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European Risk Governance

Its Science, its Inclusiveness and its Effectiveness

Ellen Vos (ed.)

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List of Abbreviations

AFSSA	Agence Française de Sécurité Sanitaire des Aliments (French Food Safety Agency)
BDH	Bundesvereinigung Deutscher Handelsverbände e.V. (German Federation of Retailer Associations)
BR	Basic Regulation
BRC	British Retail Consortium
BSE	Bovine Spongiform Encephalopathy
CCs	Citizens' Conferences
CCP	Critical Control Points
CEVA	Ceva Santé Animale
CFI	Court of First Instance
CIAA	Confédération des Industries Agro-Alimentaires de l'UE (Confederation of Food and Drink Industries of the EU)
CIES	Comité International d'Entreprises à Succursales (International Committee of Food Retail Chains)
CLIC	Comité Local d'Information et de Concertation (Local Committees for Information and Dialogue)
CMRs	Carcinogenic, Mutagenic and Reprotoxic Chemicals
COM	European Commission
CPMB	Committee for Proprietary Medicinal Products
CPVO	Community Plant Variety Office
CRA	Committee for Risk Assessment
CSEA	Committee for Socio-Economic Analysis
DG SANCO	Directorate General for Health and Consumer Protection
DNEL	Derived No-Effect Levels

EASA	European Aviation Safety Agency
EC	European Commission
EC	European Community
ECB	European Central Bank
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECOSA	European Consumer Safety Association
ECR	European Court Reports
ECSC	European Coal and Steel Community
EEA	European Environmental Agency
EEC	European Economic Communities
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EINECS	European Inventory of Existing Chemical Substances
EMA	European Medicines Agency
EMSA	European Maritime Safety Agency
ENDS	Environmental Data Services Ltd
EP	European Parliament
EP ENV	Environment Committee of the European Parliament
ERA	European Railway Agency
EU	European Union
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
FP	Framework Programme
FPA	Food Products Association
FSA	Food Standards Agency
GFL	General Food Law
GFSI	Global Food Safety Initiative
GM	Genetically Modified
GMO	Genetically Modified Organism
HACCP	Hazard Analysis and Critical Control Point
ICAO	International Civil Aviation Organisation
IFS	International Food Standard
IGO	Inter-governmental Organisation
ILO	International Labour Organization
IPHB	Institution Patrimoniale du Haut-Béarn (Patrimonial Institution of the Haut Béarn)
ISO	International Standardization Organization

JAA	Joint Aviation Authority
JRC	Joint Research Centre
MEP	Member of the European Parliament
NAA	National Aviation Authorities
NAFTA	North American Free Trade Agreement
NASA	National Aeronautics and Space Administration
NGO	Non-governmental Organisation
NRA	National Regulatory Authority
NRC	National Research Council
OGM	Organisme Génétiquement Modifié (Genetically Modified Organism)
OJ	Official Journal
OLAF	Office pour la Lutte Anti Fraud (European Anti-Fraud Office)
PNEC	Predicted No-Effect Concentrations
PPP	Public-Private Partnership
PTA	Participatory Technology Assessment
PTBs	Persistent, Toxic, Bioaccumulative Substances
QMV	Qualified Majority Voting
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RAISE	<u>R</u> ecognition of the <u>A</u> chievements of Women <u>I</u> n <u>S</u> cience, <u>M</u> edicine, and <u>E</u> ngineering
RPWS	Regulatory Procedure With Scrutiny
SCCP	Scientific Committees on Consumer Products
SCENIHR	Scientific Committee on emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental
SEA	Socio-economic Analysis
SH2	Securing Health Together
SPS	Sanitary and Phytosanitary Measures
SSC	Scientific Steering Committee
STOA	Scientific and Technical Options Assessment
TBT	Technical Barriers to Trade
TIA	TRUSTNET in Action
TPCs	Third-Party Certifiers

TSE	Transmissible Spongiform Encephalopathies
UK	United Kingdom
UNCITRAL	United Nations Commission on International Trade Law
US	United States
vPvBs	very Persistent and very Bioaccumulative Substances
VWA	Voedsel en Waren Autoriteit (Dutch Food and Consumer Product Safety Authority)
WHO	World Health Organisation
WTO	World Trade Organisation
WWF	World Wide Fund for Nature

Foreword and Acknowledgements

Ellen Vos

The question of how public authorities should deal with risks and uncertainties has become a dominant concern in the wake of the 1992-programme on the creation of the internal market. CONNEX Research Group 6, *The Transformation of the European Policy Space*, co-ordinated by Renaud Dehousse, thus provides a critical assessment of the devices that have been established to ensure cooperation between the national and the European level in various areas. It addresses the mighty problem of how to integrate scientific expertise into policy decision-making.

The major institutional shortcomings of EU policies (along with those of the Member States) were put under the spotlight by the BSE crisis and triggered a severe crisis of public confidence in both scientific advice and in the management of risks by EU and Member States authorities. It provided a classic illustration of uncertainty in science and of the complex and vital relationship between science and society. Both regulators and the general public have consequently become increasingly aware of the risks that are intrinsic to the food industry, whilst the continuous stretching of the frontiers

of science in areas such as biotechnology have raised public anxiety levels still further. It thus has become clear that risks must be approached as political issues. This is all the more the case since their emergence cannot be dissociated either from the more important transformations within regulatory regimes (such as food production in the 1980s), or from the resurgence of contestation and political mobilizations within most European countries (for example, in relation to GMOs). These crises, scandals and controversies have, in turn, shaped the way in which risks are perceived and subsequently managed, with strong implications for understandings of political accountability, the role of science and stakeholder participation.

Hence, whilst it is true that innovation may improve the quality of life, and is essential for economic growth, at the same time it raises uncertainties and concerns, and can bring new hazards to human health and the environment. Hence, how should regulators react to scientific studies which show the carcinogenic effects of UV-filters in sun creams, presumably because they disturb the human hormone balance? And what should they do with studies indicating that carcinogenic substances (acrylamide) are formed when baking bread or frying potatoes, and thus pose a health risk when consumed; or that farmed salmon contains potentially hazardous levels of dioxins and PCBs?

It is clear that risk governance – embracing risk identification, assessment, management and communication – has become a crucial but often highly controversial component of public policy, particularly at the EU level.

Since the outbreak of the 1996 BSE crisis, there has been much debate on the role of science in European regulatory decision-making and in particular on the need to separate risk assessment from risk management. The Medina Ortega report concluded, *inter alia*, that the relationship between scientific and political decisions was blurred. Moreover, it held that the

Commission suffered from poor internal management; decision-making procedures were not transparent; some national interests held too much weight in the decision-making process; and the resulting legislative controls were not effectively implemented. In particular, the existing committee system was the subject of critique because of its complexity, obscurity and its undemocratic character. Moreover, the Medina Ortega report concluded that the EU institutions, the Commission in particular, had failed to take public health seriously, and that they had attached more importance to the national interests of agriculture and the interests of industry than the protection of public health. The Report thus urged greater transparency as regards action on BSE, particularly in relation to the conditions of the functioning and contribution of the scientists on the scientific committees; moreover, the Report stressed the need for transparency and reform of the rules governing the work of these committees to ensure independence and appropriate funding of the scientists, and the publication of debates within committee and any dissenting opinions.

Not surprisingly, in the aftermath of this crisis, far-going reforms were carried out both at European and national level so as to relate scientific advice more concretely to the principles of excellence, transparency and independence, and to allow for greater stakeholder participation. Whilst at the European level a strict separation between science and politics has been introduced in the area of food, in other countries a more blurred relationship between science and politics has been admitted. Moreover, in the aftermath of BSE, we are witness to an increased emphasis on transparency of science- and decision-making as well as the participation of stakeholders and the public.

Based on experience that can be drawn from risk governance in practice, this volume aims to discuss the role of institutions, both scientific and regulatory, in European risk governance, and the dialogue that takes place between risk assessors, risk managers and stakeholders in order to overcome the crisis of confidence. In this manner, it seeks to define what

lessons have been learnt and put into place more than 10 years after the outbreak of the BSE crisis. Are the principles of transparency and participation truly applied to risk governance, in particular to risk assessment? What is the impact of the precautionary principle on European decision-making and the role that science and scientific experts/expertise play in risk governance (both in the science- and decision-making and before courts)? Should scientific advice be separated strictly from regulatory decision-making? In other words: should risk assessment be strictly separated from risk management? What is the role of agencies in this? Importantly, too, what is the role of lay people in the production of scientific advice: is science and scientific advice only produced by the recognised experts (natural science), or do citizens or specific stakeholders also have a role to play? Should stakeholders and/or the general public participate in science-making? If yes, why, in what form and to what extent? To what extent should stakeholders, civil society and/or the general public participate in decision-making?

In addition, we may observe that the intermingling of public and private regulation is increasingly used as a tool for effective risk governance. Here questions are raised as to how emerging public-private partnerships should be understood and their degree of effectiveness. Do we need more self-regulation? Do we need more powers at the EU level to control safety regulation? And, what is the risk of transferring more such powers to European agencies?

These questions were addressed in the CONNEX workshop that was held on 14-16 June 2007 at the Faculty of Law, Maastricht University, Maastricht, The Netherlands (the activity report is available on the CONNEX website under past activities, <http://www.connex-network.org/>). The current Report contains a selection of the papers presented at this Workshop.

I would like to thank a few colleagues without whom the realisation of this Report would not have been possible. I would like to thank Morag Goodwin for the English language correction of all the Chapters. Special thanks go to Marina Jodogne who provided invaluable assistance through her able and patient work in the preparation of the camera-ready copy of this Report. Many thanks also to Laura Tilindyte and Tanja Ehnert who helped me enormously in the organisation of the workshop, the writing of the activity report, the proof-reading and the checking of all the footnotes. I would also like to express my gratitude to the CONNEX-coordinators for providing me with the opportunity to organise the workshop and to publish this report. I would like to thank in particular Fabrice Larat and Thomas Schneider for all their support. Moreover, I would like to thank the European Commission and the Netherlands Organisation of Scientific Research (NWO) under the Innovational Research Scheme for financing this project. Last but not least, I wish to thank Diana Schabregs for all her able assistance in navigating our way through the financial administration of the projects.

Chapter 1

European Risk Governance in a Global Context

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Introduction: The Crisis of Confidence

The ramifications of the BSE crisis of the 1990s have stretched far into the 21st century. The collapse of consumer confidence caused *inter alia* by shortcomings in the institutionalisation of scientific knowledge within both the EU Member States and within the Union itself prompted wholesale re-evaluation of prevailing structures of science-based decision-making. However, losses in consumer confidence have not been the only catalyst for the change in the manner in which we view the legitimate use of science within government. In addition to the indisputable need for a review of the quality of scientific advice used to verify agricultural production methods, the extraordinary degree of public political disquiet about the authorised use of genetically modified organism within agriculture and industry has raised new issues about science-based governance. Today, the issue is not merely one of ensuring that the science used in governance is sound. Instead, thought must be given to the balancing of scientific opinion against wider ethical and social values.

Burning cows in English fields and images of slaughterhouses, cattle-blood and -brains led not only to a fall in beef consumption but also to a drop in citizens' belief in the credibility of government. How could citizens ever trust governance structures which gave priority to agricultural concerns over the protection of their health?¹ Governmental responses entailed institutional and procedural reform to ensure the quality and transparency of science-based decision-making, and the participation of citizens throughout the process. A similar political outcry in relation to the authorisation of GMOs only intensified the need for such governmental efforts to reform the institutions of risk governance. In addition to exposing failings in the quality of scientific advice used within decision-making, the BSE crisis also highlighted problems of scientific uncertainty. It became common knowledge amongst the public that scientists would not always have answers to problems of risk. To what degree would infected beef within the food chain result in full scale infection of the human population with the new-variant Creutzfeldt-Jakob disease? The debate around GMOs was not only marked by an even greater degree of conflict around scientific uncertainty, but also began to raise issues of whether under conditions of scientific uncertainty, it would be legitimate to demand that scientific rationalities could ever be overruled by ethical or social values.

New approaches to risk analysis, introduced in the wake of BSE and in the face of a growing controversy about the authorised use of GMOs, sought to combat the 'organised irresponsibility' (see Beck 1986, 2005) that had marked much risk policy at both Member States and EU level in the previous years. Reform was carried through at an institutional level, with a clearer separation being made between risk assessment and risk management; a reform which consolidated executive management of risk, making clear which portions of risk policy would be attributed to scientists and bureaucracies and the rules under which scientific advice was to be collated and adopted.² Further, reform also saw an increase in procedural standards of

risk oversight, above all with regard to the strengthening of the principles of openness and participation as well as the precautionary principle, a seemingly 'neutral' standard allowing pre-emptive regulatory intervention to combat uncertain risks (see in particular Fisher 2007).

One side-effect of the effort to regain public trust in the credibility of risk regulators and regulation was the strengthening of the bureaucracy and executive centred around risk regulation; the newly consolidated executive, with its newly apportioned responsibilities within the process of risk analysis, was to be the main vehicle through which public trust might be regained. Equally, the consolidation of executive powers and profile within the risk constellation was only augmented by virtue of the globalisation of markets and the consequent internationalisation of risks and institutions. Even though the Commission and other Member States were keen to portray BSE as a purely British problem, consolidated food markets within the EU ensured that the Commission and national regulatory authorities were inevitably confronted with the management of the BSE risk. By the same token, GMOs are not geographically confined such that a consolidated EU GMO policy will still require co-ordination with national and international policies and institutions of market management. Within the ever more global trade context, normative, practical and legal pressures tend to encourage networking of executives and of bureaucratic/legal rationales. For example, the technical standards generated within the framework of the Codex Alimentarius Commission gain in significance as an evidential aid within the science-based WTO framework and, thus, inevitably function as a magnet for the executive agenda-setting preoccupations of national and supranational bureaucracies such as the European Commission (see Mason-Matthee 2007).

In this ever more global world of risk management, the EU executive has an increasingly complex task to manage risks. As the most powerful supranational bureaucracy, the European Commission has unparallel

significance acting as a nodal management structure between national and international frameworks of risks. In this contribution, we aim to understand the dynamics of European risk governance and its embeddedness in the ever more global context of risk regulation.

Science as a Panacea?

Faced with the shortcomings identified above, in particular the European Commission, in handling the BSE crisis, one line of reform concerned the separation of risk assessment and risk management at the EU and national level. As such, it involved conceiving of the movement of science, and the responsibility for scientific advice, out of the traditional executive framework into independent bodies. From this, regulatory provision that risk assessment and management must be made institutionally independent from one another both at European and at Member State level, hereby linking with the international concept of risk analysis of the Codex Alimentarius Commission, flowed.³ This new regulatory philosophy whereby the hazard potential is, where possible, formulated as a quantifiable risk solely with reference to technical and scientific criteria has thus found institutional approval in the creation of independent scientific/technical bodies such as the European Food Safety Authority (EFSA) at the European level and the British Food Standards Agency (FSA), the French *Agence Française de Sécurité Sanitaire des Aliments (AFFSA)* and the Dutch *Voedsel- en Warenautoriteit (VWA)* at the national level. By the same token, the risk management function, or the final decision on the acceptability of risk, is made a clear responsibility of traditional executive bodies such as the European Commission at European level and national administrations within the Member States.

Within this emergent regulatory philosophy of rationalisation of risk assessment and management functions, the growing reliance on technical and scientific criteria for the framing of the risk problem as well as the mode of

combating risk interestingly may also extend to constellations of scientific uncertainty and to the overcoming of uncertain risk. In other words, even in cases where science cannot adequately quantify risk, or situations in which there are suspicions of hazard, although scientific or historical evidence is lacking, rationalising regulatory strategies may yet prevail. Typically, ‘uncertain risks’ concern particular instances of suspected possible hazards that are usually associated with complex causalities, large-scale, long-term and trans-border processes, and which are usually difficult to control (see Van Asselt, Vos and Rooijackers 2008). Equally typically, these uncertain risks not only reveal the limits of science but also unveil their political character as a wider public perceives that those hazards could impact negatively upon society and therefore demand that some action be taken by political actors.

Nonetheless, with a notion of ‘precaution’, constitutionalised within the European Union as the precautionary principle, uncertain risk may yet be treated within a rational framework of decision-making devoid of direct interaction, whether deliberative or otherwise, between societal and technical values. Alternatively, in one analysis, precautionary action – or the notion that restrictive interventions are justified where hazard may not be verified in a quantifiable manner, but qualitative analysis suggests that potential damage is large-scale, irreversible and impacts significantly upon large sectors of society – is still founded in rational-technical science.

Fisher’s analysis demonstrates that executives – whether made up of traditional bureaucratic bodies such as the European Commission or now found in independent bodies dedicated solely to technical analysis and the promulgation of science – can restore and secure public faith in the credibility of risk regulation through application of a rational instrumentalist model of administrative decision-making (Fisher 2008). Risk may pose great threats to the joint enjoyment of the social environment. Equally, hazard and uncertain risk remains a constant source of social anxiety. Nonetheless, the distinction

made between risk assessment and risk management, clear rules guaranteeing the quality of scientific advice and the independence of experts, together with the rationalist constitutional reading of the precautionary principle seemingly provide us with a rational framework that obviates irrationality fears. It thus ensures that decision-making takes place in a context free from interest politics and the value irrationalism that otherwise marks unstructured public political debate.

Offering us a tool to combat the negative externalities of the global risk society that has developed in tandem with global, liberal patterns of trade and development, rational instrumentalist philosophies both help to structure executive action and further facilitate interaction between executives within the global complex of national, supra-national and international executives. One language is spoken by all; a language, furthermore, which, with its Weberian claim to establish common truths out of diversity, is perfectly suited to the management of risk between diverse societies.

However, the ‘panacea’ of science and instrumental rationality is perhaps not all it would seem to be. Where it would mean that paradoxically more resort to science is taken in situations of uncertainty (see Weingart 1999: 151-161), it is by definition in these situations of uncertainty that science reveals its true limits and that other factors, such as social and ethical concerns, are bound to play a role. In this way, the European Commission for example recognises that in situations in which the precautionary principle is applied, other factors than science should also be taken into account in the decision-making process.⁴ Inevitably, this has led to much controversy surrounding the precautionary principle, where it is considered by some as a principle that gives almost *carte blanche* to arbitrary decision-making and by others as a principle that allows for a more reflexive and pluralistic decision-making process.⁵ Interestingly, it is increasingly recognised that there cannot be a single definition of this principle across the European Union, the

national levels and the global level, as the principle strongly depends on its context and the legal culture in which it is embedded (see *inter alia*, particular Fisher 2007).

We have already noted that failings within the historical scheme of ‘organised irresponsibility’ for risk regulation led to an immediate crisis of public confidence and a governance response which stressed the need to re-establish credibility through the scientification of knowledge production on risk and the clear apportionment of assessment and management responsibilities to the traditional executive bureaucracy and newer independent technical-scientific bodies. This governance response, privileging technical rationalities and leading to a consolidation of the executive in the broad sense, was also well suited to the complexities of a global trade regime and the need to find decisional criteria which might overcome cultural sensitivities and the clash between economic and non-economic values. However, the expanded and consolidated executive function which this evolution has entailed, together with the technically-rational philosophy within which it is founded, is itself a new governance threat: executives thrive on consolidation and conformity. Thus, for example, notwithstanding its recognition that socio-economic values impact upon the precautionary decisional equation, the European Commission nonetheless seeks to promote a monolithic conception of precaution, viewed in some sections of society as an arbitrary yardstick, which fails to take account either of science or of the very series of diverse social and cultural interests it was designed to protect (see Fisher 2008).

At one level, the monolithic nature of the principle of precautionary action that the Commission promotes, raises a very old spectre indeed. Although he argued in favour of formal bureaucratic rationalities, Max Weber expressed concern that rationalising tendencies within modernity would also give new life to the danger of despotic behaviour (Weber 1976).

A rational administration would also be deaf to human concerns that are not recognisable within rationally structured discourse. Within the expanded and consolidated executive function, spanning national, supranational and international entities we might accordingly be concerned that the emphasis laid on the use of science to define and frame the problems which risk regulation must address, together with the instrumental rationality that marks processes of interlinked risk management across the global institutions of trade regulation, might lead to a fatal disregard for ethical and social sensibilities (Everson and Eisner 2007).

Equally, however, the spread of the executive function across local boundaries to embrace a global world can also be argued to obscure the real rationales that underlie decision-making. As empirical analysis of the case of Pfizer, a European refusal to authorise the use of particular antibiotics as growth promoters within European pork markets, demonstrates (Van Asselt, Vos and Rooijackers 2008), executive decision-makers may be tempted to hide behind ambiguous scientific findings to pursue their own agendas. In this case, the European Commission did not listen to the relevant European scientific body's conclusion that there was no immediate risk to human health and preferred to refer to other scientific bodies (the Dutch Health Council, WHO, UK House of Lords) who adduced scientific uncertainty. On the basis of the findings of those bodies and some use of the language of the uncertainty by the European scientific body, the European Commission constructed its argument of scientific uncertainty that formed the basis of its precautionary measures: i.e. a ban on the relevant antibiotics on the European market, whilst it could have more openly acknowledged that the ban was an outcome of its desire/policy to combat resistance to antibiotics, which is in fact a human health concern within the Community. On the other hand, empirical analysis also makes clear that the Commission desperately needs advice from scientists in what is an area of highly technical and complex

issues to help them with identifying the human health concerns and to guide them in their decision-making. For example, one interviewed Commission official pictured the relationship between the European Commission and EFSA as being one of a blind driver, the Commission, and a directions-giving passenger, EFSA (Vos and Wendler 2006: 122).

Seen in this light, the executive nature of global risk governance raises a dual and interconnected problem of too great an emphasis on the decisional legitimacy of scientific and technical criteria, together with a refusal to make transparent the social and economic values that guide decision-makers. The problem is one of de-politicisation, or, better stated, a politicisation of the scientific executive function, which might and can lead to obscure and insensitive decision-making at the level of the simple application of science to complex social relations, and which might furthermore also deny its own normative underpinnings or commitment to positive values such as human health.

In a final analysis, then, the tension between the functionalist necessity for science-based decision-making and the wider demand for a form of public participation within risk governance continues to be the primary characteristic of modern risk governance regimes. The potential inhumanity and obscurity of a science-based rationally instrumentalist executive must be balanced by public participation, which is more transparently dedicated to the re-introduction of ethical and social criteria within the bureaucratic discourse. At the same time, however, explicitly political debate must be subject to the limits of science, and more particularly must continue to be disciplined in the light of neutral, technical-scientific criteria.

Precaution and the Problems of Political Pluralism

If modern schemes of risk governance might be said to be characterised by ongoing tension between scientific/technical rationalities and the demand for appropriate consideration of the ethical, social and economic values that may also be affected by global trade regimes; then, by the same token, the primary function of risk governance might also be argued to be the effort to bring scientific rationales and social/ethical values into a lasting equilibrium within stable institutional structures of governance. As a consequence, the process of risk management which, as we have seen, is sometimes simply conceived of as a bureaucratic exercise of adapting regulatory intervention in the light of technocratic/scientific analysis, might be viewed in a wholly different manner. Where the task is one of balancing rationales and values, risk management is a political exercise, a discursive process of the establishment and implementation of a policy about risk and its regulation.

As the case studies reveal, in practice as well theory, the precautionary principle is coming to be regarded less as a neutral procedural standard to be applied in the exceptional context of uncertain risk and more as an institution in its own right within which risk policy is drawn up. As Rothstein notes in relation to the activities of the UK Food Standards Agency, recent regulatory debates within the UK reveal ‘how scientific, normative and institutional uncertainties provide significant scope for conflict on what constitutes precautionary action’ (Rothstein 2008). The core of this contention is provided by the insight that, even in relation to simple (quantifiable?) risks, ‘scientific knowledge does not provide an uncontested universal evidential basis for decision-making’. Instead, a proposed UK ban on sausage skins teaches us that where a country has no economic and societal interest in maintaining a product on its market, it is not difficult to address uncertain risks within a precautionary action, which was then considered to be proportional. This was not the case within the whole of the EU, and more

particularly in Germany where natural sausage skins are used on a very large scale. The notion of proportional precautionary action allowed the Scientific Steering Committee at EU level to shift its evidential basis and reject a precautionary ban on sausage skins on the basis of the relative lack of risk posed by them in comparison to normal carcass meat (Rothstein 2008).

The perception that precaution is a policy and not a simple neutral cost-benefit criterion since costs and benefits may vary in relation to the overall socio-economic context within which risk is posed, is further confirmed by the legal reasoning structures adopted by US courts in their oversight of food regulation. Here precaution does not have a meta-legal status as an independent criterion that may be applied to all cases regardless of their factual constellation. Instead, it is argued to be a 'high level policy' which political actors must use to elaborate particular rules to apply to particular fact-finding procedures (see Walker 2008). The legal contextualisation of the principle underlines its relational status. Precaution and the evidential basis for precaution alters in the light of the particular circumstances of production, the socio-economics of particular production processes, as well as with regard to the legal culture within which evidence for precaution must be established.

The recognition that the evidential basis for precaution and the evaluation of risk will necessarily fluctuate in light of institutional, social and economic contexts, in its turn, raises new questions about the renewed emphasis upon 'participation' within governance that we have seen since the BSE crisis. At one level, the move towards the securing of greater degrees of public participation within risk governance structures might be considered to be part of the overall effort to improve regulatory institutional credibility through greater participation and transparency with the consequential enhancement of the trust of citizens in the risk management regime. However, once we have admitted that risk management is itself a necessarily

political process, entailing the weighing of relative substantive costs and benefits of fluctuating interests, the inevitable political contestation which such processes entail may also be argued to necessitate public participation with the executive for other normative and efficiency reasons.

Thus, participation, and more particularly public participation within institutional structures of risk governance, can serve a variety of rationales. As has been suggested, in contrast with traditional bureaucratic structures whereby delegation was itself considered to be a manifestation of public trust in the efficacy of the executive process, and further, was designed to overcome complexity in regulatory matters, trust in modern risk management can only be assured where the public is afforded participatory tools that allow it to oversee each stage in the management of complex issues. In contrast, however, public participation within executive structures can also be viewed to be a part of a general normative scheme of government which demands that executive action always be integrated within democratic decision-making. Participation then, in this constellation, is seen as a vital element of democratic legitimacy. Finally, participation may also be conceived of in an ‘instrumentalist-normative light’, focusing on the quality of the outcome of the decision-making process, and thus aimed at enhancing the quality of decisions.⁶

In this latter perspective, the recognition that scientific evidential bases are not monoliths, nor are they indisputable truths in their own right, but are instead both necessary to structure and constrain debate, and are at the same time, relative both to the institutional context and the material problem constellation to be addressed, has as its necessary corollary an alteration in the significance that is attached to the material views and opinions that participation brings to the risk management and risk assessment process. In this context, participation does not simply serve abstract normative goals of government such as enhancing trust or meeting democratic requirements, but

also acts *as a part of knowledge creation itself*, as a material contribution to the evidential bases for assessment and management of risk. In this way, participation thus aims to enhance the *quality of both scientific opinion and the management decision*. By allowing citizens and/or stakeholders to provide knowledge about the scientific issues at stake on both a scientific/technical level as well as on the level of ethical and social values, scientists are confronted with knowledge within a wider context, also allowing for lay knowledge to be introduced in the ‘hard science’ context (see e.g. Wynne 2001: 445-481). In addition, allowing stakeholders and/or citizens to participate in management decision-making may also enhance the quality of the ultimate decisions as they would be able to express themselves on the management options/preference at hand, thus augmenting the knowledge-base for decision-making.

Participation as a contribution to knowledge creation seems thus a sensitive response to the threats thrown up by a global risk governance regime. Ameliorating the potential ‘inhumanity’, insensitivity and opaqueness of bureaucratic and scientific rationales, participation as knowledge creation can be argued to represent a shift within conceptions of governance and to be a positive response to the complexity of uncertain risks. However, participation as knowledge contribution must also be recognised to give rise to its own particular problems of the institutional structuring of risk governance. In contrast to traditional bureaucracies which ensured unitary and universal decision-making through the exclusion of public participation from implementation processes, the re-evaluation of participation as a positive contribution to knowledge creation also demands that we identify institutional mechanisms and procedures which reconcile potentially irreconcilable rationalities of science and ethics, and which further guard against executive capture by inappropriate interests, or even an utter collapse in the executive function as plural processes of knowledge creation descend

into meaningless and fruitless conflict between varied views and interests. Historically, trust was a communitarian good established within normal political processes. It predated and justified delegation in the effort to reduce regulatory complexity.

Three Models of Plural Risk Governance

In the preceding sections we argued that within the traditional models of bureaucracy maintained within the nation states of modernity, the major concern was one of ensuring the authority of bureaucratic rationales and decision-making through a strict delimitation between political processes of policy and decision-making and bureaucratic processes of implementation. The plurality of interests which circle each regulatory task were first neutralised within the conventional democratic processes of the national polity; subsequently, a unitary will for action was transmitted to an implementing executive. Within plural global risk governance structures contestation continues between scientific and ethical/social rationales as well as between diverse interests from the moment of problem definition through to the point of regulatory intervention of the establishment of a precautionary approach. Here the problem is a heightened one, both of the identification of a principle that might reconcile conflicting rationalities and that may legitimate a final (universal) decision, which transcends all particularistic interests that arise within particular constellations of risk.

Broadly speaking, we may distinguish three models within which we might begin to conceive of a plural risk governance institutional structure and within which the dangers of particularistic plural contestation and a lack of final regulatory authority might be combated.

1) For the political scientist Andreas Klinke, the primary problem is one of how the identification of a universal rationality of 'justice' within

scientific and ethical-social rationalities may be reconciled and the varying cost-benefit calculations of individual actors be conflated. The process of global risk management must be dedicated to the identification of a 'common good' that will then legitimate the final decision. However, this model of *'the common good-orientation' of risk management strategies* also raises the question of inclusion or exclusion, whose good ought to be taken into account and, what, substantively-speaking is the common good' (Klinke 2008). To Klinke, a deliberative conception of the common good is the only possible outcome. Certainly, 'resort may be made to the category of justice'; however, justice will necessarily be a 'relational' concept to be established in each concrete case of risk management by constant cognitive reflection by and between all interested parties.

At the practical of institutional design, then, global schemes of risk governance must be informed by, and processes of risk management are only legitimated by, 'inclusive risk governance through discourse, deliberation and public participation'. Publicly acceptable common good rationality is a product of a political pressure which ensures that policy-making and advisory bodies consider and condense unadulterated and reliably collated public opinion and input throughout the whole of the risk governance process. The model is one that locates authority for final decision-making within constitutive deliberation, whereby no one rationality can ever claim to represent and embody objective criteria for decision-making: the common good is an epistemological product of concrete deliberation (Klinke 2008).

2) The notion that decisional authority can never be derived from one rationality but must instead be teased out of deliberation between competing and contested rationalities is one which science also recognises. The model of *'sound science'* can be distinguished as a second model. It extends deliberation into the process of risk assessment and the amelioration of the public sensitivity of science by contrasting the scientific rationales with varying

public ethical and social concerns at the very point of the creation of the scientific knowledge base. In this model, active stakeholder participation may occur at a number of levels, for example '(i) during the process of problem identification; (ii) during the organisation of the risk analysis process, and, above all, decisions about who should participate within that process; (iii) in relation to the identification of the relevant technical, social and economical parameters that should be applied during risk analysis; (iv) with regard to the establishment of judgement values on the acceptance and mitigation of identified and characterised risks; and (v) with regard to the measures to be taken to monitor and control risk factors that have already been released into the environment' (Kuiper 2008).

The pivotal point to note is that although the common good cannot be found within the purported 'objective' criteria to be found within any one rationality (scientific, bureaucratic, social or ethical) and must instead be established by the constant deliberative process of cross-referencing between competing rationalities, the institutional structures and procedures of global risk governance must also take care never to dilute the individual rationalities that are brought to bear upon the search for a common good and decisional authority. Science must not be contaminated by ethical considerations. Likewise, the ethics and social mores current amongst and supported by a wider process of public participation may not simply be set aside with reference to scientific criteria. This process of constitutive deliberation founded within mutual respect and cross-referencing between rationalities likewise finds a supportive partner within the disciplines of law and administrative design.

3) A third model, '*administrative constitutionalism*' (Fisher 2007) or '*reflexive proceduralism*' (Everson and Eisner 2007), focuses upon a reorientation of the logics that drive institutional administrative design and legal oversight of risk regulation. Neither the institutions of risk management, nor the law

that oversees them, can claim to embody or apply substantive criteria to legitimate constitutive deliberation. Constitutive deliberation cannot be tested or ensured simply within the logic of scientific discourse. Nor can it be measured purely against ever changing ethical and social mores. Accordingly, both the notion of administrative constitutionalism and the notion of reflexive proceduralism aim to secure a change in administrative and legal cultures. The administration may no longer simply rely on instrumental rationalism. Law cannot simply promote science. Instead, both administrative design and law must be dedicated to ensuring that constitutive deliberation between competing rationalities and interests is promoted and structured to ensure respect for contestation within the risk governance regime and, further, they must establish a clear set of procedures and rules which address conflict. Most importantly, legal and institutional structures guiding constitutive deliberation are not simply concerned with the provision of a neutral forum for debate between conflicting rationalities. Instead, both aim to guarantee the quality of this debate by ensuring that each scientific, rational or ethical rationality promoted within the global risk governance regime is not simply subsumed within an obfuscating melting pot of values, but instead retains its own integrity and, thus, ability to convince in concrete cases. Thus, concrete administrative and legal structures are likewise used to enhance the philosophy of constitutive deliberation, further strengthening discursively established legitimacy through procedural values of transparency, participation, independence and excellence.

European Risk Governance in the Global Context:

The Cases of Food and GMO Regulation

With its constitutionalised precautionary principle and its ever more differentiated institutional efforts to rationalise the process of risk regulation and scientific uncertainty, the European Union might initially appear to have

developed the most streamlined of responses to risk and scientific uncertainty. However, when we investigate the specific examples of food and GMO regulation, the hidden subtleties and complexities of both risk and regulatory intervention become apparent. They demonstrate the particular difficulties of acts of risk assessment and management in light of long-standing contestation between industrial and consumer interests that are difficult to maintain in equilibrium within institutional structures. Which forms of food might be deemed safe? Should we pay greater attention to the efficiency demands of a global food market for consolidated foods standards than to local perceptions of food as a product anchored within ethical and social values? How might a European executive best mediate between global trade efficiency interests and national/local preconceptions about the cultural embedding of food? By the same token, case studies on GMOs unveil the difficult demands made upon a European executive in relation to the structuring of public participation within the regulatory regime and the effort to reconcile the ethical and social demands that public participation entails with the more rational interests and outlook of a global market and of global and European institutions of legal regulatory oversight. Such case studies are exemplary for the way in which ‘contested governance’ and (dis)trust challenge the legitimacy of existing institutional arrangements (Ansell and Vogel 2006: 10).

Above all, the current global framework for risk governance, encompassing national regulation, supranational regimes and international regulatory bodies and treaties, is still strongly characterised by inherent tension between instrumentalist rationality and demands that political participation and, above all, the ethical and social values that participation entails, be better structured and given a clearer profile within risk governance structures. In practice, the global risk regime presents us with a paradox, a dual and intertwined process of re-scientification and re-politicisation, whereby neither scientific/technical rationales, nor political deliberation are

properly structured or secured to ensure the integrity of the risk governance regime.

As noted, maintenance of the integrity of scientific discourse is a vital component within risk governance regimes. Scientific discourse is a universal discourse that creates objective values, which may be tested and which in turn may be used to test the validity claims of other political, social or ethical discourses and, above all, may be used to unveil hidden motivations, such as protectionism or the hidden evolution of, say, health protection policies within competing rationalities. At the same time, however, scientific rationalities, if never challenged within competing discourses, can prove to be insensitive to established ethical values and simple social realities. If further embedded within expansionist executive and bureaucratic logics and rationales, science and technical rationality harbour the potential to disenfranchise necessary political debate and to contribute instead to the expansion of a hegemonic executive function.

Pressures for the re-scientification of the European and global risk governance regimes are manifold. However, perhaps the most powerful of pressures for re-scientification remains the 'global' nature of trade, which, when taken together with the political aspirations of individual segments of the global risk governance executive, sees actors motivated to use the universal rationality of science to gain the upper hand within interconnected national, supranational and international regimes (see Scott 2008). Thus, for instance, we witness the curious efforts of the European Commission to colonise the standard-making procedures of the Codex Alimentarius Commission by asserting the overwhelming scientific excellence of the activities of the European Food Safety Authority (see Vos and Wendler 2006: 128). Thus, the argument is made, this excellence should – for wholly rational reasons – be deployed in the global effort to identify a 'state of the art' for food standards that will apply throughout the whole of global trade. A

fine and worthy endeavour? Perhaps not: the Commission's efforts to colonise the Codex using scientific rationale is surely also informed by political motivations and, more particularly, by the WTO recognition of the Codex as a state-of-the-art set of standards, which means that they might then form the evidential basis for evaluation of potentially restrictive precautionary regulation at national and supranational level (see Mason-Matthee 2007).

At once, science has become a tool in the endless controversy between US and European regulatory regimes that centres on WTO dispute settlements. The exact significance of scientific rationality within this dispute is highly opaque. The GMO dispute, recently heard by a WTO panel,⁷ presents us with a scenario whereby the EU has chosen to allow its member states to continue to apply precautionary regulatory provisions, which appear, in the eyes of the US regulatory regime, to have very little to do with scientific and market rationalities and, instead to represent the continuing pre-occupation of European market cultures with the maintenance of cultural traditions within modes of production (see Joerges 2008; Joerges and Petersmann 2006: see also Zürn and Joerges 2006). Above all, the continuing restrictions placed upon GMOs reflect a 'European' notion that a (food) product is more than simply an end product but also encompasses the mode of its production: cheese is only cheese and beer is only beer where the same production methods have been used for generations (Everson and Joerges 2006). The old world 'feudalism' of such constructions are a necessary affront to US market liberalism; an affront that they seek to overturn with reference to scientific rationality. In this view, the European notion of precaution is context-based, founded not in rational, objective and universal criteria but in the social constructions of European markets, taking into account, next to scientific rationales, other legitimate and lifestyle concerns of European citizens. This kind of thinking and argumentation will be tested as soon as the

EU labelling regime on GM products is challenged before the WTO dispute body.

What then of the strategic use of European science to capture and colonise the Codex? Are we witnessing the de-politicisation of the Codex Commission and the establishment of a hegemonic rational discourse of science? Alternatively, is this trend just one further strategic European effort to assert its context-based evidential bases above US market liberalism and scientific rationality? The intertwined, yet not fully integrated, structures of governance within the global trade market make it very difficult to determine what form of science and what form of executive political action is taking place.

The strategic use of science perhaps has its most important manifestation within the global context of risk governance. However, this is not to say that re-scientification and the use of science to dominate political debate is not also present at more local levels. Above all, national authorities within the European Union have often been forced to deploy scientific rationality, not simply since they embody empirical truths, but rather since they are a convenient tool to set aside inconvenient interests that may block trade in particular products; a trend most apparent within the early efforts to establish new scientific structures for food regulation in France (Noiville 2008). By the same token, however, they may also be used to create or maintain barriers to trade. Thus, French authorities were also quick to seize upon science and the notion of scientific uncertainty to justify their continuing refusal to lift their ban on British beef following the BSE crisis (Besançon and Borraz 2008).

So, what is the real danger posed by re-scientification of the spread of instrumental rationalism through global structures of risk governance? Is it perhaps seen most clearly in the tortuous re-alignment of once hierarchical structures of political control of foodstuffs in Poland to suit the demands of

the integrated European market for clear distinctions between risk assessment and risk management (Surdej and Zurek 2008), where it is felt that a scientific rationality with no sensitivity towards human social and ethical concerns will simply sweep away all of our more refined notions that goods are also the sum effect of their socially-embedded modes of production? Alternatively, is it that an ever expanding global executive function it itself poses a danger to the integrity of the evidential scientific knowledge base for decision-making, proving itself all too willing to use and misuse science in a strategic manner that obscures an underlying confusion of scientific, ethical and social rationalities?

Clearly, the solution to both such dangers is a re-politicisation of the risk governance regime, which makes use of the legitimating quality of ethical and social values within the deliberatively constitutive debate on the nature of risk and the status of scientific uncertainty. The integrity of science itself can surely only be assured where transparent frameworks of discourse recognise the contested nature of risk governance allowing political and ethical concerns to be given explicit expression rather than be hidden within or behind instrumentalist scientific rationalities. At the same time, however, participation, allowing for the expression of social and ethical values can help to place truly universal scientific rationality in its necessarily embedded social context, enabling the establishment of equilibrium between competing and contested discourses.

However, at a practical level of risk regulation we can again see that equilibrium is far more easily established in practice than in theory. The problem is not simply one that participation tends only to occur at national level and cannot easily be accommodated within the bureaucratic and legal rationalities that characterise the essential interlinking institutions of risk governance within the global trade regime. The structures of the Codex Alimentarius Commission are thus not easily opened up to diffuse public

debate and instead can only be made accessible to stakeholders, with all the fears of regulatory capture that such a constellation gives rise to. By the same token, however, the legal rationality of, say, WTO panels is of necessity closed to direct public interest participation: law decides issues in isolation. Rather, the problem is a far deeper one of a failure to identify the criteria that allow for the reconciliation of ‘incommensurate rationalities’. The dicta of Max Weber still hang heavily over our modern efforts to establish a universal decision-making that gains its authority from the willingness of all parties to the process to recognise the quality of the final decision.

In the absence of one overarching rationality that allows the process of contestation to be brought to its natural conclusion through the exclusion of all competing rationalities from the final decision, the tendency remains one of bad structuring and possible misuse of participation. Thus, GMO debates in both the Netherlands and the UK reveal that participation is not viewed as a means to enhance the *quality* of debate and the decision by means of mutual re-adjustment of the evidential bases for scientific uncertainty, but is instead reduced down to its lowest common denominator: with the UK Government viewing participation as a means to educate the public in scientific rationalities (Lee 2008) and the Dutch Government treating participation as a simple exercise in democratic legitimation and trust enhancement, final decisions were still to be taken apparently within the rationality criteria of science and the market leaving the indelible impression that all social and ethical criteria raised in debate were simply extraneous to the final decision-making process (Somsen 2008).

Concluding Remarks

In the effort to re-establish the credibility of risk governance following the BSE crisis, many institutional and procedural reforms, encompassing greater independence for the scientific knowledge-base and greater public

participation within decision-making, have at the very least helped policy-makers, the public and academics in their efforts to enhance the quality and legitimacy of decision-making on risk and uncertain risk. However, each reform also reveals the complexity of the regulatory problem to be addressed as the gap between scientific rationality and trust has proven to be difficult to address in practice.

However, in the continuing effort to bridge demands for safety and for trust we can now begin to sketch out the vital elements within an effective global risk governance regime. The conceptualisation of participation helps us also to identify in which cases and under which conditions participation should be allowed. Above all, participation must serve to improve the quality of decision-making and be recognised as a vital substantive element within the knowledge base for decisions on scientific uncertainty. The substantive rationale of participation pleads for some form of participation by stakeholders in science-making itself so that knowledge can be transferred to the risk assessors, which will lead to better scientific opinions. Using a theatre metaphor, Stephan Hilgartner suggests that both transparency and participation should not be about dissolving the difference between onstage and backstage of science- (and decision-)making but more about creating public spheres in which differences in opinion can be ventilated and viewpoints can be exchanged and discussed between all relevant parties (Hilgartner 2000). Other authors suggest that expert bodies should open up to scientific uncertainty and reveal the uncertainties at stake, which would avoid the situation wherein the risk managers hide behind science and experts. This would imply that scientific bodies should not only include experts on the relevant issues of uncertain risks, but also experts who are tolerant towards uncertainty so that they may 'neutralise' the production of plausibility proofs with the help of uncertainty language whilst they can also help to frame and phrase scientific opinions so as to make them

understandable for a lay public. Further suggestions for reform relate to the proceduralisation of the precautionary principle and the stimulation of more independent research carried out by public scientific bodies themselves (Van Asselt, Vos and Rooijackers 2008).

Linking these empirical reform suggestions back to the structural theories of administrative constitutionalism and reflexive proceduralism, future global risk governance should seek to establish its own constitution, which not only secures the vital independence and transparency of scientific advice, but also guarantees public participation, whether by stakeholders or a wider public, to ensure that scientific rationality, even as it is used to discipline the potential irrationalities of political debate, is nonetheless not the sole criterion for risk decision-making. Instead, individual rules must be developed within the ambit of a procedural understanding of the precautionary principle, which recognises the case specific context of a definition of scientific uncertainty and which ensures rationalisation of public participation and a widening of the knowledge base upon which precaution is established. Rationality in this latter sense is inextricably linked with notions of transparency. Decision-making in situations of uncertain risk can and often must also be political in nature. The theatre metaphor teaches us that we should not strive for an opening up and shedding light on the 'backstage' activities of both scientific and political bodies, but instead that we create public areas of discussion. Hereby it is of utmost importance that when upholding the separation between what is happening on- and backstage, scientific and political bodies will not be secretive about their 'backstage' activities. Transparency about the arguments and science used, the values involved and the way they have been addressed as well as the procedure followed should guarantee that no capricious and arbitrary science-and decision-making takes place and show how science and non-market values have been balanced.

Notes

¹ See as regards the UK, BSE Inquiry Report, 2000, at <<http://www.bseinquiry.gov.uk/report/index.htm>> and as regards the EU, Medina Ortega Report, Inquiry Committee set up by the European Parliament (1997), A4-0020/97/A, PE 220.544/fin/A.

² See e.g. the contributions by H. Rothstein, J. Besancon and O. Borraz, A. Surdej and K. Zurek, B. Van der Meulen and E. Vos in Everson and Vos 2008.

³ Working Principles for Risk Analysis, Codex Alimentarius Commission – 14th Procedural Manual.

⁴ CEC, Commission of the European Communities, *Communication on the precautionary principle*, COM(2000) 1, 2 February 2000, Brussels.

⁵ See e.g. as regards the former e.g. Forrester and Hanekamp 2006: 1013–1019; Marchant and Mosman 2004. As regards the latter e.g. de Sadeleer 2005, 2006.

⁶ See Harremoës, Gee, MacGarvin, Stirling, Keys, Wynne and Guedes Vaz 2002. Stirling makes a threefold distinction for participatory engagement rationales: *normative democratic* ('because it is the right thing to do'); *substantive* ('because it leads to better decisions') and *instrumental* ('because it facilitates particular favoured decisions'). See Stirling 2003: 381–401.

