29 January 2004

agronomic, ecological and environmental aspects. The BfN would like to see further and more extensive field trials of GM crops in a wider variety of climatic and environmental conditions than the BNVL, RKI and BfR consider necessary. The BfN also called for more comprehensive studies of effects on non-target organisms and more often recommends post-release monitoring than the other institutions. The RKI has, for example taken a quite different approach, arguing that no monitoring is necessary provided that seed and biologically viable materials will be transported in ways that ensure that no unintended release would occur.¹⁹⁴ To the extent that they set the benchmarks of acceptability at different levels they are implicitly making different interpretative RAP judgements. Over time, the BVL in its role as risk manager has discounted the dissenting views of BfN when issuing official comments to EFSA or the Commission.

Japan

An example of implicit RAP in Japan can be found in the discussion about the possibility of synergetic effects of two proteins produced by inserted genes of maize DAS-59122-7 (see Sec. 4.3), which were recorded in the minutes of ECGMF meetings. It illustrates the case where an encounter with unanticipated phenomenon could lead to revealing underlying assumptions of risk assessment. In this case, the hidden assumption is that there is no possibility of interaction between proteins produced by inserted genes in cross-bred varieties (strains with stacked genes) made of a combination of insect-resistant and/or herbicide-tolerant GM crops. Based on this premise, the risk assessment of that type of strains is exempted in the guidance document.¹⁹⁵ However, the case of DAS-59122-7 cast a doubt on this assumption; although that maize itself was not a stacked genes strain: namely if the synergetic effects of proteins

are not specific to a particular combination of Cry34Ab1 and Cry35Ab1, it implies the possibility that such interaction could take place in various strains with stacked genes. While this possibility was finally denied by a new plausible explanation of the phenomena, the case brought a hidden assumption to the light.

More generally, as mentioned in Section 4.3, meeting minutes of relevant committees show that Japanese risk assessors of GM foods and crops share implicit conventions on how to address uncertainties. In principle, they have tried to resolve all significant uncertainties and to reach unanimous, clear-cut conclusion about safety of GM foods or crops.

Argentina

In Argentina, numerous GM crops have been deemed acceptable. However, CONABIA rejected an application for a variety of GM oil seed rape (canola) in 1997 on environmental grounds. It was not satisfied that it did not pose a significant risk of gene flow and out-crossing with wild relatives. That decision indicates at least two risk assessment policy assumptions, one concerning the scope of the assessment, and another concerning the amount of data sufficient to sustain a recommendation not to approve a proposed GM plant variety.¹⁹⁶

Most aspects of the procedure in Argentina remain unclear because they are either undocumented or because none of the documents has entered the public domain. Risk assessments are not published or made publicly available. What emerges in public is prescriptive advice to ministers from a hybrid committee of scientists, industrial representatives and civil servants, but no detailed assessment of possible risks is published.

¹⁹⁴ Interviewees also confirmed that effects of Bt crops on both insect-resistance of target species and on non-target organisms are also included in the scope of assessments, but their exact scope remains unclear

¹⁹⁵ op cit page 112 paras 34-36

¹⁹⁶ www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf

■ 7. Implementation of Codex and national guidelines

How does the organisation and conduct of risk assessments compare to the Codex guidance, and such domestic guidance as has been articulated?

Codex

The Codex Procedural Manual requires all its subsidiary risk management committees (e.g. CCFAC, CCPR and CCRVDF) to provide their risk assessment bodies (JECFA and JMPR) with risk assessment policy guidelines. Moreover, those guidelines: "...should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties." The document entitled *Risk Analysis Principles Applied by The Codex Committee on Food Additives and Contaminants* is as close as CCFAC comes to complying with that requirement, but the degree of compliance is partial and fragmentary. The corresponding draft documents from CCPR and CCRVDF, if adopted, would be even less compliant with the requirements of the Codex Procedural Manual.

CCFAC's *Risk Analysis Principles* represents a retreat from the text and spirit of the Codex requirement, and emerged as a compromise with JECFA. The document was not '...established by risk managers...in consultation with risk assessors and all other interested parties.' It was established following lengthy and relatively opaque exchanges between CCFAC and its secretariat, and with JECFA and its secretariat. There is no indication that 'all other interested parties' were able to engage in the process, or even know about it.