⁷ See for a discussion of this case e.g. Prévost 2007: 67–101.

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Chapter 2

EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review

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Introduction

This Chapter aims at exploring the role that scientific experts and, more particularly, scientific expertise play within European risk governance. While the first part of the Chapter looks at the way in which scientific expertise is integrated into the decision-making process, the second part examines how science and science-based measures are, or may be, judicially reviewed by European courts. This last part also ventures to suggest some ways to help the judge when reviewing science-based measures by looking into expert consultation systems and peer review mechanisms.

In taking this approach, the Chapter will focus primarily on the area of food safety, as it provides a privileged perspective from which to examine the emergence of a European risk regulatory framework. Indeed, although confined to regulating food safety issues, the risk regulatory model laid down by EP and Council Regulation 178/2002 in the aftermath of several food scandals reflects the state of the art in ongoing European reflection about risk governance.¹

Scientific Expertise in Decision-Making

The Genesis: the Role of Science in EC Law

Today the use of science as one of the sources of evidence to support decision-making is relevant in a wide range of policy areas, such as food safety, emission limits,² chemicals,³ biocides,⁴ GMOs,⁵ pesticides,⁶ food additives,⁷ water protection,⁸ consumer protection, worker safety and health.⁹ As scientific evidence is crucial at all stages of the drawing up of new legislation and for the execution and management of existing European and national legislation, it is worth illustrating how this process has occurred within the European legal order.

The original 1957 Treaty of Rome did not impose either on the EC institutions or on Member States a duty to justify their health, safety and environmental protection measures according to the latest scientific information. Indeed, its text did not contain any reference to scientific justification or expertise.

However, as Member States began invoking Article 36 (currently Article 30) EC, which allowed them to adopt restrictions on trade justified *inter alia* on grounds of protection of health,¹⁰ they often submitted scientific evidence to the European Court of Justice in order to demonstrate that their measures were covered under this exception. Thus, for instance, in the *Beer Purity case*,¹¹ Germany, after having banned the marketing of beer containing *any* additive (not just those additives for which there was evidence of risks),¹² tried to justify its measure by arguing not only that Germans drank a lot of beer (*sic*), but also that the long-term effects of additives were unknown. To support its scientific claim, Germany also cited experts' reports referring to the risk inherent in the ingestion of additives in general.¹³ Moreover, it was not just the parties to the case that picked up on the scientific element, but also the Court. The ECJ, referring to the previously decided *Sandoz*,¹⁴ *Motte*¹⁵ and *Müller*¹⁶ judgments, held that a Member State's possibility to restrict the

free movement of a foodstuff legally marketed in another Member State is subject to ‘the *findings of international research*, and, in particular, the work of the Community's scientific committee for food, the Codex alimentarius committee of the FAO and the World Health Organization’.¹⁷ Having deferentially referred to the scientific findings of these entities, the Court, however, found that not only did the additives not present a risk to public health but also that the German policy was inconsistent insofar as it allowed the use of these same additives in other drinks. References to ‘the findings of international scientific research, and in particular of the work of the Community's Scientific Committee for Food, the Codex alimentarius Committee of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization’ may also be found in subsequent judgments, such as *Bellon*¹⁸ and *Debus*,¹⁹ both involving national measures restricting the use of additives.²⁰

Thus, without being formally introduced within the Rome Treaty, a *de facto* scientific requirement grew up within the regulatory practice developed around the rules governing the free movement of goods within the EC. However, it was only in 1999 that scientific justification was expressly inserted into Article 95, paragraph 5, as one of the requirements Member States must satisfy in order to *introduce* a measure derogating from European harmonisation legislation.²¹ In particular, a Member State that deems it necessary to introduce a national measure aimed at the protection of the environment after the adoption of a Community measure on the matter must provide ‘new scientific evidence’.²²

As a consequence, an embryonic scientific discipline has evolved over time not with the purpose of protecting human health but rather of resisting national protectionism, and thereby of permitting the establishment of the internal market.

At the same time, the scientific justification discipline that originally developed in relation to Member State measures based on public health had been extended to the acts adopted by the European institutions. In 1992, when the aim of achieving a 'high level' of health was given the status of a general objective in the EC Treaty (Article 3, paragraph 1, (p)), a specific legal basis has been laid down in Article 152 EC for public health measures. Moreover, in the same year, EC environmental policy was redirected to the attainment of a 'high level of protection'²³ and, to this purpose, it was required to 'take account of available scientific and technical data'.²⁴ Subsequently, in 1997, Article 100a (current 95 EC), which allows the EC institutions to adopt directives aimed at harmonising national provisions that 'directly affect the establishment or functioning of the common market', was amended in order to specify that these objectives should be pursued and based on 'scientific facts'.²⁵

Thus, from the moment that the Amsterdam Treaty entered into force in 1999, all Community legislation concerning health, safety and environmental and consumer protection is to aim at achieving a high level of protection by 'taking account in particular of any development based in scientific facts'.²⁶ This is because the Commission intends 'to use this advice for the benefit of the consumer in order to ensure a high level of protection of health'.²⁷ As the Commission has pointed out in its 1997 Communication on Consumer Health and Food Safety:

'[...] scientific evidence is of the utmost importance at all stages of the drawing up of new legislation and for the execution and management of existing legislation'.²⁸

Recently, scientific justification has been expressly defined as 'an essential requirement for Commission proposals, decisions and policy' relating to consumer safety, public health and the environment.²⁹ To fulfil its function,

scientific advice on matters relating to consumer health must be based on the principles of excellence, independence and transparency.³⁰

These are the only references contained in the Treaty laying down a general duty for the EC and national decision-makers to provide for scientific justification when adopting legislation concerning consumer safety, public health and the environment. However, although it establishes a risk assessment duty, the Treaty does not define who is charged with ensuring such an assessment by leaving open the controversial question of whether risk assessors should be distinguished from those who have to decide if and how to act. In other words, our analysis shows that the Treaty does not set forth a complete risk analysis model aimed at defining the role of the different actors involved in such an analysis. As a result, it is up to the secondary legislation to do so by choosing the risks assessors and establishing their relationship with the risk managers.

EC Sources of Scientific Advice and Expertise

Contrary to conventional wisdom, there is currently no common system providing scientific advice to EC policy-makers. Scientific support is ensured through a range of different mechanisms, depending on the policy area at issue.

The most common sources of advice used to support EC policies, legislation and regulatory decisions are the following: scientific committees under the control of EFSA and EMEA,³¹ three non-food scientific committees that operate under the responsibility of the Directorate General for Public Health and Consumer Products (DG SANCO),³² reports by advisory agencies, such as the European Environmental Agency (EEA); reports provided by external consultants (individuals, groups or companies, possibly using research contracts); national reports provided by Member States' advisory bodies; reports by ad-hoc expert groups; in-house analysis

conducted by Commission officials; reports and opinions by the Joint Research Centre (JRC) and the Scientific and Technical Options Assessment group in the European Parliament (STOA).

In an attempt to ensure some consistency in the delivery of advice from so many different sources of expertise, the EC Commission has developed a set of policies and guidelines for the use of scientific advisors. This growing scientific advice policy is contained in three main documents: the Science and Society Action Plan (2002), the Commission Communication on the Collection and Use of Expertise (2002),³³ and the Commission Decision to set up Scientific Committees in the Fields of Consumer Safety, Public Health and the Environment (2004).³⁴ These documents impose ‘sound and timely science’ as an essential requirement for risk management in the areas of consumer safety, public health and the environment, and they recommend a set of guiding ‘core principles’ for the collection and use of scientific expertise by the Commission departments: quality, openness, effectiveness, independence, pluralism, excellence, impartiality, proportionality and transparency.³⁵

Moreover, since 2000, some efforts have been made at setting up a harmonised approach to risk assessment procedures among the Scientific Committees advising the European Commission in the areas of human, animal and plant health and on the environment.³⁶

However, these principles and guidelines are not legally binding. Nor do they apply to the formal stages of decision-making as provided by the Treaty and in other EC legislation. Therefore, the formal legislative procedures as well as the formal exercise of the Commission’s implementing powers through the ‘comitology’ committees are excluded from their scope.

The Emerging EU Risk Regulatory Framework

The Principle of Risk Analysis

To understand the role played by experts within the European decision-making process, it is necessary to describe the context within which they are expected to provide their advice. If one looks at the European risk regulatory framework as it emerges from the general food regulation, this framework contains the following three different components: risk assessment, risk management, and risk communication.

As is well known, this structured approach incorporating the three distinct but closely linked stages of risk analysis was firstly developed and popularized by the US National Research Council (NRC)³⁷ and today finds support in the main guidelines developed by national and international organisations dealing with risk analysis.³⁸

In particular, the EC food risk analysis model interprets and promotes the relationship between risk assessment and risk management in terms of clear-cut separation, by giving, for the first time, a normative expression to the 'functional separation' between these two components.³⁹ The primary reason given for such a distinction or separation between these two components of risk analysis is a desire to ensure the independence and objectivity of the scientific process as conducted during the risk assessment stage. The idea is that only the introduction of a clear-cut separation between risk assessors, who discuss facts, and managers, who discuss values, would effectively insulate scientific activity from political pressure and, accordingly, maintain an analytical distinction between the magnitude of a risk and the cost of coping with it. Following the development of this design, several steps have been undertaken within the Commission to institutionally implement this approach to risk analysis by functionally separating those responsible for production, or the promotion of the market, from those responsible for the assessment of food safety. Thus, for instance, the management of the scientific

committees was transferred to what is now the Directorate General for Health and Consumer Protection (DG SANCO), and subsequently to the EFSA, a supposedly independent scientific body lacking any decision-making power. Thus, a watertight separation between the risk assessment and risk management stages in the field of food safety has been increasingly seen as essential not only to guarantee independence and objectivity to the scientific process,⁴⁰ but also as a means of enhancing the democratic legitimacy of the decision-making process by ensuring that decisions are ultimately taken by those who are accountable to the public.⁴¹ According to A.G. Mischo, this distinction meets a dual goal: it ensures a rational technocratic dimension to the decision-making process, while enabling the political process to be independent from the results of scientific assessments.⁴²

Finally, the duty to rely on scientific expertise appears to have been given general application to all science-based measures by the Court of First Instance (hereinafter: the 'CFI'), which has stated that

'when a scientific process is at issue, the competent public authority must, in compliance with the relevant provisions, entrust a scientific risk assessment to experts who, once the scientific process is completed, will provide it with scientific advice'.⁴³

The EU's Approach to Risk Analysis

Under the emerging EU Risk Regulatory framework, once a risk has been identified, it is the decision-maker's responsibility to decide if it is acceptable, which may imply adopting an attitude of zero tolerance. In particular, risk managers (EC institutions and Member States' authorities) have to take into account:

- a) the results of risk assessment, in particular the 'opinions' of the EFSA;
- b) 'other factors legitimate to the matter under consideration' (the so-called 'social factors' (Echols 1998: 530) or 'non-economic factors'), and

- c) the 'precautionary principle', within the limits laid down in Article 7 of the Regulation 178/2002, in order to achieve the general objectives of food law.

Then, Article 5, paragraph 3, adds to this list:

- d) 'international standards [...] except where such standards or relevant parts would be:

- a) an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law, or
- b) where there is a scientific justification, or
- c) where there would result in a different level of protection from the one determined as appropriate in the Community'.

Therefore, although science plays the major role in the risk management stage, the Regulation reserves the right of risk managers to take other factors into consideration when reaching a final decision⁴⁴. This is because

'it is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based'.⁴⁵

Relevant factors in the area of health protection of consumers may consist, for instance, of societal, economic, traditional, ethical and environmental factors.⁴⁶ This approach is in line with the Communication on the precautionary principle, which indicates that in cases of scientific uncertainty

'[...] judging what is an 'acceptable' risk for society is an eminently political responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers'.⁴⁷

The perceived need to also consider non science-based factors within the decision-making process characterises the European approach to risk analysis

by differentiating it greatly from the one adopted by US regulatory agencies and by the WTO/SPS legal framework.⁴⁸

The EU approach to risk analysis has been effectively described as a system in which ‘scientific knowledge is authoritative, but not exclusively so’ (Skogstad 2001: 490).

What are the consequences stemming from such a non-exclusively science-based approach to risk analysis?

The well-known *Hormones* dispute,⁴⁹ ‘one of the longest running trade disputes in the modern trading system’ (Sykes 2006: 260), between the EC and the US exemplifies the impact that the EC’s particular risk analysis approach may have, not only on its external trade relations, but also on its internal market dimension.⁵⁰ The regulatory regime that was challenged in this dispute was adopted by the EC institutions notwithstanding the advice of the Scientific Working group that the banned growth-hormones were harmless to human health. The ban triggered not only a reaction in the U.S. and Canadian reactions but also encountered internal resistance.⁵¹ Member States were split over the decision: while France, Germany, Italy and the Netherlands supported the total prohibition of these growth hormones, the UK and Ireland opposed it so strongly as to lead to the controversial legislation being brought before the European Court of Justice.⁵²

The EC ban turned out to be motivated by a complex mix of political, social, economic and conflicting scientific factors that, as we have seen, may now formally enter into the EC food decision-making process. Today we would probably define such a mix of different interests under the ‘collective preference’ label launched by Pascal Lamy (see Lamy 2004).

Notwithstanding the existence of a scientific consensus concerning a certain substance, the possibility of taking ‘other legitimate factors’ into consideration may lead to divisions across Member States over controversial

food safety measures, while at the same time bringing the EC measures into conflict with the WTO framework.⁵³

The Flaws of the Emerging EU Risk Regulation Framework

The distinction between the purely technical assessment of risks by scientists and the management of these risks by decision-makers is being increasingly questioned today.⁵⁴

The critique takes the form of suggesting that the division is not credible insofar as it appears to be totally cut off from the concrete reality of scientific and political work processes (Noiville and De Sadeleer 2001: 408). Risk assessment cannot be conceived as a wholly objective exercise. Not only is it influenced by the extensive use of 'science policies',⁵⁵ but also by the values and beliefs of scientists and the judgments of the profession. In other words, when dealing with decisions involving technical and scientific aspects, scientific expertise and political decisions become so intertwined as to become impossible to separate. In fact, the elaboration of these policies and assumptions boil down to a risk management activity (Walker 2003: 263).

This entirely legitimate process inevitably leads to stripping the 'functional separation' between risk assessment and risk management of its original goals: the purity of scientific assessment and accountability of risk managers. These observations suggest that the EC's dichotomous model of risk regulation, which has found both institutional and normative expression in the general food law regulation, fails to normatively recognize the value judgments implicit in the first stage of risk analysis.⁵⁶ The risks stemming from this insistence on the need for a clear-cut separation is that the values and uncertainties inherent in risk assessment may go unexamined because they do not formally translate into 'science policies'. Notwithstanding the growing rhetoric over transparency in the EC scientific expertise,⁵⁷ the current reductionist Community approach to risk analysis does not seem to ensure

that the reasons underlying the decisions are clearly laid out in the policy choices adopted (judgments, uncertainties and biases in scientific assessment), thus setting them apart from the scientific results on which they rely, so that every citizen (and, eventually, the courts) can identify them. To avoid this and to maintain the original goals pursued by the functional separation between risk assessment and risk management, it is absolutely imperative not only to render science policies explicit by furthering the current efforts aimed at elaborating guidance documents for each EFSA panel,⁵⁸ but also to clarify and frame the role played by EC Commission officials attending EFSA scientific panel meetings.⁵⁹ In fact, although EFSA is institutionally independent, there are, however, some tensions arising out of the 'grey areas' existing in its relationships with the Commission and from the current emphasis on the EFSA's contacts with stakeholders, including industry.⁶⁰ While the need for industry's involvement in EFSA's scientific activities is questionable, improved participation of consumer groups is already an indisputable necessity in order to avoid that consumer interests are overwhelmed by those of industry.

At the same time, it may be advisable to continue the current Commission's efforts aimed at harmonising risk assessment procedures within the Community. In its attempt to develop a harmonised common methodology for the Scientific Committees activities, the Commission should improve consistency in the horizontal application of science policies and risk assessment techniques by developing some robust assessment practices.⁶¹ The Scientific Steering Committee⁶² advised the Commission to establish a Working Party on the 'Harmonisation of Risk Assessment Procedures' to specifically address the general principles of risk assessment and their application to broad consumer health issues, with particular reference to measures that would enhance compatibility of approaches within the Scientific Committees. Although it has been recognized that a completely

common methodology for the activities of the Commission Scientific Committees may not be achievable, it is imperative to avoid the same chemical, biological or physical agent being dealt with quite differently by the EFSA panels and the other scientific committees in different contexts, resulting in potential inconsistency in assessment and confusion in application.⁶³

The Legal Status and Authority of the Experts' Opinions (EFSA's Scientific Opinions)

The Lack of a Principle of Supremacy of EU Science over National Scientific Advice

Historically, scientific opinions delivered from any of the different sources of scientific advice to the Community have not been recognised as legally binding.⁶⁴ As a consequence, although the EC institutions are expressly required to take EFSA's opinions into account when drafting a Community measure,⁶⁵ the Agency lacks formal authority to reach binding resolutions on potentially contentious scientific issues.⁶⁶ Therefore, similar to the old scientific committees and any other European source of scientific advice,⁶⁷ it does not have the final word in cases of diverging scientific opinions between its own decisions and those issued by other bodies. This may be inferred from Article 30 Regulation 178/2002 ('the Regulation') which, while establishing a procedure aimed at solving problems arising from 'diverging scientific opinions', attributes neither an authoritative nor a mediating role to EFSA, but simply duties of 'vigilance' and 'cooperation'. This outcome is, at least at first glance, surprising if analysed in light of the EFSA's ambition to become 'the point of reference in risk assessment' for the whole Community.⁶⁸ More precisely, under the Regulation, the Authority is to exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the opinions issued by national food agencies or

other bodies carrying out similar tasks.⁶⁹ Where there is a conflict between its opinion and those of bodies carrying out similar tasks, the EFSA is ‘obliged to cooperate’⁷⁰ with the aim of resolving the differences or of presenting a joint document, which will be made public, identifying the uncertainties and the ‘contentious scientific issues’.⁷¹

The introduction of a mere duty of co-operation appears to fall short of providing an effective answer to the fundamental question as to the relationships between the European source of expertise and the national scientific responsible authorities.

By not endowing EFSA opinions with scientific supremacy over national scientific studies, the Regulation promotes an alternative method of tackling the issue of diverging scientific opinions between the EFSA and the national scientific bodies. In order to prevent the emergence of scientific controversies, EFSA is required to promote European networking of organisations operating in food safety risk assessment.⁷² More specifically, the official aim of such networking is ‘to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices’.⁷³ In order to facilitate this, the Authority may require national organisations to provide some preparatory work for scientific opinions, scientific and technical assistance, some collection of data and identification of emerging risks.⁷⁴ This sort of network activity is not without precedent (Börzel 1998: 253) and it plays a vital role within EFSA’s operation. In fact, the establishment of this network is necessary in order to support EFSA’s scientific activities, in particular in conducting scientific opinions.

The Indirect Legal Effect

Notwithstanding their lack of legally binding nature, the Authority's opinions are likely to produce some significant indirect normative effects. In particular, EFSA's opinions have the potential to become a source of constraint not only for the EC institutions, but also for Member States and private parties.

In terms of the EC institutions, the *Pfizer Animal Health* judgment has clearly established a general duty to consult the available scientific reports prepared by experts on behalf of the EC.⁷⁵ EC institutions are allowed to depart from this duty only in those exceptional circumstances where equivalent scientific evidence can be found and a justification for relying on it is provided. There are therefore good reasons to believe that these constraints on the possibility of departing from scientific evidence will be maintained by the EC courts with regard to EFSA's opinions by transforming them into *de facto* authoritative measures. In other words, it is likely that within the new food safety regime it will be increasingly difficult for the EC institutions to exercise their discretion beyond the boundaries drawn by a scientific administrative network led by an independent and authoritative authority such as EFSA. This is suggested by Directive 1829/2003 governing the marketing of GMO foods within the EC, where it provides that, should the Commission decision not be in accordance with an EFSA opinion, the Commission must 'provide an explanation for the differences'.⁷⁶

It is submitted that EFSA's opinions are likely to acquire some authoritative value vis-à-vis national decision-makers as well. Although the Regulation introduces the presumption that, in the absence of specific Community provisions, all food is deemed to be safe where it complies with the specific national provisions of the country where it is marketed,⁷⁷ the same regulation imposes on Member States the duty to take account of the results of risk assessment, particularly the opinions of the Authority, when regulating the food sector. In sum, while domestic authorities are not

procedurally required to consult the EFSA, they are still required to abide by its scientific opinions in passing new legislation.⁷⁸ It would therefore seem impossible for the national authorities to derogate from EFSA's opinions without giving some reasons justifying their rejection.

The Authority's position also has the potential to acquire some legal significance for private parties. As seen above, the Regulation also imposes a general obligation on private business operators engaged in production, processing and distribution to ensure that food placed on the market is safe.⁷⁹ Any breach of this duty gives rise, at least in principle, to two separate violations of EC law: a breach of the general obligation to ensure that food is safe, established by Article 14 of the Regulation, on the one hand, and violation of the Product Liability Directive on the other (Chalmers 2003: 534). Although national courts are not required to consult the Authority when investigating such violations, they are likely to rely on its scientific opinions. In other words, if the EFSA has issued an opinion suggesting that a product is unsafe, it would be extremely difficult for a private individual to claim the opposite.

Finally, EFSA's opinions may also produce legal effects vis-à-vis national courts. In *HLH Warenvertiebs*, where the ECJ had expressly been asked to determine whether the scientific opinions of that Authority may have binding force on the national courts, it held that

'[a]n opinion delivered by that Authority, possibly in a matter forming the subject-matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute'.⁸⁰

Notably, the Court has stated that national courts should ascribe to such an opinion the same value as that accorded to an 'expert report'.⁸¹ Thus, EFSA's scientific opinions appear susceptible to acquiring a legal status similar to that of scientific expertise requested by the same national courts of third parties.

Although not binding *per se*, the scientific report ‘should be taken into consideration in the context of the dispute’.⁸²

In conclusion, while EFSA’s opinions have not been expressly granted a direct regulatory authority, they are likely to acquire a *de facto* legally binding value for both the EC and the Member States authorities when passing legislation and amount to a strong probative authority against private business operators placing unsafe food on the market. More generally, it can reasonably be expected that EFSA’s opinions will structure the terms of debate on these issues by influencing enforcement within the Member States as well as directing public opinion.

Scientific Expertise before Courts

Having illustrated the role played by scientific expertise within decision-making, the second part of this chapter focuses on how science and science-based measures are, or may be, judicially reviewed by European courts. In so doing, it refers primarily to the scientific advice provided within the food safety area by EFSA.

European Courts and Scientific Opinions

Although the issue as to whether Community courts may review the legality of the opinions delivered by EC sources of scientific advice is an open question to the extent that it has not definitively been resolved, it is possible to make some reasoned suggestions for how it is likely to unfold.

A comparative analysis of the ‘judicial accountability’ of the different European agencies does not offer any help in developing an answer to the question of the reviewability of EFSA opinions insofar as their constituent regulations provide for very different solutions. Thus, for instance, while some of these regulations explicitly provide that the acts adopted by the

agency are challengeable under Article 230 EC,⁸³ others entrust a specific chamber of the agency⁸⁴ or the same Commission⁸⁵ with the task of reviewing the legality of the agency's decisions. In the case of the EFSA, the general food regulation that establishes that agency does not contemplate the possibility of submitting its acts to legal review. Rather, a role for EC courts is envisaged exclusively in the area of contractual and non-contractual liability of the Authority.⁸⁶

As a result, the question as to whether EFSA opinions or any other EC source of scientific advice may be challenged before the European courts is governed by Article 230 EC.

The application of this provision to scientific opinions raises several problems. Firstly, Article 230 EC does not contain any reference, either explicit or implicit, to acts of European agencies or any other scientific committee or source of expertise.⁸⁷ It merely refers to the 'acts adopted jointly by the European Parliament and the Council, [...] acts of the Council, [...] the Commission and [...] the ECB, other than recommendations and opinions, and [...] acts of the European Parliament intended to produce legal effects vis-à-vis third parties'.⁸⁸ Moreover, it is difficult to envisage EFSA or any other source of scientific advice being considered as one of the institutions or bodies listed therein. Put differently, EFSA decisions or those coming from external sources do not, strictly speaking, stem from one of those EC institutions listed in Article 230, paragraph 1, EC.⁸⁹ Secondly, being 'preliminary or purely preparatory acts', scientific opinions would not seem to fall within the category of acts which can be subject to an action for annulment, i.e. which covers solely those acts 'intended to produce legal effects vis-à-vis third parties'.⁹⁰ Last but not least, not being addressed to any individual, scientific opinions could not be assimilated to Community decisions, but fall within the scope of the fourth paragraph of Article 230, which provide for very demanding standing requirements.⁹¹

Notwithstanding their non-binding legal nature, it has been established, with reference to the scientific opinions given by the EMEA's Committee for Proprietary Medicinal Products (CPMB), that the opinions are

'[n]onetheless extremely important so that any unlawfulness of that opinion must be regarded as a breach of essential procedural requirement rendering the Commission's decision unlawful'.⁹²

In other words, although these scientific opinions do not bind the Commission, they provide it with the scientific evidence that is necessary to determine, 'in full knowledge of fact', the appropriate measure to ensure a high level of health protection. Therefore, whenever the scientific opinions are procedurally vitiated, their unlawfulness will reflect on the subsequent decision which might be subject to judicial review.

In light of the above, in the *Artegodan* judgments,⁹³ subsequently confirmed by the ECJ, the CFI held that EC courts may be called upon to review the formal legality of an agency scientific committee's opinion as well as the Commission's exercise of its discretion. Although the CFI has stated that it cannot 'substitute its own assessment for that of the scientific committee', it has held that it may nonetheless review the proper functioning of the committee, the internal consistency of the opinion and the statement of reasons contained therein.

Should the Courts extend this approach to EFSA's scientific opinions, EC courts might rely on the growing number of guidance documents which are prepared by the EFSA's scientific panels in order to define their own method for conducting risk assessment.⁹⁴ In fact, these are the only documents which may potentially provide a useful legality benchmark in reviewing the proper conduct of the panel when carrying out the risk assessment.

A series of very recent opinions delivered by the CFI seem, however, to rule out the possibility that EFSA scientific opinions may be judicially

reviewed as such.⁹⁵ In these decisions, having examined all the arguments adduced by the applicants concerning the nature of the contested acts, it held that

'[...] the applicant has not prima facie put forward evidence to establish that the Court has jurisdiction to hear and determine actions for annulment challenging EFSA's acts as such, on the one hand, or to support the conclusion that whether or not EFSA's acts may form the subject of an action for annulment is not to be assessed in relation to the requirements of Article 230 EC'.⁹⁶

European Courts and Science-based Measures

While the review of scientific opinions by Community Courts has not become reality yet, the judicial review of Community science-based measures already occurs. As scientific evidence is becoming crucial at all stages of the drawing up of new legislation, EC Courts are increasingly called upon to review measures that are grounded in scientific data.

The Standard of Judicial Review of Science-based Measures

As seen above, the European scientific discipline has emerged gradually and quite recently, having first been spontaneously introduced by the Member States in order to support measures that derogated from EC law. This introduction of science was then subsequently codified and extended to EC action in the field of health and environmental protection, notably in the food safety area. As a result, there is a growing body of science-based case-law by the European courts dealing with measures adopted by EC Member States and by EC institutions to address risks to health and the environment.

In the absence of an express indication of the standard of review to be applied to those measures, it is necessary to look at this body of case-law in order to determine the level of intensity of the scrutiny exercised by the EC courts.

At a general level, the EC Treaty, unlike the ECSC Treaty,⁹⁷ does not provide any indication as to the standard of review that courts should apply when scrutinising EC acts. Finding themselves in a normative vacuum, the European courts filled it by drawing inspiration from the ECSC treaty, which set forth a rather deferential standard. Thus, in solving a specific legal dispute, EC courts tend, traditionally, to limit their review to questions of whether the authorities have or have not used their regulatory discretion in an arbitrary or unjustifiable manner.⁹⁸

While the review of EC action is limited in principle to examining ‘whether the exercise of its discretion is vitiated by a manifest error or a misuse of power’, this standard of review has, through time, been specifically adapted and shaped so as to apply science-based measures, notably in the food safety area.

Thus, for instance, when the ECJ was called upon to determine whether the Commission lacked the competence to adopt Decision 96/239 providing for a total ban on exports of bovine animals, bovine meat and derived products from the territory of the United Kingdom to the other Member States and to third countries in the aftermath of the BSE crisis,⁹⁹ it declared that

‘[...] since the Commission enjoys a wide measure of discretion, particularly as to the nature and extent of the measures which it adopts, the EC judiciary must, when reviewing such measures, restrict itself to examining whether the exercise of such discretion is *vitiated by a manifest error or a misuse of powers or whether the Commission did not clearly exceed the bounds of its discretion*’.¹⁰⁰

Furthermore, it is settled case-law that

‘[...] where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action’.¹⁰¹

This deferential approach to the judicial review of Community measures has been further elaborated in the *Upjohn* judgment, which dealt with medicinal products. Here, the ECJ declared

‘[...] where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which *the EC judicature may not substitute its assessment of the facts for the assessment made by the authority concerned*. Thus, in such cases, the EC judicature must restrict itself *to examining the accuracy of the findings of fact and law* made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion’.¹⁰²

This deferential standard of review has recently been specifically extended by the CFI to those situations where Community institutions are

‘[...] required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts’.¹⁰³

Accordingly, in the *Bellio* case,¹⁰⁴ the ECJ upheld the right of the EC to pursue a policy of ‘zero tolerance’ in regard to the contamination of animal feed by material that possibly contained the BSE-causing agent, even in circumstances where the contamination was probably accidental and there was scientific uncertainty as to the minimum amount of infected material needed to cause the disease in humans (see Alemanno 2004: 319–323). The Court came to this conclusion on the basis that that policy had been adopted ‘on the recommendation of experts having at their disposal the relevant scientific data’ and that it formed ‘part of a coherent body of legislation the purpose of which is to combat TSEs’.¹⁰⁵ By relying on the same deferential standard of review, the Court has recently overturned, in *CEVA*, a CFI finding that the Commission had failed to act to establish a maximum residue level for progesterone under Regulation 2377/90.¹⁰⁶ While the CFI found

that the political and scientific complexity of the progesterone scientific file ‘does not excuse the Commission’s inaction’, the ECJ confirmed that

‘in delicate and controversial cases, the Commission must have a sufficiently broad discretion and enough time to submit for re-examination the scientific questions which determine its decision’.¹⁰⁷

Although EC courts have developed different standards of review depending on whether the health claim stems from the EC or a Member State,¹⁰⁸ they have generally tended, under both standards, not to get involved in the scientific issues underlying the contested measure and have refrained from examining the merits and the methodologies of the scientific findings advanced by the parties.

However, the *Pfizer* judgment casts some doubts not only on the EC courts’ traditional deferential approach in reviewing EC science-based measures,¹⁰⁹ but also on its traditional reticence in addressing the scientific basis of the contested regulations. This judgment has recently been followed by a line of cases in which the ECJ has shown some willingness to involve itself more in the technicalities of scientific matters when judicially reviewing science-based regulations.

The Pfizer Judgment

In this judgment,¹¹⁰ the CFI showed a readiness to become more involved in the examination of the scientific evidence adduced by the parties to the dispute, even though the contested measure was of Community origin.¹¹¹ Immediately following the adoption of an EC Regulation banning the use of four antibiotics as additives in animal feedstuffs,¹¹² Pfizer, the producer of one of these antibiotics (virginiamycin), challenged the measure by alleging manifest errors in the process of risk assessment and a misapplication of the precautionary principle.

Although the CFI clearly stated from the outset that it was not for it ‘to assess the merits of either of the scientific points of view argued before it and to substitute its assessment for that of the Community institutions’, it could not prevent itself from discussing the scientific validity and merits of the scientific evidence advanced by the parties. This inevitably led the Court to engage in a quasi-scientific debate on the main scientific controversy underlying the legal dispute, i.e. whether there is a link between the use of virgiamycin as an additive in feedstuffs and the development of streptogramin resistance in humans. In particular, the Court expressly decided to consider whether, as maintained by Pfizer, the contested regulation was unlawful ‘because of the inadequate nature of the scientific data’ provided by the parties. In other words, the Court went so far in its judicial-scientific involvement as to directly ask itself whether the scientific evidence available to the EC institutions was ‘sufficiently reliable and cogent for them to conclude that there was a risk associated with the use of virgiamycin as a growth promoter’.¹¹³

For the first time, an EC Court felt the need to make an express reference to the quality of the scientific evidence that the EC institutions had relied upon. Such evidence, so the CFI found, must be ‘sufficiently reliable and cogent’.¹¹⁴

Before beginning its analysis, the CFI recalled that, due to the complex assessments of scientific and technical nature behind the challenged regulation

‘[...] judicial review is restricted and does not imply that the Community judicature can substitute its assessment for that of the Community institutions’.¹¹⁵

Notwithstanding this declared limitation, the CFI carried out a detailed review of the scientific findings brought by the parties so as to determine whether the EC institutions erred when they concluded, ‘on the basis of the scientific knowledge available at the time of the adoption of the contested

regulation', that the use of virginiamycin as an additive in feeding stuffs entailed a risk to human health. By engaging in a quasi-scientific analysis of the scientific studies advanced by the parties to the dispute, the Court found that

'[...] the Community institutions could *reasonably* take the view that they had a *proper scientific basis* for a possible link between the use of virginiamycin as an additive in feeding-stuffs and the development of streptogramin resistance in humans'.¹¹⁶

In other words, the Community was right to take the view that

'[...] the various experiments and observations [...] were *not mere conjecture* but amounted to *sufficiently reliable and cogent scientific evidence*'.

The Vitamins Line of Cases

A trend towards greater involvement in scientific debate by the EC courts, inaugurated in the *Pfizer* case, appears to have been followed up by a recent line of cases decided by the ECJ. In this series of cases involving fortified foods, the Court was called upon to examine four infringement proceedings brought against Denmark,¹¹⁷ France,¹¹⁸ Italy¹¹⁹ and the Netherlands.¹²⁰ In particular, the Commission contested, firstly, the Danish and Dutch practices of requiring enriched foodstuffs lawfully produced and marketed in other Member States only to be marketed in their territories if it could be shown that such enrichment with nutrients meets a need in the Danish and Dutch populations and, secondly, the French and Italian systems of prior approval for fortified foods lawfully produced and marketed in other Member States.

In these judgments, the Court established that in order to show that the national measures are necessary to give effective protection to public health the competent authorities must base their decisions

'[...] on a *detailed assessment* of the risk alleged by the Member State invoking Article 30 EC'.

This detailed scientific requirement had originally been sketched out by the EFTA Court in the *Kellog's* case, where it was established, although within the EEA context, that Member States must, when invoking the precautionary principle, conduct a 'comprehensive evaluation of the risk to health'.¹²¹

In reference to the Italian situation the Court found directly that the Italian government had failed to show 'any alleged risk to public health' and could not 'explain on what scientific data or medical reports' it had relied.¹²² In the case brought against France, the Court found that the scientific opinions cited by the government were not specific enough to prove the alleged risk since they refer

'vaguely to the possibility of a general risk of excessive intake, without specifying the vitamins concerned, the extent to which those limits would be exceeded or the risk incurred'.¹²³

Moreover, in the same French case, the Court found that, contrary to the studies focusing on L-tarrate and L-carnitine, the studies it relied upon concerning drinks such as *Redbull* fulfilled the requested scientific requirement ('detailed assessment') and proved that excessive caffeine content and the presence of taurine was harmful to human health. On this basis, it concluded that the Commission had failed to explain or to adduce evidence to rebut those studies. However, the Court's opinion simply raises the question of who is to decide whether the scientific opinion a State relies upon in the adoption of public health measures is a 'detailed assessment' within the meaning of the ECJ's case law.

This line of cases shows clearly that the Court, by imposing a stricter scientific assessment process, (a 'detailed assessment') seems to be willing to get involved in scientific matters. Both the CFI (in *Pfizer/Alpharma*) and the ECJ (in the *Vitamins* line of cases) were eager to play with science by weighing the merits and assessing the validity of scientific opinions set forth by the parties to the dispute. Both courts have thus inaugurated a new

approach to scientific issues that allows them to ‘pick and choose’ those scientific opinions they believe better fulfil the minimum scientific requirements for a measure to be considered as ‘based on a detailed risk assessment’.

The Role of Scientific Experts before the Courts

Following the *Pfizer* and *Vitamins* line of judgments, one may legitimately wonder whether the EC courts need a source of external expertise in order to assess the scientific plausibility of the scientific claims being put forward both by Member States and EC institutions. There are good reasons to believe that reliance on such external help might facilitate the role that EC courts are increasingly called upon to play when reviewing science-based measures.

Although under the current Statute¹²⁴ and their respective Rules of procedure,¹²⁵ both the CFI and ECJ ‘may at any time entrust any individual, body, authority, committee or other organizations it chooses with the task of giving expert opinion’, they have so far been quite reluctant to rely on external advice. This seems to be especially true for scientific matters. While the courts, notably the CFI, have ordered expert reports *inter alia* to assess the quality of a translator’s work,¹²⁶ an official’s mental state,¹²⁷ to examine the rates for and conditions of transport of mineral fuels,¹²⁸ price rises and the market in dyestuffs¹²⁹ and the economic consequences of certain gas tariffs,¹³⁰ they have rarely done so in scientific matters. Occasionally, the parties have themselves submitted an expert’s report or, at the hearing, an expert has addressed the Court on behalf of one of the parties.¹³¹

The decision to obtain an expert’s report is made by the Court in the form of an order after the parties have been given an opportunity to be heard. The same order appoints the experts, defines the scope of the expertise and sets a time limit for the drafting of the report.

Despite this rather simple framework for having expertise at its disposal, EC courts have traditionally been unwilling to use it.

Therefore, before sketching out a possible expertise system within the EC judicial system, it might be crucial to look at the reasons that have so far discouraged the EC courts from relying on this possibility. An explanation for the European courts' reticence in asking for external advice may be found within the EC institutional framework itself. One can easily imagine that where the courts are called upon to review scientific assessments from EC scientific committees (especially where reviewing a Community measure, for example), they might feel that submitting one of these studies to a third party review would amount to questioning both the scientific and institutional legitimacy of these committees, which ultimately belong to the same system of governance. However, this argument, which boils down to the idea that the CFI/ECJ belong to the same institutional family than the Community legislator, does not seem to be entirely persuasive if examined from a US perspective. In fact, US Federal Courts do not hesitate to review the risk assessments undertaken by federal regulatory agencies.¹³² One can therefore wonder therefore whether this 'legitimacy' argument alone can explain the EC courts' deferential attitude vis-à-vis the scientific reports prepared by the European scientific committees.

A more credible argument for understanding this deferential approach to science marked by a Europe label refers to judicial tradition. Having traditionally not relied on scientific expertise, judges (notably the judge *rapporteur* in the EC judiciary jargon) might be somehow discouraged from proposing recourse to expertise under the courts' rules of procedure to other Court members. Finally, if tradition plays a crucial part in explaining the courts' wariness to rely on scientific experts, fears of ultimately delegating the task of solving a dispute may also exist.

In attempting to develop a credible and effective expert consultation system for EC courts when dealing with scientific matters, it is important to take due account of the institutional scientific framework upon which the Community relies when adopting legislation.

Unlike the WTO's judicial bodies, the European courts, when called upon to review a science-based measure, are likely to already have a scientific study supporting that measure or, at least, dealing with its scientific foundations. While this is certainly the case when the courts are called upon to examine the legality of an EC measure, it might not be the case when the contested regulation has been adopted by a Member State. In the latter case, the national measure is supported instead by a national scientific opinion produced by its own authorities.

Against this backdrop, one may wonder what body might be available for consultation by the EC courts to examine the scientific adequacy of the evidence brought by the parties to the dispute. Should they ask the EC scientific committee members, perhaps those sitting within EFSA, to review the evidence they have themselves developed? Or should they rely on some third-party scientists? And *quid* in cases of science-based national measures? Should the Court submit the national scientific evidence to the scrutiny of the EC scientific committees?

It is extremely difficult to answer this very last question as there is no hierarchy between research bodies and their scientific advice. It is therefore problematic to see how, in the event of conflicting scientific studies, it could be justified to follow one set of scientific opinions rather than another.

Peer Review as an Alternative Method to External Expertise

A valid alternative method to external expertise might be represented by reliance on peer review.¹³³ This is a formal science-based process that is traditionally used when a scientific work is nearly complete, and utilises

independent experts who were not involved in the development of the scientific study.

Although it is used primarily by publishers to select and screen submitted manuscripts,¹³⁴ and by funding bodies, to decide the awarding of research funding, the peer review process is also utilised for risk assessment procedures. In these circumstances, it involves an in-depth assessment of the assumptions, calculations, alternate interpretations, methodology and conclusions. In particular, by taking the form of a deliberation, it involves an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.¹³⁵

The practice of peer review of risk assessment products is not entirely unknown in the Community or in the WTO. Thus, for instance, within the framework of the European directive on the placing of plant protection products on the market, EFSA has launched a peer review of the assessments made by Member States with the aim of creating a 'positive list' of pesticides.¹³⁶

It is thus suggested that, like decision-makers, courts can also rely on peer review, by either asking experts to peer review the scientific evidence advanced by the parties or by simply showing deference to that evidence whenever it has been subject to peer review.

One of the main advantages stemming from judges' reliance on peer review is that, via this tool, they might determine the exact scope of experts' review, by, for instance, asking them to distinguish scientific facts from professional (science policies) judgments.

This might turn out to be especially useful in the current EC risk analysis framework, which does not recognise that uncertainty is inherent in science and that in many cases scientific studies do not produce conclusive evidence.

In particular, it is suggested that proof of a prior peer review must give rise to a presumption of conformity of that evidence with the relevant scientific evidence. However, prior peer review is not by itself sufficient ground for triggering such a presumption. There is clearly a need for some evidence proving the adequacy of prior peer review. Thus, for instance, publication in an important scientific journal may mean that adequate peer review has been performed.

An example of such a deferential approach to peer reviewed scientific evidence may be seen in *Methanex*,¹³⁷ a recent case decided by the North American Free Trade Agreement's NAFTA Tribunal under the provisions in the NAFTA Chapter 11 on investment and the UNCITRAL arbitration rules.¹³⁸ At the heart of this case was an investment dispute between the Canadian-based Methanex Corporation and the United States. Methanex is a major producer of methanol,¹³⁹ a gasoline additive that was banned by California in 2002 on environmental and human health grounds. Methanex, having submitted a claim to NAFTA, argued, *inter alia*, that the ban was not a genuine environmental measure but a disguised restriction of trade.¹⁴⁰ In replying to this argument, the NAFTA Tribunal, 'having considered all the expert evidence adduced', accepted the scientific evidence underpinning the contested measure 'as reflecting a serious, objective and scientific approach to a complex problem in California'. In particular, the Tribunal came to this conclusion by taking account of the fact that this scientific evidence 'was subject at the time to public hearings, testimony and peer-review'. In light of the above, it concluded that

'its emergence as a serious scientific work from such an *open and informed debate* is the best evidence that it was not the product of a political sham engineered by California'.¹⁴¹

I believe that there is a great deal to be learned from this use of peer-review within the EC judicial review of science-based measures and that, if well-

tuned, it might even represent a valuable alternative to expert consultation mechanisms.

Conclusion

Despite the flaws and limitations that we have highlighted, the emerging risk regulatory framework, by denying any supremacy to the EC sources of scientific opinions over national advice, preserves Member States' rights to carry out their own scientific studies and even strengthens their roles through the establishment of the European networking of scientific authorities. In particular, it is argued that the deliberate choice not to turn EFSA into an Oracle of Delphi, spelling out the 'truth' in all scientific matters, while likely to bring about conflicts among Member States, may be seen as an attempt to reconcile science, traditions, consumer concerns and free movement. Accordingly, in cases of diverging opinions between the EFSA and national food authorities, it is up to the EC courts, and not to EFSA, to solve these conflicts by striking a balance between the European (universal) and a national (local) vision of both safety and of the socio-cultural perception of a particular food (Chalmers 2003: 534). Furthermore, the EC risk management policy, which allows risk managers to take into account 'other factors legitimate to the matter under consideration' and the precautionary principle in addition to hard scientific opinions¹⁴² must be applauded to the extent that it embraces the political nature of risk regulation. However, to maintain the original goals pursued by the functional separation between risk assessment and risk management, it is absolutely imperative to render science policies explicit by furthering the current efforts aimed at elaborating guidance documents for each EFSA panels.¹⁴³

As to the role played by scientific expertise before courts within the emerging European regulatory framework, it has been illustrated that

scientific opinions, as non-legally binding acts but rather mere preparatory acts, do not seem susceptible of judicial review as such. However, as scientific evidence is becoming crucial at all stages of the creation of new legislation, EC Courts are increasingly called upon to review science-based measures. In so doing, Courts have generally avoided becoming enmeshed with scientific evidence by showing great deference to the technical and complex assessments underpinning the contested measures. However, some recent cases show a readiness of the Courts to become more involved in the examination of the scientific evidence presented, even where the contested measure has a Community origin. To mitigate partly the difficulties faces by the Courts in performing this difficult task it has been suggested that they should rely primarily on peer-review mechanisms rather than on external consultation procedures.

Notes

¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 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, *OJ* 2002 L 31 (hereinafter: the Regulation).

² See, e.g., Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air (*OJ* L 163) and Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants (*OJ* L 309).

³ Risk assessment of existing chemicals is provided by Council Regulation (EEC) 793/93 (*OJ* L 84) and Commission Regulation (EC) 1488/94 (*OJ* L 161). As for new chemicals, risk

assessment procedures are imposed by Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548/EEC, *OJ L 227*. See also CEC, Commission of the European Communities, *Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (on Persistent Organic Pollutants)* COM(2003) 644 final, 29 October 2003, Brussels.

⁴ Directive 98/08/EC concerning the placing of biocides on the market, *OJ L 150*, p. 71.

⁵ See Articles 4(1) and (2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, *OJ L 106*. Moreover, under Article 8 of the Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (*OJ L 43*), a novel food or food ingredient is considered to be “equivalent” to its conventional counterpart unless established risk assessment techniques can prove that this is not the case.

⁶ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, *OJ L 230*, p. 1-32. See also the 1998 Rotterdam PIC Convention which requires a “risk evaluation” as a precondition for regulatory action.

⁷ Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (*OJ L 40*) according to which the food additive must be subjected to appropriate testing and evaluation.

⁸ See Article 16(2) of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, *OJ L 327*.

⁹ Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemicals, physical and biological agents, *OJ L 327/8*; Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage the improvements in the safety and health of workers at work, *OJ L 183*; Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work, *OJ L 196*.

¹⁰ While Article 28 prohibits Member States adopting quantitative restrictions on imports and all measures having an equivalent effect to a quantitative restriction, Article 30 “shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans,

animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property”.

¹¹ Case 178/84, *Commission v. Germany* [1987] ECR 1227.

¹² According to the *Reinheitsgebot* (the German beer purity law), originally enacted in 1516 by the Bavarian duke Wilhelm IV, only beer containing the following ingredients could be marketed on the German territory: water, hops, barley, and yeast.

¹³ Case 178/84, *Commission v. Germany* [1987] ECR 1227, para 48.

¹⁴ Case 174/82, *Sandoz BV* [1983] ECR 2445, para 214. In this case, the Court had to face a Dutch refusal to grant authorization for the importation of muesli bars with added vitamins from Germany (where they were lawfully sold). For a comment on this case, see Slotboom 2003: 557.

¹⁵ Case 247/84 *Motte* [1985] ECR 3887. This case concerned the import of lumpfish roe prepared with colorants banned in Belgium but allowed in the country of export.

¹⁶ Case 304/84 *Ministère Public v. Muller and others* [1986] ECR 1511.

¹⁷ Case 178/84 *Commission v. Germany* [1987] ECR 1227, para 44.

¹⁸ Case C-42/90 *Bellon* [1990] ECR 4863, at 14.

¹⁹ Case C-13/91 and C-113/91 *Debus* [1992] ECR 3617, at 17.

²⁰ In *KYDEP*, involving the Community rules governing the maximum levels of radioactive contamination permissible in foodstuffs following the Chernobyl nuclear accident, the ECJ has even referred not only to “the opinions of national experts on radioactivity and foodstuffs, the recommendations of the International Commission on Radiological Protection (ICRP)” but even to “the instructions of the US Food and Drug Administration”. See Case C-146/91 *Koinopraxia Enóseon Georgikon Synetairismon Diacheiríséos Enchorion Proïonton Syn. PE (KYDEP) v. Council and Commission* [1994] ECR 4199, at 42.

²¹ According to Article 95, paragraph 5, “if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them”.

²² Although a similar scientific requirement is not expressly provided for with reference to the situation in which a Member State does *maintain* a measure derogating from a harmonized measure (Article 95, paragraph 4), it may reasonably be argued that a scientific requirement is also *de facto* imposed within the context of the application of paragraph 4 of Article 95. See Alemanno 2007a: 300.

²³ Article 174, paragraph 3, EC.

²⁴ See Article 174, paragraph 2, EC.

²⁵ Article 100a(3) of EC, current Article 95, paragraph 3.

²⁶ Article 95, paragraph 3, EC. See also, Articles 152 (1) and (4), 153, 174 (2).

²⁷ CEC, Commission of the European Communities, *Communication from the Commission on consumer health and food safety*, COM(97) 183 final, 30 April 1997, Brussels.

²⁸ *Ibid.*

²⁹ See Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment, *OJ L* 66, recital 6 of the Preamble.

³⁰ Communication from the Commission on Consumer Health and Food Safety, *supra* note 27, and CEC, Commission of the European Communities, *Communication on the precautionary principle*, COM(2000) 1, 2 February 2000, Brussels.

³¹ Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, *OJ L* 214.

³² Commission Decision 2004/210/EC, *supra* note 29, pp. 45-50. There are three committees: Scientific Committees on Consumer Products (SCCP); Scientific Committee on Health and Environmental (SCHER) and Risks Scientific Committee on emerging and Newly Identified Health Risks (SCENIHR). To coordinate these committees an Inter-Committee, made up of the Chairs and Vice-Chairs of the three Committees, has been established. Its main task is to assist the Commission on matters relating to the harmonisation of risk assessment. In addition, it deals with questions which are common to more than one Committee, diverging scientific opinions and exchange of information on the activities of the Committees.

³³ CEC, Commission of the European Communities, COM(2002) 713 final, 11 December 2002, Brussels.

³⁴ Commission Decision 2004/210/EC, *supra* note 29, p. 45.

³⁵ Whenever the Commission departments collect and use the advice of experts from outside the responsible department they should ensure quality, by seeking advice from an appropriately high quality source (i.e. based on the principles of excellence, independence and pluralism), by showing flexibility when looking for advice, and effectiveness, by making sure that its methods for collecting and use of expert advice are effective.

³⁶ According to the Updated Opinion of the Scientific Steering Committee on Harmonization of Risk Assessment Procedures, adopted on 10-11 April 2003, a full Second Report on the

Harmonization of Risk Assessment Procedures is currently being editing and will be published shortly (*sic!*).

³⁷ For decades the National Research Council (NRC) has been called on to consider how to improve decisions about risks to public health, safety and environmental quality. The NRC has conducted a series of studies on how society can understand and cope with those risks. In particular, the distinction between risk assessment and risk management was originally conceived in 1983 with the publication of *Risk Assessment in the Federal Government: Managing the Process* (also called the Red Book), a study that sought "institutional mechanisms that best foster a constructive partnership between science and government". Subsequently, this distinction played a crucial role in the development of an organizational separation of risk assessment and risk management in many US regulatory agencies. However, as we will see further, later publications of the NRC recognized the difficulties of maintaining a sharp dividing line between the two processes and emphasized the importance of ensuring interaction and communication between risk assessors and risk managers. See Stern and Fineberg 1996 and for a brief account of this development see also Suezener, Tamplin, Buchanan, Dennis, Tollefson and Hart 2003.

³⁸ See, within the U.S., National Academy Press 1994: 4 (prepared by a Committee of the National Research Council/National Academy of Science in response to a U.S. Environmental Protection Agency request mandated by the Clean Air Act Amendments of 1990); see, within the OECD 2003; see within FAO/WHO 1995:6; Joint FAO/WHO (1997); Joint FAO/WHO (1998).

³⁹ This separation was originally introduced by the 1997 Communication on Consumer Health and Safety, *supra* note 27, and subsequently confirmed by the CEC, Commission of the European Communities, *Green Paper on Food Law*, COM(97) 176 final, 30 April 1997, and the *White Paper on Food Safety*, COM(99) 719, 12 January 2000, para 32.

⁴⁰ Among the major drivers for this separation was a clear desire to remove value judgments from risk assessment and to prevent risk assessors from being unduly influenced by risk managers.

⁴¹ According to the Commission's White Paper, the EFSA should not be entrusted with risk management tasks because this would reduce democratic accountability within the Union, *supra* note 39, at 32.

⁴² Opinion in Case 192/01 Commission v. Denmark [2003] ECR 9693.

⁴³ Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305, at 157. See already Case 212/91, Angelopharm v. Freie Hansestadt Hamburg [1993] ECR I-171, paras 31-33.

⁴⁴ Several provisions of the Regulation provide that risk management decisions may consider not only risk assessment but also “other legitimate factors”. See preamble (19), Article 3 (12) and Article 6 (3). See also, e.g., Article 7(1) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *OJL* 287.

⁴⁵ The Regulation, *supra* note 1, Recital (19).

⁴⁶ The list of examples provided by the Preamble of the Regulation seems slightly narrower than that contained within the White Paper (see *supra* note 39, para 4), which mentions “environmental considerations, animal welfare, sustainable agriculture, consumers’ expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods”. However, as both lists contain only mere examples, their differences do not carry any particular value and should not be overemphasised.

⁴⁷ Commission Communication on the precautionary principle, *supra* note 30, at 5 of the summary.

⁴⁸ For a comparison between the EC and WTO risk analysis schemes, see Alemanno 2007a: 387 ss.

⁴⁹ See Appellate Body Report, European Communities – Measures Concerning Meat and Meat Products, WT/DS26/AB/R, WT/DS48/AB/R (January 16, 1998) (adopted February 13, 1998; Panel Report, European Communities – Measures Concerning Meat and Meat Products, WT/DS26/R/USA (August 18, 1997) (hereinafter: *EC-Hormones*). For a detailed reconstruction and insightful analysis of the dispute, see Christoforou 2003: 239 and Wüger 2002: 777.

⁵⁰ On this dispute, notably on its genesis, see, e.g., Christoforou 2000: 622 ss.; Scott 2000; Pardo Quintillán 1999: 147; Howse 2000: 2329.

⁵¹ Thus, for instance, an association of pharmaceutical manufacturers sought the annulment of the Directive prohibiting the use of certain hormonal growth promoters for the purpose of fattening cattle. See Case 160/88 Fedesa v. Council [1988] ECR 6399.

⁵² Case C-180/96, United Kingdom v. Commission [1998] ECR 3903, at 93. See also Case C-157/96, The Queen v. Ministry of Agriculture, Fisheries and Food, ex parte National Farmers’ Union et al. [1998] ECR I-2211. Contrary to the former case, the latter was not a direct action for annulment of the EC ban, but rather a preliminary ruling pursuant to a question about the validity of the EC measure from the UK High Court.

⁵³ This Agreement subjects all sanitary and phytosanitary measures to scientific evidence and risk assessment procedures by imposing on Member States the duty to demonstrate that their measures are necessary to protect human health. Under the existing SPS Agreement, scientific

evidence is, at least textually, the only legitimate criterion upon which to base SPS measures. For more on the WTO/SPS framework, see Alemanno 2007a: 227-290.

⁵⁴ This distinction has been criticised for being artificial and difficult to maintain in reality. For a European perspective, see Noiville and De Sadeleer 2001: 406-408; and, more, recently, Ladeur 2003: 1465. For a U.S. perspective, see Walker 2003: 252 and Wirth 1994: 833-834.

⁵⁵ These may be defined as “decision rules about the way in which risk assessment scientists should proceed when they encounter specified types of uncertainties”, which are established at political level. See Walker 2003: 214. One of the most common science policies is the presumption that a certain agent that can cause disease in laboratory animals can equally cause disease in humans. Other examples include the use of a linear dose-response model, the assumption that absorption in animals and humans is approximately the same or the use of body weight scaling for interspecies comparisons.

⁵⁶ It is argued that in the EC food context, where the question of science policies has not specifically been addressed at regulatory level, the European Food Safety Authority is never simply conveying information, but is inevitably endorsing a particular ideological model of politics. Along these lines of thought, see Chalmers 2003: 543.

⁵⁷ CEC, Commission of the European Communities, *European Governance: A White Paper*, COM(2001) 428 final, 25 July 2001, Brussels; CEC, Commission of the European Communities, *Communication on the Collection and Use of Expertise by the Commission: Principles and Guidelines*, COM(2002) 713 final, 11 December 2002, Brussels; CEC, Commission of the European Communities, *The Operating Framework for the European Regulatory Agencies*, COM(2002) 718 final, 11 December 2002, Brussels.

⁵⁸ Most of the EFSA scientific panels are in the process of adopting guidance documents aimed at establishing a method for conducting risk assessment. Thus, for instance, the Scientific Panel on Genetically Modified Organisms has adopted a Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (The EFSA Journal (2006) 374, 1-115 Summary) and also a Guidance document for the risk assessment of genetically modified plants and derived food and feed (the EFSA Journal (2004) 99, 1-94).

⁵⁹ Although officials' attendance is subject to the condition that they “shall not seek to influence discussions”, it is likely that their mere presence at the meetings may in some cases influence the delivery of scientific opinions. Thus, the scientists, depending on the circumstances, may be inclined to deliver the anticipated opinion or they may fail to take due account of some scientific information available to them. According to Greenpeace, the latter has already happened in EFSA's assessment of the first two genetically engineered crops

submitted to its examination. Greenpeace has severely criticised European scientists for having ignored two critical scientific factors. See Alemanno 2007a: 213–215.

⁶⁰ For more on the relationship existing between EFSA and the Commission, see Gabbi 2007: 131 and Alemanno 2007b: 610–611, 627–629.

⁶¹ A recent initiative has been launched by the European Consumer Safety Association (ECOSA) on the occasion of the Edinburgh Risk Assessment Conference. A working party has been established with the aim of developing a common nomenclature for risk assessors and a more standardised framework for the actual risk assessment process.

⁶² The European Commission decided on 10 June 1997 to create a Scientific Steering Committee (SSC) in the field of consumer health and food safety. The detailed mandate of this Committee is available at <http://ec.europa.eu/food/fs/sc/ssc/index_en.html>.

⁶³ Updated Opinion of the Scientific Steering Committee on Harmonisation of Risk Assessment Procedures, adopted on 10 April 2003, at 2.

⁶⁴ Case 247/84 Motte [1985] ECR 3887, para 20, in which the Court said that Member States must “take into account” the results of international scientific research, but where it also stated that “it must be emphasised that the Opinions of the Committee do not have binding force”.

⁶⁵ The Regulation, *supra* note 1, Article 22 (6).

⁶⁶ This conclusion deserves to be further elaborated by reference to those situations in which EFSA risk assessment is required by EC vertical legislation. In these circumstances, EFSA opinions enjoy the express status recognised by the legislation. Thus, for instance, under the GMO pre-market approval system, where the Commission decision is not in accordance with the EFSA opinion, the Commission must provide an explanation for the differences. See Article 7 of Regulation 1829/2003, *supra* note 44 (which reads: “[...] where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences”). See on this point Krapohl 2004: 532.

⁶⁷ Case 247/84 Motte [1985] ECR 3887, para 20, where the Court said that Member States must “take into account” the results of international scientific research, but it also stated that “it must be emphasised that the Opinions of the Committee do not have binding force”.

⁶⁸ The Regulation, *supra* note 1, Preamble (34) and (47), Article 22 (7).

⁶⁹ The Regulation, *supra* note 1, Article 30 (1).

⁷⁰ Although it is not expressly provided within the Regulation, this duty of cooperation must be read in light of Article 10 of the EC Treaty.

⁷¹ The Regulation, *supra* note 1, Article 30 (3–4). This system recalls the compulsory notification system of draft technical regulations to the extent that it functions as a preventive

mechanism (sort of 'early-warning') aimed at solving *ex ante* any conflict arising between the national and European views of risk.

⁷² The Regulation, *supra* note 1, Article 36 of the Regulation titled "Networking of organisations operating in the fields within the Authority's mission".

⁷³ The Regulation, *supra* note 1, Article 38.

⁷⁴ Article 4 of Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the field within the European Food Safety Authority's mission, *OJ L* 379. Under the same regulation, Member States are required to forward to the Authority, with a copy to the Commission, the names and details of the designated organisations, evidence that they comply with the criteria set out by Regulation 2230/2004 and details of their specific fields of competence.

⁷⁵ Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305. See also the parallel case T-70/99 Alpharma v. Council [2002] ECR II-3495.

⁷⁶ See Article 7 of Regulation 1829/2003, *supra* note 44.

⁷⁷ The Regulation, *supra* note 1, Article 14 (9).

⁷⁸ The Regulation, *supra* note 1, Article 6 (3).

⁷⁹ The Regulation, *supra* note 1, Article 14 (1).

⁸⁰ Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HLH Warenvertriebs GmbH [2005] ECR 5141, at 94.

⁸¹ *Ibid.*, at 93.

⁸² *Ibid.*, at 94.

⁸³ Article 17 of Council Regulation (EEC) No 302/93 of February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction, *OJ L* 36, p. 1. This provision clearly states that "the Court of Justice shall have jurisdiction in actions brought against the Centre under the conditions provided for under Article 173 [now 230] of the Treaty". See also Article 15(3) of Council Regulation (EC) No 1035/97 of 2 June 1997 establishing a European Monitoring Centre on Racism and Xenophobia, *OJ L* 151, p. 1.

⁸⁴ Articles 57 and 63 of Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark, *OJ L* 11, p. 1.

⁸⁵ This is the case, for instance, of the Community Plant Variety Office (CPVO) as established by Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, *OJ L* 227, p. 1.

⁸⁶ According to the Regulation, *supra* note 1, Article 47: "1. [t]he contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of

Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority. 2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage. 3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority”.

⁸⁷ Article 230 EC Treaty, paragraph 1, reads: “[t]he Court of Justice shall review the legality of acts adopted jointly by the European Parliament and the Council, of acts of the Council, of the Commission and of the ECB, other than recommendations and opinions, and of acts of the European Parliament intended to produce legal effects vis-à-vis third parties”.

⁸⁸ This obstacle would per se not appear insurmountable to the extent that the ECJ, in the past, has shown itself to be ready to interpret broadly the category of acts reviewable under Article 230 EC. See Case 294/83, *Les Verts v. Parliament*, ECR 1986, p. 1339 and Case 193-4/87, *Maurissen v. Court of Auditors*, ECR 1989, p. 1045. In these judgments the ECJ considered that insofar as the Community is based on the rule of law, acts not mentioned in Article 230 EC are also capable of forming the subject of an action for annulment.

⁸⁹ It is precisely by relying on this argument that the CFI, in *Associazione delle cantine sociali venete*, declared inadmissible an action for a failure to act directed against the European Ombudsman. Case T-103/99 *Associazione delle cantine sociali venete v. Médiateur européen and Parliament* [2000] ECR II-4165, paras 44-48. For a detailed analysis and comment of this judgment, see Raimondi 2004: 547 ss.

⁹⁰ Case 60/81 *IBM v. Commission* [1981] ECR 2639, paras 9-10 and order of 24 March 2006 in Case T-454/05 *R Sumitomo Chemical AGRO Europe and Philagro France v. Commission*, not published in the ECR, paragraph 50.

⁹¹ Under Article 230 EC, judicial persons can easily challenge the legality of Community decisions when these decisions are *addressed* to them. However, the same article provides for a very demanding *locus standi* requirement where the act challenged is not a decision. Under the fourth paragraph of Article 230 EC, an individual may institute proceedings against other acts only when these are "of direct and individual concern".

⁹² Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 *Artegodan a.o. v. Commission* [2002] ECR II-4945, at 197.

⁹³ Joined Cases T-144/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00 and T-141/00 *Artegodan a.o. v. Commission* [2002] ECR II-4945.

⁹⁴ Thus, for instance, the Scientific Panel on Genetically Modified Organisms has adopted a Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (The EFSA Journal (2006) 374, 1-115 Summary) as well as a Guidance document for the risk assessment of genetically modified plants and derived food and feed (the EFSA Journal (2004) 99, 1-94).

⁹⁵ Orders of the President of the CFI delivered on March 1, 2007, Case T-397/06 R Dow AgroSciences Ltd v. EFSA and Cases T-311/06 R I, T-311/06 R II, T-312/06 R I and T-313/06 R FMC Chemical SPRL, Arysta Lifesciences SAS and Otsuka Chemical Co. Ltd, not yet reported.

⁹⁶ Dow AgroSciences, *supra* note 95, at 39.

⁹⁷ Article 33(1) of the European Coal and Steel Community reads: “[...] The Court of Justice may not, however, examine the evaluation of the situation, resulting from economic facts or circumstances, in the light of which the Commission took its decisions or made its recommendations, save where the Commission is alleged to have misused its powers or to have manifestly failed to observe the provisions of this Treaty or any rule of law relating to its application”.

⁹⁸ This is settled case law. See, in particular, in the competition law field, Joined Cases 56/64 and 58/64 Consten and Grundig v. Commission [1966] ECR 299, at page 347; in the agricultural field, Case 55/75 Balkan-Import Export v. Hauptzollamt Berlin-Packhof [1976] ECR 19, at 8 and Case 98/78 Racke v. Hauptzollamt Mainz [1979] ECR 69, para 5; Case 265/87 Schröder [1989] ECR 2237, para 22; Joined Cases C-267/88 to C-286/88 Wuidart and Others [1990] ECR I-435, para 14; Case C-331/88 Fedesa and Others [1990] ECR I-4023, at 14; Case C-157/96 National Farmers' Union and Others [1998] ECR I-2211, at 39; in the civil servants case law, Case 9/82 Øhrgaard and Delvaux v. Commission [1983] ECR 2379, at 14; in the state aid field, Case C-225/91 Matra v. Commission [1993] ECR I-3203, at 24-25. However, it should be noted that in the field of competition law the CFI has recently shown that it was ready to perform an in-depth analysis of the Commission's decisions. See for instance, the Babyliis case, T-114/02 [2003] ECR II-1279.

⁹⁹ Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy, OJ L 78.

¹⁰⁰ Case C-157/96, National Farmers' Union and Others [1998] ECR I-2211, para 39; referring to Case 98/78 Racke v. Hauptzollamt Mainz [1979] ECR 69, para 5.

¹⁰¹ Case 138/79 Roquette Frères v. Council [1980] ECR 3333, para 25; Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 Ludwigshafener Walzmühle v. Council and Commission [1981] ECR 3211, para 37; Case C-27/95 Bakers of Nailsea [1997] ECR I-1847,

para 32; Case C-4/96 Nifpo and Northern Ireland Fishermen's Federation [1998] ECR I-681, paras 41 and 42; Case C-120/97 Upjohn [1999] ECR I-223, para 34; and Spain v. Council, cited at para 115 above, para 29 and, lastly, T-13/99, Pfizer, *supra* note 75, at 168.

¹⁰² See Case C-120/97, Upjohn Ltd [1999] ECR 223, para 34. See, also, Case C-405/92 Mondiet [1993] ECR 6133. See, for a similar statement, in the competition law field, Joined Cases 56/64 and 58/64 Consten and Grundig v. Commission [1966] ECR 299, at page 347. See, in particular, the most recent interpretation of this judgment in Case C-168/01 GlaxoSmithKline Services Unlimited v. Commission [2006] not yet reported, at 241 where it is said that: "the Court dealing with an application for annulment of a decision applying Article 81(3) EC carries out, in so far as it is faced with complex economic assessments, a review confined, as regards the merits, to verifying whether the facts have been accurately stated, whether there has been any manifest error of appraisal and whether the legal consequences deduced from those facts were accurate".

¹⁰³ See Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305, paras 168-69 and 323.

¹⁰⁴ Case C-286/02 Bellio F.lli Srl v. Prefettura di Treviso [2004] not yet reported.

¹⁰⁵ Case C-286/02 Bellio F.lli Srl v. Prefettura di Treviso [2004], para 61.

¹⁰⁶ Case C-198/03 P, Commission v. Ceva/Pfizer [2005], not yet reported.

¹⁰⁷ *Ibid.*, at 75.

¹⁰⁸ While the EC judiciary shows itself to be quite deferential in examining the EC's efforts to attain a high level of protection of health, through the adoption of food (and feed) safety regulations, when it comes to the Members States' use of science in pursuing health protection goals, it adopts a more intrusive approach. In particular, the Courts are demanding in assessing whether the contested measure is adequately backed up by credible scientific evidence. For a possible explanation of this phenomenon, see Alemanno 2007a: 325-336.

¹⁰⁹ Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305.

¹¹⁰ See also the parallel case that concerned the same decision, revoking the authorization of some antibiotics as growth promoters: T-70/99, Alpharma Inc. v. Council [2002] ECR II-3495. For a comment on these two judgments, see *ex multis*, Walker 2003: 207-208; Vos 2004; Mariatte 2002: 12; Gonzalez Vaqué 2002: 925, n. 13 and Alemanno 2002: 842.

¹¹¹ Contra, see Peel 2004: 43 who argues that "Although the Court stressed that regulatory authorities must have at their disposal scientific information which is sufficiently reliable and cogent to allow them to understand the ramifications of the scientific questions raised and to make a decision on policy measures in full knowledge of the facts, the CFI displayed a

“strongly deferential attitude when reviewing the institutions’ interpretation of the scientific material and their judgments as to the existence of genuine scientific uncertainty”.

¹¹² These antibiotics were used as growth promoters, with the useful side effect of preventing certain animal diseases.

¹¹³ Case T-13/99 Pfizer Animal Health v. Council [2002] ECR II-3305, at 322.

¹¹⁴ *Ibid.*, para 162.

¹¹⁵ *Ibid.*, para 323.

¹¹⁶ *Ibid.*, para 393.

¹¹⁷ Case 192/01 Commission v. Denmark [2003] ECR 9693.

¹¹⁸ Case C-24/00 Commission v. France [2004] ECR I-1277.

¹¹⁹ Case C-270/02 Commission v. Italy [2004] ECR I-1559.

¹²⁰ Case C-41/02 Commission v. Netherlands [2004] ECR I-11375.

¹²¹ EFTA Court of 5 April 2001, Case E-3/00 Efta Surveillance Authority v. Norway, in EFTA Court Report 2000/2001, p. 73, para 30. For a comment of this case, see Alemanno 2001: 947-950.

¹²² Commission v. Italy, *supra* note 119, para 24.

¹²³ Commission v. France, *supra* note 118, para 61.

¹²⁴ EC Statute Article 25.

¹²⁵ ECJ Rules, Article 49 and CFI Rules, Article 70.

¹²⁶ Case 10/55, Mirosevich v. High Authority [1954-56] ECR 333.

¹²⁷ Case 12/68, X v. Audit Board [1969] ECR 109.

¹²⁸ Case 24 and 34/58 Chambre syndicale de la Sidérurgie de l'Est v. High Authority [1960] ECR 281.

¹²⁹ Case 48/69 ICI Ltd v. Commission [1972] ECR 619.

¹³⁰ Case C-169/84, Société CdF Chimie Azote et Fertilisants SA [1990] ECR 3083.

¹³¹ Case 204/80 Procureur de la République v. Vedel [1982] ECR 465.

¹³² See on this point McGarity 2003: 155.

¹³³ For an introduction to peer-review and to the different types of peer involvement, see, e.g., Office of Management and Budget, Final Information Quality Bulletin for Peer Review, 15 December, 2004 and Patterson, Mekk, Strawson, Liteplo 2007: 1609-1621.

¹³⁴ As a result, publications and awards that have not undergone peer review are likely to be regarded with suspicion by scholars and professionals in many fields.

¹³⁵ See the Final Information Quality Bulletin for Peer Review by the Office of Management and Budget (OMB), December 2004, at 2.

¹³⁶ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (*OJ L 230*, p. 1-32) was required to be implemented by Member States from 26 July 1993. The peer-review process is managed by EFSA's Pesticide Risk Assessment Peer Review Unit (PRAPeR).

¹³⁷ *Methanex Corp. vs. the United States of America*, Final Award of the Tribunal on Jurisdiction and Merits, in the matter of an international arbitration under chapter 11 of the north American free trade agreement and the UNCITRAL arbitration rules (Sagarika 2006: 110-114).

¹³⁸ The text of the NAFTA Agreement is available at <<http://www.nafta-sec-alena.org/>>.

¹³⁹ This substance is a key component in MTBE (methyl tertiary butyl ether), which is used to increase oxygen content and act as an octane enhancer in unleaded gasoline.

¹⁴⁰ In particular, the plaintiff argued that the California ban was tantamount to an expropriation of the company's investment; a violation of NAFTA's Article 1110, and was enacted in breach of the national treatment (Article 1102) and minimum international standards of treatment (Article 1105) provisions. By relying on these arguments, Methanex sought financial compensation from the United States to the amount of over \$900 million U.S.

¹⁴¹ *Ibid.*

¹⁴² The Regulation, *supra* note 1, Article 6 (3).

¹⁴³ Most of the EFSA scientific panels are in the process of adopting guidance documents establishing a method of conducting risk assessment. Thus, for instance, the Scientific Panel on Genetically Modified Organisms has adopted a Guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use (The EFSA Journal (2006) 374, 1-115 Summary) and also a Guidance document for the risk assessment of genetically modified plants and derived food and feed (the EFSA Journal (2004) 99, 1-94).

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Chapter 3

Some Suggestions for a Structured Approach to Participation in Food Risk Governance with a Special Emphasis on the Assessment Management Interface

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Introduction

Food safety policy in Europe is currently a particularly interesting field of empirical risk research as it is striving to revise the rules and routines of the governance¹ of food risks. At the EU-level as well as in some of the EU Member States, the overarching objective of this reform process is to restore what is perceived as a most valuable, however, scarce resource: *public trust* in food safety and those responsible for protecting the food supply and consumer safety. A significant loss of public trust has been diagnosed as the main consequence of a series of food scares that occurred in the 1990s, with BSE as the most prominent issue, and of the persistent debate over genetically modified foods, a technological innovation which despite revised and (in some aspects) more rigid regulation continues to be a highly controversial issue.

One of the major governance measures designed to remedy the deficit of public trust is *wider public consultation* in the process of regulating food safety risks. At EU-level, declarations of the value of and the need for ‘connecting with citizens and stakeholders’, ‘open dialogue’, and ‘understanding and addressing the concerns of stakeholders and consumers’ now represent a standard part of the official rhetoric. The most significant structural innovation in this respect is possibly the setting up of stakeholder fora with the mandate to consult the institution responsible for providing independent, high quality scientific advice, the authority for risk assessment (the European Food Safety Authority, EFSA).

At the same time, wider stakeholder involvement in food safety governance is also a highly disputed issue. Major questions raised by practitioners and academics alike include: At which stages should the involvement of so-called ‘interested and affected parties’ reasonably occur? How is the stakeholder policy of EFSA compatible with the declared aim of safeguarding the independence of assessment by keeping it separate and free from the influence of non-scientific considerations? How should the relevant resources of social groups and possibly also the wider public be fed into the process without an overkill of participatory procedures that would abuse the scarce resources (particularly time) of both the responsible institutions and actors from the ‘outside world’?

This Chapter seeks to address these questions in a discussion of the new emphasis on ‘improving stakeholder consultation and participation processes’ and related structures and practices in EU food safety governance. It will first highlight some recent developments in stakeholder involvement in this risk governance field. This sketch will point out that ‘connecting with citizens and stakeholders’ continues to be largely restricted to consultation activities. Drawing on empirical research that was carried out within a larger project context, the subsequent section will highlight some of the views of key stakeholders on the recent developments. Subsequently, the authors will

make some suggestions on how to design and put into practice a more structured approach to stakeholder and public involvement that goes beyond mere consultation. This approach distinguishes between different purposes of participation (at the different governance stages) and different levels of intensity of participation (linked to the likelihood of major societal debate or conflict surrounding the food safety threat at issue). It comprises permanent and flexible mechanisms of participation and proposes to institutionalise stakeholder participation through a committee structure at the *interface* between assessment and management, namely at the intermediary stages of framing and evaluation (at which the inherent inter-linkages between the scientific and the political aspects of food safety governance are considered to be particularly strong). The last section will draw some main conclusions.

The New Emphasis on ‘Open Dialogue’ and First Steps to Open up the ‘Black Box’ of Risk Assessment

The BSE crisis in particular fostered demands for a more effective, fairer, and more transparent and participatory regulation of food risks. These demands were motivated by concerns that behind closed doors powerful industry interests were being advanced at the expense of consumer interests – with increasing pressures resulting from broader developments such as economic globalisation and trade liberalisation making this preferential treatment more likely – and that, partly as a result of this political bias, food substances, products, or production techniques might be represented and treated as if they were ‘certainly safe’ while in fact uncertainties were denied or ignored. Another related underlying concern was that due to food safety regulators giving precedence to the goals of economic growth and competitiveness the public’s diverse attitudes and values might not be sufficiently recognised and respected in the handling of food safety issues. In addition, concerns were

expressed relating to the independence of scientific advice, particularly where considerable political pressure was brought to bear upon scientists.

These demands and worries have been interpreted by academics and policy makers alike as manifestations of serious legitimacy problems. By the late 1990s the prevailing diagnosis in European policy circles was that the level of public trust in both food safety and food safety institutions had seriously declined and that institutional frameworks needed to be improved in order to restore public trust and social legitimacy.

At the EU-level (as well as in a number of EU Member States) food safety institutions were subjected to review and reform. The core of the reforms at the EU-level is the allocation of responsibilities for risk assessment and risk management to separate institutions destined foremost to assure the *independence* of scientific analysis and advice. This division of responsibilities is codified in the new European Parliament and Council Regulation 178/2002, widely known and referred to as the 'General Food Law'.² The EU (and among the Member States also very much the UK) has also resorted to reforms designed to uphold the *procedural legitimacy*³ of food safety governance by incorporating democratic norms in the process of dealing with food safety issues.⁴ Advancement of the *democratic quality* of the governance process forms another major response to the situation of 'contested governance' (Ansell and Vogel 2006).⁵ It is formulated on the website of the European Commission's Directorate General for Health and Consumer Protection (DG SANCO) as follows: 'Transparency of legislation and effective public consultation are essential elements of building this greater [consumer] confidence'.⁶ There are three major modes by which this purpose was expected to be served in food safety regulation (Dreyer, Renn, Borkhart and Ortleb 2006):

- by making the risk analysis process, including risk assessment, more transparent through wider public documentation (including the publication of all the opinions adopted by EFSA's Scientific Committee

- and Panels on the Authority's website; in future all mandates will also be posted on EFSA's website⁷);
- by offering more readily comprehensible and process-oriented information on the risk to the public at large, specifically addressing major consumer concerns;
 - and by providing more and improved opportunities for the consultation of economic and civil society actors in relation to both assessment activities (with EFSA's Stakeholder Consultative Platform taking a prominent position) and management activities (with the Advisory Group on the Food Chain and Animal Health taking the lead⁸).

Consultation on the concerns, views, and interests of commercial and civil society actors operating in the food chain is the typical form which the involvement of social groups in food safety regulation takes. Stakeholder and public consultation constitutes one of the major pillars on which the General Food Law rests.⁹ The Law stipulates that, with the exception of urgent matters, there shall be 'open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law'.¹⁰ Furthermore, it specifies that EFSA shall develop 'effective contacts with consumer representatives, producer representatives, processors, and any other interested parties' in the course of risk assessment.¹¹ The Law is also specific about the participation component in risk management, which is defined as being about 'weighing policy alternatives in consultation with interested parties'.¹² This is in line with the concept of risk communication advocated by the Commission's White Paper on Food Safety, which defines it as an interactive and involving dialogue with and feedback from stakeholders.¹³ Public consultation directly relates to *participation* as one of the five normative principles of 'good governance' which the European Commission has identified in its White Paper on European Governance. It requires governance institutions to ensure wide participation from the

conception of policy options right through to the implementation of decisions.¹⁴

The practice of consultation in food safety governance is certainly not new, at least in relation to decision-making in the area of risk management. At the EU-level, representatives of the various interest groups were consulted through the Advisory Committee on Foodstuffs. This committee, which in the past was not regularly convened by the Commission (Joerges and Neyer 1997; Vos 2000: 230), was restructured and revived in 2004 as the Advisory Group on the Food Chain and Animal Health (Vos and Wendler 2006). In addition to this formalised setting of consultation, stakeholders have always been consulted on an informal basis. The frequency, intensity and selectiveness with which this occurred have been heavily dependent on the discretion of individual risk managers. Empirical research suggests that these informal contacts behind closed doors continue to be of high importance.

The most notable change to the traditional policy of involvement so far is possibly that the former 'black box' of risk assessment has been opened up (in part) to stakeholder consultation. Meanwhile, the consultation activities of EFSA, which has the role of the risk assessor,¹⁵ comprise such various practices as public consultations, annual colloques,¹⁶ technical meetings/hearings, conferences, scientific colloquia, and the Stakeholder Consultative Platform. With the setting up of the Platform, EFSA institutionalised stakeholder consultation through a permanent body. The Platform was established in 2005 as a forum of regular dialogue and exchanges; it is composed of EU-wide stakeholder organisations operating in the food chain and within EFSA's remit and has the task of assisting the Authority in developing its overall relations and policy with regard to stakeholders.¹⁷

The subject matters of the different consultation activities of EFSA include the Authority's broader policy such as its strategic objectives, its work programme and its overall approach to stakeholder involvement (dealt with

foremost by the Platform), as well as such practical matters as guidance documents for risk assessors and authorization applicants.¹⁸ Increasingly, EFSA also subjects matters which are closer to the core of the risk assessment activities to stakeholder or public scrutiny. These consultation activities include stakeholder or public consultations on draft opinions, on general or issue-specific approaches and methodologies for risk assessment,¹⁹ and also, envisioned for the near future, consultations on draft opinions dealing with complex food safety issues.²⁰ Furthermore, EFSA uses web-based consultations for public requests for input of relevant data and information.²¹

The above sketch of some of the recent developments in the policies of involvement in food safety governance at EU-level indicates that there is *continuity* in organising public involvement in most part as the ‘elicitation of responses to pre-formed proposals’²² (i.e. to consultation activities) that is in contrast to ‘symmetrical two-way deliberation’ with the potential to empower inputs from different social actors. At EFSA, empowerment to influence decision-making is restricted to the management level where the Authority provides for a formal representation of different interests (four of the Management Board members, out of fourteen, are required to have a background in organisations representing consumers and other interests in the food chain).

There is *change* in that the risk assessment business, now segregated from risk management in a separate institution, has been opened up to stakeholder consultation in selected matters. There is also change from the *status quo ante* in that consultation in both risk assessment and – even though EFSA does not have authority over this – risk management occurs on a more regular basis (mainly through the Advisory Group on the Food Chain and Animal Health and the Stakeholder Consultative Platform), and also increasingly in a more open manner (which contrasts with and assumedly

complements rather than substituting, informal and confidential ‘behind closed doors’ consultations).

A Sketch of Stakeholder Views of the Reform Policies

The present section highlights some of the responses of stakeholders towards the recent reform efforts in EU-level stakeholder policies. They were elicited during the past three years through interviews and workshops with key stakeholders in the field of food safety governance.²³

One of the findings of this empirical investigation is that the consultation of stakeholders during the governance stage of risk management is widely acknowledged, while the new practice of opening up the stage of risk assessment to some degree to stakeholder and public consultation is not accepted unquestioningly. The inclusion of stakeholders in the course of risk assessment is still disputed and has an exploratory character. By no means were all interviewees convinced about the necessity of having ‘affected and interested parties’ involved in an activity that should be governed by data gathering and analysis, and safeguarded against inappropriate non-scientific influences; but nor did they have clear ideas about appropriate ways to do justice to this legal imperative (Vos and Wendler 2006: 124). According to various Commission officials who were interviewed, a viable option to greater public involvement as regards risk assessment would be to consult stakeholders more regularly at the moment of drafting the terms of reference and after the presentation of the assessment report (Vos and Wendler 2006).

Not surprisingly, the greater importance attached to the representation of consumer interests – through the Commission’s Advisory Group on the Food Chain and Animal Health, EFSA’s Stakeholder Consultative Platform and EFSA’s Management Board – is generally welcomed by representatives of

non-governmental organisations (NGOs). Various participants at a workshop with NGO representatives (conducted within our empirical research, cp. ft. 24) pointed, however, to the continuing challenges faced by NGOs as a result of unequal power relations and access to resources between different actors in food safety governance, in which informal contacts behind closed doors would continue to be of high importance. In particular, the possibility that governance questions would be framed by the powerful corporate sector means in their view that it is important to have formal NGO involvement already at the earliest stage of the governance process when the problem is defined and the terms of reference are set, and certainly at those stages at which necessary action and means of action are deliberated and concluded (Ely and Stirling 2006; Vos and Wendler 2006: 124).

Public consultation is at present for the most part organised as stakeholder consultation. This gives in particular the bigger and more prominent organisations (the 'Brussels stakeholder establishment') a voice (prominently within the framework of the Advisory Group on the Food Chain and Animal Health and the Stakeholder Consultative Platform).²⁴ Several representatives of smaller NGOs challenged this practice emphasising that NGO inputs to the governance process should be as diverse as possible, rather than focussing on a small number of the large NGOs. They stressed the need to recognise and respect the greater diversity of voices, perspectives, and values that are usually involved in food safety issues. At the same time, they underlined the generally limited resources of NGOs and the scarce resources of the smaller NGOs or of citizens to invest on a regular basis in the regulation of food safety (Ely and Stirling 2006).

Some Suggestions for a Structured Approach to Participation Including ‘Interface Deliberation’

This section²⁵ aims to address the issues set out above by providing some suggestions for how to achieve a more structured engagement of EFSA and the Commission with a diversity of social groups in a way which includes the earliest stage of the governance process, maximises valuable input (knowledge, interest, value preferences) into the governance process while avoiding the process and participants’ resources being overburdened by excessive participation on every food safety issue, and which goes beyond mere consultation.

Participation at Four Stages of Governance Tailored to the Purposes Served at the Different Stages

A recent publication on the role of expert advice in the governance of science and technology states rightly that ‘public engagement is not a stage of governance that can be completed, tidied up and filed away’ (Stilgoe, Irwin and Jones: 2006: 53; see also Jasanoff 1993: 123–129). Instead, public engagement should be understood as an inherent element of the whole process of governance and thus raises the more exigent question of how to incorporate the perspectives and specialized knowledge of interested and affected parties early and meaningfully into the process.

One way in which to address this question in a first step is to distinguish between *different purposes* of participation that are served at the different stages of the governance process. We propose to distinguish four essential stages of governance: assessment and management as the two well-established components of risk analysis, and two additional stages: firstly, *framing* which encompasses the definition of the respective problem and the setting of the terms of reference for assessment, and, secondly, *evaluation* which relates to the process of assimilating and deliberating upon the outputs

of the assessment phase and considering the tolerability or acceptability of a given food safety threat more explicitly.²⁶

Advocating the addition of these two stages is not to claim to propose something entirely new: in the current food safety governance system framing and evaluation activities are inevitably also carried out, so to speak. However, these activities are carried out in a manner that is barely transparent. The step of evaluation is, moreover, exercised in a manner that is largely implicit and ad-hoc, and responsibilities are not clear: is evaluation a task carried out/to be carried out by assessors or by managers or by both?

The key feature of framing and evaluation is that they constitute *interfaces* between the assessment stage, which is focused on knowledge generation and collection, and the management stage, which is focused on value-laden decision-making in a jigsaw puzzle of facts, uncertainties, stakeholder interests, and public concerns. They are interface tasks in so far as they draw on *both* scientific knowledge and political and socio-economic considerations: the tasks of framing need to be governed by societal values (stating the goals, objectives and contextual conditions) and inspired by what we already know about the threat (suspected impacts, exposure, persistence, and others). Similarly, during the phase of evaluation, the tolerability/acceptability judgement requires a good understanding of the web of evidence, residual uncertainties, and ignorance (i.e. of the scientific characterization of the threat), as well as a judgmental competence for making the necessary trade-offs between risk, benefits and other relevant impact categories. In that sense, framing and evaluation are, so-to-speak, 'hybrid' activities. The proposed formalisation of these two activities as governance stages in their own right is a way to account for the inherent inter-linkages between the scientific and political aspects of food safety governance (which are in the current governance system often obscure and lie outwith the view of democratic accountability), and at the same time to not compromise the

functional differentiation between assessment and management activities (as provided for in the General Food Law).

The proposed four-stage-structure of food safety governance avoids, on the one hand, the naïve decisionistic separation in values here and facts there, and, at the same time, escapes post-modern relativism in its extreme version by honouring the analytical distinctions between the factual and the desirable world even if they clearly interact. That way, the four-stage structure has potential to create more *accountability* by enhancing clarity over the nature of the reasoning underlying governance outcomes, in particular over the way in which knowledge and value inputs relate to management decisions. Moreover, the formalisation of the stages of framing and evaluation improves political and public accountability by clarification of the responsibilities for essential governance activities.

In order to define the different purposes of participation served at the four governance stages we propose to distinguish between *four discourse categories*: a design discourse (generic to the framing stage); an epistemic discourse (generic to the assessment stage); a reflective discourse (generic to the evaluation stage); and a practical discourse (generic to the management stage).²⁷ The following paragraphs provide a brief description of the four discourses and the role participation takes in them.

Participation at the stage of framing means involvement at the earliest stage of governance. Participation here concerns contributing to a *design discourse*. This discourse is aimed at setting the terms of reference, including the scope, focus and design of assessment, and at specifying the way (breadth, concrete procedures) in which stakeholders and/or the wider public are included in the assessment process.

The *epistemic discourse* at the stage of assessment comprises communication processes, in which experts of knowledge (not necessarily scientists) grapple with the clarification of a factual issue. The goal of such a discourse is the representation and explanation of a phenomenon as close to

reality as possible. By knowledge, we refer to *systematic* knowledge collected by established means of natural and social sciences and *experiential* knowledge collected by interactive techniques such as hearings or focus groups. Both types of knowledge are important for describing what we generally know about the food safety threat (or about a set of functional equivalents to a threat source) and what we have learned in dealing with the threat or a similar threat source in the past. Subject to the provisions of framing, civil society actors and also the wider public may contribute to the broadening and refining of the infrastructure of knowledge and information upon which evaluation and management decisions draw. It is important to note, that it is *not* the task of stakeholders and representatives of the wider public in the epistemic discourse to deal with normative questions pertaining to the acceptability or tolerability of either the threat itself, different strategic options (a set of products/processes/practices which are possible alternatives to the option in question), or management measures for dealing with the threat. These normative issues are part of the evaluation and management phases. They are based on value judgements about what is 'desirable' rather than what is 'true'.

The *reflective discourse* encompasses communication processes dealing with the interpretation of factual issues, the clarification of preferences and values and a normative judgement of tolerability or acceptability. It is mainly suitable for balancing pros and cons, weighing the arguments and reaching a balanced decision on the basis of the epistemological discourse and social values and preferences. The main purpose of participation here is to ensure that all values and preferences are included in the weighing procedure, and that the final judgement reflects the societal balance between innovativeness and caution.

The *practical discourse* involves communication processes aimed at the identification, assessment, and selection of different management measures for

reducing and managing ‘intolerable threats’ or ‘tolerable but not acceptable’ threats. This discourse looks at the variety of possible interventions, addresses the pros and cons for each measure or package of measures and suggests a set of measures that appear to be effective, efficient and fair. The main purpose of participation is here to assure that relevant knowledge and different preferences are considered in the conclusions on the selection of one or more management measures.

Each of the four discourses produces different types of outcomes that are fed into the next governance stage and enlighten the politically accountable decision makers. It is stressed that, while all participants should have equal rights in the deliberation processes themselves, the responsibility for the final decision lies with the risk managers.

Institutionalisation of Participation in a Committee Structure at the Interface Stages of Framing and Evaluation

It was underlined above that the inter-linkages between the scientific and political aspects of food safety governance are particularly strong where food safety problems are framed and evaluated. This ‘hybrid’ character of framing and evaluation is likely to explain at least in part the need for the improved interaction between assessors and managers in the performance of these activities called for by several EU-level and Member State assessors and managers, whose views were elicited in the study of the governance systems at the EU-level and in France and Germany, where assessment and management responsibilities are allocated to different institutions (Dreyer, Renn, Borkhart and Ortleb 2006: 24-30).