CCFAC's *Risk Analysis Principles* is in effect a 'peace treaty' between CCFAC and JECFA. They were able to agree to this text primarily because of its orthodoxy, and its avoidance of acknowledging that risk assessments are framed by some prior upstream risk management RAP assumptions. In February 2004, in the context of a disgruntled response to CCRVDF, JECFA insisted that: "**The de-**

velopment of risk assessment guidelines is an inherent part of the corresponding scientific work which **needs to be accomplished by risk assessors.**" (emphases added) CCFAC's *Risk Analysis Principles* does not state explicitly that the development of risk assessment guidelines will be accomplished by JECFA and by JECFA alone, but it included no suggestion that CCFAC could or should provide JECFA with such guidelines nor does it include any substantive or interpretative risk assessment guidelines.

It does, however, include a few procedural risk assessment policy provisions. JECFA is enjoined to: "...**communicate** to CCFAC **the magnitude and source of uncertainties** in its risk assessments. When communicating this information, JECFA should provide CCFAC with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment...JECFA should communicate to CCFAC the basis for **all assumptions** used in its risk assessments including default assumptions used to account for uncertainties...JECFA's risk assessment output to CCFAC is limited to presenting its deliberations and the conclusions...in a **complete and transparent** manner."¹⁹⁷ (emphases added)

Traditionally, JECFA was not instructed to draw attention to the existence, magnitude and significance of scientific uncertainties, to be explicit about its assumptions (let alone about **any or all** of them) or to present its deliberations completely and transparently. Implementing that procedural RAP guidance would represent a radical change of practice. JECFA continues to report only few uncertainties, and unevenly and inconsistently and in a relatively unprecautionary fashion, while numerous assumptions remain unacknowledged. In the context of a discussion about JECFA's comments on the genotoxic carcinogenic contaminant acrylamide, a JECFA member said: "JECFA is, in reality, not allowed to say 'we don't know and we cannot assess the risks' because that would be unacceptable to risk managers at CCFAC." This sug-

¹⁹⁷ e.g. Decision 2002/811/EC

gests that, in practice, JECFA has historically been under pressure to understate uncertainties, rather than to be entirely explicit, let alone exhaustively explicit, about the limitations and imprecision of the available scientific evidence.

The CCFAC text portrays JECFA as conducting scientific risk assessments within a policy-free zone, and CCFAC as making down-stream risk management policy judgements; any acknowledgment that up-stream policy judgements inform scientific risk assessments was in effect deleted. With the exception of a few, but important, procedural RAP provisions, the remainder of the document represents a retreat, as far as possible, from a transparent model (as in Figure 3, on p. 15) to a decisionist Red Book model (as in Figure 2, on p. 14). The CCFAC document is an attempted reinstatement of the supposed *status quo ante*. That text was, moreover, the product of a substantially opaque process, involving a small fraction of those with relevant interests. Consequently, not even CCFAC, or CCPR/CCRVD, has followed the procedure stipulated for them in the *Codex Procedural Manual*. Instead, they have contrived to veer away from full and proper implementation, and made a bid for reinstating the *status quo ante*.

USA

The contrast between the USA and the global institutions is quite striking. Accountability to Congress and the Courts, along with the implications extensive legislation, compels risk managers in the US Federal government to articulate at least some of the risk assessment policy parameters that guide substantive, procedural and interpretative aspects of risk assessment. Furthermore, the accountability to Congress and the Courts compels risk assessors to appear to comply with the explicit RAP guidance that risk managers have issued. Risk managers in the Executive Branch have established some RAP guidance and some has been embodied in Congressional legislation.

Procedurally, risk assessors are highly selective about which issues are emphasised for public con-

sultation, and which are left in the background. Official documents take account of uncertainties in implicit ways but rarely expound on uncertainties *per se*. Risk assessment policies have evolved markedly over the past 30 years. In the 1970s they were often more precautionary than those in Europe, but since the BSE crisis of the late 1990s that contrast has reversed. Currently, US agencies are required to provide quantitative 'scientific' justifications of any further tightening of regulations; while the requirements for deregulation or decisions not to restrict some product or ingredient are less exacting.