As was already mentioned in Section 2, this institutional divide is the primary feature of the current institutional framework of EU food safety regulation (with the newly established EFSA being located in Parma, and the European Commission being located in Brussels). In terms of loss of trust, the

remedy resorted to in this new institutional design is the trust-generating power of what is represented as ‘*independent risk assessment*’.²⁸ Safeguarding scientific analysis against distortion by inappropriate policy influences and considerations is intended to re-establish and assure the credibility of risk assessment activities and results on which risk management decisions are to be based.²⁹ However, it is precisely the segregation of risk assessment responsibilities that highlights that scientific activities cannot be performed in complete isolation or in a political vacuum.³⁰ In the first couple of years following the establishment of EFSA, much of the official rhetoric tended to evoke the idea of assessors and managers doing their jobs in strict separation and sequence. Various interviewees and also several participants at the stakeholder workshops stressed, however, that this concept has never represented the practical reality in which interaction occurs and is deemed necessary. There exist obvious tensions between public legitimisation needs (insulating science from policy) and practical action requirements. The experience with the new institutional divide has increasingly brought to light that problems might arise if the need for interaction is not adequately accounted for in the risk governance process, and many assessors and managers see here room for improvement.³¹

We propose to account for this need for improvement by assigning framing and evaluation tasks to a committee that brings together managers and assessors *as well as* key stakeholders and act in an *advisory function*. This ‘interface committee’ would advise on the terms of reference at the stage of framing and reconvene at the stage of evaluation to use the new knowledge from the assessment to draw normative conclusions about the food safety threat under consideration, which would then advise the risk managers in the decision-making. Through membership in this committee, key stakeholders in food safety governance (including industry and consumer organisations) would be involved at an early stage in the governance process. Moreover, the

setting up of such a committee would facilitate the co-ordination between political decision-makers, knowledge experts, and social groups at those stages at which accounting for facts *and* values is of primary importance. The role of the stakeholders sitting on the committee would go beyond mere consultation. Instead, they would participate in deliberative exercises as members with equal rights.³²

The selection of a few 'key stakeholders' to sit on the interface committee would inevitably provoke questions of representativeness, power, and fairness. Therefore, the establishment of a second interface link that is more inclusive in terms of the voices that it invites to engage in deliberation over framing and evaluation issues might be considered. This broader link could take the form of a web-based function that offers platforms for an exchange of views and consultation that relate to the (draft) outcomes of the four governance stages that are documented and opened up for public scrutiny. The proposal for such an 'internet forum' has been spelled out elsewhere.³³ The main idea is to invite and expect participants of the internet forum to not merely state their opinions but to also exchange views, i.e. to discuss each others' standpoints and arguments. Hence, this participatory instrument also extends beyond (however, is intended to include) consultation: it should provide the European Commission and the proposed interface committee not only with individual feedback but with feedback based (at least in part) on discussion, reflection, and persuasion, i.e. with opinions mutually informed by a diversity of views. Certainly, the breadth and intensity with which individual cases would be discussed can be expected to vary greatly depending on the potential for conflict that might be implied in the cases. In that sense, the internet forum could act both as an *entry point* at major governance stages of a diversity of viewpoints into the governance process, and as a *signal* for highly controversial issues with a great potential for social mobilisation.

A Guiding Tool for Deciding on Extended Participation

Particular cases might require a more extensive participatory programme (extending beyond the inclusion of stakeholders through the framing/evaluation committee and web-based consultations and deliberations). We would propose to *proceduralise* decision-making over any possible extension of the scope of participation and concerning the selection of appropriate processes. It would be part of the mandate of the interface committee to give advice on this matter in consideration of the specific case and the given context and the overall socio-political climate.³⁴

Aspects that could inform this decision-making process may come from the internet forum as well as the stakeholders who sit on the interface committee, who can act as ‘sensitivity sensors’ for highly controversial issues that call for broader participation. In addition, those consultative stakeholder bodies that have been established in the recent years, namely EFSA’s Stakeholder Consultative Platform and stakeholder colloquia and the European Commission’s Advisory Group on the Food Chain and Animal Health, might be of some assistance in this respect.

While these sources of information already have some potential for facilitating decision-making around the need for broader participation, we would recommend, in addition, to apply the *preliminary assumption* that under more intractable conditions of *high levels of scientific uncertainty* and/or *socio-political ambiguity* a higher degree of participation is required. Uncertainty, as defined here, includes those states of knowledge where either the possible outcomes are clear, but it is difficult to quantify probabilities, or where neither probabilities nor outcomes may be fully or confidently characterised (more specifically the latter state may be referred to as a state of ‘ignorance’). Under the circumstance of ambiguity, the problem lies not with probabilities, but in agreeing the appropriate values, priorities, assumptions, or boundaries that apply in defining the possible outcomes. Socio-political ambiguity

focuses on the degree to which a given food safety threat may be subject to strongly divergent cultural attitudes, political perspectives or economic interests.³⁵ The presumption is that under the circumstances of high levels of scientific uncertainty and/or socio-political ambiguity the likelihood of major societal debate or conflict surrounding the threat under review is also higher and hence extended participation advisable.

What could such an extended participation look like? Under conditions of *scientific uncertainty*, stakeholders should be asked to administer their specific knowledge in the assessment process regarding the likely consequences of the product/process/practice in question that carries a certain threat. The more uncertain the given threat is, the more a communicative exchange among experts of a *great diversity of disciplines and also practical backgrounds* is required to reach a coherent description and explanation of the phenomenon. Frequently, these discourses are capable only of showing the range of the still methodically justifiable knowledge, i.e. defining the boundaries between the absurd and the possible, between the possible and the likely, and the between the likely and the certain. Methods for this type of involvement include the Delphi and Group Delphi method, scientific consensus conferences and meta-workshops (Turoff 1970: 84-98; Webler, Levine, Rakel and Renn 1991: 253-263). Under conditions of high scientific uncertainty stakeholders should also be invited to engage in a comparative review and administer their specific knowledge in relation to a range of *alternative options* (i.e. functional equivalents) to the product/process/practice in consideration. The realm of knowledge that is needed to characterise uncertain threats expands the scope of traditional risk analysis and includes expertise about social benefits associated with the threat or its alternatives, about possible substitution pathways, potential for using 'forgiving' technologies, etc. Methods such as stakeholder surveys, qualitative interviews, focus groups and public hearings are most appropriate for this task. Stakeholder participation is also advisable at the stage of evaluation, to reflect collectively on the balancing of the

possibilities for over- and under-protection, and at the stage of management, to balance the pros and cons associated with each of the potential intervention measures. Methods for these purposes include round tables, negotiated rule-making exercises or mediation (Stolwijk and Canny 1991: 33-48; Bacow and Wheeler 1984; Burns and Ueberhorst 1988; Review in Fiorino 1990: 226-243).

Food safety threats characterised by a high level of *socio-political ambiguity* require the most inclusive strategy for participation since not only groups directly affected but also those indirectly affected have something to contribute to the debate. Dealing with ambiguity in food safety debates necessitates, at the stage of assessment, eliciting as widely as possible the *concerns, perspectives, and preferred options* that the relevant social groups, on the basis of their specific knowledge and information, have regarding the case under review. If there are indicators (for instance through the deliberations on the internet forum) that a major debate involving the wider public is desired, it might be necessary also to conduct face-to-face inquiries among different groups and representatives of the wider public. Methods for this type of involvement include focus groups, stakeholder interviews, hearings and other interactive elicitation methods, such as value tree analysis, option mapping, and others. At the evaluation stage, a platform – complementary to the interface committee – is required where citizens are also involved, and competing arguments, beliefs and values are openly discussed. The opportunity for resolving these conflicting expectations lies in the process of identifying common values, defining different angles or perspectives that allow people to apply their own vision of a 'good life' to judging the acceptability or tolerability of threats without compromising the vision of others. Available sets of deliberative processes in which a randomised or deliberately stratified group of citizens work to scope and explore the issues and options in contention include citizen panels, citizen juries, consensus

conferences, ombudspersons, and citizen advisory committees, and others (see Kasemir, Clark, Gardner, Jaeger, Jaeger and Wokaun 2003; Joss 1999: 290-373; Renn, Webler, Rakel, Dienel and Johnson 1993: 189-214; Kathlene and Martin 1991: 46-63; Crosby, Kelly and Schaefer 1986: 170-178; for reviews see Hagendijk and Irwin 2006: 167-184; Rowe and Frewer 2000: 3-29; Lynn 1990: 95-101). In addition, classic stakeholder engagement processes such as hearings and web-based consultations might accompany the public participation program. Furthermore, if the management measures are also highly contested, it seems advisable to organise a broad societal discourse about the appropriateness of these measures and the best way of finding a consensus or an agreement on the measures to be taken. The methods for addressing ambiguity in the evaluation process are also appropriate for handling ambiguity in the selection of management measures.

Concluding Remarks

Scholars in the field of science and technology policy have noted that public participation in techno-scientific issues 'has recently gained mainstream support in Europe' (Levidow 2006) in response to greater conflict around innovation and the regulation of disputed technologies, and as a remedy for 'deficits' of public trust. The BSE crisis and other food-related scares and the controversy over genetically modified food have greatly contributed to this general development and to the current emphasis on public participation in food safety governance. What has been stated for the general field of scientific governance by a science and technology studies' scholar seems to be good advice for the field of food safety governance as well: to take an 'analytically sceptical (but not dismissive) perspective' (Irwin 2006: 300) on the 'new' governance mode because 'enhanced engagement alone cannot be presented as an antidote for public scepticism over technical change' (Irwin 2006: 315). While there is much to be said in favour of public scepticism as one

instrument of democratic control (so why eliminate it), it is also the position of the authors of this paper that inclusive governance is neither a panacea for better risk governance nor a guarantee for more democratic processes. Yet, it is also the firm conviction of the authors that given the right conditions, structures and processes, inclusive governance has the potential to improve decision-making and to add substantially to the rationality and democratic quality of risk governance.

Participation in food safety governance is currently a dynamic policy field, where the use of new participatory mechanisms – largely restricted to new consultation mechanisms – is still at an exploratory and experimental stage. We have presented in this Chapter some suggestions for how to respond to some of the key issues that are currently discussed in regard to these dynamics (for an overview of our suggestions see the table below).

The distinction between stage-specific purposes of participation is proposed as a conceptual basis on which to organise valuable input (knowledge, interests, value preferences) into the governance process without compromising the functional separation between assessment and management, while at the same time accounting for the interface stages at which activities aimed at ‘understanding’ risks and activities aimed at ‘acting’ on risks are strongly interlinked.

The representation of stakeholders on the interface committee at the stages of framing and evaluation allows for an early involvement of stakeholders in the governance process and for real engagement (in the sense of symmetrical two-way deliberation) at the two stages at which facts and values most strongly interact. The internet forum could add to the inclusiveness of the governance process by opening up all governance stages to public scrutiny and by inviting a much greater diversity of social groups to engage with the governance process. These two institutional provisions have the potential to improve the coordination between political decision-makers,

expert advisors, and corporate and civil society actors in the governance process, and to create a greater accountability for contesting political-economic interests and socio-cultural values that can underpin the outcomes of food safety governance.

We recommend additional participatory processes for those food safety threats that are associated with high levels of scientific uncertainty and/or socio-political ambiguity. No major effort is required to include stakeholders or citizens for 'routine' food safety risks. This provision is proposed to account for the particular challenges implied in the handling of uncertain and/or ambiguous food safety threats and as a way to ensure that participatory policies do not end up in 'stakeholder fatigue' (this term seems to develop into a buzzword in academic and stakeholder circles) or, in more general terms, into 'dialogue fatigue' (Irwin 2006: 316). This could result from participatory policies that rely upon quantity rather than the quality of participation processes. It is important to note that both the food safety institutions and those invited to engage with the governance process need to ensure that their resources are used efficiently. It is, however, the firm conviction of the authors of this Chapter, that for some of the most challenging food safety threats a broad participatory programme can lead to governance outcomes that are better informed, better balanced, and socially more robust.

A structured approach to participation³⁶

Governance stage	Style of discourse	Purpose As a contribution to:	Institutionalised Participation	Additional participatory processes
Framing	Design	Drawing up the terms of reference	Via an Internet Forum throughout the governance cycle	Procedurally , context dependent, and specified at the stages of framing and evaluation Prima facie default: high levels of scientific uncertainty and/or socio-political ambiguity require extended participation
Assessment	Epistemic	Gathering of knowledge and information	At the stages of framing and evaluation: via stakeholder representation on the Interface Committee	
Evaluation	Reflective	Value-based judgements on tolerability or acceptability		
Management	Practical	Selection of appropriate measures		

Notes

¹ The food safety governance process is understood to include, but also to extend beyond, the three conventionally recognised elements of risk analysis (risk assessment, risk management and risk communication). ‘Governance thus includes matters of institutional design, technical methodology, administrative consultation, legislative procedure and political accountability on the part of public bodies and social or corporate responsibility on the part of private enterprises. But it also includes more general provision on the part of government, commercial and civil society actors for building and using scientific knowledge, for fostering innovation and technical competences, for developing and refining competitive strategies and for promoting social and organisational learning’ (Ely et al. 2007: 9).

² Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 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, *OJ* 2002 L31/1 (hereafter: ‘General Food Law’).

³ The exposition adopts here the argumentation by Grace Skogstad, who suggests in her analysis of GMO regulation in the EU that, ‘all strategies to render policies acceptable by virtue of democratising the procedures by which they are arrived at can be viewed as input-oriented legitimation’ (Skogstad 2003: 324). While the ‘test of appropriateness’ under output (or results-based) legitimation standards was the perceived merit of policy outcomes, the merit of this test under input (or procedure-oriented) legitimation standards was the conformity of decision-making procedures with democratic norms of public participation and control (324–325).

⁴ The same holds true for the UK and Germany, and to a lesser extent for France, which have also declared the (re-)establishment of consumer confidence as one objective of their revised food safety policy (Dreyer, Renn, Borkhart and Ortleb 2006: 57).

⁵ The editors of this book refer to the situation of ‘both sudden and pervasive loss of trust and legitimacy and an uphill battle to restore it’ (Ansell and Vogel 2006: 20) as ‘contested governance’ and argue that European food safety regulation over the past decade exemplified such a case.

⁶ DG SANCO website: <http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm> (accessed on 15 March 2007). For the overarching field of policy-making on health and consumer protection, DG SANCO has recently launched the ‘Health Democracy’ initiative (Health Democracy: Building Stakeholder Involvement in DG SANCO). This initiative has as its purpose the identification of the areas of possible improvements in the existing consultation

system as well as the tools that are necessary in order to enable DG SANCO to better consult its stakeholders. DG SANCO was assisted in this effort by a Peer Review Group composed of key stakeholders, Member States and consultation experts.

⁷ Currently, only a few mandates are available, including mandates on nutrition, cloning, and risk-benefit analysis.

⁸ Moreover, the European Commission has established a system of online consultation, 'Your Voice in Europe', under which specific consultations in the area of food safety management and policy have been realised.

⁹ Two further major cornerstones are the application of principles of independence, objectivity and transparency in risk analysis, and the application of the precautionary principle in the face of scientific uncertainty.

¹⁰ General Food Law, *supra* note 2, Art. 9.

¹¹ General Food Law, *supra* note 2, Art. 42.

¹² General Food Law, *supra* note 2, Art. 3(12).

¹³ CEC, Commission of the European Communities, *White Paper on Food Safety*, COM(1999) 719 final, 12 January 2000, Brussels.

¹⁴ CEC, Commission of the European Communities, *European Governance: A White Paper*, COM(2001) 428 final, 25 July 2001, Brussels.

¹⁵ Put more precisely, EFSA has the dual role of both risk assessor and risk communicator, and thus the mandate to provide the European Commission, the Member States and the European Parliament with independent, high quality scientific advice *and* to communicate about its findings.

¹⁶ The Colloque is targeted at industry, farmer groups, consumer groups, and other non-government organisations and intended to be 'an interactive and participative event that facilitates work, debates and breakout sessions' (EFSA website).

¹⁷ The inaugural meeting took place in Parma, 6-7 October 2005. The Platform holds meetings twice a year in Parma (EFSA website). Currently it consults the Authority on an external review of EFSA's stakeholder policy.

¹⁸ EFSA is currently (May/June 2007) undertaking a public consultation via the Authority's website on a Guidance Document for Application to Authorizations of Health Claims; speech by C. Geslain-Lanéelle, the Executive Director of EFSA, at the meeting of EFSA's Stakeholder Consultative Platform on 26-27 April 2007, Parma, Italy.

¹⁹ To give some examples: the scientific panel of EFSA that deals with genetically modified organisms undertook a stakeholder consultation in relation to a Draft Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, and only

recently a public consultation on a Draft Report on the Safety and Nutritional Assessment of GM Plant Derived Foods/Feeds: The Role of Animal Feeding Trials; EFSA's Scientific Committee carried out a public consultation on a Draft Opinion on a Harmonised Approach for Risk Assessment of Compounds that are Both Genotoxic and Carcinogenic; also very recently, a working group at the Stakeholder Consultative Platform has been established to consult EFSA's Scientific Committee on the issue of 'Transparency in Risk Assessment'.

²⁰ It is planned that the Draft Opinion on Animal Cloning will be open for comment and public review, likely to be followed by a public consultation meeting; speech by H. Koeter, Deputy Executive Director of EFSA, at the meeting of EFSA's Stakeholder Consultative Platform on 26-27 April 2007, Parma, Italy. Other envisioned areas of further stakeholder involvement in addition to cloning are nutrition and nanotechnology; speech by C. Geslain-Lanéelle at the same meeting.

²¹ For instance, the work on the European Commission request for an opinion on animal cloning will start with a public request for input of relevant data/information through a web consultation; speech by H. Koeter at the meeting of EFSA's Stakeholder Consultative Platform on 26-27 April 2007, Parma, Italy.

²² A. Stirling uses these terms to describe the 'bottom line recommendation' of a European Commission Workshop dealing with the topic of 'From Science *and* Society to Science *in* Society: Towards a Framework for 'Co-operative Research' (24-25 November 2005): '... European activities in these areas [the governance of research and the scientific advice process] should be informed by, and should themselves incorporate, more effective forms of symmetrical two-way deliberation, empowering inputs from a wide diversity of social actors' (Stirling 2006: 4).

²³ This empirical work was conducted within the fifth subproject (so-called work package 5) of the EU-funded Integrated Project 'SAFE FOODS'. The interviews were conducted for an account of current institutional arrangements and recent reforms in food safety governance at the EU-level (see Vos and Wendler 2006: 65-138). For the purpose of this study 13 persons were interviewed (between April and July 2005), of whom 9 were from DG SANCO of the Commission, 1 from EFSA, and 3 from stakeholder associations. The workshops were held to inform on the development of a proposal for an innovative food safety governance framework, which includes the suggestion for a structured approach to participation (see Dreyer, Renn, Ely, Stirling, Vos, Wendler 2007). The workshops involved, successively, industry representatives, NGO representatives, risk managers, and risk assessors. The fifth and final workshop brought together all of the four actor groups. The first four workshops were conducted through the Autumn of 2006, with the final 'mixed' workshop being held in May

2007; the participants were selected from across Europe including the EU-level. In each case, a summary report of the workshop was produced and circulated to the participants to ensure accuracy and provide the opportunity for further feedback.

²⁴ To be sure, the Commission also organises regular public consultations on various topics where everyone is invited to comment.

²⁵ The section draws on parts of the chapter 'A Structured Approach to Participation' (see Dreyer, Renn, Ely, Stirling, Vos and Wendler 2007: 90-97).

²⁶ The four-stage structure draws on the Integrative Approach to Risk Governance advocated by the International Risk Governance Council (see Renn 2005).

²⁷ The labels for these different discourse types were first introduced by Renn 1999: 115-130.

²⁸ While official rhetoric often evokes the idea of 'science only' in this respect, scholars in the field of science and technology policy have persuasively argued that this model is misleading even in theory: the specific approach of a particular risk assessment, including e.g. the selection of impacts to assess, the disciplinary perspectives to shed light on these impacts, and the choice of more or less conservative safety factors, inevitably involves non-scientific considerations and value judgements, be they explicit or implicit (Millstone 2000: 818; Millstone and van Zwanenberg 2002: 603; Jensen and Sandøe 2002); see also the National Research Council's 'Red Book' which argues that the description of risk assessment as a strictly scientific undertaking was a misconception (National Research Council 1983: 150).

²⁹ At Member State level, this approach is especially pronounced in France and Germany, where responsibility for the functions of risk assessment and risk management have also been allocated to different institutions.

³⁰ The NRC's 'Red Book' also highlighted a central and well-founded criticism of 'full organizational separation', stating that 'simply separating risk assessment from the regulatory agencies would not separate science from policy', *supra* note 28, p. 139.

³¹ Cp. EFSA document 2006; DG SANCO 2005: 2. The increasing emphasis on the need for interaction corresponds with the Codex Working Principles for Risk Analysis, which emphasize that risk analysis is an iterative process and interaction between risk managers and risk assessors essential for practical application (Article 9), Codex Alimentarius Commission (CAC) 2005: 102. The NRC's 'Red Book' is emphatic on this point: 'The importance of distinguishing between risk assessment and risk management does not imply that they should be isolated from each other; in practice they interact, and communication in both directions is desirable and should not be disrupted' (National Research Council 1983: 6).

³² A more differentiated and elaborate proposal (offering and discussing alternative options) for putting framing and evaluation on a formal footing is presented in Vos and Wendler 2007: 67-

70. One of the major differences between the proposed options refers to the mandate of the 'interface committee': while one option would imply that the committee deals with all food safety cases, one of the alternative options would mean that the committee deals only with specifically challenging cases.

³³ *Ibid.*

³⁴ In all cases it should be the responsibility of the European Commission to take the decision over the need for additional participatory processes.

³⁵ For this conceptualisation cp. Ely et al. 2007: 11-12; on these concepts see also: Stirling 2006: 225-272; Stirling, Renn and van Zwanenberg 2006: 284-315; Klinke and Renn 2002: 1071-1094.

³⁶ This table is drawn from Dreyer, Renn, Ely, Stirling, Vos and Wendler 2007: 97.

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Chapter 4

Innovative Approaches to Stakeholder Involvement in Risk Governance.

Lessons from TRUSTNET IN ACTION
European Research Project

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Introduction

The TRUSTNET European Network (1997-2003) was set up as an attempt to bring a fresh and pluralist approach to the severe difficulties encountered by decisions on risks for public health and environment within the European Union. It relied from the very beginning on a co-expertise process involving the various categories of concerned players and stakeholders. Its work focussed on the actual decision-making processes supporting hazardous activities throughout their lifetime, both practical aspects and governance, as well as in relation to the quality and practicability of those decisions in the eyes of the actors involved. It identified a new approach to managing hazardous activities based on a more inclusive, participatory regime that opens up decision-making to concerned people and organisations. In 2000,

the concept of inclusive governance was introduced into the Trustnet framework as an attempt to rethink and improve the nature of the relationship between public authorities, experts and stakeholders in the context of hazardous activities.

Building on the work of the TRUSTNET network, the TRUSTNET IN ACTION (TIA) European project¹ was started in 2003 with the objectives of exploring new roles and relationships of mutual trust amongst all categories of actors involved in risk governance and of developing and testing structures for active participation. The project involved a multidisciplinary team of experts and researchers (law, risk assessment, ethics, economics, sociology, political sciences, philosophy, psychology) from 17 institutions across Europe.²

At the root of the TRUSTNET network was the understanding that the classical approaches to decision-making in European countries had difficulty in providing European citizens (and more specifically those at the local or territorial level who had to live with the results of decisions on risks) with the ability and means to actually contribute and influence decisions in the context of activities entailing risks straddling areas of serious concern (such as the environment, human health, economic development). It was also acknowledged in particular that the main difficulties lay in the inherent characteristics of classical decision-making and regulatory processes. Thus, there was a need for sustainable changes towards inclusive governance involving the appropriate institutional and procedural instruments as well as new roles and relations for the various categories of players. It was also recognised that the current processes of stakeholder engagement should be valued to the extent they they contributed to the production of sustainable changes towards inclusive governance.

TIA therefore examined factors that would enable sustainable progress towards inclusive risk governance in such situations. It focussed particularly

on nine innovative processes taking place in seven Member States of the European Union³ at the local, regional and national level that were characterised by the implementation of innovative participatory features of governance. These processes share a dimension of innovation as they constitute a break with the traditional governance methods. They are, in essence, experimental tools developed in order to cope with the complexity of local, national and European situations, which bring together a range of interrelated factors (e.g. health, economic development, environment, preservation of resources ...) that cannot be handled in isolation.

These processes were not closed cases and continued to evolve to varying degrees throughout the TIA project. They existed before TIA was initiated and are not therefore an artefact of the project. There was no prior assumption that the approaches developed in the nine innovative processes were more or less efficient or 'successful'. The aim of the analysis was to learn from what the stakeholders themselves understood to be successful or unsuccessful.

The methodology of the project continued the TRUSTNET approach of involving experts and stakeholders in the analysis of activities and in the development of thinking. The analysis has been iterative, dynamic and inclusive. Regular exchanges between the experts and researchers carrying out the project and the stakeholders involved in the nine innovative processes allowed the latter to influence the framing of the research process, making both important contributions to the outcomes and allowing them to take advantage of the thinking and experience developed in the course of the TIA work.

TRUSTNET IN ACTION has enabled a new model of inclusive governance to be constructed that represents an evolution of previous approaches. That new model of governance is now no longer concerned solely with local decision-making or the nominal involvement of stakeholders

in decision-making; rather it involves the full engagement of local actors as full, permanent and influential players in inclusive governance of activities or situations entailing risks or impacts on health or the environment.

This Chapter presents three particular aspects of the outcomes of TRUSTNET IN ACTION. The first aspect is the identification of key features of the philosophy of governance that underlies this inclusive governance model. The second point developed in this article is the characterisation of the societal and institutional evolutions that support change towards inclusive governance of activities entailing risks for health or the environment. Finally, specific methodological patterns that support sustainable evolutions towards Inclusive Governance will be presented. They are referred to as ‘Cooperative Inquiries’ and are characterised by a double perspective of aiming both at the production of reliable knowledge for action and at the creation of the conditions that enable concerned local actors to become full democratic players in the longer term.

Box 1: The nine innovative processes of TIA**Participatory biomonitoring in Belgian Flanders**

The bio-monitoring-campaign in Flanders investigated the relationship between environmental pollution and health effects. Answers to important questions concerning the relationship between the bio-monitoring and local situations were sought through local discussion groups in order to start up a dialogue about the campaign.

Participatory management of industrial pollution in the city of Brescia, Italy

The city of Brescia suffers from long-standing pollution from toxic substances derived from industrial production and which pose serious risks to health and the environment. The municipality, stimulated by the action of a local citizens group, has set up a process to encourage the participation of all stakeholders and affected citizens in risk analysis and management.

Implementation of Local Committees for Information and Dialogue (CLICs) in the vicinity of industrial Seveso sites, France

As a result of the Toulouse catastrophe of 21st September 2001, a new law on risk prevention introduced the creation of 'Local Committees for Information and Dialogue'. The aim is to promote debates on technological risks among the stakeholders and increase transparency in the decision-making process related to risks from 'Seveso' industrial sites.

Sustainable management of fish stocks in the South West of England: Invest in Fish

Invest in Fish South West is the first project in the UK to undertake a co-operative approach between environmentalists, fishing industry and other stakeholders and it seeks to find solutions to current fishing challenges through consensus, collaborating with those most affected by the fishing industry.

Sustainable development, including the protection of wild bears in the Haut Béarn, France

The Haut Béarn Heritage Institution (IPHB) was established in 1994 in a situation characterised by a local dispute between conflicting social demands, amongst which local sustainable development was a key issue, as was the preservation of wild bears. In order to integrate these different issues into a single decision-making process, the IPHB was established as a participatory institution involving all the concerned local, regional and national stakeholders.

Developing a cooperative framework for occupational health in Great Britain: Securing Health Together (SH2)

The Health and Safety Executive, the UK regulator for health and safety in the workplace, has realised that its current strategy for reducing work-related illnesses would struggle to meet this goal, in particular because of the challenges in reaching smaller companies. To improve collaboration, the Securing Health Together initiative was launched to increase stakeholder participation by setting up groups to tackle specific issues relating to occupational health.

Further development of societal risk policy in the Netherlands

The Netherlands has developed an extensive policy distinguishing between the protection of individual citizens against harm and the protection of society against disastrous events. The latter part of the policy came under renewed scrutiny after tragic events in Enschede and Volendam. The Dutch government has embarked on a nation-wide discussion on how to build on the existing policy to improve the structure of decision-making in this field.

The Vienna Airport Mediation Process, Austria

The authorities in charge of organising the extension of the airport asked an Ombudsman agency to set up a mediation process involving people from the local area. The mediation structure involved interest groups (including operators and authorities). The process led to a contractual engagement between the different parties involved.

Community Cooperation for Industrial Site Zoning, Germany

The main objective of the dialogue process is to design a joint initiative allowing the communities to operate as part of a joint venture one or several industrial and commercial parks and to share the costs as well as the tax revenues. A Round Table with the 24 mayors and other stakeholders has been formed to develop a mutually acceptable solution for this new inter-community cooperation project.

An Emerging Philosophy of Inclusive Governance

The TIA model of inclusive governance relies on a particular philosophy of governance that is grounded on a robust intellectual and academic premise. This philosophical approach can be divided into four main areas: Philosophy of Governance, Concrete Humanity, Experimental Democracy, and Pragmatic Methodology.

Governance

Governance, in the meaning developed by TRUSTNET, is not a substitute for traditional 'nation-state' government; rather it is an alternative regime applicable to a wide range of activities and organisations. According to Rosenau, 'Governance is a more encompassing phenomenon than government. It embraces governmental institutions, but it also subsumes informal, non-governmental mechanisms whereby those persons and organisations within its purview move ahead, satisfy their needs, and fulfil their wants' (Rosenau 1992: 1-29).

Gerry Stoker (see Stoker 1998: 17-28) identifies five aspects of governance: (1) Governance concerns a range of organisations and actors, not all of which belong to the government sphere (2) It modifies the respective roles and responsibilities of public and private actors as established in traditional paradigms of policy-making (3) It involves interdependence between organisations and actors engaged into collective action in contexts in which none of them has the necessary resources and knowledge to tackle the issue alone (4) It involves autonomous networks of actors (5) A key principle is that actions can be pursued without necessarily possessing the power or the authority of the State.

The aim of the inclusive governance processes in TIA is to restore citizens' ability to influence decisions in order to allow them to bring about changes, and to lead an enjoyable life by contributing to the sustainable

development of their territoriality-based community. Through inclusive participation, to be differentiated from the principle of subsidiarity, inclusive governance empowers concrete persons to become actors at the various local, national and European levels in the structures where decisions are taken that will influence their life and future.

In TIA, hazardous activities may be considered as a paradigm of the public/private conception as set out by Dewey, since these activities have consequences outside their perimeter. The principle of precaution is a means for opening a way into the risk issues monopolised by the experts and for changing technical/economic issues into political issues.

Concrete Humanity

The concept of concrete humanity sees human beings as neither purely rational nor purely irrational. They are multi-dimensional beings whose tendencies and needs cannot be reduced to a single dimension of existence nor to a single form of rationality. This view of humanity suggests that, as both natural and social beings, men and women are always in search for a life balance, that is for an equilibrium of their experiences, abilities and feelings. However, although risks are inherent in all social and economic structures within which people live, events or situations that critically increase the level or degree of such risks can seriously disrupt people's life balance. People are essentially vulnerable beings both physically and mentally, and normal development depends on balancing the various aspects of people's behaviour and personality.

Identity is an important component in that development. Identity building processes articulate several dimensions from the most local ones (family, village, district, region) to the most global ones (country, Europe, mankind). Identity, however, is much more than a nostalgic communitarian claim opposing novelty and calling for a defence of immutable traditions; it is

also an imaginative individual and collective structure that enables people to have a continuity of experience and to build a meaningful life.

The pictures of mankind emerging from the TIA process are obviously very diverse; however, all of them merge to the figure of a concrete person as opposed to the abstract person of the technocrats, the planners or the utopists. The concrete person is someone who articulates and adapts the multiple dimensions of his/her identity, his/her personality and his/her existence, which are rooted in a territory provided with a peculiar nature and culture. The existence of a 'concrete person' is the outcome of a life rooted in a local community, in close interaction with a natural and cultural environment, and which has developed through meaningful experiences, whether constructive or destructive, creating a special relationship to (and vision of) life and the world.

Experimental Democracy

Democracy is a political regime in which the organisation and the exercise of political power within society are an outcome of the will and the control of the people. Democracy can be direct, or indirect (where the ideal of citizens' participation in public affairs is often limited by a system of representation based on some constraining requirements e.g. competence, reputation, heredity). It could be suggested that 'real' democracies are in fact a combination of participation, deliberation and representation.

The concept of experimental democracy is not far from the thinking of the American philosopher Dewey, for whom democracy is less the political form of a regime than the method by which the people can deal with the consequences of actions; such consequences can be direct or indirect depending on whether people are associated, or not, with the initiating actions. On this basis, the public consists of 'all those who are affected by the indirect consequences of transactions to such an extent that it is deemed

necessary to have those consequences cared of' (Dewey 1927). The state then is a consequence of the will of the people; through their representatives, it takes care of the negative consequences of the others' actions. A key tool in such experimental democracies are social inquiries, which enable society 'to bring conflicts out into the open where their special claims can be seen and appraised, where they can be discussed and judged' (Dewey 1935).

The concept of experimental democracy in TIA means that the requirements of democracy in terms of the deliberation and participation of the citizens apply potentially to any field (science, technologies, morals, law etc) that can be of interest to the public. It involves in particular, as in Latour and Callon's approach (see Latour 2004 and Callon, Lascoumes and Barthes 2001), cooperative mechanisms that gather together citizens and experts and through which citizens can stretch and influence socio-technical decisions. However, experimental democracy is not limited to technical issues, neither is it merely radical as in Habermas' approach (see Habermas 1989 and Habermas 1996), because citizen engagement is not only experienced through social communication, but is also expected to be included within the institutional structure of power.

Pragmatic Methodology

Experimental democracy engaging concrete persons requires the use of a reflexive pragmatic methodology to address the complex issues (in particular risk issues) that impact upon multiple aspects of people's actual life. This methodology involves citizens, civil society organisations and other stakeholders (local communities, interest groups etc), working together with an inter-disciplinary group of scientists and experts through processes of *cooperative inquiry* (see section 3) to investigate a problem which matters to the public. Such processes that mingle 'experts-scientists' and 'experts-citizens' represent a modern version of Dewey's 'social inquiry' and allows the complexity of the issues under investigation to be addressed.

Thus, the relations between the expert and the public must be changed so that the experts are 'ordinary servants' of the public; they then become just one set of participants among many, following up a process of governance that has its own dynamic and whose goals are shaped by the actors. The aim of expertise is therefore no longer solely the production of valid knowledge, but, if possible by means of a 'double culture', is also to build up a common understanding with the other actors engaged in the process. This collective work must be meaningful for both the other actors and the experts and must reinforce, through an ethics of research, the link between science and humanity. The aim, then, is not to produce objectivity, but subjectivation, that is to say the emergence of a subject who can again be an actor within his own life and within the life of his territory, and can participate in the definition of the common good.

Change towards Inclusive Governance: A Joint Evolution of Civil Society and Institutional and Legal Frameworks

The nine governance processes followed in TIA (see Box 1) were not only considered in terms of how they were organised and taken forward, but also in how they addressed or took into account the broader context (e.g. institutional, territorial, historical, cultural) in which they were set. They have all been initiated by local actors and NGOs or by regional or national institutions. They were all characterised by their precise (but often limited) objectives, by being time limited (with a clear starting point and, usually, end point), by the engagement of stakeholders, by the involvement of professional facilitators and by the use of other tools to encourage participation.

The institutional changes observed in the context of the nine governance processes were in pursuit of different goals: balancing competing dimensions within a complex issue (e.g. risks prevention versus development

of economic activities), improving the informational and cognitive basis of the decision-making process, enhancing the quality of public policies and decisions in terms of efficiency, legitimacy, transparency and accountability.

Governance processes such as the ones considered in TIA do not operate in isolation of other processes in society; they both contribute and are influenced by broader and longer Processes (with a capital 'P') of evolution of their social, cultural, political, legal and institutional context. These broader Processes may both influence and be influenced by specific experimental processes (with a small 'p') of inclusive governance that thus contribute to a more global and longer term evolution towards inclusive governance beyond their specific remit and objectives.

This more global evolution towards inclusive governance of activities or situations entailing risks involves both transformations of the legal and institutional context and transformations of the territorial context. The cross-cutting analysis of the nine governance processes demonstrates that sustainable change towards inclusive governance necessitates, on the one hand, the emergence of structured entities from civil society (concrete people and communities sharing a democratic culture) rooted in a kind of territoriality (see section 2.2) and that are becoming sustainable, autonomous and influential players in the public and private decision-making processes that drive the innovation process at local, national and international levels. It involves, on the other hand, the actual transformation and opening up of traditional knowledge-building and decision-making processes, as well as the setting of inclusive regulatory and institutional frameworks at local, national and European levels in order to meaningfully support and integrate societal participation. These two aspects are complementary and constitute two different facets of a single co-evolution process.

It is important to note that the cross-cutting issues described hereunder do not constitute a description of the reality of each of the nine processes

considered in TIA. They are however rooted in the reality of these processes as they are composed of elements extracted from the description and analysis of the nine processes; these elements have been found to be paradigmatic points, be they present in the some processes or be their absence identified as a problem in other ones. The following elements are not a predictive tool. Rather they aim to draw out key dimensions of the development of inclusive governance in Europe and in doing so, to reflect both the commonalities between the nine processes and their diversity.

Transformations of the Legal and Institutional Context: Making Room for Permanent, Competent and Influential Engagement of Civil Society

The cross-cutting analysis of the nine innovative processes involved in TIA allowed a great number of difficulties, resistance to change and limits that represent an obstacle to sustainable change towards inclusive governance to be identified. Inclusive processes have often been considered in the past by decision-makers as a way of solving problems but from the perspective of returning to traditional governance as soon as the crisis is over.

A gradual transformation from traditional regulatory systems (based on centralisation, prescriptive decision-making, with a heavy reliance on experts) towards a more inclusive system of governance, which involves in most cases legal and institutional changes, is, however, noted in the processes considered in TIA. This may be observed in processes where the main players in the traditional systems (public authorities and experts, Government) were the main drivers of change, often as a result of previous crises. Institutional and legal issues also play an important role in inclusive governance processes when triggered by local or regional actors, who may challenge the existing traditional system of regulation and decision-making or whose vulnerability may stem from the rigidity of the existing institutional framework. The institutional and legal context and its evolution thus represent a key dimension for the analysis of inclusive governance processes.

The major contribution of the observed changes in legal frameworks and institutional settings is to give a statutory position to the contribution of stakeholders in the decision-making process, leading to the redefinition of roles of stakeholders and local actors and of their relationship with traditional decision-makers. This evolution in law and institutions also represents a resource for autonomous stakeholders (in particular local stakeholders) to stretch public decision-making processes. Ensuring that stakeholders take part in decision-making processes is a key issue.

The changes observed in the institutional and legal frameworks reveal three underlying trends: a movement from prescriptive to procedural regulations, the establishment of favourable conditions for the engagement of local actors and stakeholders in policy- and decision-framing (including having access to public expert institutions), and the development of multi-level institutional frameworks that allow for the devolution of decision-making to territorial entities.

The first trend is a move from regulation by establishing what is to be done to fixing, in some cases by law, the way the different actors in the various levels will take decisions together. This move towards procedural regulation involves in particular resorting to experimentation in the field of public policies and in the participation of stakeholders; the latter may occur both upstream, during the process of definition of the laws or regulations, and downstream, in the assessment of experience of experimental phases of the decision-making process or in the implementation of the regulations. Such experimental approaches may include the development of 'sunset laws' with a restricted period of existence.

The second evolutionary trend is a change in the legal or regulatory provisions that allow a greater role for local actors and stakeholders in policy- and decision-framing at the regional, national and international levels. This evolution of institutional frameworks may include the creation of

consultation bodies that involve the participation of a diversity of local stakeholders at higher levels of decision-making. In the opening up of public legal and regulatory frameworks to local stakeholders, the governance system takes into account the needs and perspectives of actual life in the territorial localities. These participation mechanisms thus differ from some form of lobbying, since local actors engaging in decision-framing at upper levels of any decision cannot focus only on local or specific interests. They need to be contributing to comprehensive and practicable decisions balancing all dimensions at stake while incorporating the actual characteristics of their local context. They appropriate and contribute to framing higher level objectives and perspectives, while keeping proximity with the local level, thus bringing into the decision-framing process an integrated view of the complexity of their context and of the various interrelated dimensions at stake at the local level.

A more specific trend is the gradual opening up of public expert institutions to societal engagement practices in order to meet societal demands for reliable, unbiased and transparent information and an active role of citizens in the construction of knowledge, in particular in the field of risks and environmental issues. These new practices run from a demand for better access of stakeholders to counter-expertise to joint knowledge building and fact-finding involving experts and stakeholders.

The third trend of evolution is the development of multi-level institutional frameworks involving devolution to territorial entities for taking and adapting elements of decisions in their specific context. This trend is complementary to the development of mechanisms integrating the participation of local actors into decision-making processes belonging to higher levels. In effect, various kinds of issues, notably in the field of risks, cannot be dealt with by dispatching them among different levels of decision-making in a fragmented way. Through such multi-level institutional

frameworks, the higher level of regulation retains the capacity to bring global constraints into consideration at local level, but allows those constraints to be adapted by local actors to the specificities of their context. A development of multi-level structures of regulation, or a need for such structures, is thus observed in the processes followed-up during the TIA project. These multi-level structures may rely on *ad hoc* or permanent bodies and processes involving local actors from concerned (in the broader sense) territorial communities as well as other stakeholders (Public Authorities, public expertise bodies, NGOs, Industry, etc). They are either created by local governments to address territorial issues (in particular regarding risks and/or sustainable development), or by law for the overall national territory. The mandates of such bodies vary from simple consultation to decision-making with a devolution of responsibilities previously belonging to higher levels of decision-making or a sharing of responsibilities between local level and other levels through a joint body. Beyond the local scope of their mandate, they may also have a mission to advise national authorities on the elaboration or update of laws or regulations.

These observed evolutions towards stakeholder engagement at upper levels of decision-making and towards multi-level governance frameworks go beyond the traditional concept of subsidiarity that is associated with a strict dispatching of issues among the various levels of decision-making. In effect, they provide room for actors involved at different decision-making levels to address together issues that have impacts at the different levels of decision-making. Such evolutions allow, in particular, the involvement of local actors in the regulation of risk issues (traditionally addressed at national or international levels) instead of regulating for them and in their absence (where upper levels decisions are often then perceived by local actors as taken against them). Through such multi-level frameworks, the local actors involved not only adopt their own local perspective, but also act as global

actors sharing common stakes and concerns with other local actors as well as with the national or international decision-makers. Such multi-level frameworks are also characterised by a proper articulation of participatory decision-framing with legitimate public and private decision-taking processes, thus reinforcing their legitimacy.

In the longer term, these evolutions of the regulatory and legal frameworks are translated into the development of corporate governance of public institutions, in order to allow different categories of societies to influence public policies.

The opening up of public regulations and institutions to stakeholder engagement also entails the development of adapted public resources to support the participation of stakeholders. These resources also need to include access to expertise capacities of public institutions and access to co-expertise and counter-expertise processes.

Transformations of the Territorial Context: New Patterns for Democratic Actions for Territoriality-based Communities

The second aspect of evolution towards inclusive governance, which is complementary to the first one, is the territorial dimension, with the observed emergence and influence of *territoriality-based communities*. In effect, in several innovative governance processes considered in TIA the change in the modes of governance is not initiated by public authorities, but by existing or emerging local community groups rooted in territoriality. In these processes, individuals and their community regain control of their life and future by integrating security, environment and economic issues in the context of a sustainable quality of life on their territory. These communities develop a vision of their territory that integrates an intergenerational perspective balancing preservation of cultural heritage and traditions with necessary updating and change in the light of life needs.

The notion of territoriality at stake goes beyond local or geographical areas, and beyond administrative entities. It involves a social construction of territoriality that is problem-sized or project-sized and constitutes a resource for common actions. The concept of territoriality may thus be defined as “a set of relations which allow groups to claim their interest in space” (see cf. Baillo and Béguin 1990) or as a “continuous or discontinuous space made by an individual or a group for their interactions and fitting a need for its identity and security” (see cf. Eyles 1971). The physical territory involved represents only one dimension of the mobilised resources. In any case, geographic and administrative structures and boundaries do not necessarily correspond to the nature of the problem affecting a group of actors.

The concept of territoriality-based communities characterises open modern communities relying on territoriality. This concept may be opposed to the one of an autarkic (or self-sufficient) community. In effect, it includes a capacity to establish links with higher levels of decision-making and with other communities, thus recognising and valuing existing dimensions of multi-level dependency that are inherent in modern societies. Territoriality-based communities may also be opposed to feudal (or top-down) political systems, in particular by their capacity to negotiate common goals and actions between various actors outside hierarchical relationships.

One of the key characteristics of the territoriality-based communities observed in the innovative processes followed up in TIA is the capacity of the various engaged actors to establish horizontal connections and to cooperate (horizontal connectivity). These horizontal connections involve a plurality of territorial actors (local elected representatives, local NGOs, lay people, professionals, workers, trade unions, local administrations, etc) in a position of steady dialogue and mutual respect. Horizontal connectivity also involves a fruitful articulation of representative democracy and participative democracy. This articulation is not a given, but results from the experience of local actors

(including the experience of conflicts). Conversely, a lack of articulation of these two complementary levels of democracy (or the absence or weakness of local debate) may represent a destabilising factor favouring tensions and conflicts at local level. The notion of horizontal connectivity also includes the capacity of the various actors belonging to the community to define agreed goals and strategies to achieve a common development project.

These territoriality-based communities are also characterised by their capacity to embrace complexity through a local perspective that avoids fragmentation of the actual issues at stake between specialised administrative sectors (e.g. economy, health, environment, safety, etc), or the reduction of complex issues to one dimension. This local perspective allows a coherent and dynamic understanding of problems, which involves all the interrelated dimensions at stake and integrates experience from the past with a perspective for the future of the community. Addressing complexity encourages a much broader co-framing of the decisions with various local stakeholders through existing or new and *ad hoc* dialogue tools. Such co-framing processes allow a richer exploration of all the dimensions of the issues at stake, and strengthen a shared common perspective. The decisions that are achieved through such co-framing processes are improved in the sense that they entail a plurality of views and therefore of knowledge, a proximity with an actual complex situation, and a capacity for feedback and flexibility. Finally, such co-framing also improves the legitimacy of trade-off decisions that balance economy with security, precaution and environment, in the context of both short and long term perspectives.

A last key characteristic of territoriality-based communities is their capacity to develop 'vertical connectivity'. This capacity of connection with higher levels is very important, since organising local democratic debates while at the same time depriving local actors of influence at the higher levels of decision-making that may severely impact local life creates frustration and

scepticism about democracy itself. Vertical connectivity is about connecting with issues and actors that belong to higher levels (regional, national, European, international). A condition for local actors to have effective influence on higher levels of decision-making is their capacity to translate local concerns into issues of common interest at the higher levels and to adopt a global perspective that gives them the legitimacy to participate in the co-framing of regulatory frameworks and public policies at those higher levels.

From this perspective, the objective of the participation of local actors in higher levels of decision-making is neither to promote one interest nor to seize the power, but to ensure that emerging multi-level governance systems continuously stick to the complex and dynamic aspects of real life of people in the territory. The capacity of territoriality-based communities to establish vertical connections also involves their ability and desire to network at the national, inter-territorial level or international level and to connect and gain influence at higher levels. Such strategies of networking have the aim of modifying the balance of influence between local and higher levels, in which local actors have traditionally not always been welcome or recognised as legitimate actors. In effect, the opening up of legal and institutional frameworks described in the first cross-cutting issue is not a natural trend and might necessitate resorting to political and legal conflicts.

Patterns of Pragmatic Processes for Change towards Sustainable Inclusive Governance: The ‘Cooperative Inquiries’

As a result of the TIA work, it is possible to formulate a hypothesis of the existence of a process pattern that is opening up a path for change towards inclusive governance of activities entailing risks. These processes have been

called ‘*cooperative inquiries*’. Their characteristics have been drawn both from aspects of the nine innovative processes investigated by TIA and from the TIA methodology itself as it evolved over the life of the project.

It is not suggested however that there is a single ‘cooperative inquiry’ model; rather, each inquiry or process has to be designed and then developed according to its context and to the opportune moment (*kairos*) at which action should be initiated. However, the TIA project has enabled the identification of key transversal methodological characteristics of cooperative inquiries as processes of a new type that mingle contributions of ‘*experts-scientists*’ and of ‘*experts-citizens*’. Such governance processes create the conditions for local actors to become *mutatis mutandis* permanent players in democracy beyond the window of each specific inclusive process. From this perspective, cooperative inquiries could represent in the future a major driver for sustainable change towards inclusive governance.

Key Characteristics of Cooperative Inquiries

Cooperative inquiries aim both at producing reliable knowledge for action and at creating the conditions for those concerned local actors to become full democratic players in the longer term. An important distinction is therefore to be made between processes that are referred to here as cooperative inquiries and forms of passive citizen participation or involvement that are mainly aimed at improving the knowledge basis of decision-makers (who are then expected to produce any change). In cooperative inquiries, it is rather the growing influence of concerned local actors that is gradually expected to create the conditions for change. A new articulation between distributed knowledge and co-action of various actors is considered here beyond the classical idea that good decisions are to be produced by decision-makers provided with good information.

Processes of cooperative inquiries involve a demonstrable *pragmatic methodology* that has both a scientific, heuristic and strategic dimension. The *scientific dimension* involves the collective inter-disciplinary co-examination and co-validation of the quality and reliability of knowledge. It makes use of methods of *collaborative and dynamic analysis of living cases*. It produces knowledge according to scientific standards while reinforcing the reliability of this knowledge in the eyes of the actors involved. This focuses attention on how citizens and stakeholders are involved and how they contribute to the collection of information, to its interpretation as well as to the development of the methodological approach of the inquiry.

The *heuristic dimension* means that the methodology allows those involved to build their own approach to evaluating the situation at stake and the governance framework involved. The actors engaged in the cooperative inquiry process therefore develop by themselves their own understanding of the considered issue in the perspective of their concerns, interests and values and eventually reframe this issue. This heuristic dimension also involves reflexive assessment of the cooperative inquiry methodology by the actors engaged as well as regular feedback.

The *strategic dimension* is the most important. The methodology produces a subjectivation of both stakeholders and experts: stakeholders and more specifically local actors are empowered to become active players in the process and beyond in the broader political context at local, national and international levels in order to regain control of their lives and future.

Beyond methodological aspects, setting up a cooperative inquiry seems to require an individual or an institution with *legitimacy and authority* (moral if not legal) to start off the process and to get the engagement of a critical mass of key parties.

Cooperative inquiries also require the involvement of *facilitators and methodological experts* (more often than not the same people) supported by

professional methodological standards. Professional inputs in cooperative Inquiry processes, in terms of effectiveness, efficiency, fairness and competency, appear to be a key factor for enabling the actual influence of local actors on decision-making processes. It is also noted that the professional facilitators often see themselves as *change managers*, recognised as bearing democratic values, beyond their technical role in a particular process. The facilitators and methodological experts are key players within the cooperative inquiries; they contribute their own critical assessment of the process as such, how it has developed, the challenges it has faced and how far it contributes to sustainable change towards inclusive governance. Bringing together all these views in an iterative, reflexive and inclusive process helps to draw out the strengths and weaknesses of each process.

Traditional public engagement has often focussed on a particular issue according to the specific remit or interest of the decision-taker. A degree of stakeholder fatigue is noted as soon as public engagement becomes an ordinary tool in the hand of decision-makers, and one which is often applied outside people's day to day concerns.

On the contrary, cooperative Inquiries are observed to be lay actor-driven rather than issue- or principle-driven processes. The result is that such processes are people focussed (concentrating on their issues of concern such as quality of life). They adopt a meaningful integrated perspective embedding security, precaution, health, environment, long term with economic and development issues. Local actors are searching for life equilibrium and therefore integrating the various dimensions of decisions. In this perspective, they represent in the decision-making process a different position from that of the classical action, interest or lobby groups that are more specifically committed to representing and pursuing one interest or one perspective.

The existence of feedback and evaluation procedures as well as visible evidence for the influence of stakeholder participation is a key factor of

stakeholder motivation. Beyond the consequence of each specific cooperative Inquiry process, a major dimension of this impact is, as described above, its contribution to changing the wider institutional and territorial context.

It should be noted that the methodological skills and know-how supporting inclusive governance need to be further developed by active research and experimentation; this means continuing to test specific methodologies, grounded, as suggested, in the active participation of the concerned categories of local actors.

The TIA Methodology: An Example of Cooperative Inquiry

A structure for the TIA methodology was established at the start of the project, with some room left for evolution and adaptation during the life of the project. Indeed, a key characteristic of the methodology was that it allowed, and encouraged, an open and on-going questioning of that methodology.

The structure of the project involved on the one hand a contractually engaged core group of experts and researchers (including the facilitators of the nine innovative processes considered) and, on the other hand, the very nine innovative processes at stake, including their stakeholders, who have participated freely and voluntarily. In addition to these two key components, the project involved a steering committee⁴ composed of both researchers and stakeholders, some of them being involved in one of the TIA innovative processes.

The aim of this structure has been to encourage extensive interaction and two-way communication between the core group of researchers and experts and the stakeholders engaged in the innovative processes; this encouraged the stakeholders to have a stake in the TIA project as well as in their own process. A cycle of annual events (meetings of the core group, annual seminars gathering all participants including stakeholders engaged in

the innovative processes, and annual steering committee meetings) over the three years of the project was established to provide a basis for knowledge sharing and review of the progress and of the methodological approach. In addition to the more set piece meetings, there were also *ad-hoc* meetings and virtual meetings via the internet.

It was recognised from the outset that there had to be a flexible and pragmatic approach to the methodology as findings emerged and as participants gave feed back on their experience of the process. This flexibility also allowed the project to take into account unexpected events or situations. In particular, this flexibility allowed the project to adapt in the light of stakeholder concerns and made it possible for stakeholders to play an active part not just in the analysis but also in the development of the methodology; this meant that at times the Core Group had to reconcile its aspirations with those of the stakeholders.

Several approaches have been developed to gather and analyse knowledge about the nine innovative processes considered in TIA; these approaches included:

- involving protagonist groups in the collection of information,
- undertaking site visits so that territorial aspects could be fully explored,
- involving all categories of participants in presentations on the innovative processes so that views could be questioned and challenged,
- processing feedback from the analysis of individual processes via templates to aid the gathering of complete descriptions of the processes.

This iterative- and stakeholder-driven approach resulted in the identification of critical pieces of information.

The TIA methodology constitutes an innovative ‘Actor-Based Methodology’ that goes beyond case-based method relying on past return of experience. TIA was looking at living and evolving processes where the information was not necessarily clear cut; indeed it was often uncertain, fuzzy, noisy and incomplete. The methodology used constituted a continuous and in vivo cooperative investigation carried out by the core group of experts together with stakeholders engaged in the processes considered. It involved considerable effort to identify facts, build collective narratives, handle controversial aspects of situations, etc. The active and practical engagement of the stakeholders all along the research process made a unique contribution to this and allowed preserving and highlighting the complexity of the nine innovative processes considered.

It has to be recognised that the application (and evolution) of the TIA methodology was not, in practice, necessarily comfortable for the participants; but that constructive discomfort helped significantly, for example, in an increasingly focussed acquisition of quality information about the nine processes and in the progressive elaboration of the outputs of the project including the global reflection about inclusive governance.

Conclusions

The TIA project brings the work of the TRUSTNET network to a conclusion; in its ten years, it has moved from examining the control of risks from major hazards to looking much more broadly at the role, and importance, of inclusive governance in decision-making concerning a much wider range of activities that entail risks for people, their life balance or the environment. This work demonstrates the benefits and need to further develop inclusive governance as a means for lay people in the European

Union to regain control on their lives and future and to influence in this perspective the decisions that affects their lives or environment.

The problem is 'How?' since our current democratic systems have not been conceived for this. The ambiguity of today's trend for public participation lies in the fact that, in most cases, it is not associated with actual changes in traditional behaviour of public and private decision makers. Not is it strongly connected explicitly with the actual decision-making processes. It is often no more than a crisis management tool that is left aside as soon as the crisis is over while decision-makers restart 'business as usual'. Opening the gates to an actual and sustainable influence of people necessitates more than occasional participatory processes. It entails an actual transformation of decision-making and regulatory systems. It also entails the spreading of a democratic culture in the population that can only result from a gradual self-empowerment and cannot be dictated. It entails changing roles and boundaries for both public and private activities and actors.

The TIA results offer a good picture of the societal evolution and the necessary transformations of the legal and institutional design that would support the actual and sustainable implementation of inclusive governance. The diagnosis made by the stakeholders and the TIA Core Group reflects the current state of risk governance in the EU (at local, national and European level). A great number of difficulties, resistance to change and limits have been identified that represent major obstacles to a sustainable change towards inclusive governance. A possible path for change has however been identified with the 'cooperative inquiries' that aim both at *producing reliable knowledge for action and at creating the conditions for those concerned local actors to become full democratic players* in the longer term. Future experimentation and research will further investigate this hypothesis. Should it be confirmed, cooperative inquiries could represent a major driver for sustainable change towards inclusive governance.

Parliamentary democracies have not been designed overnight. Inclusive governance will necessitate creativity, invention and most importantly: ‘experimentation’. This trend is not seen here as a revolution but more as a gradual transformation that will evaluate, adapt or complement the existing organisation of democracy and will fruitfully articulate participation and representation. Such transformation is expected to reconcile science and humanity, putting people at the heart of innovation and change in order to orient it and give it a shared meaning.

There is a clear need to give more space for experimental approaches to inclusive governance, to provide more opportunities for those involved in such approaches to share experience and to develop methodologies that increase the capacity of individual actors to play a full and effective role in such processes. The TIA Framework, including the methodology used, provides a robust platform for such experimentation.

Work to promote inclusive governance needs, however, to be about much more than research; its future development now needs a political imperative from a diversity of actors at the territorial, national and European level. Such imperatives can take the form of actual initiatives in inclusive governance as well as campaigning. Making explicit their motivation, the participants of the TIA project have expressed their will: *“To belong to a community of persons that operate for Human Beings to be at the heart of debates rather than things or economy”* and *“To develop a European culture to stimulate people’s interest in issues affecting them, thus allowing them to gain influence and to form a critical mass of engaged people throughout Europe that could provoke actual change”*.

The 2006 International Conference on ‘Sustainable development of territories and risks governance: participatory governance for Europe’ held in Dunkirk, France (5th and 6th October 2006) could be seen as the starting point for such a network. This conference has gathered a pluralist group of about

200 actors involved in activities or situations entailing risks for people or the environment across Europe (local and national NGOs, policy makers at national and European level, regional and local governments, industries, experts and researchers). The Dunkirk Appeal of 6th October 2006 has suggested the creation of a 'European Laboratory of Sustainable Territories' in order to develop, federate and support the active experimentation in Europe of Inclusive Governance of activities and situations entailing risks and impacts for mankind and the environment. European and national public institutions should now actively consider how such networks can be promoted in future and how the knowledge and know-how stemming from experimental processes can be further disseminated.

Notes

¹ The European Commission (DG Research) has funded both TRUSTNET and TIA as Concerted Actions. For more extensive information about TIA, see the project website: <www.trustnetinaction.com>.

² Administrative Science Studies and Research Centre (CERSA, France), Centre Ethics Technology and Society of ICAM Lille (CETS, France), Dialogik (Germany), Health and safety Executive (HSE, UK), Institute for organisational communication (IFOK, Germany), INERIS (France), Haut Béarn Heritage Institution (IPHB, France), Institute of International Sociology of Gorizia (ISIG, Italy), Nuclear Evaluation Protection Centre (CEPN, France), Mutadis (France), National Institute for Public Health and the Environment (RIVM, Netherlands), University of Aberdeen (Scotland), University of Antwerp (Belgium), University of Maastricht (Netherlands), University of Stuttgart (Germany), University of Vienna (Austria), and the European Commission Joint Research Centre.

³ Austria, Belgium, France, Germany, Holland, Italy and the United Kingdom.

⁴ The Steering Committee was composed of representatives of the Health and Safety Executive and Health and Safety Laboratory (HSE & HSL, UK), the University of Aberdeen, the

University of Stuttgart, the University of Vienna, the National Radiation Protection Institute (IRSN, France), the Regional Development Agency of Neckar-Alb (Germany), the Pro-Natura NGO, CEPN (France), the European Commission (DG Research), the European Commission Joint Research Centre and Mutadis (France).

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Chapter 5

A Europe of Lay People: A Critical Assessment of the First EU Citizens' Conferences

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Introduction

Much of the literature on new modes of governance in the EU stresses the importance attached to their participatory nature. 'Inclusiveness' is a defining characteristic of the new generation of policy instruments: the actors affected by a policy decision are to participate in its elaboration and possibly in its implementation (See eg. Heritier 2002). While this trend can be discerned in all democratic systems, it is of particular relevance for the European Union, which is seen as particularly weak in terms either of parliamentary representation or of political accountability (Smismans 2006). The European institutions themselves have stressed the importance of participation, by which they generally refer to the involvement of 'stakeholders' or 'civil society organizations' (See e.g. Commission 2001). As the EU has gradually got involved in the area of risk regulation, in which the scientific and technological components of policy choices is prominent, they have paid ever greater attention to the wide range of techniques developed in technology

assessment as the faith in the positive effects of scientific and technological developments began to decline (Joss and Bellucci 2002; Abels 2007).

Most of these techniques, however, assume a degree of self-organization on the side of the participants, who must elect to define themselves as stakeholders, organize themselves to protect their interests, and often struggle to secure a degree of recognition. Our interest in this Chapter is for another kind of instrument of 'participatory technology assessment' (PTA), in which the key actors are lay people. By lay people, we refer to ordinary citizens, who may express him or herself in the public arena and participate in debates and socio-technical decision-making side-by-side with academics, specialists, and experts, despite the fact that they do not enjoy specific expertise in the area at issue.

Dialogue with lay people is conceived of as a way of counterbalancing the elitist character of representative democracy. This type of participation may take place in different ways. First, it may occur in the form of *vocal participation*, where lay people seek to mobilize various forms of support, including public opinion, to make their voices heard by political powers. To this end, they turn to unconventional political participation (petitions, boycotts, street protests etc.). A second method of participation consists of *organized participation with experts*, where lay people establish contacts with professionals or experts. In such 'hybrid forums' (Callon, Lascoumes and Barthes 2001), both contributions coexist, support each other, mutually enrich each other and seek to express themselves via the traditional channels of lobbying and campaigning. The third and final possibility is the *participation that is solicited, even institutionalized, by public authorities*. In this case, it is the political authorities who choose to consult them and, through this, recognize and legitimize their participation. Several measures have been envisaged by the legislator and/or empirically adopted to further this type of participation, such as public surveys, the creation of a national commission for public

debate in France, the implementation of citizen consultation committees, the organization of public hearings, or the summoning of citizen juries (Banthien, Jaspers and Renner 2003).

Consensus conferences, or citizens' conferences as they are also called, generally belong to this third category and thus may be added to the long list of measures conceived by the public powers to attempt to include citizens in the decisional and political process. Created to foster deliberation and public debate on disputed issues, they place ordinary citizens in the spotlight and ask them to express their views after having debated the issues with specialists. Whereas the conferences conducted in a domestic context have been analyzed (see e.g. Joss and Durant 1995; Boy and Bourg 2005), little attention has been given so far to the first attempts to replicate the experience at the European level, and to the specific problems that may be encountered in so doing. In the first part of this Chapter, we will examine the reasons that have led to the development of citizens' conferences and the way in which they are generally organized (section 1). The second part will be devoted to the reasons that have prompted the EU to pay interest to this participatory mechanism (section 2) and to the structure of the first EU citizens' conferences (section 3). Finally, we will discuss some of the problems that have arisen in the framework of these transnational deliberation processes (section 4).

Citizens' Conferences (CCs) as an Instrument of Participatory Democracy

The idea of citizens' conferences first appeared in the medical field of the United States in the late 1970s to help define reference practices for doctors. The concept as we know it today took its particular form and meaning in the field of public decision-making from a Danish experiment in 1987. Launched

by the Danish committee for technology, the idea of citizens' conferences was designed to aid in resolving the problem of genetic technologies in agriculture and industry. It was then that lay people were first invited to discuss major issues with the experts. The Danish Board of Technology defined the experimental concept as follows: 'a consensus conference may be described as a public enquiry at the centre of which is a group of 10-16 citizens who are charged with the assessment of a socially controversial topic of science and technology. These lay people put their questions and concerns to a panel of experts, assess the experts' answers, and then negotiate among themselves. The result is a consensus statement which is made public in the form of a written report at the end of the conference' (Joss/Durant 1995: 9).

Since that time, the same experiment has been repeated across Europe and in the United States. More than one hundred such consensus conferences have taken place, most often centered around topics related to medical and biotechnological issues ('national consensus conferences on plant biotechnology' in the United Kingdom; 'Bürgerkonferenz Streitfall Gendiagnostik' in Germany; 'citizens' conferences on genetically modified food' in Denmark; 'genetic testing' in the Netherlands; or the 'conférence sur les OGM et les plantes transgéniques' in France). Other issues have also been addressed; for example, a conference was held in Denmark on the topic of transportation and traffic in the city of Copenhagen, and Norway has held a similar event on the relationship between the elderly and communication and information technologies. In the context of the Aarhus Convention, (June 1998) which encourages 'access to information, public participation in decision-making and access to justice in environmental matters', citizens' conferences were conceived of as a tool for public debate that would put the principle of participation into practice. The objectives were twofold: to give citizens a say in public policy choices and to clarify the decisions made by the elite.

In the PTA literature, several arguments are proposed in an attempt to justify this resort to ‘participatory democracy’, incarnated by the CCs. First, there is a *democracy argument*: faced with the crisis in representative democracy, the development of a public debate is seen as a way to perfect the participatory dimension of democracy. Citizens’ direct involvement in the decision-making process is encouraged to counterbalance the lack of transparency and public discussion that is said to characterize the ‘ordinary’ political process. The citizens’ conferences are perceived as a means of facilitating the exercise of public reason by reintroducing transparency and deliberation in the decision-making process. The principles upon which these conferences rest – which will be described in the following section- aim to ensure a truly democratic deliberation. In particular, they make an effort to avoid any ‘pollution’ of the debate by partisan considerations, while ensuring a balance between the different opinions. This is facilitated by the fact that the participants in those processes will not be in charge of implementing the solutions they propose, which is perceived as a guarantee of neutrality. The absence of any direct stake in the question at issue is indeed one of the criteria used during the selection process, in order to ensure their impartiality, thereby facilitating the emergence of a truly common interest. At the same time, however, the exchange of opinions that would precede any decisions taken is perceived not as a substitute for representation, but rather as a useful complement to it.

Secondly, there is a *functional* argument: in an increasingly burdened scientific and technological context, controversies extend beyond the scientific field and require that the societal impacts (on the society or the environment, for example) of specific decisions be considered. Such impacts being generally uncertain, the citizens’ conferences are seen as an innovative way of determining the general interest on the basis of preliminary scientific information. This helps to explain why such conferences flourished in the

domain of socio-technological controversies centered on such issues as genetically modified foods, gene therapy, foodstuffs regulation, nuclear issues or neuroscience.

Proximity is a third argument used to justify resort to this type of experiment. Citizens' conferences have been often organized to debate such territorial problems as the installation of high-voltage lines in a village, the burying of nuclear waste, or the development of city transportation. In these cases, we are dealing with local issues which, in contrast to the national issues previously mentioned, can be influenced by what has been termed 'interested knowledge' (Boy and Bourg 2005; Boy, Donnet Kamel and Roqueplo 2000): the people implicated in this process are generally directly affected by the problem that has been raised, which may alter the quality of deliberation and the conference results.

Finally, an *educational* argument is also frequently put forward. Participatory procedures are often perceived of as an instrument capable of educating citizens: they allow them to become more aware of potential threats to their standard of living and connect the population with the potential consequences of individual behaviour (in particular for that which may harm the environment and put the well-being of future generations at risk).

It is interesting to note that, participatory democracy being fashionable, the developers of certain techniques have felt it useful to trademark them, the declared objective being to avoid any misuse thereof. Thus, Professor James Fishkin from Stanford University, who developed another participatory tool, known as the deliberative poll, has registered it (Boucher 2005). Similarly, *America Speaks*, a non-profit organization that promotes citizen involvement in public policy decisions, has developed and registered a method called the '21st Century Town Meeting'. It was used *inter alia* to consult 4 500 citizens from New York City and the region on what was to be done with the

Ground Zero site following the September 11 terrorist attacks.² Despite these attempts at normalization, there remain variants in the organization of citizens' conferences. However, a number of recurrent organizational aspects can be discerned in the experiments conducted so far.

The conferences are organized over a period of between 6 to 8 months, based on a public or private initiative taken by a *sponsor* – generally the authority holding decision-making powers in a specific area, which will delineate the objective of the conference and designate, in part, the *steering committee*, which is then integrated into the executive body of the conference. Composed of specialists in the subject at issue, this committee must fulfill two essential tasks: the recruitment of lay people and the selection of instructors.

Three criteria determine the selection of the *panel of instructors*, which is responsible for the preliminary training of participating amateurs: the pedagogical quality of its members, their competence in the pertinent field, and the extent of their involvement in the issues to be discussed (which is measured by a study of their convictions and declarations of interest). One of the major contributions of the citizens' conferences to decision-making lies in the belief that knowledge is an essential prerequisite for the debate: the objective of the preliminary training is thus to partially reconstruct a balance of information by endowing amateurs with enough knowledge to allow them to 'question' the beliefs of the experts. At the conclusion of the training session (which usually extends over a period of two weekends), amateurs are aware of having gained enough knowledge to be able to formulate new questions – questions other than those that society has asked spontaneously concerning the technical objective to be analyzed – and to enter into a constructive dialogue with the experts.

As for the *lay participants*, they may be recruited in various ways: although the 'call for applications' procedure had been favoured during the first citizens' conferences, it rapidly appeared that it had an elitist bias. Now

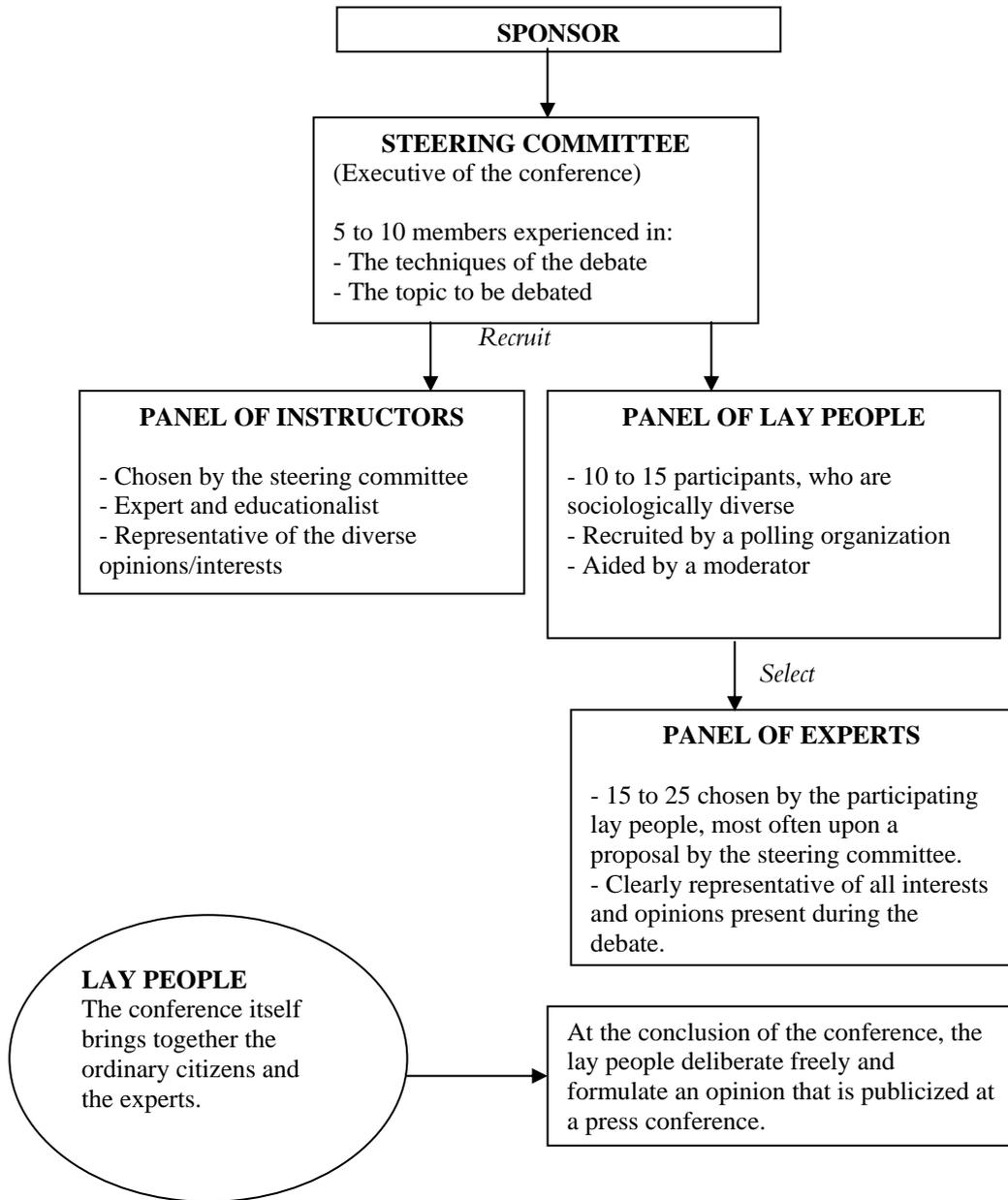
recourse is frequently had to a professional polling organization for the selection of the panel of lay people. Although a representative cross-section of the entire population is generally out of reach, as this would require the recruitment of large numbers of people, the larger socio-demographic features of the population as a whole may be represented by defining diversification criteria (age, sex, cultural level, profession, residence). Added to this initial selection is a brief questionnaire focused on attitudes so as to ensure that the ideological balances of the panel (political and religious beliefs, attitudes towards the issue of the conference, etc.) are respected. The panel so constructed may not be a representative cross-section in a statistical sense (the individuals concerned are usually motivated and interested, which separates them from the normal profile of the average attitude), yet the separation from the rest of the population remains less than it would be in a situation in which self-selection was used.

This panel is assisted in its work by *facilitators*. These are qualified professionals (most often in the field of psychology or other related disciplines) who are familiar with the techniques of group moderation. Their role is indispensable in several different ways. During the first stage of training, they are responsible for helping some of the amateurs (in particular those with a weaker level of education) to 'familiarize themselves' with the tasks requested of them. They are also supposed to convey the 'culture' of the consensus conferences to the lay people involved. Facilitators must also ensure the openness of the debates by allowing each participant to express him or herself and by controlling any potential tensions that may arise during the course of the debate, since there are often large socio-cultural differences amongst the members of the panel.

Finally, the last 'institution' of the citizens' conference is that of the *panel of experts*. Its members, generally between 15 to 25, are chosen by the participant lay people, usually with the help of the steering committee, at the

conclusion of the second stage of training. The term 'expert' takes on a broader meaning here: it may describe both an academic specialist in the subject area of the conference, as well as an individual representing the opinions of the various stakeholders (administrative, political, industrial, associated militant, etc.). The aim of the panel is to represent all of the interests and opinions present during the debate, so that all points of view may be taken into consideration during the exchange of views with the lay people.

Figure 1: Flowchart of a ‘citizens’ conference’.



In practice, a citizens' conference is a long-term process which may be divided into several phases:

- Phase 1: The sponsor launches the initiative; a steering committee is formed and recruits a panel of instructors and a panel of lay people.
- Phase 2: Two training sessions for the lay participants are organized (usually over the course of two weekends) and taught by the panel of instructors, at the conclusion of which the lay people choose the panel of experts.
- Phase 3: The conference itself takes place publicly and brings together the lay people and the experts, who debate over the theme of the conference. The debate is usually divided into several different sessions.
- Phase 4: The lay people deliberate in a closed-door session in order to formulate an opinion or recommendations.
- Phase 5: Their opinion is made public during a press conference.
- Phase 6: An external evaluation procedure is launched *a posteriori*, made possible in particular by video recordings taken during the training sessions and the debates.

When all is said and done, three main criteria make these conferences truly unique (Boy and Bourg 2005): the contribution of knowledge (which distinguishes the conferences from opinion polls, for example); the closed-door deliberation, designed to avoid any potential pressures (in contrast with simple consultations); and the search for a balance at all levels: within the steering committee, the panel of instructors and amongst the experts. CCs are therefore an original approach, allowing citizens to deliberate on a subject before a decision is made in the hope of improving the quality of decisions and the legitimacy of decision-makers.

Why Europe is Interested in a Dialogue with Lay People

For the European Union, the recent beginning of dialogue with lay people is part of a two-fold evolution. On the one hand, the European institutions increasingly intervene in the field of risk regulation, in order to determine the response that is best adapted to scientific and technological challenges. On the other hand, the European institutions have been searching for ways to establish direct links with the citizens over the past 15 years as an attempt to respond to the recurring criticism of the lack of democracy in EU decision-making.

That Europe has been able to play an increasingly preeminent role in risk regulation should not be surprising, as this evolution is a corollary of the functionalist strategy presiding over integration since the launch of the European Coal and Steel Community. One of the key aspects of European integration has been the establishment of a large market, within which goods, services, individuals, and capital may be allowed to circulate freely. Yet putting a market of continental dimensions into place does not merely presuppose the removal of barriers to free movement. Each time that fundamental interests are protected at the national level, the preservation of the acquired level of protection may only be achieved in two ways: either by tolerating the maintenance of national 'protective' legislation (as is occasionally permitted by the Treaty of Rome³), or by harmonizing protection rules. The latter solution offers the advantage of avoiding any distortions in the conditions for competition. Unsurprisingly, it has long been the preferred solution of the European Commission as well as the member states with the most advanced regulation: both pushed for a massive intervention on the part of the Community and then the European Union in such fields as environmental and consumer protection, workplace health and safety, or public health (Héritier 1994). In other words, as Giandomenico

Majone observed at a very early stage, despite the deregulatory outlook of the 1992 programme launched by the Delors Commission, it contained the seeds of a re-regulation movement at the European level (Majone 1990).

This logic led to a progressive extension of European competencies via the Single European Act as well as the Maastricht and Amsterdam treaties, and to a constant development in European legislation within the field that can be broadly defined as 'risk regulation'. This trend was accelerated by a series of crises in such areas as food safety (the mad cow crisis) or marine pollution (the *Prestige* and *Erika* shipwrecks). To a growing extent, Europe is thus a level towards which citizens as well as economic operators tend to turn whenever their interests are at stake (Majone 1996).

This gives rise to new questions, since intervention in these particular fields often implies mastering complex scientific and technological issues that often go beyond the expertise available within the European institutions. The Court of Justice has established, in principal, the need to consult experts where necessary in order to ensure the fulfillment of the protection aims of Community legislation.⁴ The Treaty of Amsterdam followed in this path by requiring the Commission to take into account 'all new evolutions based on scientific facts' when formulating its proposals in the area of health, safety, environmental and consumer protection.⁵

These requirements are based on a classical division of tasks between scientists and political leaders, with the former providing the latter with the elements to make a decision based on the most up-to-date scientific knowledge. Unfortunately, reality is often more complex and the borderline between political decision and scientific debate is relatively porous. Science does not always produce univocal judgments, and disagreements often exist at the heart of the scientific community on the magnitude of a problem or on the best way to deal with it (Godard 1997). Political leaders may thus be criticized for rubber-stamping the opinion of selected experts. The European

Commission has, for example, been brought before the Court of Justice for having pursued the recommendations of a committee of experts concerning the prohibition of a cosmetic believed to be cancerous.⁶ In other cases, the national origins of scientists bring the neutrality of deliberations into doubt. Thus, in its opinion on the European Union's handling of the mad cow crisis, the Inquiry Committee of the European Parliament painted a rather gloomy picture of the functioning of the veterinary scientific committee, criticizing in particular the large number of British experts within the committee.⁷ The malfunctioning noted on this occasion thus led to a radical reform of the scientific committees established by the Commission in order to guarantee the objectiveness and transparency of their activities.⁸ Finally, even where scientific assessments seem to converge, there may be disagreement as regards non-scientific aspects of an issue. Similarly, public opinion may be reluctant to accept new technologies, even where their dangers have not been proven, as illustrated by the resistance to genetically modified foods or the presence of hormones in meat.

While the uncertainties that often surround scientific evaluation may be a problem for most contemporary decision-makers, they are magnified at the European level by the fact that the European institutions have never boasted a strong political legitimacy. Without entering into a theoretical debate on this question, let us recall here that the last European elections brought only a minority of voters out to the polls, and despite the increasing role played by the Parliament in the nomination of the President and members of the Commission, the voter's preference is not directly reflected in the designation of the executive. It is thus difficult to consider a decision to be valid simply because it was taken by those validly chosen to do so. Thus, the quest for alternative sources of legitimacy designed to overcome the weaknesses of representative democracy, is of particular relevance in a political system which finds more support in the elites than among 'ordinary citizens'.

In a context marked by the increasing responsibilities of the European Union in scientifically and technologically-oriented fields and by the decline of a 'permissive consensus' on the benefits of integration, the interest of European leaders in forms of participatory democracy such as the citizen's conference is easy to understand. This has prompted the Commission's Forward Studies Unit to pay attention to these techniques even before its White Paper on Governance (Dehousse and Lebessis 2003; De Schutter and et al. 2001) was published in July 2001. However, those concerns found only weak echo in the White Paper. Beyond generic statements in favor of more openness, greater involvement of civil society and the need to ensure the integrity and pluralism of expertise, the Commission merely notes:

'Scientific and other experts play an increasingly significant role in preparing and monitoring decisions. From human and animal health to social legislation, the Institutions rely on specialist expertise to anticipate and identify the nature of the problems and uncertainties that the Union faces, to take decisions and to ensure that risks can be explained clearly and simply to the public. The advent of bio-technologies is highlighting the unprecedented moral and ethical issues thrown up by technology. This underlines the need for a wide range of disciplines and experience beyond the purely scientific'.⁹

Although the White Paper did not give any indication of the method by which an opportunity for extra-scientific considerations may be ensured, the Commission has never ceased to pursue its quest for channels through which lay persons may express their views. In particular, the 'science and society' section of the 6th Framework Programme on research and technological development encouraged research on this subject in the hope that this would allow participatory methodology to be tested.¹⁰ Community funds have therefore allowed theoretical research on the role of the citizen and the organization of the first citizens' conferences to take place on a European scale. It is within this framework that the first two experiments discussed below took place.

The Citizens' Conference Experiments at the European Level

The first citizens conference organized at the European level took place in December 2005 within the framework of the RAISE project¹¹ ('Raising Citizens and Stakeholders' Awareness and Use of New Regional and Urban Sustainability Approaches in Europe'). Focusing on 'the city of tomorrow', it was financed by the European Commission as part of the 6th Framework Programme on Research and Development. It was rapidly followed by a second one, 'Meeting of Minds: European Citizens' Deliberation on Brain Science',¹² dealing with the impact of new developments in neuroscience. This conference was part of a two-year project that concluded in January 2006 with a meeting of European citizens and the public presentation of this convention's report before the European Parliament. Since our research was undertaken, another two pan-European conferences have been organized, dealing with the role of rural areas in tomorrow's Europe¹³ and with the future of Europe¹⁴ respectively. However, the remarks that follow are based on the analysis of the first two experiments.

Objectives and Structures

At first sight, these two conferences correspond closely to the model provided by the original citizens' conference. Both concerned issues about which such meetings are thought to be useful: in the first case, territorially defined issues; in the second, a theme linked to the social implications of scientific development.

The 'Meeting of Minds' involved citizens from 9 different European countries who were invited to debate the impact of neuroscience on daily life and on society as a whole. The aim of this project, which was coordinated by a Belgian charity, the 'Fondation Roi Baudouin', was to formulate recommendations that may help in policy formation in the fields of scientific

research and health at both the national and Community levels. The timing was appropriate since it took place right after the launch of the 7th Framework Programme in Research and Development and the release of a Commission green paper on mental health.¹⁵

In contrast, the decision to hold a citizens' conference on urban development and the various depictions of the 'city of tomorrow' was disputable. A classic scenario would organize the citizens' conference before legislating, since the very goal of deliberation is to enlighten the decision-makers. However, the European Union does not have the proper jurisdiction to take decisions in this area. Moreover, having recourse to citizens' conferences for aspects involving urban politics is often justified using proximity grounds since the participants are directly concerned by the problems addressed. Yet, the situation is different at the European level, where the questions to be debated are inevitably more abstract given that the EU is not directly in charge of urban policy. Finally, the goal of the project was to test earlier research findings and to persuade people to accept them:¹⁶ the questions of the conference were centered on the concept of 'urban sustainable development', linked to several concrete options established by former successful projects within the 5th and 6th Framework Programmes.¹⁷ Given these conditions, the real impact of a deliberation could only be a limited one: the lay people of the conference were involved only at a phase in which the implementation of pre-established principles could be discussed.

The selection of panel members is a key element of a successful citizens' conference. In theory, the exercise must be as inclusive as possible. To overcome the traditional weaknesses of democracy, whose resources are mainly used by the most well-to-do and best organized socio-professional categories, an effort is made to recruit panel members in such a way that all categories of society are represented. But representativeness is more an instrument than an end in itself: it is meant to ensure that the deliberation

process, which is at the heart of citizens' conferences, is not biased by the origins or the experience of panel members.

In this regard, the two initial conferences that we have surveyed differ profoundly. Although they are both marked by a will to exclude experts and professionals working in the sector in question, they also illustrate two different conceptions of the panel of lay people and what these panels represent.

During the conference on neuroscience ('Meeting of Minds'), 126 citizens from 9 European countries¹⁸ (14 individuals per country) were chosen at random by sending invitations to a number of addresses. Specific criteria, such as age, sex, level of education and place of residence were then used to select those individuals who would participate in the process. Each national group needed to reflect the diversity of its country of origin. In the end, 51% of the panel was composed of women, 65% were city residents, 31% were between 18-34 years of age, 42% between 35-54 years and 27% were 55 years and older. The goal of this mode of random selection was to retain as much of the diversity of the population of these nine countries as possible.

In the case of the RAISE project, the recruitment of lay people was done via an application process. A questionnaire was posted on the project's website at the end of January 2005, and from the 570 applications received, 26 participants (one from each member state as well as one Romanian) were chosen. Although the declared ambition of the project was to create a representative panel composed of average citizens from the member countries of the EU, the organizers themselves acknowledged that they did not fully achieve this goal.¹⁹ An analysis of the sociological profile of the applications received reveals the elitist nature of the selection procedure, since it shows there was an over-representation of intellectual professions, or 'knowledge workers' (lawyers, judges, translators, students, researchers, managers). In addition, a number of candidates were living in a different country from that

in which they were born, or had lived several years outside their country of origin. The admissions procedure (online and in English) and the constraints related to participation in such a conference (flexibility of schedules) no doubt contributed to these distortions. The demographic profile of the candidates reflected this: 56% were men; only 4.3% unemployed; 44.8% lived in a city center. Remarkably, the sociological profile of the standard applicant was close to that of the average internet user,²⁰ or 'Netizen': often male, young, and a city dweller with a high level of education. Figures concerning the level of education are quite telling, for the large majority (88.1%) of candidates had a university diploma. Clearly, the initiative seems to have attracted those individuals who may be defined as 'true European citizens', being both mobile and educated.

These findings confirm what Daniel Boy had observed in his study on citizen panels (Boy 2005: 80-85): a voluntary admissions procedure has the effect of 'over-selecting' candidates (Boy 2005: 80.) and accentuating the elitist nature of the panel. In contrast, a random selection procedure, with well-defined criteria for diversification, may allow for the constitution of a panel that is in sync with the rest of the population, although it will never be a completely representative panel in a statistical sense.

The Functioning of Citizens' Conferences

Finally, an exhaustive analysis of the experiments carried out at the EU level requires us to focus also on the very functioning of these deliberative meetings. At this level, the problem is not merely to bridge the gap between lay people and experts, as is the case in 'standard' citizens' conferences. An additional difficulty must be overcome: how can a deliberation be efficiently organized in a transnational setting, within which political cultures, traditions and languages vary considerably? Again, our two case studies demonstrate that different approaches can be found to tackle these problems.

As we previously emphasized, one of the key characteristics of the citizens' conferences concerns the importance granted to appropriate knowledge. Training is offered to lay people in order to provide them with the tools for analysis that allow them to converse efficiently with experts. Although the two experiments undertaken so far at the European level have attempted to respect this founding principle, they have nevertheless approached the idea differently, conditioned by the choices made within each project, the size of the panel of lay people and the difficulties surrounding the organization of a true deliberation at the European scale.

The RAISE project followed the 'classical' model very closely: the process was divided into four stages, with the first two consisting of preparatory citizen panel workshops that could be assimilated to the training sessions. The goal of these workshops, which took place over the course of two days at the beginning and the end of September 2005, was to familiarize citizens with the issues up for discussion. In particular, the workshops aimed at providing citizens with an idea of what sustainable urban development is²¹ as well as a presentation/evaluation of the possible responses proposed by current European research.²² They were conceived as indispensable prerequisites to the third workshop, which took place in Brussels in October 2005 and during which the 'Citizens Declaration on the European City of Tomorrow' was written.

The 'Meeting of Minds' project took a different approach, in large part due to the magnitude of the project, which involved more than one hundred citizens. The sequence of events was somewhat different to that above, starting with the training stage of the lay people involved. Preliminary information was circulated within national amateur panels via a brochure²³ created as an introduction to brain sciences. The first weekend meetings were organized at the national level in April and May 2005 for the purpose of training the participants for the upcoming procedure. The national

coordinators and moderators presented the project to the various groups of citizens, preparing them for the steps to follow during the next stages, and placing great emphasis on the difficulties inherent in the organization of multilingual and multicultural discussions. Finally, the citizens began to explore the issue in question on the basis of the common information brochure, and to elaborate the different points of view that needed to be submitted to the first European convention. Thus, the project innovated to overcome the tension that exists between the will to ensure the unity of the deliberative process (for example, through the dissemination of a unique brochure to the participants from different countries) and the diversity inherent in the variety of participants' origins and languages. This has led to the emergence of a multi-level process, the national meetings serving as a preliminary to the European citizen's conference. The transnational nature of the deliberation has thus required a reinterpretation of existing procedures.

The very agenda of the citizens' conference also reveals a different understanding of the 'European' nature of the two projects in question. In the case of RAISE, the idea of organizing a consultation and a deliberation of lay people at the European level does not seem to have had an impact on the structure of the exercise: the size of the citizens' panel (26 members) is not far from that of conferences organized at the national or local level, and the four stages of the project correspond to those of the traditional schema analyzed earlier.²⁴ However, it seems that the experts played a limited role in this process: as the discussion principally concerned the findings and the options proposed prior to the deliberation, the dialogue with the lay people seems to have been a one-way conversation.

For its part, the 'Meeting of Minds' project made an effort to adjust the citizens' conference tool by taking into account the inherent requirements for the organization of a transnational deliberation. As indicated earlier, this project was organized on two different levels: the introductory national

meetings preceded the first European convention of citizens on topics in neuroscience (3-5 June 2005), during which a common framework for analysis was established in addition to an initial series of questions that were designed for the pursuit of deliberation at the national level. Following this, national evaluative meetings, during which experts were convened, have allowed for the preparation of the second European convention of citizens, concluding the project in January 2006. In addition, given the size of the citizens' panel (126 participants in total), several original initiatives had been planned for the organization of the two meetings that took place at the EU level. The organizers adopted a technique used for a similar initiative in the United States, the so-called '21st Century Town Meeting' Method,²⁵ in which all participants assemble in a large hall in order to create a community feeling. In the case of 'Meeting of Minds', however, they were divided into smaller groups around different tables to allow for more in-depth discussion and exchanges of opinion concerning the topic at hand. This method was refined between the two European conventions, in particular to overcome the language barriers that created problems during the first conference. It is in this way that the 'carousel method' was implemented during meetings at the end of January 2006: eight smaller monolingual tables encircled large multilingual tables, like the petals of a flower. The citizens moved amongst these tables in a complex ballet, which allowed them to alternate between discussions in their respective languages and broader exchanges around the multicultural table. Obviously, this requires an important logistical set-up: 75 people were recruited to help the discussions run smoothly, they were assisted by 48 additional translators and professional moderators. However, as with the former case study, the project received most criticism in relation to the role of the experts. In this case, the experts did not participate until the second phase of the process, beginning with the second series of meetings at the national level. Some participants seem to have regretted this situation. In

an initial report presenting the overall results of the first European convention, an Italian participant observed that: ‘the democratic process worked well, but more expert input prior to the discussion may have been helpful’.²⁶

On the basis of the two experiments conducted so far, one can conclude that the organization of such citizen deliberations at the European level is not a straightforward exercise. It requires careful consideration of the problems inherent in the organization of such an event at the transnational level, as well as on the usefulness of such an instrument in a structure like the European Union. It is to these questions that we shall now turn.