In March 2006 the US Federal government's Office of Management and Budget issued a *Proposed Risk Assessment Bulletin*.¹⁹⁸ Interpretations of what the OMB calls 'new technical guidance on risk assessments' is contested, but to a substantial extent it sought to formalise prevailing practices. The OMB proposes that all risk assessment bodies should be obliged to acknowledge all the uncertainties, while also quantifying the extent of those uncertainties; in practice, US risk assessors tend to focus on quantifiable rather than unquantifiable uncertainties.

Since risk assessors often deal with issues that go beyond those formally set out in the official guidance documents, some RAP decisions have been taken by risk assessors rather than by risk managers. Official US RAP guidance has often retrospectively codified existing practices, rather than prospectively setting benchmarks for judging issues that had not previously been settled, although the OMB's emphasis on quantification of uncertainties constitutes an attempt explicitly to set a new benchmark.

UK

In the UK, prior to the creation of the Food Standard Agency, the only domestic risk assessment policy concerning food safety was provided by Department of Health/Committee on Toxicity data requirements documents. They indicated which kinds of data would be required, and approximately how much of those kinds of data would be necessary. In

¹⁹⁸ Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW). *Standard Operating Procedure of Risk Management for Food Safety in MHLW and MAFF*, 25 August 2005. To implement this procedure, MAFF created the Investigation Committee for Risk Management (ICRM) as a private advisory body to the Director-General of the Food Safety and Consumers Bureau (FSCAB) of MAFF, whose membership comprises representatives of consumer unions and food industries, and the Food Safety Risk Management Support Team comprising the officials of FSCAB.

the UK, food safety risk appraisal and decision-making is organised in technological sectors, and separate administrative divisions, while separate expert committees deal with food additives, pesticides, GM foods and crops. In each sector, the risk assessors have some limited substantive RAP guidance; the Committee on Toxicity is evidently expected to consider toxicological issues. Similarly, ACRE is expected to consider risks to the environment of the release of GM crops and the ACNFP considers possible adverse effects on consumers from ingesting GM foods. Substantive RAP guidance is however vague, and defines only core issues not peripheral ones or the location of boundaries. The CoT and the ACNFP decide for themselves when and how far they consider issues of allergenicity and other types of acute intolerance.

Prior to the late-1990s, the UK system was more like the CODEX-JECFA system than it was like that in the USA. The Food Standards Agency, along with the government's Chief Scientist, has, in the aftermath of the BSE crises, issued some explicit procedural guidance. When the FSA developed that procedural RAP guidance it acted in a relatively transparent and inclusive manner, enabling a wider range of stakeholders to participate than had ever previously been the case in UK food policy-making. When the government Chief Scientist, and the Office of Science and Technology, developed its procedural guidance the process was less transparent or inclusive.

On the other hand, the FSA's procedural RAP instructions are not being fully implemented. Risk assessment committees are often, but not always, meeting in public, but the public do not have full access to all the information available to committee members. Risk assessors report some uncertainties, but in uneven and inconsistent ways. They make considerable efforts to identify and discount potential false positives, but pay far less attention to trying to identify, and take account of, false negatives. In that respect they are interpreting data in relatively unprecautionary ways. UK risk assessors are not providing full audit trails to their deliberations and decision-making, and they are drawing attention to only very few of their interpretative assumptions.

Germany

In Germany, in the GM field, there is not one set of risk assessment policies, but several sets that apply in different institutions. On the other hand, there is very little openness, and no transparency, and it is therefore difficult accurately to characterise the RAP regimes operating in those institutions. The processes by which they have been set have not been transparent or accountable, and there is no evidence that stakeholder groups have been consulted.

On generic procedural RAP, it is unclear if BfR risk assessors are actually following the BfR formal guidance on health assessments. Some aspects are increasingly being followed in relation to non-threshold toxicity; for instance with respect to the type of risk management advice that legitimately could be provided by risk assessors. In respect of policy on GM foods and crops, the only explicit RAP takes the form of an Interagency Agreement that sets mandatory procedures in the event of conflicting institutional advice, but it remains unpublished. It is explicit to the institutions that are parties to the agreement, but not to German citizens or stakeholder groups.