Conclusion: When can Lay People’s Participation make a Difference?

The interest of European leaders in the participation of lay people at the Community level, or even the consultation of these citizens concerning certain issues, is easy to understand. In fact, as emphasized earlier, both functional reasons – the need to take a position on a socio-technological controversy whose stakes are controversial and the absence of a strong democratic legitimacy at the EU level – provided incentives to explore new ways to liaise with the European citizens.

However, achieving such citizen deliberations is not without problems, as the two examples of European citizens’ conferences that we have analyzed have shown. In many respects, these problems point to the difficulty entailed in the creation of a European public space or even a political Europe. Four key points deserve particular attention.

The elusive quest for a ‘European people’ is the first difficulty that emerged in the two citizens’ conferences we surveyed. We clearly saw that serious difficulties are encountered when attempting to constitute a panel that

represents a microcosm of European society as a whole. The selection techniques in themselves may contribute to the elitist nature of the panel. Having recourse to self-selection, as in the case of the RAISE project, introduced a bias into the panel, an overrepresentation of higher-educated categories of the populace. In any event, it is difficult to achieve a panel that would perfectly reproduce the various components of the European people. As indicated above, representativeness is but an instrument; yet it is important if one intends to ensure that a wide enough range of views are included in the deliberation process. It would be fallacious to think that this would be the case without due regard for the plurality of the panel.

On the other hand, the two projects studied here attached great importance to the truly transnational nature of the lay people's panel. This in turn gave rise to a problem, well-known to those who have studied the construction of a political Europe: how should countries of variable size be represented at EU level? In both cases, a strict principle of equality was maintained, apparently without much debate – 14 citizens per country in the case of the 'Meeting of Minds'; one citizen per country for the 25 member states in the case of RAISE – as if the two citizens' conferences sought to represent the sovereign states. However, for all societal issues linked to the development of science and technology (which constitutes the sphere of election for the citizens' conferences), we know that there may exist very different national sensitivities. The question is to figure out whether the weight of each of these sensitivities should be identical. Clearly, the principle of equality risks creating an over-representation of some views to the detriment of others. This issue, which has had such an impact on political integration, will certainly leave its mark on citizens' conferences. Indeed, evidence suggests that on several occasions, participants construed their role as that of a national representative, insisting on the fact that recommendations put forward at the national level should be incorporated in the final

document, even when this threatened the final consensus (Renn and Goldschmidt, 2007).

A third notable point concerns the issue of languages, a recurrent question in discussions about a European public space. In all cases, this issue represents an obstacle for experiments in citizen deliberations at the European level. If one language (unavoidably, English) is be privileged in the name of efficiency, this considerably reduces the number of potentially mobile citizens for the conference and accentuates the elitist nature of the citizens' panel, as demonstrated by the RAISE example. Alternatively, a multilingual conference may be organized, as was done during the 'Meeting of Minds', in which eight languages were used during the deliberations. Yet, in addition to the costs and logistic issues that a multilingual conference raises, such an option may also have an effect on the content of the debates, as the project's coordinator explains: 'The numbers of people were not a problem [...], but the language is really the limiting factor. Simultaneous translation with headphones worked fine for the plenary sessions. But when the people were holding detailed, small-table discussions, trying to express delicate ideas, some sophistication was lost as the translators batted the conversation around'.²⁷ As with all issues linked to the establishment of a European public space, the languages problem remains central for EU citizens' conferences.

To these methodological difficulties is added a more general question, involving possible the misuse of citizens' conferences. Participatory democracy has become trendy, and it may be tempting to set up experiments whose primary impact would be mainly symbolic, namely to demonstrate the openness of the public authorities. Without going so far as to say that this was the case of the two experiments studied in this article, we cannot help but notice that their influence in decision-making was bound to be limited. In the case of the RAISE project, citizen deliberation took place only at the stage where the implementation of previously established principles could be

discussed. Moreover, both experiments were conducted in areas in which the European institutions possessed only limited jurisdiction, and where their decisions could therefore have at best a limited impact. One could even envisage that citizens' conferences could be resorted to not so much to enlighten public authorities before they take a decision, but rather to convince citizens of the wisdom of choices made elsewhere. This clearly suggests that one should not fall into the temptation of regarding all of these experiments as necessarily positive in themselves, as is sometimes the case with participatory devices. Much depends on why and how they are used. If citizens' conferences are to be organized more frequently, it would be wise to require that citizens demand, one way or another, that one should be held.

It does not follow from all this that citizens' conferences organized at the European level may have only a limited effect on decision-making. Despite all of the difficulties that we have identified and the criticism that we have formulated, one should not be unduly negative. First, the experiments we surveyed were largely tentative, conducted in part to test a new participatory methodology. Secondly, even if the impact of these conferences on the decision-making process is questionable, their contribution can be relevant. As Daniel Boy remarked (Boy and Bourg 2005), the citizens' conference may succeed in publicizing certain problems and promoting public debate on the chosen topics. They also allow the problem to be analyzed from a different perspective, by taking into account points of view that do not necessarily appear in the traditional horizon of the decision-makers. This aspect was correctly perceived during the 'Meeting of Minds' project, whose declared ambition was to 'give relevant inputs into European policy-making and widen public debate on brain science'.²⁸ On the other hand, in addition to their influence on agenda-setting and decision-making, the exchanges that the citizens' conferences encourage may favor a shift in the positions of the various actors involved. Even if most legislative

interventions that will follow will take place on the national level, one may still witness a convergence in the schemas of analysis as well as in the conduct of scientific research on the topics discussed. The advocates for reform may find here arguments that can be mobilized in their respective countries. For their part, national leaders may find inspiration in the conferences for the redefinition of their policies. In other words, the impact of European citizens' conferences should not necessarily be measured by the number of European directives that they inspire into being. Their main potential may lie in the above-mentioned cognitive aspects.

Notes

¹ Translated by Juliana Galan. Earlier versions of this article were presented at the first meeting of French Europeanists (AFSP, Bordeaux, April 2006), at the CONNEX conference on 'European Risk Governance: its Science, its Inclusiveness and its Effectiveness' (Maastricht, June 2007) and at the Meeting of Minds workshop on 'The Challenges of Public Deliberation at a Transnational Level' (Brussels, July 2007). The authors thank participants in these meetings for their comments.

² For more details on this technique, see <http://www.americaspeaks.org/services/town_meetings/what_is.htm>.

³ See, for example, Article 95, paragraph 4: 'If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them'.

⁴ Case C212/91 *Angelopharm GmbH v. Freie und Hansestadt Hamburg* [1994] ECR I-171.

⁵ Article 95, paragraph 3.

⁶ Affair T-199/96 Bergaderm and Goupil v. Commission [1998] ECR II-2805.

⁷ PE Doc A4-0020/97A, 7 February 1997.

⁸ Commission Decision 97/404/CE of 10 June 1997 setting up a Scientific Steering Committee, *OJ L* 169, pp. 85-87.

⁹ CEC, Commission of the European Communities, *European Governance. A White Paper*, COM(2001) 428 final, 25 July 2001, Brussels.

¹⁰ Interview with Rinnie Van Est, Rathenau Institute, in charge of methodology in the Meeting of Minds project, The Hague, 12 July 2006. The above-mentioned report concerning the role of civil society in the Europe of research (Banthien, Jaspers and Renner 2003) is also a product of the FP6 programme.

¹¹ <<http://www.raise-eu.org>>.

¹² <<http://www.meetingmindseurope.org>>.

¹³ European Citizens' Panel, <www.citizenspanel.eu>.

¹⁴ European Citizens' Consultation, organized in the framework of the Commission's 'PlanD' programme. See <<http://www.european-citizens-consultations.eu>>.

¹⁵ CEC, Commission of the European Communities, *Green Paper. Improving the mental health of the population: towards a strategy on mental health for the European Union*, COM(2005) 484 final, 14 October 2005, Brussels.

¹⁶ 'RAISE aims at testing the acceptance and usability of results achieved by the recently closed or ongoing EU research projects on urban sustainability', in the project description, 'About RAISE'. <<http://www.raise-eu.org/about.html>>.

¹⁷ 'The questions must be centred on the concept of "urban sustainable development" and they shall be related to a portfolio of concrete options that appear to be offered by some of the 5th Framework City of Tomorrow and Cultural Heritage Key Action research projects, as well as by some projects on urban sustainability funded under the 6th Framework Programme'. <<http://www.raise-eu.org/conference-concept.html>>.

¹⁸ Belgium, Denmark, France, Germany, Greece, Hungary, Italy, Netherlands, United Kingdom.

¹⁹ Interview with Carlo Sessa, President of ISIS (Istituto di Studi per l'Integrazione dei Sistemi) and coordinator of the RAISE project, Roma, 24/07/2006.

²⁰ See, for example, the study on 'The French and the Internet' conducted by SOFRES in 2002. <http://www.tns-sofres.com/etudes/corporate/280302_internet.htm>.

²¹ 'First Citizen Panel Workshop: Developing a vision of what "urban sustainable development" is, using the ten Bellagio Principles. 9-10 September 2005, Vienna, Austria'. <<http://www.raise-eu.org/conference-dates.html>>.

²² 'Second Citizen Panel Workshop: Evaluation of what possible answers are provided by the current EU-research on urban sustainable development. 30 September – 1 October 2005, Rome, Italy'. <<http://www.raise-eu.org/conference-dates.html>>.

²³ *Meeting of minds. Food for thought and debate on brain science. Information brochure*, <http://www.meetingmindseurope.org/europe_default_site.aspx?SGREF=16&CREF=1279>

²⁴ That is to say, the two training sessions, the citizens' conference itself with deliberation and the formulation of recommendations ('*Citizens Declaration on the European City of Tomorrow*'), and, finally, the public presentation of the declaration to decision-makers.

²⁵ See *supra* note 2.

²⁶ European Citizens' Deliberation on Brain Science, June 3-5, 2005, Report on the 1st European Citizens' Convention, p. 6. See <www.meetingmindseurope.org/Download.aspx?ID=269>.

²⁷ Interview with Gerrit Rauws, director at the King Baudouin Foundation and project coordinator, Brussels, 29 November 2006.

²⁸ 'What are the objectives of Meeting of Minds?', *About the project*, <<http://www.meetingmindseurope.org>>.

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Chapter 6

The EU Chemicals Policy: Towards Inclusive Governance?

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Introduction

This contribution analyses contemporary European risk regulation as an arena for inclusive governance, concentrating on the regulatory regime for the control of chemical risks. The focus on chemicals is rewarding for a number of reasons. First, the threats to health, safety and the environment posed by dangerous chemicals, and the abiding uncertainties surrounding the links between chemical exposure and health and environmental degradation, have long elicited high levels of public concern. Moreover, since the risks attach to the product of chemicals itself, rather than to a side effect of commercial enterprise as is the case for, say, the risks of air pollution caused by industrial emissions, measures introduced to manage and reduce these risks tend to have a very direct impact on the marketability of commercial wares. Thus, the various interests that inform the shape and substance of market regulation -- ranging from competitiveness, innovation, and market stability and fairness,

to worker, consumer, and environmental protection -- collide in chemical risk decision-making in a highly visible and explicit way.¹ Finally, since the EU regulatory framework for the production, marketing and use of chemicals has recently undergone a major overhaul, it offers a good insight into how and the extent to which notions of inclusiveness are currently being integrated into governance of the European market.

The analysis will show that, formally at least, the EU regulatory regime for chemicals control is far more inclusive than its predecessor. However, when looking below the surface of formal arrangements, and particularly taking into account that the effectiveness of inclusion is determined not only by the creation of entry points into the regulatory debate, but equally by determinations of what is debatable, it is unlikely that the chemicals control regime will foster effective participatory decision-making.

Before reviewing the current “REACH” regime for chemicals control, Part II briefly goes over the salient features of the old regime, and adds some information on its level of inclusiveness. Part III summarily maps out the key features of the recently adopted REACH Regulation. The core of the analysis then follows in Part IV, which examines the inclusiveness of REACH at the different stages of “input” (i.e., participation into the negotiation and adoption of REACH), “throughput” (participation in the decision-making processes taking place under the REACH framework) and “output” (participation in the critical evaluation of regulatory decisions taken under REACH). Part V Critically reviews REACH’s provision for public participation, in particular by extending the idea of inclusiveness to take into account the scope and integrative structure of the regulatory framework. Part VI summarises and concludes.

The Old Regime for Chemicals Control in the European Union

Prior to 2007, chemicals control in the EU was governed by a network of Directives and Regulations.² The old system operated on the basis of a double distinction, first, between dangerous substances/preparations and other chemicals³ and, second, between old or “existing” substances, and substances introduced on the EU market after September 1981 or “new substances”. The latter distinction was mostly the result of political and economic expediency. As awareness grew throughout the 1970s that the availability of timely and reliable information concerning the health and environmental impacts of the release of chemical substances was crucial for the design of a risk management framework that had a fighting chance of effectiveness, EU institutions conditioned market access upon the notification of a compendious technical dossier to the competent authority located in the Member State where a manufacturer or importer first sought to market a new chemical, or a preparation containing a newly engineered substance. In exchange for the new information production and supply burdens, manufacturers and importers gained a one-stop shop facility, whereby a single notification would be recognised by all Member States.⁴ For chemicals that were already in circulation however, the imposition of information supply and testing requirements was considered too onerous and potentially disruptive to the economy.⁵ Hence, during the first decade after notification duties were introduced, EU law did not foster information supply concerning existing chemicals in a systematic way. The notification requirement, and its absence of a counterpart for existing substances, was a textbook example of a regulatory control mechanism that favours the old over the new.⁶ In addition to stifling innovation, the approach was undesirable from a health and environmental protection perspective, since old chemicals tend to pose greater risks than newer generations of substances.

The Member State competent authority was the pivotal actor in the notification process. Importers and manufacturers submitted technical dossiers to the national authorities, which were in charge of checking the completeness of the file, and circulating it to the Commission and the other Member States for review. Furthermore, as of the early 1990s EU law instructed national authorities to perform a risk assessment on the basis of the information in the technical dossier, in accordance with newly enacted Community risk assessment standards.⁷ The risk recommendations flowing from the risk assessment could constitute a basis for regulatory action, either at the Community level or, residually, at the Member State level.⁸ At the EC level, such regulatory intervention would typically take the form of a new restriction on marketing and use, adopted via legislative amendment of Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations (Marketing and Use Restrictions Directive).⁹

As mentioned above, the situation was different for existing substances. Very little was (and still is) known about the most of the 30,000 chemicals that have been regularly traded since before September 1981. To address this data gap, the Council adopted Regulation (EEC) 793/93 on the Evaluation and Control of the Risks of Existing Substances (Existing Substances Regulation).¹⁰ The data gathering approach established therein was distinctly more centralised than in the framework of notification. Pursuant to the Existing Substances Regulation, manufacturers and importers were to report all available chemical data directly to the European Commission. The various submissions were collected by the European Chemicals Bureau,¹¹ established under the auspices of the Joint Research Centre Environment Institute, which processed everything into a comprehensive, EU-wide database (“EUCLID”). The information in EUCLID then constituted the starting point for a priority setting exercise. The Commission drew up priority lists

enumerating those substances which, on the basis of available information, had the highest risk potential. These substances were assigned to different Member States for further data gathering and risk assessment. The Member States authorities, acting as delegates to the Commission, would report their findings back to the Commission in the form of a risk recommendation. If the risk recommendation indicated that regulatory interventions were necessary to control identified health and/or environmental risks, the Commission would draft a legislative proposal for risk reduction, either under the Marketing and Use Restrictions Directive, or under an alternative EU regulatory framework (for instance, the Control of Chemicals Agents at Work Directive¹³). In contrast to the notification procedure, which after a few years performed reasonably well, the Existing Substances Regulation failed to deliver. It would exceed the scope of this paper to scrutinise the different factors that led to the failure of the existing substances regime, however in the framework of this analysis it should be noted that the absence of either positive or (credible) negative incentives for the chemical sector to cooperate in the regime fatally crippled the Regulation.¹³ This serves as a reminder that no matter how formally binding, rules are vulnerable. Hence, the greater legitimacy that inclusiveness aspires to convey is not only normatively attractive, but can crucially influence regulatory effectiveness.

As is already apparent from even a snapshot overview, the old regime was institutionally dominated by public authorities, in the first place national regulatory authorities (NRAs). NRAs administered the notification process, performed risk assessments for new substances and, as rapporteurs, for existing ones post-1993, and through the process of Council amendment were intimately involved in the negotiation and adoption of new and tightened restrictions. The Commission, too, played a prominent role, as it orchestrated that data gathering and evaluation regime under the Existing Substances Regulation and, which rather more success, formulated and adopted harmonised classifications for dangerous substances. This representation does

somewhat understate the inclusiveness of the old regime, particularly with regard to the involvement of chemicals producers and importers. The notification provisions under Directive 67/548, as amended, offered notifiers the opportunity to prepare and submit a preliminary risk assessment. Moreover, traders were required to formulate and affix a preliminary classification for the dangerous chemicals they were trading. More generally, while imposing a regulatory burden, producers' and importers' responsibility for information supply, both in the context of notification and for existing substances, simultaneously created an access point to regulatory decision-making processes that were facilitated by data supply.¹⁴ Even though formal guarantees were thin on the ground, the chemical sector was usually informally and at times extensively consulted prior to, for instance, the formulation of a harmonised classification. However, the lack of formal provisions for participation did keep private parties dependent on goodwill rather than entitlement, and importantly meant that parties external to the data supply, evaluation and decision-making process, such as public interest NGOs, had even more limited opportunities of engagement.

The preceding paragraphs offered a rudimentary sketch of the Community approach to chemical risk regulation between 1980 and 2007. REACH, however, has brought about a transformation of regulatory chemicals control, and arguably even of the EU's approach to complex risk governance more broadly. The following sections briefly review the main features of REACH, and then concentrate on the question of inclusiveness.

REACH

On 1 December 2006, the Environment Committee of the European Parliament (EP ENV) and representatives of the Council of Ministers agreed on a compromise text on REACH, the new and controversial regulatory framework for the control of chemical substances in Europe. The REACH

Regulation,¹⁵ as duly voted on by the EP plenary on 11 December and adopted by the EP and Council on 18 December, entered into force on 1 June 2007. Its provisions will be gradually implemented over a period spanning from now until 2018.

REACH stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH is intended to provide an encompassing regulatory framework that enables information production and decision-making relating to all chemicals produced and/or circulating in the EU market,¹⁶ covering every stage of the chemicals production and use cycle. The information allows identification of dangerous chemicals, a cost-effective assessment of the risks posed by the production, marketing, use, and disposal of such chemicals, and the development of cradle-to-grave risk management policies, which must be passed on and refined through the chemicals supply chain. The following sections give a short description of the salient features of the REACH regulation, covering registration, evaluation, authorisation, risk reduction, institutional design, and enforcement.¹⁷

Registration¹⁸

REACH's philosophy is that no chemical substance, in whatever form, should circulate on the market without adequate documentation. To this effect, REACH imposes a generalised registration requirement: manufacturers or importers of chemicals produced or imported in volumes of over 1 tonne per year must apply for registration, which is conditioned on the submission of a technical data file supplying health, safety, and environmental information. Registration extends previous data reporting requirements¹⁹ in a number of significant ways. Most importantly, registration targets the roughly 30,000 chemicals which have been traded in substantial volumes within Europe for over 25 years, but for which scant or no information is available.²⁰ Moreover, Registration affects chemicals substances as well as chemicals in

preparations²¹ and in articles. This means that registration duties not only fall upon chemicals manufacturers and importers, but also on the vast groups of traders selling goods that contain chemicals, ranging from cars to disposable lighters.

Evaluation²²

The data gathering requirements under REACH connect to the framework's second risk management stage; the evaluation procedure. Evaluation covers the evaluation of *dossiers* submitted pursuant to registration, which is compulsory for those containing proposals for animal testing, in order to minimise duplication of information. *Substance* evaluation, in turn, is carried out when initial data raise suspicions concerning the health and/or environmental impact of chemicals. An EU-wide rolling action plan will be established, where substances targeted for evaluation are allocated to a Member State which acts as rapporteur. Where suspicions are confirmed, evaluation may trigger further risk management actions, such as the inclusion of the chemical on the list of substances subject to authorisation, or the drafting of risk reduction measures.

Authorisation²³

The most controversial pillar of REACH is the authorisation requirement for highly dangerous chemicals, such as CMRs,²⁴ PTBs²⁵ and vPvBs.²⁶ After the lapse of a sunset date, those chemicals that have been identified as subject to an authorisation requirement can only be produced, traded and/or used if Commission approval has been obtained. It is incumbent on the private applicant for authorisation to furnish proof, in the form of an extensive data file including a risk assessment and risk management recommendations, that the risks posed by the chemical are either adequately contained, or that no usable alternatives currently exist but substitutes are being investigated.

Applications are reviewed by the newly established European Chemicals Agency (ECHA), which produces an opinion for the Commission. According to the wording of the REACH Regulation, if the risks are shown to be adequately contained, the Commission must authorise. If, on the other hand, it is impossible fully to contain the risks, the Commission *may* grant authorisation, depending on the severity of the risk and viability of alternatives. Authorisations are subject to review and monitoring.

Manufacture, Marketing and Use Restrictions²⁷

A risk management alternative to authorisation is the adoption of Community-wide restrictions curbing the production, marketing and/or use of dangerous chemicals. The REACH Regulation both incorporates pre-existing measures, which were enacted in the 1976 Marketing and Use Restrictions Directive and ensuing amendments, and maps out the process for the adoption of new restrictions. As with authorisation, risk reduction measures are adopted by the Commission acting on an ECHA opinion. Before REACH, the adoption of each new restrictive measure required Council (and, after Maastricht, Council and European Parliament (EP)) decision-making,²⁸ which slowed down the introduction of chemical risk measures to the point of ineffectiveness.²⁹ The shift towards a Commission decision-making process is intended to speed up this process, and thus deliver a higher level of up-to-date health and environmental protection standards. Interestingly, the procedure designated for the adoption of restrictions is the new 'regulatory procedure with scrutiny', which was introduced in a 2006 amendment to the 1999 Comitology decision.³⁰ The regulatory procedure with scrutiny responds to demands for greater EP involvement in Commission decision-making.³¹ It is the sole comitology procedure where agreement between the Commission and the consulted Committee of national representatives does not automatically result in adoption of the

Commission proposal. Instead, even Committee-approved proposals are forwarded to the EP and the Council ‘for scrutiny’, which institutions may oppose the proposal by simple (EP) or qualified majority (Council) respectively. The regulatory procedure with scrutiny certainly provides a high level of accountability of the Commission and Committee vis-à-vis the primary EU law-makers. However, checks and balances make for lengthy procedures, and we might wonder whether this new form of comitology will still be able to deliver results more efficiently than the Council and EP decision-making process which it replaces.

Institutional Design

With the new standards and procedures mapped out in REACH comes a new institutional design to manage the regulatory framework. Most importantly, the REACH Regulation establishes the European Chemicals Agency (ECHA),³² which will function as both the designated supplier of scientific expertise and opinions to the Commission, and the chief administrator of the scheme. Whereas formerly Member State national authorities were the first point of contact with private parties complying with EU regulatory requirements, and thus the chief liaison with Community authorities, applicants for registration under REACH directly submit their applications to ECHA, which will: review registration dossiers; check the completeness of the file and, where necessary, request additional information; perform the registration; and assign a registration number. In the case of applications for authorisation, applicants submit to ECHA, which then orchestrates the scientific review of the technical file and risk assessment submitted by the applicant, and drafts a recommendation for the Commission. Member State involvement in the process is primarily arranged through a permanent Member State Committee under ECHA’s auspices. As mentioned before, the Commission takes the lead in decisions relating to

substance evaluation and its outcome, and decides on authorisations, as well as on restrictions on manufacture, marketing, and use. Member States do however have an opportunity to be closely involved in the identification of substances for evaluation, and perform the crucial task of substance evaluation. Additionally, the Member State is represented in Commission decision-making through the familiar channel of comitology.

This brief overview cannot do justice to the delicate balances and intricacies that the institutional settlement under REACH reflects. In broad lines, however, REACH could be said to represent an exercise in regulatory centralisation, as both the pivotal administrative and decision-making functions are exercised by Community institutions (respectively, ECHA and the Commission). Also, and perhaps of even greater importance, whereas before REACH communications between public authority and the private sector were predominantly conducted through the intermediary of national regulatory authorities, REACH not only enables but even requires a direct dialogue between EU institutions and regulatory addressees. Shifting patterns of communication can seriously affect the relationships and relative dependencies between the various actors in a regulatory network. In the REACH scenario, they could in the long run contribute to divert familiarity, allegiance, recognition of regulatory practice and even authority from the national to the European level.

Enforcement

REACH firmly embraces a policy of ‘no data, no market’. After the transition dates, any unregistered chemical (or chemical use) should be taken out of circulation. For old or ‘existing’ chemicals, this daunting penalty for non-registration is precisely what distinguishes registration from preceding data reporting duties under the Existing Substances Regulation, the failure of which to deliver results was broadly attributed to the absence of a credible

threat in case of non-compliance.³³ Hence, the credibility of REACH as a workable system for risk control, both within the EU and on the global scene, will hinge largely on the effectiveness with which regulatory provisions are enforced. This is where the role of the Member State is crucial, as enforcement of the REACH requirements is entirely a national responsibility.

Inclusive Governance in REACH

As a prominent strand of the pervasive discourse on “good governance” which has so dominated the last ten years of EU regulatory studies, the most commonly understood version of inclusive governance focuses on the question of how, and to what extent, different stakeholders get to represent their interests and participate in the process of law- and decision-making.³⁴ For reasons that have been thoroughly discussed elsewhere, attention tends to centre around those stakeholders and interests that, although affected by regulatory processes and their outcomes, traditionally had very limited opportunities for direct engagement.³⁵ Often, such categories of stakeholders are loosely grouped under denominations such as “the public”, “the public interest”, or “civil society”; terms which all construe oversimplified but workable representations of those entities that do not have a privileged status in regulatory decision-making by virtue of authority or specific designation in the regulatory framework.

The analysis below follows this format as it looks at opportunities for private stakeholders, and particularly stakeholders that are not the direct addressees of the regulatory prescriptions in the REACH Regulation, to be involved in the regime for chemicals risk control, in terms of its development (input), its operation (throughput), and vis-à-vis the decisions it generates (output).

Input

The history of the REACH reform is one of extensive consultation and debate. From its inception, REACH was a pronouncedly high-profile enterprise. Speaking before the plenary, Head of EP ENV Committee Karl-Heinz Florenz called REACH “one of the largest and most significant reports” ever to be debated within EP Chambers.³⁶ The level of interest and controversy surrounding the initiative was, first of all, a function of its scale, as REACH was the outcome of a review process, started up in 1998, which involved no less than four key pieces of EC internal market legislation: Directive 67/548 on the Classification, Packaging and Labelling of Dangerous Substances;³⁷ Directive 88/379 on Dangerous Preparations;³⁸ the 1993 Existing Substances Regulation;³⁹ and Directive 76/769 on Marketing and Use Restrictions for Dangerous Chemicals.⁴⁰ The review process was a prominent and early example of the Commission’s willingness to orchestrate broad-based consultation and some level of participation in policy reform initiatives, which obviously further raised stakeholder awareness of the impending changes.⁴¹

Going on from there, every further step leading up to the adoption of what would become known as the REACH Regulation, along landmarks such as the 2001 Commission White Paper on a Strategy for a Future Chemicals Policy,⁴² the 2003 release of the Commission Proposal for a REACH Regulation,⁴³ and a range of impact assessments to gauge the anticipated regulatory costs and benefits of proposed risk control schemes, was accompanied by a high level of intensive, at times acrimonious but reasonably transparent public debate. Moreover, this debate was fuelled by an impressive array of different actors, including domestic and non-EU chemical industry associations, representatives of small and medium sized businesses, consumer organisations, national EU and non-EU governments,

environmental NGOs, trade unions, IGO and regional organisations, research institutes and academics, etc.

It would be disingenuous to claim that the process was insufficiently inclusive or accessible; the great pains that the Commission, for one, took broadly to consult and respond indicate otherwise. In fact, we could very plausibly hold up the REACH reform process as blue print for participatory law-making. Yet, equal opportunities for access to not imply equal opportunities for influence. Pesendorfer argued that, while consultation was formally inclusive, the terms of the debate, and the regulatory context in which it took place, favoured the promotion of private over public interest perspectives, and of economic over health and environmental considerations.⁴⁴ We will revisit this connection between access to and context of the debate when considering the impact of the scope and risk management prescription in REACH on inclusive governance.

Throughput

A key question in examining the inclusiveness of the REACH framework, inquires into the extent to which different interests and stakeholders are represented in decision-making pursuant to REACH. As indicated before, REACH comprises a range of decision-making procedures, going from procedures to determine whether a registration is complete, and hence whether a registration number can be assigned which validates a product's new or continued circulation on the EU market, to the identification of highly dangerous chemicals that should be authorised, the authorisation itself, and the adoption of risk reduction measures for substances that are not subject to authorisation but nonetheless pose unacceptable risks. To gain a preliminary insight into the level of inclusive risk governance under REACH, this paper focuses on the interplay between institutions and interests taken into account in the authorisation process of a substance

identified as falling under the authorisation requirements. Admittedly, authorisation constitutes but one pillar of the REACH framework; a complete picture of the organisation and degree of inclusiveness of the contemporary EU chemicals control regime, as an example of modern risk regulation, would additionally require the consideration of consultation and participation provisions in the registration, evaluation, authorisation identification, and risk reduction processes. However, since selectiveness cannot be avoided within the confines of a paper, the focus on the authorisation process is warranted because this process involves the marketing and use of precisely those chemicals that stir the highest level of public concern. Consequently, authorisation is the regulatory process in which the public arguably has the strongest interest in participating, and where exclusion from decision-making is least justifiable. The authorisation procedure therefore is a good indicator of the degree of inclusiveness aspired to under REACH, and of the likelihood of effectiveness.

Stage 1: Application

For purposes of simplicity, we can divide the authorisation process into three segments: the application, review, and decision stages.⁴⁵ In each of the three stages, a different player assumes the lead in the authorisation process. Applications are formally industry-led: it is incumbent upon manufacturers, importers or downstream users to prepare and submit the application dossier. In practice, dossier preparation will be predominantly expert-driven, as the central documents are a chemical safety report (or risk assessment) covering the risks to human health and the environment from the use of the substance arising from its intrinsic properties, and an analysis of alternatives including, where appropriate, research and development activities undertaken by the applicant. With regard to the chemical safety report, Annex I.0.2. stipulates that the assessment “shall be prepared by one or more competent person(s)

who have appropriate experience and received appropriate training”. The chemical safety report follows the traditional science-based risk assessment pattern of human, physico-chemical and environmental hazard assessment;⁴⁶ exposure assessment, and risk characterisation. It is interesting to note that the required description of exposure scenarios, which map out the conditions under which the substance is manufactured and/or used, is to include “a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users”. This does create scope for existing risk management information, which is generated and developed in a practically applied context, to be integrated within the science-based assessment process and influence the ultimate risk characterisation. This risk characterisation, ultimately, compares the predicted or known exposure with the DNEL⁴⁷ (human health) and/or PNEC (environmental health),⁴⁸ and assesses the likelihood and severity of an event occurring due to the physico-chemical properties of the substance (such as explosiveness and flammability). If exposure does not exceed the DNEL and/or PNEC, and if risks relating to the substance’s physico-chemical properties are negligible, the risks posed by the substance are considered “adequately controlled”, which crucially affects the outcome of the authorisation process. However, before turning to those, it should be observed that Article 62(5) of the REACH Regulation allows applicants to include a socio-economic analysis in the application dossier, which broadens the scope for alternative types of information to be introduced early in the decision-making process.⁴⁹ Similarly, the analysis of alternatives “considering their risks and the technical and economic feasibility of substitution”⁵⁰ allows for the integration of non-scientific information into the application stage.

Stage 2: Review

The dominant player in the second or “review” stage of the authorisation process is the European Chemicals Agency (ECHA). ECHA receives applications directly from manufacturers, importers and downstream users, and produces a draft opinion on whether the reviewed substance should be authorised for (continued) sale and/or use, and on the applicable conditions for authorisation. ECHA, which opened shop in mid-2007, and which will gradually expand its regulatory, administrative and advisory operations to meet all the responsibilities assigned to it in the REACH Regulation by 2010, is an independent European Community Agency, conceived and structured along similar lines as the European Food Safety Agency (EFSA).⁵¹ Thus, at first glance the review stage of the authorisation process should be heavily technocratic, dominated by a group of independent, unelected civil servants located in the beautiful but rather remote Helsinki. However, to represent the review stage as purely technocratic, and in the hands of one monolithic institution, rather underplays the complexity of the review process for two reasons.

First, it does not take into account the checks and balances built into the authorisation process. Once an application is submitted to ECHA, it forwards the application dossier to its Committee for Risk Assessment (CRA) and its Committee for Socio-Economic Analysis (CSEA) to produce a draft opinion within 10 months of submission. Consultation with “third interested parties” is foreseen in Article 64(2) of the REACH Regulation. Beyond this provision, CSEA can ask either the applicant or third parties to give additional information on substitutes, and both Committees are to “take into account any information submitted by third parties”.⁵² Once the draft opinion is ready, the applicant is invited to comment upon it.⁵³ If the applicant avails herself of this opportunity, the ECHA Committees must consider the comments before producing their final opinion. ECHA then

forwards the final opinion, together with the applicant's comments, to the Commission, the Member States, and the applicant. If the applicant does not comment, the draft opinion is confirmed as final opinion and equally passed on to the Commission, the Member States, and the applicant.

Second, it pays to take a closer look at the institutional set-up of ECHA, and the inclusiveness of representation within the organisation.⁵⁴ In a nutshell, the Agency is run by an Executive Director (Geert Dancet) and Management Board of 32. Each Member State appoints a member to the Board. Of the remaining five, two are appointed by the EP, and three by the European Commission. The latter include one industry, one employees and one NGO representative (without voting rights).⁵⁵ ECHA's work load will be spread over six planned Directorates, most of which will be staffed by scientifically trained personnel. However, Directorate A is destined to house a unit for international cooperation and stakeholder relations, which will *inter alia* be responsible for risk communication with and between the various stakeholders. Moreover, ECHA will be assisted by three Committees and a Forum⁵⁶. The Member State Committee is the main channel through which national interests are represented internally. Additionally there are the aforementioned CRA and CSEA. The latter particularly would seem to constitute a locus for non-scientific risk considerations to be integrated into the authorisation review process.

Stage 3: Decision

Finally, the Commission heads the decision stage of the authorisation process. It formulates a proposal on the basis of the final opinion delivered by ECHA, which is adopted following the regulatory comitology procedure.⁵⁷ As known, the regulatory procedure requires committee approval by qualified majority for the adoption of the proposal to go forward. In the absence of a positive qualified majority within the committee, the Commission must forward a measure relating to the proposal to the Council, which has the

option to reject it by QMV within three months. In the absence of a Council rejection, or if the Council comes out in favour of the Commission's proposal, the Commission adopts the measure. In the context of the REACH authorisation procedure, three points are of particular interest. First, even though it is the procedure of choice for several other implementing mechanisms under REACH,⁵⁸ the newly introduced regulatory procedure with scrutiny (RPWS)⁵⁹ is not appropriate the adoption of authorisations, since the latter are executive measures rather than quasi-legislative measures.⁶⁰ The EP's involvement will therefore be restricted to the alarm bell procedure set out in Articles 5(5) and 8 of the 1999 Comitology Decision. Second, the reference to the regulatory procedure is an amendment to the original text of the REACH Regulation, according to which authorisation decisions followed the advisory procedure.⁶¹ In the realm of comitology, the advisory procedure is unequivocally the most supranational of the implementing decision-making processes. The Commission is bound to obtain and take account of the advice of a committee of Member State representatives, however the Commission has the authority of adopt its proposal even in the face of a negative committee opinion. Although the shift from advisory to regulatory procedure was played off in the press as a minor adjustment,⁶² it represents an important recalibration between the national and supranational influences in what will certainly be the most controversial and politically sensitive decision-making procedure under the REACH umbrella. Finally, with regard to the substantive decision on authorisation, the Commission's discretion differs depending on whether the applicant can show that the risks are "adequately controlled". If so (in other words, if the applicant can make a plausible case that the known or anticipated exposure will not exceed the no-effect exposure), Article 60(2) in principle *requires* the Commission to authorise marketing and/or use. The Commission only has discretion to refuse an authorisation where risks are not adequately controlled. In this case, the authorisation and conditions will hinge on the

risk-benefit ratio which commercialisation of the substance represents, and the availability of alternatives.⁶³ It should be noted in this context that, for many PBT, vPvB and CMR substances, it is at the moment scientifically impossible to define a safe level.⁶⁴ These fall under the category of “not adequately controlled”, and will therefore be subject to a substitution requirement and discretionary decision-making.

Output

What are the provisions and conditions to engage with the outcome of an EU regulatory process, in this case, the Commission decision to approve grant or withhold authorisation? Beyond the purely informal (though powerful) avenue of openly praising or criticising a Commission decision in the media, stakeholders need to resort to judicial review mechanisms. The notoriously unforgiving nature of access to justice conditions for non-privileged applicants (i.e., stakeholders other than the main Community institutions, the Member States, and the party/parties to whom the decision is addressed) under Article 230 EC has been exhaustively documented and reviewed,⁶⁵ and need not be repeated here. It is, however, useful to point out that, in 2006, a ray of light appeared in the form of Regulation (EC) No. 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community Institutions and Bodies (the Community Institutions and Bodies Regulation).⁶⁶ As to access to information, Articles 11 to 13 of the Regulation require the availability of databases or registers giving information on, *inter alia*, authorisations with a significant impact on the environment, thus further strengthening the publicity requirements under the REACH Regulation.⁶⁷ Moreover, Title IV of the Regulation provides that environmental NGOs, provided they have the qualifications spelled out in Article 10, can make a request for internal

review to a Community institution or body that has adopted an administrative act under environmental law. This provision could be relied upon by environmental NGOs to request review of Commission decisions pertaining to chemicals authorisations. If authorisations are indeed understood as “administrative acts under environmental law” – and there could be some debate about this – then the availability of internal review is indeed a further step towards inclusiveness. However, we do need to be aware of the Regulation’s limitations. First, it only grants review opportunities to NGOs, and environmental NGOs at that. Other public interest groups, and private actors operating outside of the framework of an NGO, remain excluded. Second, the provision is for *internal*, not judicial review. A 2006 ECJ ruling confirmed that the provisions of the Community Institutions and Bodies Regulation have to be read in compatibility with Article 230 EC, and cannot be deployed as to bypass the stringency of its provisions.⁶⁸

A Contextual Appraisal of Inclusiveness

Reviewing the inclusiveness of the REACH framework at the stages of input, throughput, and output, there is certainly some cause for satisfaction. Broad-based consultation and debate enriched to the point of nearly overburdening the legislative reform process. Interested third parties have an opportunity to submit information during the authorisation process. Engagement at the output stage is still the weak link of the governance regime,⁶⁹ but the new Community Institutions and Bodies Regulation may at least create some form of access for a limited category of stakeholders relating to some of the public concerns regarding the control of chemicals.

The apparent high level of inclusiveness described in the preceding section should not come as a shock. REACH is, after all, the culmination of an intensive and high-profile nine year review process; its provisions have been carefully plotted and exhaustively discussed and negotiated in a wide-

spanning array of public and private settings, in regional, national, European, and international fora. The European Community is, by now, an experienced risk regulator, wizened by past controversy and regulatory failure in areas such as pharmaceuticals control, chemicals, and GMO regulation, and therefore unlikely to design new regulatory frameworks that overtly and bluntly sideline major stakeholders and interests. Yet, whether the provisions in REACH will secure full and effective public participation remains dishearteningly doubtful, particularly when we take into consideration the context in which participation takes place.

The Terms of Article 64(2) REACH

A first and smaller point relates to the exact terms of the provisions on public consultation in the framework of an authorisation application. Article 64(2) of REACH stipulates that: “The Agency shall make available on its web-site broad information on uses (...)for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested parties”. Now, it is reasonable to expect ECHA to interpret this provision broadly, if necessary after some prodding by the ECJ, but it nevertheless remains pertinent that Article 64(2) allows ECHA to construct and, hence, select, the body of information to be disclosed. More worrying is the explicit reference to information on alternative substances and technologies. For reasons of commercial confidentiality alone, this is not the type of information that will typically be at the disposal of non-industrial stakeholders. It would probably go too far to argue that Article 64(2) should be read to exclude submission of information submitted by interested third parties and relating to other issues than substitution, particularly when read in conjunction with of the new Community Institutions and Bodies Regulation, however it may at least foster an informal prioritisation of

information on alternative substances and technologies and, hence, of those (industrial) stakeholders that possess this type of knowledge.

Structured versus Unstructured Access

A more general observation relates to how the dialogue between public authority and third parties is structured. An invitation is more welcoming than an unlocked door. Or, in the context of REACH, explicit solicitation of opinions, as for instance provided through the forwarding of draft opinions to applicants, accompanied by a request for comments,⁷⁰ fosters more a productive exchange than a simple permission to comment. This, in turn, can significantly improve the effectiveness of participation.⁷¹ Reviewing the participatory arrangements under REACH, we observe that exchanges with applicants and with third parties who have information on substitution are more structured, and therefore arguably more conducive to genuine deliberation, than those with other interested parties.

The Scope of the REACH Regulation

The degree of inclusiveness of EU regulation tends to be reviewed within the confines of a specific regulatory framework. However, stakeholder involvement in regulation is only meaningful if the regulation adequately covers those activities, practices, and arrangements surrounding which stakeholders seek to express their interests and public concerns. In this scenario, if public concern relates to chemicals, or to aspects of their production, processing, or marketing that are not covered under REACH, then these concerns cannot find adequate expression within the discursive space created by regulatory procedures. Reviewing the REACH Regulation, it is quickly apparent that this regime is much more inclusive in scope than its predecessor. As mentioned, it covers both old and new substances, and importantly includes substances in articles, which widens the reach of the

Regulation to cover most industrial sectors. Whereas formerly information supply duties for new substances were only triggered upon marketing, registration is required for production, marketing and use. With the more inclusive substantive scope of application also comes a wider group of affected regulatory addressees, as REACH imposes obligations down the supply chain. However, REACH does have a regulatory blind spot, in that only chemicals produced or imported in volumes of at least 1 tonne per manufacturer and per year are subject to registration. This means that about 60,000 substances listed in the EINECS, many of which produced or traded in small but non-negligible quantities, are not processed and, hence, not debatable, within the regulatory system. Also, REACH excludes, *inter alia*, chemicals used in agriculture, biocides and cosmetics, which will continue to be governed by separate regulations.⁷² The inclusiveness of the EU regime for chemicals control can therefore only partly be guaranteed by REACH.

Inclusiveness through Integration

A further contextual element to take into account, is that we only obtain a narrow account of inclusiveness if we restrict our analysis to the development of formal, or even the formal and informal, channels of communication between public authorities and stakeholders under the auspices of regulation. Inclusiveness can however additionally be encouraged through the introduction of requirements which compel regulatory addressees to identify and take into account a broadened range interests within assessment and evaluation processes. Such integrative requirements can be particularly effective where exclusion is a consequence of oversight rather than deliberate, and where regulatory addressees may derive potential benefits from interest integration.

REACH could be said to respond to this version of inclusiveness as it provides a more integrative approach to the successive steps of risk

identification, risk assessment, and risk management than before. It requires private actors to draw up guidance notes for safe use and, for substances above a 10 tonnes threshold, chemicals safety assessments (i.e., risk assessments) and safety data sheets as a precondition to registration. Thus, contextual factors pertaining to the use and anticipated or known exposure of a substance become attached to and can influence the initial risk identification process. The need to contemplate use and exposure, and to formulate protocols for safe use, may affect decisions on whether to pursue commercialisation of a new substance at an earlier stage in the engineering and design process, before massive costs are sunk in, and may impact on decisions on whether to apply for registration of older chemicals, thus hopefully fostering a higher level of responsiveness to health and environmental concerns, and a stronger practice of self-selection within the chemicals industry, determined by more than the commercial viability of the contemplated product. Similarly, within the framework of the authorisation process, Article 55 of REACH insists that all manufacturers, importers and downstream users must analyse the availability of alternatives and consider their risks and the technical and economic feasibility of substitution. This opens up opportunities for a self-imposed, early, perhaps rather rudimentary comparative risk assessment that can weed out the more obvious cases where substitutions should be made, thus obviating the need for a lengthy, vexatious and perhaps ultimately unsuccessful authorisation procedure.⁷³

We should take care however not to overstate the extent or the promises of integrated assessment requirements. The overwhelming majority of substances subject to REACH are marketed in volumes of between one and ten tonnes per year. Registration of this category of substances does not require a chemicals safety report (risk assessment). Thus, for an estimated 30,000 substances, the new chemicals control policy will mainly consist of an information gathering and limited testing exercise. Apart from the requirement to supply available guidance notes for safe use, very little scope

exists for risk considerations, whether of a scientific, social or economic nature, to be integrated into the control process. Koch and Ashford have voiced a concern that, for most chemicals, the REACH framework will amount to little else than data collection and box-ticking.⁷⁴

Moreover, even within the narrowly delineated field of testing data to be produced in compliance with the registration provisions, questions emerge as to the effectiveness of the Regulation's inclusive approach to health and environmental protection. The process of hazard identification and short term toxicity testing may generate plausible results for human health assessments, but it is notoriously feeble when it comes to the identification of environmental risks. In light of, to name but a few factors, the endless variety of recipients within ecosystems, the scope for synergic impacts caused by multiple exposure and opportunities for long term build-up and mutation, the snap-shot, substance-by-substance approach in laboratory testing makes for a poor predictor of environmental impacts.⁷⁵ More robust assessments generally require a combination of testing, epidemiological studies and monitoring mechanisms.⁷⁶ On the latter aspects, REACH is particularly weak. It is interesting to observe that the critiques on the effectiveness of the data gathering provisions for environmental risk control are not new; they have been around since well before the 1998 review.⁷⁷ However, in contrast to the criticism on the expediency of the former regulatory framework to deliver regulatory outcomes, they were not included or addressed in the reform process.

Finally, where the REACH framework does provide an opportunity for the inclusion of contextual, socio-economic information within the earlier stages of identification and assessment, we need to ask ourselves exactly what can be included. We recall that, within the authorisation procedure, the applicant may include a socio-economic analysis (SEA), details for which are mapped out in Annex XVI to the Regulation. When reviewing the elements that an SEA may cover, it is hard to escape the conclusion that this is

overwhelmingly conceived as an opportunity for the applicant to mitigate any unfavourable indications in the risk assessment; there is a strong emphasis on the predicted impact of a refusal on industry, on pricing and consumer choice, on job security and employment, and on trade and competitiveness. A reference to consumer and environmental health effects cuts a lonely figure compared to the plethora of economic impacts to be considered. Moreover, no mention is made of any information relating to risk perception or risk communication. In any event, since the SEA will be drawn up by applicants for authorisation, their incentives to include information that might strengthen the case for risk control are highly dubious.

The Organisation of Interest Representation

Beyond the challenges posed by the disparities in access for different groups of stakeholders, and by the substantial limitations of the terms of the regulatory debate, lies the even more intractable problem of uneven resources and expertise. Collective action and free rider problems make it a sure bet that public interest representation will be under-resourced compared to private interest groups. This is certainly the case for the area of chemicals control, where one of the major stakeholders, the chemical industry, constitutes Europe's third largest industry, employing approximately 1.7 million people, with another 3 million employees in jobs that are directly dependent on the chemicals sector.⁷⁸ It is also a rather apprehensive industry, as in the last seven years growth rates in the chemicals sector, both within EU-25 and globally, consistently lag behind overall industrial growth rates.⁷⁹ As indicated before, public interest NGOs did participate vigorously, and some assert quite successfully,⁸⁰ in the REACH negotiation process, but it is undeniable that the chemical industry's resources and specialised expertise far outstrip their own, which hampers their ability to participate in decision-making as effectively as commercial interest representatives. This

disequilibrium is pushed further by the fact that public interest NGOs tend to have wide portfolios, and therefore need to be very strategic and selective in their allocation of resources. Thus, the elevated level of NGO participation in the “input” phase of REACH does not necessarily imply there will be a similarly heavy involvement in “throughput” and “output”. A 2007 article in the ENDS Report on new institutional developments within WWF does convey the impression that chemicals control is considered a finished project: “(the) finalisation of the EU’s REACH chemicals regime marks the end of an era. WWF now wants to focus on climate and resources with its ‘one planet living’ agenda.(...) Chemicals is one of the areas which has fewest cross-overs with climate and benefits least from its high profile. WWF is certainly not alone in dropping its chemicals campaigning – a relatively technical topic that can be difficult to explain to the public.”⁸¹ If this is indeed a marker of a more general trend, we might wonder whether NGOs have not missed a trick, since the real impact of substantive risk control requirements hinges to a considerable extent on their interpretation and application, and it is therefore crucial to be involved in the interpretation and application process.

Conclusion

The sober tones of the last few paragraphs above notwithstanding, it would be unfair, and unproductive, to condemn the REACH framework for lack of inclusiveness. Compared to the old regulatory framework for chemicals control great improvements have been made in terms of the openness of the debate leading to the adoption of REACH. Moreover, REACH does provide a good level of transparency⁸² -- a prerequisite for any for of workable participation -- and some opportunity for consultation. Access to justice remains a weak link, but the 2006 Community Institutions and Bodies Regulation might create a modest and partial scope for *ex-post* scrutiny. On

balance, this is a reasonably good scorecard from the point of view of inclusive governance.

However, a contextual appraisal does indicate that the participatory and integrative arrangements incorporated in REACH are very brittle, and casts serious doubts over whether REACH will result in genuinely inclusive risk management. The organisation of consultation, the scope of the Regulation, the selection of criteria and reference points to be integrated in assessment and management processes, and the perennial problem of relative lack of support and funding for NGO involvement, all conspire to erode, even trivialise, the inclusive nature of the decision-making framework. This echoes a message long familiar to those active in anti-discrimination law: the provision of formal equality is the beginning, not the end of a reform process towards an inclusive, non-discriminatory society. Drawing the parallel, and recalling that REACH still falls short of full formal “equality” for all stakeholders in terms their opportunities for engagement with regulation, the new EU regime for the control of chemicals could be said to constitute a first firm step towards the beginning of a reform process leading to inclusive governance in risk regulation.

Endnotes

¹ Cf. Veerle Heyvaert, “No Data, No Market. The Future of EU Chemicals Control under the REACH Regulation” Vol. 9 *European Law Review* (2007), 201.

² See generally Veerle Heyvaert, *Coping With Uncertainty. The Regulation of Chemicals in the European Union* (PhD Dissertation, European University Institute, Florence, Italy, 1999).

³ Dangerous chemicals: chemicals falling into one of the hazard categories set out in Community law (expanded from 8 initially to 15 now). Identification of a chemical as dangerous entails imposition of a range of risk management requirements: classification, R-Phrases and S-phrases, packaging, labelling, enclosing safety data sheets to be passed on to professional users, worker safety obligations, etc.

⁴ Council Directive 79/831/EEC amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1979] OJ L259/10.

⁵ Twelve years later, the Existing Substances Regulation would try to correct the information deficit concerning chemicals for which no notification dossier had been submitted. However, as will be discussed further below, the information supply obligation in the Regulation were never properly enforced.

⁶ Cf. Richard Stewart, “Regulation, Innovation and Administrative Law: A Conceptual Framework” Vol. 69 *California Law Review* (1981), 1259-1377.

⁷ Commission Directive 93/67/EEC of 20 July 1993 laying down the Principles for Assessment of Risks to Man and the Environment of Substances Notified in accordance with Council Directive 67/548/EEC [1993] OJ L227/9.

⁸ C-473/98, *Toolex Alpha* [2000] ECR I-9741; Heyvaert, “Balancing Trade and Environment in the European Union: Proportionality Substituted?” Vol. 13 *Journal of Environmental Law* (2001), pp. 395-398.

⁹ [1976] OJ L262/201.

¹⁰ [1993] OJ L84/1.

¹¹ See Commission Communication to the Council and the EP – The European Chemicals Bureau [1993] OJ C1/3.

¹² [1998] OJ L131/11.

¹³ Veerle Heyvaert, “Guidance Without Constraint. Assessing the Impact of the Precautionary Principle on the European Community’s Chemicals Policy” Vol. 6 *Yearbook of European Environmental Law* (2006), 46; and Royal Commission on Environmental Pollution, “Twenty Fourth Report – Chemicals in Products. Safeguarding the Environment and Human Health” 26 June 2003, published on the Internet at: <http://www.rcep.org.uk/chemicals.ch00-rep.pdf>.

¹⁴ Christopher Arup, “Chemical Notification Laws in the OECD Member Countries”, *Journal of World Trade Law* (1987), 65.

¹⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L396/1.

¹⁶ Provided they are not covered by other, more specific Community legislation, such as Directive 91/414 (pesticides) and Directive 98/8 (biocides).

¹⁷ See also Heyvaert, “No Data, No Market”, n. 1 above, 201–6, and the detailed yearly overviews by Candido Garcia Molyneux on “Substantive European Community Law – Chemicals”, *Yearbook of European Environmental Law*, vols. 5 onwards (2005–2008).

¹⁸ REACH Reg. n. 15 above, Title II.

¹⁹ See Part II above.

²⁰ See Part II *in fine*.

²¹ E.g., detergents.

²² REACH Reg., n. 15 above, Title VI.

²³ *Ibid.*, Title VII.

²⁴ Carcinogens, mutagens and substances toxic to reproduction.

²⁵ Persistent, toxic and bioaccumulative substances.

²⁶ Very persistent, very bioaccumulative substances.

²⁷ REACH Reg., n. 15 above, Title VIII.

²⁸ Article 251 EC.

²⁹ N. 13 above.

³⁰ Council Decision 2006/512/EC amending Decision 1999/468/EC laying down the Procedures for the Exercise of Implementing Powers conferred on the Commission [2006] OJ L200/11.

³¹ D. Pocklington, “Comitology Under Greater Scrutiny” Vol. 15 *European Environmental Law Review* (2006), No. 11, pp. 306–311.

³² REACH Reg., n. 15 above, Title 10.

³³ N. 13 above.

³⁴ See Commission White Paper on European Governance COM(2001)428, 25 July 2001; Commission Communication – Towards a Reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the

Commission COM(2002)704, 11 Dec. 2002; Commission Communication – European Governance: Better Lawmaking COM(2002)275, 5 June 2002; Commission Communication – A Strategic Review of Better Regulation in the European Union COM(2006)689, 11 Nov. 2006. See Daniela Obradovic & Jose M. Alonso Vizcaino, “Good Governance Requirements concerning the Participation of Interest Groups in EU Consultation” Vol. 43 *Common Market Law Review* (2006), 1049-85; Deirdre Curtin (ed.), *Reflections on Concepts, Institutions and Substance* (Antwerp, Intersentia 2005); and Stijn Smismans (ed.), *Civil Society and Legitimate European Governance* (Edward Elgar, 2006).

³⁵ Ibid.

³⁶ M. Florenz, Head of the Committee on the Environment, Public Health and Food Safety, speaking before the Plenary of the EP discussing the proposed REACH Regulation, 15 Nov. 2005, published on the Internet at:

<http://www.europarl.europa.eu/members/public/yourMep/view.do?name=florenz&partNumber=1&language=EN&id=1038>.

³⁷ [1967] OJ 196/1.

³⁸ [1988] OJ L187/14.

³⁹ [1993] OJ L84/1.

⁴⁰ [1976] OJ L262/201. See Commission Working Document – Report on the operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) 793/93, Directive 76/769/EEC SEC(1998)1986, 18 Nov. 1998.

⁴¹ Cf. Dieter Pesendorfer, “EU Environmental Policy Under Pressure: Chemicals policy Change Between Antagonistic Goals?” Vol. 15 *Environmental Politics* (2006), no. 1, 105-8.

⁴² COM(2001)88, 27 Feb. 2001.

⁴³ Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} {SEC(2003 1171} COM(2003)644 , 29 Oct. 2003.

⁴⁴ Pesendorfer, n. 41 above, 111.

⁴⁵ It should be noted that the authorisation process itself is preceded by another decision-making sequence, namely decision-making on the inclusion or exclusion of substances in Annex XIV, which lists substances subject to authorisation. See REACH Reg., n. 15 above, Arts. 55-59.

⁴⁶ This stage comprises identification of intrinsic properties and establishment of dose-response relationships in order to determine either Derived No-Effect Levels (DNELs) or Predicted No-Effect Concentrations (PNECs).

⁴⁷ See above.

⁴⁸ Ibid.

⁴⁹ But see Part V, Inclusiveness through Integration, below.

⁵⁰ REACH Reg., n. 15 Above, Art. 62(4)(e).

⁵¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 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 [2002] OJ L31/1.

⁵² REACH Reg. n. 15 above, Art. 64(3).

⁵³ Ibid., Art. 64(5).

⁵⁴ See http://ec.europa.eu/enterprise/reach/docs/calls/ed_echa_organisation.pdf.

⁵⁵ ‘Chemicals Agency Finalises Director, Budget’, ENDS *Europe Daily* 2451, 17 Dec. 2007. See also http://echa.europa.eu/about_en.html.

⁵⁶ The Forum will support Member States’ coordination of enforcement activities.

Furthermore, the Commission is assisted by a “High Level Chemical Group”, see “EU High Level Chemical Group Gives First Report”, ENDS *Europe Daily* 2454, 20 Dec. 2007.

⁵⁷ Council Decision 1999/468/EC [1999] OJ L184/23, Art. 5.

⁵⁸ Such as the adoption of marketing and use restrictions, see Part III above.

⁵⁹ Dec. 1999/468/EC, as amended, n. 57 above, Art. 5(a).

⁶⁰ See Gregor Schusterschitz & Sabine Kotz, “The Comitology Reform of 2006. Increasing the Powers of the European Parliament without Changing the Treaties” Vol. 3 *European Constitutional Law Review* (2007), 80.

⁶¹ Dec. 1999/468, n. 41 above, Art. 3.

⁶² ‘Verheugen Charts Green Path for EU Business’ ENDS *Europe Daily* 2289, 23 Mar. 2007.

⁶³ REACH Reg., n. 15 above, Art. 60(4).

⁶⁴ Bjorn Hansen & Mark Blainey, “REACH: A Step Change in the Management of Chemicals” Vol. 15 *RECIEL* (2006), No. 3, p. 277

⁶⁵ See, *inter alia*, John A. Usher, ‘Direct and Individual Concern – An Effective Remedy or a Conventional Solution?’ Vol. 28 *European Law Review* (2003), 575–600; AG Jacobs’ Opinion in Case C-50/00 *Union de Pequenos Agricultores v Council* [2002] ECR I-6677; C. Koch, “‘Locus Standi’ of private applicants under the EU Constitution: preserving gaps in the protections of an individual’s right to an effective remedy” Vol. 40 *European Law Review* (2005), n. 4, 511–27; and M-P Granger, Towards a Liberalisation of Standing Conditions for Individuals Seeking Judicial Review of Community Acts: *Jégo-Quére et Cie SA v*

Commission and Unión de Pequeños Agricultores v Council' 66 *Modern Law Review* (2003) 124.

⁶⁶ [2006] OJ L264/13.

⁶⁷ REACH Reg., n. 15 above, Arts. 118-119.

⁶⁸ Case T-94/04, *European Environmental Bureau (EEB), Pesticides Action Network Europe, International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Worker's Associations (IUF), European Federation of Trade Unions in the Food, Agricultural and Tourism sectors and allied branches (EFFAT), Stichting Natuur en Milieu and Svenska Naturskyddsföreningen v. Commission* [2005] ECR II-4919. See also joined cases T-236/04 and T-241/04, *European Environmental Bureau (EEB) and Stichting Natuur en Milieu v. Commission* [2005] ECR II-4945.

⁶⁹ Cf. Olivier De Schutter, "Europe in Search of its Civil Society" Vol. 8 *European Law Journal* (2002), 214.

⁷⁰ REACH Reg., n. 15 above, Art. 64(5).

⁷¹ Obradovic & Alonso Vizcaino, n. 34 above, 1060-61.

⁷² See Nicolas de Sadeleer, "The Impact of the Registration, Evaluation and Authorization of Chemicals (REACH) Regulation on the Regulatory Powers of the Nordic Countries" in Nicolas de Sadeleer, *Implementing the Precautionary Principle. Approaches from the Nordic Countries, EU and USA* (London: Earthscan, 2007), p. 334, questioning whether the overlaps and possible contradictions between the different regimes have been adequately addressed within REACH.

⁷³ Lars Kock & Nicholas Ashford, "Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH" Vol 14 *Journal of Cleaner Production* (2006), p. 40.

⁷⁴ *Ibid.*, p. 45.

⁷⁵ See Veerle Heyvaert, *Coping With Uncertainty. The Regulation of Chemicals in the European Union* (PhD Dissertation, European University Institute, Florence, Italy, 1999), pp. 126-130.

⁷⁶ Stuart Dobson, "Why Different Regulatory Decisions When the Scientific Information Base is Similar – Environmental Risk Assessment" Vol. 17 *Regulatory Toxicology and Pharmacology* (1993), pp. 333-345.

⁷⁷ E.g., Karl-Heinz Ladeur, "Risikowissen und Risikoentscheidung. Kommentar zu Gotthard Bechmann", Vol. 74 *Kritische Vierteljahresschrift fuer Gesetzgebung und Rechtswissenschaft* (1991), p. 249; Vicki Norberg-Bohm, William C. Clark, Bhavik Bakshi, Joanne Berkenkamp, Sherry A. Bishko, Mark D. Koehler, Jennifer A. Marrs, Chris P. Nielsen & Ambuj Sagar, "International Comparisons of Environmental Hazards: Development and evaluation of a method for linking data with the strategic debate on management priorities for risk management," *Working Paper of the Center for Science & International Affairs, John F. Kennedy School of Government* (1992), p. 7.

⁷⁸ CEFIC, Barometer of Competitiveness 2002, Business impact of New Chemicals Policy, published on the Internet at: <http://www.cefic.org/Files/Publications/Barometer2002.pdf>.

⁷⁹ CEFIC Facts and Figures, December 2006, published in the Internet at: <http://www.cefic.be/factsandfigures/downloads/CHapter%203.pdf>.

⁸⁰ But see Pesendorfer, n. 41 above, 111.

⁸¹ “Chemicals NGO forms as climate takes centre stage” *ENDS Report*, May 2007. Issue 388, p. 5.

⁸² REACH Reg., n. 15 above, Arts. 118-119.

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Chapter 7

The Public-private Regulation of Food Safety through HACCP: What does it mean for the Governance Capacity of Public and Private Actors?

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Introduction

Public-private partnerships (PPPs) and different forms of private self-regulation have gained in prominence as elements of policy-making, not just within the nation-state but also increasingly within international as well as European governance, where they are discussed as one of various innovations to policy-making through the traditional 'Community method' (Knill and Lenschow 2004). The private actors involved in these new forms of governance as partners of public authorities include not only non-profit organisations such as environmentalist or humanitarian NGOs, but also to an increasing degree companies, who are emerging as important direct partners of both national governments and international organisations in evolving structures of international governance through voluntary self-regulation.

Examples for the application of voluntary standards by companies include the commitment to Corporate Social Responsibility through codes of conduct, or voluntary codes in the financial markets or the chemicals sector (Haufler 2001), but also the emergence of ‘private authority’ in fields such as global commerce or the regulation of pharmaceuticals (Ronit and Schneider 1999). In many other fields, private actors are involved in public policy-making either through delegated self-regulation, co-regulation or other forms of public-private partnership. The evolution of these structures of governance raise a range of questions about the effectiveness and legitimacy of policy-making beyond the nation-state, but also about more fundamental questions of sovereignty, as structures and competences of policy-making are recalibrated both between the national and international level, and between public and private actors. Only recently have attempts been made to describe the patterns of ‘complex sovereignty’ resulting from the simultaneous shifts of political authority both on the vertical dimension between the nation state, supranational institutions such as the European Union and the international level, and on the horizontal level between the public and private sphere (Grande and Pauly 2006; Schepel 2006).

The regulation of food safety is at the centre of these developments, as this policy-field has also undergone major changes through both the internationalisation and privatisation of governance functions. In addition to the rapid internationalisation of trade flows and the emergence of corresponding regulatory frameworks through the WTO and its TBT and SPS agreements, as well as the Europeanisation of food safety regulation in the recent decade, the policy-field has also witnessed a strong expansion of different forms of private self-regulation, ranging from publicly-mandated hygiene and quality management systems to voluntary standards and labelling schemes. The rise of private actors as direct partners in the regulation of food safety is also reinforced by the principles of traceability and liability established

by the General Food Law, 'due diligence' clauses in national legislation, and the role of companies as applicants in authorisation procedures for genetically modified food, pesticides, and additives.

Within this range of private contributions to food safety regulation, the introduction of company-based food safety management systems through Hazard Analysis and Critical Control Point (HACCP) is a particularly interesting example for the role of companies as direct partners of public regulators, and for the (incremental, fragmented) internationalisation of regulatory standards. Therefore, the development of HACCP changes the structure of regulation both on the national-supranational and the public-private dimension: while the introduction of HACCP systems follows on initiatives to establish an internationally recognised standard of food safety regulation across regional and national jurisdictions on the level of the Codex Alimentarius Commission, it allows for a great degree of diversity of food safety management systems according to regional, national, and local legislative frameworks. Similarly, with regard to the public-private dimension, the introduction of HACCP leaves a great degree of leeway for private actors to implement food safety systems by prescribing key process characteristics to be implemented in the quality management systems of firms, although the verification and documentation of these characteristics is made compulsory through legislative requirements. Therefore, whereas the introduction of HACCP obviously entails a shift of responsibility to the private sector, the public element of this regulatory approach can hardly be said to be being simply driven out by private activities, but is re-constituted on different levels of regulation such as national jurisdictions, European directives and regulations, and the general requirements of the Codex Alimentarius, which are also reflected in the WTO agreements. The boundaries between public and private authority are thus reconstructed, albeit on different levels of regulation.

This view apparently confirms the common assumption in the literature on private self-regulation that public and private authority do not evolve in a zero-sum game, but that they are interrelated in dynamic, synergetic relationships in which the contributions of both sides might mutually reinforce each other over time (Knill and Lehmkuhl 2002: 99). This assumption, however, leaves us with the puzzle of how the emergence of public-private partnerships such as HACCP affects the ability of public and private actors to define goals and procedures of regulation. Questions in relation to this puzzle include the following: are the basic objectives of public policy and the political and legal frameworks through which they should be delivered still developed by public actors and then delegated to private actors? Or are we observing private actors – especially firms – assuming the status of norm entrepreneurs for the definition of common goods themselves, increasingly replacing the state in this role? What exactly are the synergetic relations between the public and private sector in the evolution of public-private partnerships? What role do regional organisations such as the European Union play in the operationalisation of such elements of private self-regulation by adopting them as part of their policies?

Against the background of these questions, this Chapter considers the consequences that the introduction of HACCP systems has had for the respective governance capacity – defined as the ability to define common goods and to design political processes and institutional structures for their delivery – of public and private actors in the field of food safety governance. Discussing the implications that HACCP has had for the definition of problem types, the congruence of problems and regulatory structures and institutional frameworks, this contribution argues that the establishment of HACCP is not just a modified procedural approach towards given ends, but that the transition from hierarchical regulation to public-private partnership is having a transformative effect on how problems, scopes of regulation and

institutions are defined, thus fundamentally changing the rationales, regulatory spaces, and power relations within an important sector of food safety regulation. Departing from functionalist accounts that explain the emergence of international cooperation from pressures emanating from economic and technological developments, the Chapter therefore seeks to highlight the strategic aspects of public-private partnerships, i.e., those related to interests, actors, and power relations. Furthermore, it seeks to show that through the establishment of public-private partnerships, important shifts of political authority occur not just between, but also *within* the public and private sectors, both between different actors involved and between different levels of regulation – an aspect not sufficiently addressed in existing typologies of public-private governance.

The Chapter proceeds in three steps. First, the following section sets out a typology of public-private partnerships and develops the notion of governance capacity. Secondly, the case study on HACCP is presented, applying the three main criteria identified in relation to the notion of governance capacity. Finally, the results of the case study are evaluated and summarised in the concluding parts of the Chapter.

The Governance Capacity of Public and Private actors in Public-Private Partnerships

The emergence of public-private partnerships is closely linked to the debate on governance and the changes with regard to the applied steering-modes and the actors involved in public policy-making described by this term. Distinctions of different forms of governance, as compared to classical forms of government, are therefore to be made both with regard to the actors involved – implying the cooperation of public and private actors in mixed policy networks in forms of governance – and with regard to the

predominant modes of steering – distinguishing new modes of governance through the application of non-hierarchical modes from the classical hierarchical intervention of the nation-state (Börzel and Risse 2006: 196). Still, the cooperation of private actors in the preparation, definition, application and implementation of public policies can take a variety of forms, with different degrees of intensity in the involvement of private actors. Correspondingly, typologies have been developed that try to distinguish various forms of public-private partnership with regard to the degree of autonomy given to private and public actors – ranging from the publicly dominated consultation and co-optation of private actors and forms of co-regulation to the public adoption of private regulation to forms of PPP dominated by private actors such as the delegation of public tasks to private actors (i.e. in standard setting) and private self-regulation in the shadow of hierarchy and voluntary agreements (Börzel and Risse 2006: 200). These typologies, however, only provide rather formal criteria for the actual capacity of both public and private actors to define the objectives and rationales of action in public-private partnerships.

This question is addressed in more detail by the term ‘governance capacity’, defined as the ability of both public and private actors to define objectives of policy-making and to design the political processes and institutional structures to realise these objectives. It has been argued that the governance capacity of private and public actors depends on the particular strategic constellation of a certain field of policy-making, in relation to three crucial factors: firstly, the problem type present in a given field of policy-making; secondly, the degree of congruence between the scope of a problem and regulatory structures; and, finally, the institutional conditions under which both public and private actors operate (Knill and Lehmkuhl 2002: 86).

The investigation of each of these three criteria give indications about the ways in which public and private actors cooperate, and how their

respective influence plays out in the definition and provision of common goods. With regard to problem types, these can range from simple coordination problems, where both an agreement on the provision of a public good and its regulatory solution exist, to agreement problems, where a common interest in the common good prevails but disagreements exist with regard to the solution (a scenario typical for, i.e., questions of technical standardisation). In this case, distributive conflicts, bargaining processes and concerns of economic competitiveness are likely to be essential for the resolution of a problem. While public actors may still have considerable influence on the resolution of conflicts, private actors are clearly more prominent in the resolution of these kinds of problem. A third problem type is formed by defection problems, where incentives are present for actors to free-ride to achieve economic gains in spite of an overall shared interest in the provision of a collective good (i.e., environmental protection, or the avoidance of food scares). It should be expected that both defection and agreement problems are present in the field of food safety regulation, depending on the economic and legal incentive structure encountered by food producers.

Second, the congruence of problem structures and regulatory structures refers to the question of how far the (geographical, social or technological) scope of a problem coincides with the institutional structure established to deal with it, both with regard to the distribution of tasks between the nation-state and supra- as well as international organisations, and the emergence of transnational structures of private actors capable of dealing with a problem. Clearly, this question concerns first of all the adjustment of regulatory systems within nation-states to international requirements and regulations. Importantly, a point of particular interest for company-based food safety management systems is that efforts of public and private actors to adjust regulatory structures to changing problem scopes emerging from globalisation

and technological change may evolve at different speeds and in different directions, suggesting either public or private leadership in the adjustment of regulatory structures. Apart from the national-supranational dimension, this co-evolution of problems and structures for their regulation therefore also entails a public-private dimension. Finally, the institutional aspect involves classical questions of power and resources in asking about the function of institutions in structuring strategic choices and interactions between the actors involved, both on the side of public frameworks of regulation and private arrangements for the provision of a good.

Large sections of the literature have portrayed the emergence of global public-private partnerships in a rather functionalistic fashion – as arrangements to maintain the problem-solving capacity and effectiveness of public policies against the background of economic interdependencies, increasing scientific and technical complexity of regulatory tasks, and resulting deficits of public authorities to fulfill their mandates. Furthermore, most studies on governance, and public-private regulation more specifically, have put their focus on issues of problem-solving capacity and effectiveness. This article seeks to extend this view by showing how the establishment of public-private partnerships changes also the constellations, interests and power relations between the actors involved in food safety regulation.

As the following case study on the evolution of HACCP systems will show, the establishment of public-private partnership can change the strategic constellation of a policy-field not just by re-distributing tasks and responsibilities between the public and the private sector for given problems and to given ends, but also by transforming fundamentally the underlying definitions of problem types, scopes of regulatory structures, and institutional frameworks, resulting in fundamental shifts in the rationales of action and power relations between the involved actors. An important implication is that shifts in the allocation of responsibility and political power occur not just

between the public and private sector, but also *within* these spheres, empowering some actors over others and privileging certain courses of action. This will be explained in more detail in the following section.

Public-Private Partnership in Food Safety

Governance: The Case of HACCP

The system of Hazard Analysis and Critical Control Point (HACCP) is a preventive approach applied in the food industry to eliminate physical, chemical and biological hazards, and which is used to identify potential hazards in the production chain to be controlled and reduced through key actions, known as Critical Control Points. A key feature of HACCP is therefore that it is not based on the inspection of finished products but on the conduct of a risk assessment and the adoption of preventive measures along the production chain. The concept originally emerged from initiatives by NASA in the late 1950 to develop a system for the production of safe nutritional products for astronauts. The first version comparable to HACCP was developed in 1959 by Pillsbury Company, which started to identify the critical points in production processes at which microbial hazards were most likely to occur. New elements introduced by this technique include in particular the definition of critical limits for different kinds of hazard at the control points at which hazards were most likely to occur, the validation of the prescribed steps by scientifically verifiable results, and the establishment of a full documentation and monitoring system, by which more costly and ineffective testing procedures for finished products could be avoided. Having been presented at the American National Conference for Food Protection in 1971 and been applied in the US Food and Drug Administration regulations in the 1970s, HACCP systems have been integrated into a range of Good Manufacturing Practices of food companies and formed part of numerous

food safety legislations since the end of the 1980s. HACCP is neither a quality management system as such nor a tool for the implementation of general hygiene requirements (concerning general requirements for technical equipment and premises, personnel hygiene, etc), but is integrated in sanitary operating procedures and can ensure food safety only in conjunction with good hygiene practices and good manufacturing practices.

Following its adoption by the American FDA, elements of HACCP have also been integrated into the legislations of many European countries and made part of regulations at the European level. A first move towards the establishment of a legal framework for the implementation of HACCP systems at the European level was made through EU Directive 93/43, mandating five of the seven principles for parts of the food industry. This framework was later followed up through the 'Hygiene Package' of three Regulations and one Directive,¹ which were adopted in 2004 and entered into force on 1 January 2006.

The methodology of HACCP is described in the Codex Alimentarius document 'Recommended International Code of Practice-General Principles of Food Hygiene', which identifies seven elements in the application of quality management systems.² These elements are implemented in three main steps: firstly, a hazard analysis for the production chain is undertaken by assembling a multidisciplinary team, setting up a description of the product (composition, structure, processing, packaging, storage, consumption, microbiological and chemical criteria etc), defining the intended use, and constructing a flow diagram with a description of the manufacturing process for the product in question (including information about working premises, equipment layout, sequence of all process steps, technical parameters of operations, flow of products, segregation of dirty and clean areas, etc). Secondly, management critical control points are identified to ensure that appropriate control measures are effectively designed and implemented;

subsequently, critical limits are specified (corresponding to the extreme values acceptable with regard to product safety in terms of temperature, time, pH, moisture, additive, salt level, visual appearance or texture, etc), monitoring procedures are designed at critical control points, and corrective actions identified. The third main step consists of the verification and documentation of the HACCP system including audits, the inspection of operations, confirmation procedures that CCPs are kept under control, validation of critical limits, and documentation and record keeping of all activities.

In practice, control of the implementation of HACCP systems by public authorities are mainly limited to checks that a HACCP plan is in place, that critical control points have been identified, and that systems for the verification and documentation of a corresponding system have been established. Another important point is that general hygiene requirements are separated from the more specific checks and measures based on HACCP, and that these have been developed according to the established guidelines (BfR 2006). It is important to add that Community legislation does not contain a requirement for HACCP procedures to be certified under specific quality assurance schemes. Initiatives to implement HACCP systems through certification schemes are therefore considered to emanate only from private initiatives; the only assessment provided for under Community law is an assessment by the competent authorities in the Member States (Commission 2005). Therefore, enterprises do not need not to resort to external assistance or expertise to put HACCP systems in place; however, the broad range of expertise required for the conduct of the first step of hazard identification often requires such a move, especially for smaller enterprises.

The establishment of a European legal framework for the implementation of food safety management systems based on HACCP reflects efforts by DG SANCO of the European Commission to develop a sufficiently open, flexible approach that recognises different approaches

towards HACCP and tries to reduce implementation costs, especially for smaller enterprises. To this end, a series of meetings were held with experts from the Member States as well as representatives of producers, industry, commerce and consumers to discuss issues related to the implementation of HACCP based procedures (Commission 2005). In this context, one of the main concerns is that in many parts of the food and retail industry, full HACCP plans cannot be developed because of the size or structure of businesses, especially with regard to the documentation and verification of quality management systems. Against this background, European regulations prescribe the application of food safety management systems based on HACCP principles without requiring the implementation of a full system in all cases.

More specifically, Regulation 853/2004 on the hygiene of foodstuffs requires food business operators to put in place quality management systems that are *based on* Hazard Analysis Critical Control Point (HACCP) principles (Article 5), while recognising that the full application of HACCP is not yet generally feasible³ and adding that the need for establishing documentation and records must be commensurate to the nature and the size of the food business (Article 5 (2) g). The regulation also seeks to strike a balance between private and public responsibilities, stating that the implementation of procedures should reinforce food business operators' responsibility (Article 1) while recognising that HACCP should not be regarded as a method of self-regulation and should not replace official controls⁴ (Rec. 13). Furthermore, it is stressed that the provision of evidence documenting compliance with HACCP should take account of the nature and size of the food business (Article 5). In this context, one of the recitals of the Regulations expressly states that the application of the HACCP requirements should provide sufficient flexibility to be applicable in all situations.⁵

The main requirement established for businesses through European legislation is therefore to establish control systems according to the key HACCP principles, while recommending the implementation of full HACCP systems to comply with the principles of consumer protection and producer liability enshrined in the GFL, and due diligence clauses in many national legislations (such as the British Food Safety Act). Many enterprises integrate HACCP in quality management systems to demonstrate compliance. Furthermore, it is recognised that in food businesses in which there is no preparation, manufacturing or processing of food, all hazards can be controlled through the implementation of the prerequisite requirements (for example in the case of marquees, market stalls and mobile sales vehicles, establishments mainly serving beverages (bars, coffee shops etc.), small retail shops (such as grocery shops), and the transport and storage of pre-packed food). In these cases it can be considered that the first step of the HACCP procedure (hazard analysis) has been performed and that there is no further need to develop and implement the other HACCP principles.

The attempts made by the European Commission to exempt smaller businesses from HACCP requirements has also given rise to controversial debates about the correct balance between flexibility and food safety in recent months. In this context, the European Commission has developed a draft proposal to amend Article 5 of Regulation 853/2004 under its Better Regulation initiative and exclude food businesses with fewer than ten employees from being required to put in place food safety management procedures based on HACCP.⁶ DG SANCO argues that its proposal would mean that small food businesses would only be excluded from the requirement of establishing a document for identifying and controlling hazards in food and would have to meet all other requirements. This proposal has met with strong resistance from some national food safety authorities, whose representatives argue that the application of hazard identification and

control techniques should not depend on the size of an undertaking but on the risk in a given production or preparation process. It has also been argued that it is precisely small enterprises that are often the source of food hazards such as salmonella.⁷

These observations indicate that the recent adoption of European regulations through the 'hygiene package' has not led to a centralisation of competences for food safety management systems at the European level. Instead, the legal framework for the establishment of company self-regulation through HACCP systems presents itself as a multi-level structure, involving both national and European laws as well as internationally defined principles and requirements.

How is the governance capacity of public and private actors affected by the emergence of this complex framework of rules and requirements? This question will be discussed in the following paragraphs, according to the three criteria of investigation presented above.

Problem Type

At first sight, the introduction of quality management systems in the food sector may appear as a defection problem: producers may have the incentive to free-ride on the introduction of food safety standards across industries, taking advantage of the contributions of other market participants and the general improvement of quality standards while compromising on their own standards to avoid costs and therefore improve their market position. This assumption, however, stands in contrast with the observation within several empirical studies that, in many cases, food companies introduce quality management systems that are more stringent and that go beyond the minimum standards prescribed by public regulation (Fulponi 2006: 4). Surprisingly, retailers frequently set their quality standards above the minimum standards even in cases where these are not communicated to

consumers (i.e., by premium labels) and, therefore, used for a differentiation of products in response to consumer demands for higher quality (Fulponi 2006: 4).

This observation raises a question about the incentives of firms to comply with voluntary quality standards. Generally, a consideration shared by all producers and retailers in the food market is the objective to keep markets stable both generally, in order to avoid disruptions through food safety crises, and to achieve and maintain consumer trust in their own products. In this sense, reputation is apparently a very strong incentive for retailers to implement quality management systems that go beyond minimum standards (Fulponi 2006: 6). Furthermore, European legislation on hygiene requirements has shifted responsibility to producers and retailers through its traceability and liability requirements and has therefore greatly increased the pressure on enterprises to implement high quality standards (ibid.). Beyond these general considerations, however, the introduction of private voluntary standards offers incentives to producers to implement food safety management systems in two quite different forms of strategy.

First, producers and retailers may agree to implement private standards in place of missing or inadequate public standards with the aim of increasing the safety of products generally and to maintain the confidence of consumers. In particular, retailers may be interested in increasing the quality of products supplied by farmers in general, thus making sure that products meet certain safety standards and to avoid food safety crises that would disrupt the functioning of markets for all retailers and producers. In this sense, the main incentive for the implementation of private food safety standards is related to a 'public good' or providing safe foods to all consumers and to raise food safety standards in general. A positive side-effect of this strategy for private actors may be that by implementing tough standards they can convince regulators to 'leave them alone' and refrain from direct regulatory

intervention (Codron et al. 2005: 272; Henson et al. 2005: 245; Bernauer and Caduff 2004: 16).

In contrast to this first strategy, however, the introduction of privately managed food safety systems offers great incentives for firms to establish systems that meet public minimum quality standards, but that go beyond them by offering specific premium products that target specific consumer segments (i.e., those interested primarily not in the price and quantity, but quality and safety of a product). Such premium product lines are frequently (although not exclusively) linked to the branding of products, which can therefore be distinguished from general product lines by the consumer. Prominent examples of such premium product lines include Loblaws' President's Choice, Tesco's Nature's Choice and Carrefour's Filière Qualité (Fulponi 2006: 7). Branded products can therefore be made to communicate quality and process characteristics through private standards that would not be visible from requirements set through public regulation – an important incentive for retailers to develop these standards and replace public by private regulation. In this sense, private standards are used as a tool for product differentiation, which can be considered a 'private good' produced through a market mechanism in which consumers agree to pay higher prices for products that are superior in appearance, quality, taste, smell, and other attributes. It is noteworthy, furthermore, that quality labels are often not confined to attributes of a product, but also relate to social and ethical aspects of production methods (fair trade, minimum social standards such as ILO conventions, etc), as well as ecological and animal welfare aspects (Hatanaka et al. 2005: 356; Fulponi 2006: 8). Although not required by HACCP principles, the establishment of branding schemes and quality labels is closely linked to the establishment of company-managed food safety management schemes: these are used strategically by companies to target specific consumer segments or gain access to specific markets (Hatanaka et al. 2005: 356).

The rationale for retailers with regard to the objective of food safety, however, is more exclusive than in the first example, as branding is used to distinguish certain products from others on the market and therefore to shield them from food safety crises on the market. The achievement of food safety and consumer trust is therefore linked to economic incentives and privatised through the instrument of consumer choice. It is also clear that firms trading primarily with brand products appear more willing to implement HACCP systems (Bernauer 2004: 14; Codron et al. 2005: 272). As stated above, the differentiation of food products through private standards appears intrinsically linked to the transition from the 'materialist', price- and quantity-based competition of retailers to a more 'post-materialist' form of competition based on the quality, origin, as well as the production and trading methods used for the production of foods (Busch and Bain 2004: 324). In this context, retailers in particular are incentivised to use the application of food safety standards strategically to insulate themselves from food safety crises, gain consumer trust, to differentiate products, and to gain access to specific segments of the market (Hatanaka et al. 2005: 356).

Against this background, many of the difficulties in relation to the introduction of quality management systems based on HACCP present themselves as agreement problems, characterised by a common interest in the provision of a common good and disagreement about the regulatory solution.

This is demonstrated by the fact that the introduction of HACCP standards in Europe has not led to the introduction of a single process standard that is recognised across Member countries. Instead, various certification systems based on the principles of HACCP have emerged mainly through initiatives of major retailers and which are not easily compatible with each other. One of the first of these standards was the British Retail Consortium (BRC) Food Technical Standard,⁸ developed in 1996 by companies including Safeway, Tesco, Sainsbury, Somerfield, Boots and

Waitrose as a list of criteria for auditors for suppliers and food companies. One of the main aims of this standard was to avoid a situation in which each of the major retailers had to conduct audits with its suppliers individually. The introduction of this standard did not, however, prevent single retailers from establishing additional requirements for their suppliers and mandating single specific auditing institutes or even its own company auditors to apply these standards. This led to the situation that producers and food companies frequently had to undergo a variety of auditing procedures required by different retailers, in spite of having undergone the audit for the generally applied food safety standard. Obviously, the multiplication of such audits creates a major burden especially for smaller companies that can face up to 15 audits in order to meet the standards of all the retailers they supply.

Parallel to this development, several quality standards based on HACCP principles were developed through the International Food Standard (IFS),⁹ according to which management systems were introduced mainly in Germany by major retailers such as GLOBUS, Metro, EDEKA, REWE and tegut, and through a HACCP system developed in the Netherlands ('Dutch HACCP').¹⁰ Recognised as a certified standard by the German Federation of Retailer Associations (BDH) in 2002, the IFS is now applied throughout the German food retail industry. Within an international comparison, these European systems for the implementation of HACCP differ significantly to the main American standard FPA-SAFE,¹¹ developed also by food producers in cooperation with retailers.

It appears as a result of these various developments described above, therefore that although HACCP is now broadly accepted as the main process standard for food throughout production and supply in Europe, a variety of certification schemes exist, thus creating obstacles for trade and especially those suppliers that produce for various retailers. Furthermore, the

transparency and effectiveness of food safety management may be impeded by the coexistence of a variety of process standards based on HACCP.

Against the background of this variety of standards, various initiatives have been undertaken by private enterprises to establish a single process standard based on HACCP, which could be applied for all certification systems. The first of these attempts was the development of the Global Food Safety Initiative (GFSI),¹² carried forward by multinational retailers organised in the Food Business Forum CIES.¹³ The success of the GFSI initiative, however, has apparently been only limited, mainly because of the reluctance of the major retailers to accept the common standard.

Another attempt at the harmonisation of food safety management systems is the establishment of the ISO 22000¹⁴ standard by the International Organization for Standardization. Developed by a working group with representatives of 14 countries from all continents, the Codex Alimentarius, the above-mentioned GFSI and representatives of the European food industry organisation CIAA, it is established with the objective of achieving international harmonisation in the field of food safety standards. The new ISO 22000 standard can be characterised as a combination of existing quality standards enshrined in the older ISO 9001 standard, and a system for the implementation of HACCP principles. An important feature of the new ISO standard is that, in contrast to existing systems such as BRC and IFS, it does not include a list of requirements for Good Manufacturing Practice. Instead, ISO 22000 puts the onus on companies to define the best practice that is most relevant to it, thus integrating the definition of best practice into the system of private self-regulation. Being less prescriptive than established standards such as the BRC, the ISO standard therefore puts a greater responsibility on producers to look at their internal system of quality management and to decide how standards can be best achieved. Compared to existing management systems, the introduction of ISO standards would

therefore require some changes in the mindset of producers. It remains to be seen, therefore, in how far the new ISO standard will be accepted as a harmonised standard for all stages in the production chain.

The transition to an internationally harmonised food safety management is, however, unlikely to be easy due to the incentive structure of companies, who use standards not just to avoid food safety problems, but also strategically to address specific markets segments and consumer groups, and to be able to isolate themselves from general developments in the food market. This emergence of 'private authority' also has consequences for the scope and structure of food safety regimes globally, as will be explained in more detail in the next section.

Congruence of Problem Scope and Regulatory Structures

A second criterion for assessing the respective governance capacity of public and private actors is the degree of congruence between the scope of a given problem and the regulatory structures that have been established to deal with it. Given the simultaneous establishment of HACCP principles on the global and European level and the proliferation of quality management systems to implement these principles, it appears that the relationship between problems and regulatory solutions develop on two different levels for the public and private sectors: whereas the development of public regulatory frameworks for the implementation of HACCP is mainly defined in terms of territorially defined units such as national legislations and supranational legal frameworks defined by the European Union, private actors define production standards primarily along production and supply chains, independently of territorial boundaries.

The regulation of the agri-food industry is therefore no longer defined exclusively within national borders but by areas of activity and supply chains defined mainly by large multinational supermarkets. A result of this

development is the emergence of interaction effects between different national legislations and regional standards of public regulation (such as European, African, Latin American levels of standards), as production and supply chains of multinational companies cut across these regulatory areas. Apparently, these interdependencies do not lead to a 'race to the bottom' of food safety standards, but have the effect that supermarket chains adapt to the most demanding standards of the markets they serve in order to reduce coordination and supply costs, thus implementing much more stringent standards than required by public legislation in some of their markets and supplier countries (Henson et al. 2005: 247). The stronger reliance on private standards in combination with the tendencies of trade globalisation and the concentration of markets may therefore have the effect of driving up standards for producers and suppliers, especially in countries with comparably low public standards. As a consequence, private standards developed by enterprises in strongly regulated markets, such as the Eurepgap system, are 'exported' to suppliers in developing countries who need to adapt to such quality management systems in order to remain in the supply chain for large retailers.

The introduction of private food safety management systems may therefore have effects far beyond the regulatory area in which these were initially developed and required by public regulation: although standards may remain voluntary, they may quickly become essential for suppliers to maintain their reputation and be accepted by the retail companies as trade partners, thus making the most established voluntary standards *de facto* mandatory for producers if they want to remain in the supply chain and thus on the market (Hatanaka et al. 2005: 360). It is obvious that very large corporations with a strong degree of buying power have the prerequisites to impose their standards on suppliers, in addition to the fact that these production chains often offer higher prices or other assistance to producers (Henson et al. 2005:

247). Producers from developing countries, on the other hand, may benefit from their inclusion in quality management systems through private standards by being recognised as reliable producers and therefore gaining wider market access.

These developments indicate, therefore, that the definition and implementation of food safety standards is not solely defined by national legislation or regional frameworks of legislation defined by the European Union, but increasingly set through private regimes of companies and their supply chains that extend across territorial borders. It is clear, furthermore, that this tendency is reinforced through the process of concentration on the food markets, especially with regard to very large supermarket chains that operate globally and have an increasing presence in the markets of developing countries as well (cp. Bernauer and Caduff 2004: 15ff.).