With respect to substantive and interpretative RAPs, given that the institutions are not remotely transparent, nor are the exchanges amongst them, it is hard to tell if and when EFSA and other EU Guidance documents are being followed, and if so which. There is some interview evidence suggesting that the RKI typically refers to the EFSA Guidance, while the BfN more commonly refers to the guidance provided by the Annexes of Directive 2001/18/EC and subsequent guidance notes.¹⁹⁹ Some commentators suggest that the BfN sometimes goes beyond the minimal requirements of the EFSA Guidance or at least interprets it in a more precautionary way, when compared with the RKI, BfR and BVL. German institutions are evidently not complying fully with the stipulations of the Codex procedural manual for risk managers to provide RAP guidance to risk assessors, and to develop that guidance in transparent and consultative processes.

¹⁹⁹ In fact, they distinguish two types of documents by name: guidance documents analyzed in this report is called 'assessment guidelines (*Hyo-ka Shi-shin* in Japanese)', while the RAP is 'assessment policy (*Hyo-ka Hou-shin*)'.

Japan

Japanese risk assessors of both GM foods and crops are provided by legislation with some substantive as well as procedural RAP guidance, but those documents do not refer to uncertainties, nor to how risk assessors should respond to uncertainties. The only explicit exception is the stipulation on monitoring for GM crops. In practice, however, evidence suggests that the attitude of risk assessors toward uncertainties is generally precautionary, although reference to that concept has rarely been explicit. Evidence also shows that risk assessors share some implicit conventions according to which they deal with uncertainties selectively but consistently. Some rules are generic ones that are shared inherently among scientists, and others have been established as particular rules specific to particular uncertainties through the discussion among risk assessors, as they are faced with those uncertainties. Additionally, the guidance document for microbiological risk assessment of food, a substantive as well as procedural RAP document, provides several stipulations that require risk assessors to conduct uncertainty analysis and sensitivity analysis.

In relation to the drafting process of guidance documents, compliance of Japanese risk assessors and managers with the *Codex Procedural Manual* seems ambivalent. On the one hand, Japanese guidance documents for GM foods, which are genuinely procedural and substantive RAP documents, were mainly developed by risk assessors in the FSC. The same applies to the risk assessment of other types of risk, such as microbiological risk and human health risk of antibiotic resistance resulting from use of antimicrobial veterinary medicinal products. In this regard, Japanese institutions are evidently not complying fully with the *Procedural Manual*. On the other hand, however, Japanese risk managers are now implementing a new risk management procedure in which establishment of risk assessment policy is allocated to risk managers in consultation with risk assessors and other inter-

ested parties,²⁰⁰ which is quite consistent with the Codex manual. This contradiction is explained by Japanese risk managers' understanding of what RAP is. In the first place, they do not recognize their guidance documents quoted in this report as RAP defined in the *Procedural Manual*. For them, RAP is more specific guidance to be set out for each case of appraisal and to include concrete information regarding what risk managers aim to achieve in their management and relevant designations to risk assessors.²⁰¹

Argentina

The Argentinean regime represents itself, as far as possible, in technocratic terms, with as few references as possible to policy matters, as opposed to scientific ones. The only extent to which some substantive RAP guidance has emerged, has been in the form of general data requirements, particularly for GM crops and foods. It is, however, not possible to tell whether or not that guidance is being followed in practice, given the lack of transparency. Consequently, the Argentinean regime accords to a lesser extent with the provisions of the Codex Procedural Manual than any of the other systems covered in this report. SENASA's food biotechnology office and its technical committees are simultaneously responsible for risk assessment policy-making, risk assessments and risk management decision-making, and the external observer is unable to discern differentiation amongst those tasks. The process by which risk assessment policy assumptions are adopted or decisions taken in Argentina is entirely un-transparent; some stakeholders in the private sector participate in the deliberations and decision-making, while all others are excluded. Argentinean institutions are evidently not complying fully with the stipulations of the Codex procedural manual for risk managers to provide RAP guidance to risk assessors, and to develop that guidance in transparent and consultative processes.

²⁰⁰ Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW). *Standard Operating Procedure of Risk Management for Food Safety in MHLW and MAFF*, 25 August 2005. To implement this procedure, MAFF created the Investigation Committee for Risk Management (ICRM) as a private advisory body to the Director-General of the Food Safety and Consumers Bureau (FSCAB) of MAFF, whose membership comprises representatives of consumer unions and food industries, and the Food Safety Risk Management Support Team comprising the officials of FSCAB.

²⁰¹ In fact, they distinguish two types of documents by name: guidance documents analyzed in this report is called 'assessment guidelines (*Hyo-ka Shi-shin in Japanese*)', while the RAP is 'assessment policy (*Hyo-ka Hou-shin*)'.

■ 8. Conclusion

The foregoing discussion demonstrates that there are at least three types of RAPs: substantive, procedural and interpretative. Furthermore, those 3 sets of RAPs are individually, jointly and severally pivotal to the construction and outcomes of scientific risk assessments. Risk assessments are routinely portrayed as if they were purely scientific; but that is always an oversimplification and misrepresentation.

RAP issues are concerned with scientific deliberations about risk but they are not themselves strictly scientific issues. They are not issues that scientific considerations on their own can settle. They are often the types of issues for which risk managers, as policy-makers rather than as scientific experts, could and should be taking responsibility.

Often, perhaps too often, RAP issues are being decided by risk assessors, pretending to scientific purity and policy neutrality. But those decisions can not be decided purely scientifically. Those issues are too often being decided in unaccountable ways.

Nonetheless, in all of the jurisdictions and institutional settings covered by this study, some RAPs have been set by risk managers, but that has not occurred consistently. There is little consistency within jurisdictions across risk categories or within risk categories across the justifications. Often RAP issues are being decided in ways that are not in accordance with the provisions of either the Codex Procedural Manual or domestic national policy guidance.

If the spirit and the letter of the Codex RAPs guidance were to be followed both by Codex and the national jurisdictions, then food safety policy-making would be conducted in more open and accountable ways. One consequence might be higher levels, and more wide-spread patterns, of domestic support. Another consequence might be, either fewer international trade disputes, or at any rate the conditions under which disputes could be resolved would be more readily appreciated.

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Title: Risk-assessment policies: Differences across jurisdictions

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Abstract

This project has examined food safety risk assessment policy (RAP)-making at the global level (in the Codex Alimentarius Commission and its joint FAO/WHO expert advisory committees) in the USA, the UK, Germany, Japan and Argentina, in relation to chemical risks and to risks from GM foods and crops. Our research shows that RAP can be understood as comprising 3 considerations that condition the ways in which risk assessments (RAs) are framed, conducted and reported. Procedural RAPs are concerned with the responsibilities of risk assessors (RA) and the processes by which risk RAs are conducted. Substantive RAP issues are concerned with delineating which potential changes and effects are included within or outside their scope. Interpretative RAP issues are concerned with the ways in which data are interpreted. Data and documents do not interpret themselves; interpretation often involves judgements and assumptions. Often, when different RA reach different conclusions, they do so because they are adopting distinct RAPs rather than because some committees provide more or less scientific answers than others. They do not provide conflicting answers to common and agreed sets of questions concerning shared and agreed bodies of evidence. Often they are answering different questions because they make different RAP assumptions and are considering different sets of data. Even when the sets of questions and data coincide, different RAP assumptions may entail interpretation in different ways. Making a wider range of RAP issues explicit, and deciding them in transparent ways, can provide resources to address disputes, both within and across jurisdictions. Some RAP issues have been explicitly addressed in all jurisdictions studied but only rarely they are fully acknowledged, and decided by risk managers (RM) in consultation with all relevant stakeholders previous to the conduct of RAs. Only sometimes are they addressed in transparent or accountable ways. Though over time, they are becoming increasingly explicit. All settings studied have at least some RAP guidelines, but none comprehensive and explicit, or covering all 3 procedural, substantive and interpretative issues. While some maintain that scientists should be left to decide the agenda for scientific deliberations, others argue that there should be more opportunities for all stakeholders to contribute to articulating the questions that the scientists are requested to address. That task has often previously been referred to as risk identification or hazard identification, which sets the agenda for the subsequent deliberations of RA. Within the policy literature, there are disputes between those who assert that risk identification is a scientific task and others who argue that it is a risk management responsibility. Our findings suggest that it is a discussion to which RA, RM, other stakeholders and individual citizens can helpfully contribute. Similar arguments apply to procedural and interpretative RAP issues too. Making RAP decisions explicit might be seen, by some RM, as an unwelcome extra burden, and by some RA as an unwelcome intrusion into matters over which traditionally they were able to exercise autonomy and discretion. However, if RM took greater explicit responsibility for RAP-making they could more readily justify and sustain regulatory decisions and policy differences, allowing comparison across jurisdictions, clarifying the basis for their differences and possibly overcoming them.

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