Institutional Context

The introduction of private self-regulation mechanisms through HACCP is embedded in a radical change of the institutional framework in which food safety regulation is conducted. Above all, this is primarily a development of internationalisation and Europeanisation: whereas HACCP is a system that was first introduced by the international Codex Alimentarius Commission, its application is now prescribed and structured by European laws and regulations; furthermore, the expansion of multinational companies and the corresponding rise of global private standards is strongly related to the opening of markets reinforced by the World Trade Organisation and the SPS and TBT agreements (Busch and Bain 2004: 325ff.). One of the main consequences for the public regulation of food safety, however, is the vertical fragmentation of authority across the national, regional and international level: whereas the general principles and main steps of HACCP systems have been defined primarily at the international level of the Codex Alimentarius

Commission, it is the regional European level of institutions that has become particularly decisive in the definition of how these principles are integrated into the specific system of risk assessment and risk management as defined by the General Food Law that binds Member States. Given the limited competences of the European Food and Veterinary Office and the leeway which the European regulations give in the application of HACCP systems, it is, however, clear that the key role in the oversight and control of the implementation of HACCP remains at the national, or even sub-national level (as in Germany, where the inspection and control of food enterprises is largely left to the *Länder* authorities; cp. Dressel et al. 2006).

An important consequence is that it has become difficult to assess the governance capacity of public actors on one level in separation from each other, but that different aspects of this capacity are now dispersed on different levels: whereas the ability to define principles of food safety management through private actors is now shared between the international (i.e. Codex Alimentarius) and European level, the capacity of designing the procedures and conditions for their delivery are still mainly defined by national legislation, leaving much room for regional and local authorities to spell out, monitor, and enforce HACCP standards, as well as cross-national diversity of regulations. The shift of responsibilities to private actors affected through HACCP is therefore accompanied by the dispersion of regulatory authority of public institutions in a multi-level system of governance (Bernauer and Caduff 2004: 17f.). Above all, this fragmentation may raise problems in terms of transparency; it is, however, also an example for the emergence of a governance system characterised by a 'complex sovereignty' (Grande and Pauly 2006: 15ff.), in which no regulatory level is independent of the actions of related actors and institutions on different levels.

The introduction of HACCP, furthermore, has also changed the institutional arrangements in which companies of the food sector operate.

Key among these changes is the rise in importance of third-party certifiers (TPCs) and the (both public, semi-public and private) accreditation bodies mechanisms through which these certifiers are authorised to verify the compliance of producers and suppliers with HACCP systems (Hatanaka et al. 2005: 357ff.). Third party certifiers have gained in importance because they are recognised as independent, thus replacing in-house experts for the certification of quality management procedures. The introduction of third-party certification, however, has important repercussions for the relationship between producers, suppliers and retailers: supermarkets are particularly likely to benefit, as they are able to control the quality standards of producers and suppliers without needing to monitor them directly; furthermore, responsibility is mainly shifted up the production chain to the producers, as is liability should a problem occur (Hatanaka 2005: 365).

The rise of third-party certification also has the effect of shifting costs to producers, who need to apply to one of the accredited bodies for certification and subsequently have to undergo pre-assessments, documentation reviews and field audits by the certifier. In most cases, the costs for these certifying procedures are met by the supplier (Hatanaka et al. 2005: 357). For smaller producers in particular, these costs can be prohibitive, as producers are asked to pay a daily fee of several hundred dollars for experts from certifying bodies to come in and inspect local operations, whereas these inspections can be very burdensome for producers in terms of documentation, hygiene, cleaning and premises requirements. Producers, therefore, face the choice of facing these costs or else losing their chance of being accepted as a supplier if they do not take the audit; obviously, this dilemma applies particularly to smaller producers in developing countries where no competent certification bodies exist, and which require external experts from Europe or the United States to come in and undertake audits¹⁵ (Hatanaka et al. 2005: 361).

The Strategic Constellation of Public and Private Actors in HACCP: the Transformative Potential of Public-private Partnerships

From what has been said above, it has become clear that the introduction of HACCP systems has fundamental consequences not just for the procedural forms of policy-making, but also for the rationales, actor constellations and power relations within the field of food safety regulation. In this context, several authors assume that the introduction of private food safety and quality management systems on the basis of HACCP mainly privilege retailers, especially multinational supermarket chains, and are conducive to the development of market concentration, while imposing heavy burdens for smaller producers particularly in developing countries (Busch and Bain 2004, Bernauer and Caduff 2004). Furthermore, the introduction of such systems are seen to lead to a fragmentation of political authority of public institutions across the national, European and international level and therefore question principles of transparency and accountability; instead of the traditional form of hierarchical regulation through law in a closed nation-state, what can be seen to emerge is the establishment of globalised private regimes of food safety regulation across territorial boundaries, which are steered mainly by large multinational food companies with significant power over the distribution of crucial resources such as market access, consumer confidence and reputation.

Several recent developments can be seen to question this perspective. Firstly, recent efforts to establish a globally harmonised standard for the certification of HACCP through the ISO 22000 standard could lead to a development in which the currently fragmented structure of private food safety management systems is re-integrated or at least re-directed towards a single standard, thus increasing transparency, lowering certification costs for producers and allowing for broader market access of companies certified

against this standard. Secondly, recent developments in the legislative framework of the European Union indicate that in the context of 'Better Regulation' initiatives, greater tolerance margins could be given to small and medium enterprises, meaning that larger firms could face more serious costs in the implementation of HACCP systems than smaller ones who are not obliged to fulfill the full circle of requirements. Furthermore, given the increasing importance of NGOs campaigning for the inclusion of social, ethical and animal welfare standards into food safety management systems, the pressure could be expected to be higher on big companies such as McDonald's or Starbucks, as these are more easily named and shamed than smaller enterprises. In the same vein, risks and losses in terms of reputation can also be assumed to be greater for big companies with regard to the principles of traceability and liability, which are now central principles of the European framework of food safety regulation. Finally, the still rather low degree of implementation of HACCP systems may put a limit on the developments described above, especially with regard to smaller producers.

It would therefore be too easy to state that only some specific actors – i.e., say, multinational companies in the retailer sector – gain from the introduction of public-private partnerships whereas others lose out. A more fundamental observation is, however, that many of the basic structures and conditions of food safety regulation are changed by the introduction of HACCP, affecting the way problems are defined, competition is organised and rules of the game are set. The introduction of elements of private self-regulation into the management of food safety is therefore not just a shift towards more private responsibilities within the same basic framework of problems, regulatory structures and institutions, but transforms these underlying conditions. As argued above, such transformative effects can be observed at all three levels of analysis in relation to the governance capacity of public and private actors:

Firstly, with regard to the given *problem types*, the introduction of HACCP signifies the transition from command-and-control systems with typical defection problems to increased responsibility of the private sector on the basis of quality-based competition, leading to a differentiation of standards, the introduction of branding and premium labelling schemes and the emergence of agreement problems between different certification systems. Whereas the governance capacity of public actors with regard to these types of problem appears limited, economic incentives for companies to maintain exclusive quality management standards and distributive conflicts on the costs and benefits of agreeing on a harmonised standards can be expected to gain in importance. Strongly related to this problem is the increased politicisation of food safety issues and the growing public perception of food scares, which can be seen to reinforce the tendency towards a quality-based competition.

Secondly, with regard to the *congruence of problem structures and regulatory structures*, we observe a discrepancy between public regulatory frameworks, which are defined mainly along territorial lines, and private quality management systems, which are organised along production and supply chains. While both structures of regulation are not congruent, interaction effects can be observed through the adjustment of standards within supply chains to the toughest market they serve, whereas the definition of standards through public regulation is differentiated in relation to size of enterprises. The effect may be that a small enterprise in Europe has to face lower food safety requirements than a fruit plant in Africa serving a European business. The level of regulation is therefore no longer entirely set by territorial boundaries, but increasingly depends on the position of an enterprise within the market.

Thirdly, with regard to the *institutional framework*, the development of HACCP takes place in the context of a dispersion and fragmentation of regulatory functions across various levels. Simultaneously, the institutional

arrangements within the private sector witness a shift of responsibilities towards producers and suppliers and the rise in importance of third-party certifiers, whereas retailers appear to benefit most from the introduction of HACCP in terms of costs and responsibilities. Fundamental changes have therefore taken place not just between the public and private sector, but within these sectors: whereas the competences of public actors generally may be strong in terms of defining objectives and procedures of food safety regulation and sanctioning non-compliance, the actual capacity to act of regulators on each of these levels is limited by the dispersion of tasks across the national, European and international levels. Whereas the general principles and tasks of HACCP are now defined almost exclusively at the international level, it is mainly the national and local level that remains responsible for the application, implementation and supervision of these systems. In between these levels, the European Union can be seen to act in an intermediate function of defining in how far national legislation should converge and how much leeway should be given in the application of company self-regulation (i.e., in the case of smaller enterprises). The European Union also appears to play a central role in balancing the objective of food safety with negative externalities in other areas, as expressed in the tension between the 'Better Regulation' objectives of providing generous exemptions to smaller undertakings, and the principle of the highest standard of consumer protection.

Conclusions

Against the background of a literature on private self-regulation that is primarily concerned with procedural and structural concerns, this Chapter has tried to highlight the strategic aspects (i.e., those concerned with conflict and power) and the transformative effect of new forms of public-private governance such as HACCP on the interests, actors and institutional

frameworks of policy-making. Public-private partnership, in this context, is not simply a different, and potentially more effective, means to address given problems through changed procedures. It changes the way problems and the scope of regulation are defined, changes the allocation of political authority in institutional frameworks, and has both empowering and excluding effects on both economic and political actors. Such questions of power and interest, however, deserve further attention in research of governance through private actors, which has focused mainly on the issues of problem-solving effectiveness.

Another lesson to be learnt from this case-study is to provide insights into how the evolution of public-private partnerships causes shifts of responsibility and political power not just between the public and private sphere, but also *within* these sectors, especially between different actors in a production chain, and between the different levels of regulation across the national, European, and international levels. To integrate these insights into existing typologies of public-private cooperation, which treat the public and private spheres as relatively closed and unitary, is an issue that research on governance through private self-regulation has only just started to address.

Notes

¹ These include: Regulation (EC) 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, *OJ L 139*; Regulation (EC) 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, *OJ L 139*; Regulation (EC) 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official

controls on products of animal origin intended for human consumption, *OJ L 139*; and Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC, *OJ L 157*.

² These steps include: (1) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels (hazard analysis); (2) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; (3) establishing critical limits at critical control points that separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (4) establishing and implementing effective monitoring procedures at critical control points; (5) establishing corrective actions when monitoring indicates that a critical control point is not under control; (6) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in paragraphs 1 to 5 are working effectively; (7) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in paragraphs 1 to 6.

³ Regulation 852/2004/EC, *supra* note 1, Recital 11.

⁴ Regulation 852/2004/EC, *supra* note 1, Recital 13.

⁵ Regulation 852/2004/EC, *supra* note 1, Recital 15 states: ‘The HACCP requirements should take account of the principles contained in the Codex Alimentarius. They should provide *sufficient flexibility in all situations*, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical points. Similarly, the requirement of establishing ‘critical limits’ does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents *needs to be flexible in order to avoid undue burdens for very small businesses*’ (emphasis added).

⁶ Cp. EU Food Law Weekly, 4 May 2007.

⁷ Cp. EU Food Law Weekly, 4 May 2007.

⁸ For further information, see: <www.brc.org.uk>.

⁹ For further information, see: <www.food-care.info>.

¹⁰ For further information, see: <www.foodsafetymanagement.info>.

¹¹ For further information, see: <www.fpa-safe.org>.

¹² For further information, see:

<www.ciesnet.com/2-wwedo/2.2-programmes/2.2.foodsafety.gfsi.asp>.

¹³ For further information, see: <www.ciesnet.com>.

¹⁴ See:

<www.iso.org/iso/en/CatalogueDetailPage.CatalogueDetail?CSNUMBER=35466&ICS1=67&ICS2=20&ICS3=>.

¹⁵ As a drastic example, Hatanaka et al. note that in Ghana only one individual is qualified, but is not accredited to certify according to EUREP standards, thus requiring certifiers from Europe to come in (Hatanaka et al. 2005: 362).

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Chapter 8

Inspecting Aviation Safety in the EU: EASA as an Administrative Innovation?

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Introduction

Following regulatory theory as presented *inter alia* by Majone (1996, 2000; Moran 2002), EU agencies can play major regulatory functions that could lead to better policies. They can contribute to, among others, more consistency between policies, providing the evidentiary basis of policies and to better enforcement and greater transparency. Moreover, agencies can support the EU administration through flexible and professional management (Gérardin et al. 2005). Their expertise and independent input is supposed to lead to a depoliticisation of policy issues and may contribute to better risk assessment and risk management as well as to greater transparency (Vos and Wendler 2006).

However, as is becoming clear from recent reviews, EU agencies have turned out to be rather different in practice (Craig 2007; Dehousse 2007; Tarrant and Kelemen 2007). Most of them have become regulatory agencies without regulatory powers (Majone 2005: 97). Although there are some

powerful agencies, such as EMEA (medicines agency) and EFSA (food agency), most have become primarily information-giving bodies (Gérardin et al. 2005: 71). Hence, EU agencies ended up in some sort of 'in between situation'. They are a nuisance to some who regard them as complicating their traditional ways of working while others see them as insufficiently developed compared to the position independent regulatory agencies could occupy (Schout 1999a). In the midst of institutional pulling and hauling, agencies have become too important and heavy for some but too weak for others.

Nevertheless, it seems that agencies somehow seem to be able to carve out an acceptable position in EU policy-making. They seem to emerge from negotiation processes in which no one gets what (s)he wants but they are nevertheless regarded as useful once in operation. This process of institutionalisation of (EU) agencies has only just begun as a research theme. In the wide set of variables that shape an agency, Selznick points in his seminal work to the role of the Executive Director (1957). Others focus on principal agency theories, political negotiations and institutional constraints to explain the EU's agencification (e.g. Moe 1987; Thatcher and Stone Sweet 2002; Kelemen 2002; Dehousse 2007).

Importantly, rational behaviour is one of the major driving forces in these theories (Coen and Thatcher 2007; Tarrant and Kelemen 2007). In the negotiations during the setup and in the subsequent negotiations in agency boards and between agencies and Commission, the actors are assumed to understand what it means to create an EU agency, to know their interests, and to be able to create the appropriate conditions for agencies in terms of budgets and other organisation conditions. These negotiations have led to compromises that seem incompatible with the nature of independent agencies. For example, most EU agencies have task descriptions that underline their independence while having Management Boards filled with

Member States meddling with many details of the agency's daily business. Even the term 'Management Board' used in some agencies is strange in view of the fact that the executive director is supposed to be the independent manager of the agency (Schout 1999a). Such outcomes are the result of the negotiations between Commission, EP and Member States who, according to the rational theories, strive for power, control and influence (Kelemen 2002; Thatcher and Stone Sweet 2002; Dehousse 2007).

Having identified rationality as one of the core elements in EU agency literature, this article examines whether the behaviour of the actors involved in the set-up of agencies is indeed rational. Evidently, 'rationality' in public sector processes is a complicated term and relates to questions such as rationality in the interest of whom? For example, rational in relation to the preferences of the public, the minister, or civil servants (compare Radaelli and de Francesco 2007)? Given information constraints, are people at all able to operate rationally (Simon 1976)? We understand rationality as the ability of actors to identify their objectives and to gather the necessary information about the variables involved (Denhardt 2007). With our interest being in identifying the rationality in the process of institutionalisation, our objective is rather limited. It is not our intention to examine whether alternative models such as the garbage can model would be more appropriate to explain the EU's agencification (March and Olsen, 1976). Instead, what we really want to know is whether the negotiators know what they are doing.

The focus of this Chapter is on the institutionalisation of EASA (the European Aviation Safety Agency) and we will examine in particular the elaboration of its inspection powers. EASA is an interesting case because it was initially supposed to acquire major inspection powers, even though Member States have been keen to respect the principles of subsidiarity and their institutional autonomy. In general, enforcement is in the first instance the responsibility of the Member States.

The set up of EASA has been very ambitious and as such it shows the trend within the EU of evermore and evermore powerful EU agencies (Monda, Schout and Vos, forthcoming). It has been given semi-legal powers. Some of its 'soft measures are quite hard' (as expressed in an interview). Law-making is the responsibility of the Commission but the implementing measures that EASA produces – often in the form of guidelines – are close to obligations. Planes and organisations have to meet the requirements of the guidelines. If Member States or national organisations opt for alternative arrangements they have to obtain approval from EASA. Moreover, EASA gives certificates to types of planes. This can have horizontal effects because, if the certificate is withdrawn, this will affect all owners of such planes. Hence, EASA measures border on rule-making. Furthermore, where EASA assists the Commission in law-making, the Commission can not change the opinions of EASA without prior coordination with the agency.

EASA's prominence is also clear in relation to inspection and enforcement. Originally, EASA was supposed to have independent inspection powers. Moreover, to give EASA more of a bite and avoid time consuming infraction procedures, it has been given the power to ask the Commission to impose fines (in 2007).

Taking these powers together, it is clear that at its creation, EASA implied a centralisation of tasks. Its creation was set in the context of moving safety regulation and enforcement tasks from the NAAs (national aviation authorities) to Köln.

This study addresses how these inspection powers have matured. Has EASA developed into the powerful and centralized body it was supposed to be at its inception? In other words, has EASA generated the major institutional innovation in aviation inspection that it was intended to do? How can this development be explained?

To understand the development of its responsibilities, we compare key texts which emerged throughout its institutionalisation process. These are mainly the Commission documents for the creation of EASA,¹ the Basic Regulation (BR1592/2002)² and the several drafts that were on the table until the final adoption of its first task enlargement at the end of 2007. The Finnish presidency in the second half of 2006 was particularly keen to finish the negotiations in the Council with a political agreement. Although few thought they would succeed, if only due to the many footnotes in the text, the presidency achieved its objective among others by producing presidency proposals without footnotes. This is already telling: Member States put a lot of energy into the negotiations, coming with negotiation instructions and scoring footnotes which were subsequently graciously removed *en masse*.

Secondly, throughout 2006 and 2007, close contact was kept with key officials from EASA, the Commission, the European Parliament, the General Secretariat of the Council, national ministries, permanent representations and several NAAs. This made it possible to follow the negotiations and to unveil the reasons behind the actions of the negotiators. The findings of the analysis was checked by writing a report for the Dutch ministry for transport on the development of EASA (Schout 2007a) and by discussing this report with the various stakeholders.

In the remainder of this Chapter, we will first discuss the development of EU agencies more generally and focus on the question of whether they are mere quantitative developments of the EU's toolbox or whether they change the EU governance system more profoundly. The subsequent section addresses the development of EASA more generally to better understand the development of its powers. The next section discusses principles of enforcement in the EU. This provides the basis for examining the formulation of EASA's enforcement role. Although this chapter deals with the emerging pattern of EASA, the interviews also give insights into the

agency's effectiveness. A discussion of its operations, followed by a review of the main arguments, concludes this Chapter.

EU Agencies: More of the Same or a New Instrument?

It is important to understand the EU's agencification and to understand their institutionalisation because, as several interviewees in the EU administration presented it: EU agencies are 'mushrooming'. This is clearly visible in the EU's transport policy, where agencies have been created for aviation safety and environmental standard-setting (EASA), maritime safety (EMSA) and rail transport (ERA). Options for additional agencies are being discussed, such as in the field of inland waterways and air traffic management (incorporating Eurocontrol into the EU). This fits the general trend of 'agencification' of the public sector more generally (Wettenhall 2005). Pollitt (2003: 6-7) defines agencies as 'functionally disaggregated' from departments and enjoying 'some degree of autonomy'. Hence, this agencification is not intended to be just a new instrument, but a change in governance towards granting a role to independent expertise.

Limiting ourselves to the EU, agencies have been created for different reasons. First of all, they are part of the governance debate which began at the end of the 1990s and which addresses – among other things – ways in which to accommodate the demands of technologically advanced societies. By complementing political decision-making with expertise and independent advice, agencies limit the freedom of politicians (as is the case with the European Central bank, Majone 1996). Generally, due to their expertise, agencies can be a major addition to political decision-making and thus contribute to better (i.e. technical) risk assessment as part of the more political risk management (Vos and Wendler 2006). Better monitoring and

enforcement can be an integral part of risk assessment and management strategies. Hence, agencies can contribute in different ways and to different phases of policy-making (from 'pork to fork' as in the food safety). With this, agencies are supposed to be more than just a new instrument – a quantitative change in the EU's administrative structures – but potentially imply a qualitative development of (European) administrative systems.

Moreover, new public management theories have fuelled agencification and this has also affected the EU (Wettenhall 2005; Gérardin et al. 2005). Agencies offer private sector techniques and means of overcoming public sector constraints such as staff policies (limitations on payment, avoiding tenure contracts, etc.). Although being far from happy with agencies, the Commission embraced them often for pragmatic considerations, viewing them as offering ways to circumvent its (human) resource limitations.

But there have been other pragmatic considerations. Some agencies were created so that all heads of state could claim successes when European Council meetings had to take decisions on the location of agencies (Schout 1999a). Other agencies were formed by accidents and crises that demanded visible proof that the EU was dealing with the problems (Krapohl 2004). This variety of backgrounds has contributed to major differences in terms of tasks and operations of EU agencies.

One of the characterising features of EU agencies is that they are, usually, a network organisation working closely with national capacities. An EU agency is usually the organiser of the network. It seldom takes over tasks from the Member States but instead provides a framework for cooperation between national authorities. Subsidiarity-type network arrangements seem to be the model for EU agencies (Everson et al. 1999; Chiti 2000). Agencies can be created bottom-up, i.e. offering network-management to national agencies (Schout 1999a). They can also be created top-down in the sense of breaking up EU competencies. For example, competition policy was first highly

centralised to the extent that DG Competition could be regarded as a very powerful EU agency. To unburden the Commission and to build up capacities for competition policy at the national level, the management of this area was decentralised by creating national competition authorities which cooperate closely within the European Competition Network (Wilks 2005).

This mushrooming is in many ways a remarkable development. Despite a growing critique of agencies in the Member States and of EU agencies, we nonetheless see ever more and ever stronger EU agencies being created (Dehousse 2007) up to the point that the EP concluded that is hard to establish how many agency-type arrangements the EU currently has (EP 2007). Moreover, although initially being heralded as solution for the EU's legitimacy crisis (Majone 1996), numerous critical assessments of agencies have since been published. Firstly, there is a discussion about the true advantages of agencies in general as well as of EU agencies (as expressed in interviews with national and EU officials, but see also Monda et al forthcoming). EU agencies and agency-type structures have been presented as, *inter alia*, a sort of a 'run-away bureaucracy' (Martens 2005), as leading to mono-dimensional expert values instead of to balanced policy judgements (Chiti 2000), and as contributing to an expansion of the Commission's influence over Member States (Wilks 2005). Similarly, MEPs have warned of a re-nationalisation of EU competencies and an uncontrollable and non-transparent development (EP 2007). Academics have commented on the limited extent to which agencies have been able to acquire powers in the 'regulatory state' (Moran 2002; Everson et al. 1999; Thatcher 2002; Gérardin, Munoz and Petit 2005: 71; Majone 2005). In short, EU agencies are one of the most criticized elements within the EU governance debate.

Even though there is very little systematic analysis of the effectiveness and efficiency of EU agencies, when it comes down to their contributions, EU agencies seem to be doing rather well. Not one of the EU agencies is

facing a fundamental discussion about whether it should be dissolved. Agencies and agency-type network arrangements seem to fill gaps in national networks and contribute to the need for more and better information and analysis (Eberlein and Kerwer 2004). Moreover, there is a rather widespread assumption that agencies have altered governance patterns (Coen and Thatcher 2007).

Almost all agencies are regularly evaluated and such assessments are generally very positive.³ Despite doubts about the appropriateness of the influence of management boards, imprecise task descriptions in Regulations, sensitive – if not hostile – relations with Commission and Member States, and a lack of resources, EU agencies somehow seem to find their niches and to develop effective patterns of functioning. The European Environment Agency (EEA) is a case in point. It started as a truly chaotic body that probably only few really wanted and which was partly created because it was, in 1994, necessary to have enough agencies to satisfy each capital (Schout 1999a). Yet, upon its launch, the EEA in fact had many tasks to fulfil because, rather than choosing between tasks, the Member States and Commission simply added all the tasks that were mentioned during the negotiations; moreover, it receives a small budget and has needed to work, in the course of fulfilling its assigned tasks, with a wide range of very different national agencies. Nevertheless, after a few years it became clear that the EEA was developing into an organisation with a workable set of roles, a set of effective work planning mechanisms and quality control procedures that no one could have anticipated from the constituting negotiations. By now, the EEA is a highly regarded organisation and its pronouncements are widely quoted in policy and academic documents (Hoorbeek, 2004; Jordan and Schout 2006).

Despite these successes, one can wonder whether the EEA is something ‘new’. It produces reports that, to a large extent, could have been presented by consultants and national agencies or similar bodies (which now work with

the EEA). The added value of the agency structure therefore remains in doubt (Schout 1999a). It has not developed into the independent regulatory type of body that is usually associated with the agency concept. That does not mean that the EEA underperforms but it shows that its role has been limited to information gathering.

The fact that EU agencies seem to be functioning rather well albeit that they do not seem to be revolutionary – leaves us with a fundamental question: why are there so many complaints about EU agencies? The answer may be that for those who had hoped that agencies were something new, the agencification of the EU is disappointing as it fell short of the regulatory agencies more common in the US (Everson 2001). Alternatively, for those less convinced of the need to create independent bodies, the new agencies add little or even tend to complicate the EU's traditional policy-making mechanisms. The latter view has been often expressed in interviews with practitioners in several EU agency studies (Schout 1999a; Schout 2007a).

EASA – A Coincidental Success

Development of the EASA System: from ICAO, via JAA to EASA

EASA is a good case to study the institutionalisation of an EU agency. It was originally intended to be centralized – taking over national tasks – but it ended up being rather 'more of the same' (Schout 2007a). Although creating fears that it would take over tasks from NAAs, it has barely done so (thus far). Nevertheless, it may have been one of the contributing elements to the improvement in aviation safety, even though it also failed to develop into the regulatory agency that one would expect on the basis of (Majone's) regulatory theories. Despite its centralized origin in relation to rule-making and enforcement, it has developed into the network-type arrangement rather similar to what seems to be the normal pattern for EU agencies (Everson et

al. 1999; Chiti 2000) and similar too to the situation that existed in the EU's aviation safety organisation prior to the establishment of EASA (Schout 2007a).

A milestone in the history of aviation safety was the ICAO agreement (International Civil Aviation Organisation) dating back to the Chicago Convention in 1944. ICAO sets minimum standards that have to be implemented at the national level. To date, ICAO knows only Member States and has no supra-governmental representation. In other words, the EU is not a formally recognized actor but this may change in the future and with this, EASA's involvement in ICAO may become a more direct one (Schout 2008). In Europe, countries were working towards harmonisation of cross-frontier air traffic on the basis of JAA standards. ICAO related work was arranged through the pan-European Joint Aviation Authority (JAA), through which the national aviation authorities from 39 countries were organised.

ICAO also has an inspection mechanism based on visits, reporting procedures and follow up inspection visits. In the light of heavy criticism of ICAO, these reports are now increasingly made available to the public with a view to transparency and sharpening peer pressure. Within Europe, JAA had organised these inspection tasks. When EASA was created, it took over these inspection tasks from JAA together with the regulation tasks.

The problems with JAA were many and proved that it was not the basis for liberalisation of the EU's aviation sector. The situation resembled the conditions in other economic sectors in which EU agencies had been created. There were many delays in agreeing on rules implementing the JAA objectives, a lack of commitment from member countries towards the JAA's non-binding legislation, industry being faced with many different national requirements, and unanimity voting preventing clear legislation and resulting in protracted decision-making (e.g. CEC 2000a). One indication of the existing fragmentation was that one Member State estimated that it had

modified approximately 4000 of the JAA rules in the national implementation process (interview in 2007). Moreover, there were inspection difficulties due to the sensitivities of inspecting each other's planes and maintenance bodies. Grounding an aircraft from major economic counterparts or from countries with sensitive political relations was not an option. For example, any country taking measures against the USA would have to be prepared for counter measures. Similarly, Belgium grounding planes from Congo would be rather problematic.

Moreover, as interviews show, the costs for industry of going through 25-27 different procedures in the EU were enormous, especially in view of the fact that a plane consists of thousands of parts. Each individual part has to be certified and these certifications have to be regularly reviewed. More concretely, the development of the Airbus 380 demanded quick market access while costs of certification had to be kept within competitive margins. During the 1990s, the Commission became more involved in aviation safety but a fully developed department for aviation rule-making and enforcement was not feasible. Enlargement imposed severe limits on the Commission's abilities to take on new tasks. Hence, the search was on for an alternative solution.

The option that was initially considered for stabilising aviation safety was to make the JAA's work binding through a pan-European treaty. The choice for the agency format was not immediately evident and in the 1990s the mood within the Commission was not in favour of yet another agency. One of the sources of resistance to agencies was the threat they posed to the roles and powers of the Commission.

However, due to the personal preferences of the relevant Director General in the Commission, Mr Lamoureux, the treaty plans were abandoned in 1999 and the proposal for EASA emerged with record speed soon after that in 2000 (CEC 2000a, 2000b). In interviews, Mr Lamoureux

was described as ‘a federalist’ who wanted a strong EU solution. He was even characterized as an ‘enemy of intergovernmentalism’. Moreover, he was in favour of agencies more generally. The change in preference signifies a move away from a more intergovernmental pan-European solution with an unclear role for the Commission towards an EU arrangement with a strong agency. This move paralleled concerns in some Member States that did not want to manage yet another treaty through their Parliament. With this coincidental dislike of handling treaty negotiations, the Member States also began to take a more relaxed view of the agency solution, making it possible for the Commission to propose an agency.

But there were other reasons for the decision to create a strong agency and for centralising tasks within the EU. The problems created by the loose JAA structure had resulted in a broadly shared belief that Member States had to be put at a distance. Aviation policy was politically too sensitive and Member States could not be trusted to loyally implement JAA standards. The incentive to impose rules that favoured their carriers or airports was too great. The aim of avoiding governmental micromanagement also affected the position of the Commission and supported the argument for an independent agency outside Brussels. Furthermore, the industry itself wanted an efficient and effective system, and feared continuous pressures and interference from – in particular – the major aviation countries. A situation had to be created that would not lead to extra powers for the big countries.

Finally, inspections of foreign planes can be very sensitive and Member States have shied away from such measures for fear of eliciting retaliation or of endangering international relations. Hence, a system based on collective oversight and European enforcement powers was seen to be the wiser approach to the inspection of foreign planes.

As a result of these pressures and convictions – and despite legal doctrines such as the Meroni principle – the EU seemed ripe for a strong agency with rule-making and enforcement powers.

Early Years

Starting in Brussels in 2003, EASA opened in Köln in 2004 and was supposed to acquire a staff of approximately 600 full time positions. The starting up phase was extremely difficult. As a result of the unavoidable looseness of drafting in the Basic Regulation (1592/2002), there were many issues to be settled including the question of how to organise inspections, who would be allowed to work on the inspection teams and what kind of transparency would apply to inspection reports. The agency also had to learn the hard way that it could not expect to have 600 staff at its disposal in the foreseeable future. Therefore, it could not operate independently from the NAAs but instead remained highly dependent on national capacities.

Hence from the start, there was a clash between centralisation (moving tasks to Köln) and decentralisation (subsidiarity or network-type arrangements with NAAs). The result was a potentially dangerous confusion. Member States were under the assumption that they could discontinue certain actions while EASA lacked the budget to hire sufficient people and, more importantly, has had to comply with the EU's complicated hiring arrangements. In order to avoid situations in which agency staff automatically become EU staff (with all the benefits that such status entails), agencies are only allowed to hire on the basis of temporary positions, and these temporary employees are paid as junior officials (Pereyra forthcoming). Hiring a test pilot on the bases of a junior EU official salary proved difficult, and seconded EU officials on temporary contracts were happy to move back to Brussels (Schout 2007a). This, plus the fact that Köln lacks the prestige and international facilities (e.g. schools) to attract staff, has prevented EASA from developing the expertise needed for its work.

As a corollary, it seemed likely that the total amount of expertise in the EU would go down rather than increase because of the lack of resources and inadequate staffing policy. NAAs started to provide less services whilst EASA was not yet able to take over. The House of Commons Transport Committee issued a highly critical report in October 2006 (The House of Commons Transport Committee 2006), which subsequently made the BBC news with the headline 'EASA threatens aviation safety in the EU'.

There were other threats to the effectiveness of EASA. EASA's Management Board did not grant the agency a realistic budget. Although EASA is formally financially independent (Articles 12 and 24 from the preambles (BR1592/2002)), the Commission and the Member States in the Board decide, on the one hand, on the budget of the agency and, on the other hand, also decide on the fees paid to NAAs and on the cost to industry of their certificates. Clearly, these numbers did not add up and the resulting losses have been compensated from the EU budget. The fees that EASA needed to pay to the NAAs for the expertise it hired (set by the Board in which NAAs are represented) did not match the prices that EASA was allowed (by the Board) to charge industry.

Furthermore, without time to establish itself properly for its first set of tasks related to the certification of types and planes, EASA has been undergoing several task expansions. The original proposal from the Commission was that EASA would have a wide set of responsibilities (CEC 2000b). The tasks of EASA were formulated in the original Basic Regulation of 2002 and these already encompassed certification of products, persons, and organisations. Its first tasks involved the certification of design, production, and maintenance of planes. The first revision of the Basic Regulation in 2005-2007 elaborated the rules and principles for the regulation of personnel and organisations. The second revision – now on the negotiation table – deals with the operation of airports and air traffic management (taking over certain

regulatory tasks from Eurocontrol). These ongoing negotiations have also had a major influence on its roles and operations in relation to rule-making and rule enforcement (see below).

Therefore, the way in which the agency actually came into being was to a considerable extent guided by chance. Despite the 'good' intentions of creating a centralised and strong EU agency, the negotiations did not address fundamental issues such as budget and personnel policy or relations with NAAs; as a result, EASA had to find idiosyncratic solutions to each of these problems as they arose. Moreover, EASA – already overloaded – is now being confronted with successive waves of task expansions. Furthermore, the Member States were happy to hand over the responsibilities encased in the first set of tasks. It is expensive for any Member State to host the expertise to certify the design of an Airbus. However, when they realised that an EASA in full operation would also assume other tasks, the interest in a centralised agency dwindled (Schout 2007a). The full implications of EASA were not clearly identified by the Member States.

EASA's Enforcement Powers

Enforcement within the EU

Enforcement encompasses the monitoring of implementation and the sanctioning of irregularities. Enforcement has been a sensitive area in the EU due to the political and economic interests at stake for the Member States as well as in relation to respecting national administrative structures for implementation and enforcement.⁴ It is not simply sensitivities that have preserved the national inspection powers. One of the principles of good governance is the principle of subsidiarity (CEC 2001) and this has implications for the way in which the EU organises enforcement. A general

starting point for inspection is that the rules are formulated at EU level, but inspection builds on the principle of the EU's shared EU legal system. In general, the Member States are responsible for enforcement. They are expected to monitor implementation and sanction irregularities. This is a fundamental principle of shared competences between Commission and Member States. Another principle guiding the enforcement of EU legislation is that the level that issues the rules is responsible for its implementation. As EU legislation is often of the sort that sets objectives while leaving the implementation of the Acts to the Member States, it is therefore the national administrations that are in charge of monitoring and enforcing policies, with the European Commission monitoring national enforcement and holding overall responsibility to see that enforcement takes place.

Over the past few years, major developments have taken place in enforcement in terms of the creation of new instruments and reinforced arrangements. However, EU lawyers still speak of a 'European enforcement deficit' (e.g. Jans, De Lange and Widdershoven 2007). There are various reasons for the difficulties in enforcing the implementation of EU policy. Trust is a key issue. Member States have a shared responsibility for enforcement. Enforcement is a collective good and, as to be expected with collective goods, countries have incentives to economise on investing in it. The internal market depends upon the way in which the Member States build up monitoring and sanction systems. However, effective monitoring may bring national administrations into trouble with the Commission; it may have economic and political costs, or – as is the case with aviation safety – it may lead to international trade retaliations. Hence, if Member States are under the impression that their fellow administrations do not take implementation and enforcement seriously, they themselves may not take their obligations seriously either.

To smoothen over enforcement problems, the EU has employed a range of alternative options including soft modes of governance aimed at creating a greater sense of ownership of obligations and at creating peer pressure to implement (Knill and Lenschow 2000). Furthermore, a range of cooperative arrangements has been created to support coordination and the sharing of information between the Member States and with the Commission (Jans et al 2007: Chapter 6). Moreover, the involvement of the EU in prescribing control methods is increasing, as is *inter alia* underlined by the requirements in the EU's energy policy that Member States must establish independent energy regulators (Schout 2007b). In other areas, the Commission has gained the power to visit and inspect sites on its own initiative. This is particularly the case in food safety.⁵ Where the EU's finances are involved, an independent authority – the Office pour la Lutte Anti Fraud (OLAF) – was created in 1999, which also has autonomous investigation powers.⁶

Hence, on the one hand there has been an increase in the development of enforcement mechanisms in the EU. On the other hand, Communitarisation has remained the exception and has developed mainly in relation to food safety and financial programmes. In general, enforcement has remained a shared responsibility between Member States and Commission. The principles of subsidiarity and national institutional autonomy, as well as the national sensitivities and fears of losing powers, will probably prevent a swift development towards Communitarisation of inspection and enforcement.

This stands in rather strong contrast to the way in which EASA was originally perceived. Given the serious challenge of ensuring aviation safety, EASA was intended to, among other things, centralise enforcement powers. As our interviews showed, some have even wanted to include a separate EASA-court in the definition of its enforcement tasks, which would be

independent of the (limited) resources of the Commission for such a specialised monitoring role.

The Development of EASA's Inspection Powers – From Intentions to Reality

Due to the sensitivities of inspections, the EU suffered from an unsatisfactory inspection system. Given the widely shared frustration with the EU's internal market for aviation, the political climate was ripe for a Commission proposal in 2000 that stated that the agency may 'investigate' and centralise inspection powers (Art. 45, CEC 2000b). Given the broad set of tasks, the investigative powers of EASA were intended to be rather encompassing. Article 1 of the Regulation 1592/2002 indicates the tasks of EASA:

'This Regulation shall apply to:

- (a) the design, production, maintenance and operation of aero-nautical products, parts and appliances, as well as personnel and organisations involved in the design, production and maintenance of such products, parts and appliances;
- (b) personnel and organisations involved in the operation of aircraft.'

EASA's tasks, each with its own origins and sensitivities, have been elaborated in the subsequent proposals from the Commission. The process of defining the responsibilities for EASA – and with that also the tasks of the NAAs – is still ongoing but the direction in which the various tasks related to certification and inspection is going is as follows:

- The certification of types has now been handed over to EASA. This involves the approval of types of aircraft (e.g. the Airbus 380) and of products (e.g. gearboxes). Due to staff and budget shortages, EASA hires experts from the NAAs. As the types are approved by EASA, it also inspects the designs and the final products.

- Supporting the Commission in rule-making. EASA proposes opinions to the Commission. Without altering the content, the Commission presents these to the committee on aviation safety. As such, this is a rather traditional comitology type of rule-making system, in which national experts figure prominently both in rule drafting and in deciding on the rules (Schout 2007a).
- The certification of planes. The certificates for individual planes are issued by the home country. It involves the implementation of the rules defined for planes and is therefore a national responsibility.
- The ramp inspection of planes from within the EU will be done by the NAAs. Since certificates of planes are the responsibility of the national authorities, the NAAs will inspect the planes. EASA monitors the procedures of the NAAs.
- The Commission – through EASA – monitors the quality of the NAAs and the extent to which they live up to the rules and requirements of aviation. This is the inspection role of EASA.
- The ramp inspection of foreign planes is also done primarily by the NAAs.
- The inspection of other organisations is divided between EASA, NAA and qualified entity.

The above implies that, in the end, the way in which inspection powers are distributed and the various roles of EASA vary considerably, and, as will be discussed below, so does the organisation of these powers. As this list shows, EASA has not become (so far) the centralised body it was intended to be.

During the negotiations on the precise formulation of EASA's inspection powers, crucial questions emerged over whether EASA was allowed to do ramp inspections and whether it could inspect foreign planes. This resulted initially in the modification in the Basic Regulation that provided that EASA would 'assist' the Commission. The consequence of this reduction of the role of EASA is that the inspections are seen as more

political and less technocratic. The Commission is regarded as a more political body than the agency. The formulation suggests that the Commission, as the recipient of the inspection report, can be influenced more easily than the experts from EASA. Hence, in the end, it is not up to the agency to investigate Member States or to publish its findings independently.

There are several references to inspection in the Basic Regulation of 2002, which followed from the original Commission proposal (CEC 2000b). These give 'EASA' far-reaching responsibilities. However, as often with EU agencies, a distinction has to be made between the agency and the agency system.⁷ Albeit that 'EASA' has several roles, the implementation of the Regulation may turn out to be more complicated than assigning full responsibility for these tasks to the agency. The Regulations and their drafts speak in several places of 'inspections', 'continuing oversight', 'monitoring'. Some examples taken from the original proposal from the Commission and the Basic Regulation, which resulted from this, include:

- Art 5 (BR1592/2002) defines the rules for airworthiness certificates for individual planes. Following the principle that who regulates – i.e. issues certificates – should also be responsible for enforcement, this Article suggests that EASA has inspection powers in relation to individual planes. It should, however, be noted that this article does not specify who does these inspections.
- Art 12 on the functions of EASA: 12.2.d (BR1592/2002): 'conduct inspections and investigations as necessary to fulfil its tasks' (note the open ended wording).
- Art 15.2. on the provision of certificates (BR1592/2002): 'The Agency shall: conduct, itself or through national aviation authorities or qualified entities, technical inspections associated with products, parts and appliance certificates'.

- Art 15 (CEC 2000b): ‘issue the appropriate type certificates [granting type approval for products and appliances], including the certification of design organisations ... and ensure continuing oversight’.
- Art 16.1 (CEC 2000b): ‘The Agency shall conduct inspections’ of the application by the Member States. It also underlines that it ‘shall report to the Commission’.
- Art 16.2 (CEC 2000b): ‘The Agency shall conduct technical investigations...’
- Art 29 (CEC 2000b): specifies the tasks of the Executive Director and specifies that he decides – ‘completely independent’ – on ‘inspections and investigations’ (as provided in Art 45/46 on inspections of Member States and of undertakings).
- Art 45 (BR1592/2002) presents the way in which EASA may inspect NAAs
- Art 46 (BR1592/2002) indicates that EASA or other bodies (NAAs, qualified entities) may inspect national undertakings.

This gives an indication of the remarkable inspection potentials EASA was granted at the beginning of its life. Given the general impression of governmental failures during the JAA era, these ambitions were broadly supported by the Commission, industry and Member States. Part of this national support was related to the fact, around 2000, some Member States were in the process of privatising tasks aviation related tasks. It was also hoped that some aviation safety tasks could be dropped due to the creation of EASA.

However, in addition to these ambitions, the proposal from 2000 and the Basic Regulation from 2002 also left ‘too much’ undecided (interviews) and required further precision by the Commission in the follow up proposals and by the Board.

Meanwhile, Member States had started to doubt whether the creation of EASA was such a good idea after all. The (first) revision and the extension

of the Basic Regulation in 2005–2007 elaborated the rules and principles for the regulation of personnel and organisations involved in aviation (CEC 2005b). The second revision, now on the table, deals with air traffic control and operations of airports. In other words, the first set of tasks that EASA received concerned the certification of the hardware (types of planes by EASA and of individual planes by Member States). The first extension concerned the people (pilots and crews) and organisations (operators). The second extension deals with the regulation of air traffic management and of airports. These expansions and the negotiations that they involve, as well as the decisions that were taken by the Board, have modified EASA's original design in fundamental ways.

The Influence of the Negotiations on EASA's Task Description

The Commission proposal and the Basic Regulation suffered from unclear language and created considerable tensions between Member States, EASA and Commission. The interviews revealed that the motives of the negotiators included an ambition to guarantee aviation safety, to negate the threat to vital national economic interests involved in losing control of ramp inspections and decisions on grounding airplanes, and to ensure tasks for NAAs. Evidently, these ambitions have been conflicting.

Proposals for revision and elaboration of the Basic Regulation of 2002 and the proposals for operating rules in relation to specific articles in the Basic Regulation have been presented by EASA to the Commission. It is the task of EASA to present opinions to the Commission. As far as rule-making is concerned, the Commission consults the EASA committee. Proposals for changes to the Basic Regulation are presented to the Council and European Parliament.

The results of the negotiations as they stood at the end of 2007 show how the various interests have been brought together. Firstly, the wording of

the original 2000 proposal for Article 15.a – which defines the tasks in relation to certification of products and appliances – is ambitious: ‘The Agency shall conduct, itself or through qualified entities, technical inspections required to check that their type is air worthy, in accordance with the rules adopted in respect of the design...’.

Art 15.b continues that the agency shall ensure continuing oversight. This has been watered down in the version that was agreed in the working party to: ‘the Agency shall... conduct, itself or through *national aviation authorities* or qualified entities, *investigations* associated with products, parts and appliances certifications’.⁸ This is a downgraded version compared to the document on the negotiation table at the end of the negotiations in the Council, which still read: ‘inspection and audits’ instead of ‘investigations’.⁹ Similar changes were introduced in relation to the articles on the certification of personnel, organisations and third country operators (Articles 21-23).

These changes underline that the creation of inspection powers has remained sensitive. The Member States, despite their original support for centralisation, were not inclined to hand over inspection tasks when the proposals were discussed article by article. It also shows the efforts the Member States have made to re-insert their NAAs where possible. Similarly, the ‘qualified entities’ referred to above were already in the Commission proposal in order to allow Member States to maintain their traditional national structures. Some Member States had organised certification tasks through private sector bodies (qualified entities) and had insisted that these should be able to carry on their tasks as before. Although in favour of a strong agency, article by article, the Member States incrementally protected the *status quo*.

The Development of EASA's Monitoring and Investigation Powers

Article 16.1 (CEC 2000b) deals with monitoring the application of rules and specifies that EASA 'shall conduct inspections to verify the application by the Member States'. After the negotiations in 2006, it read 'The Agency shall conduct *standardisation* inspections in the fields covered by Article 1(1), in order to monitor the application by *national competent authorities...*'.¹⁰ These changes specify that the agency is not going to take over the role of the national authorities in terms of inspecting planes, but is mainly to function as an 'inspector of the inspectors'.

Similarly, Article 46 in the Commission proposal (2000) states that: 'Without prejudice to the enforcement powers conferred by the Treaty to the Commission, the Agency *may undertake all necessary investigations and inspections* for the purpose of carrying out the duties assigned to it by this Regulation' (emphasis added). As regards the role of NAAs or other bodies, the 2000 proposal specified that the manner of co-ordination with the national bodies was to be determined by EASA: 'it may also allocate investigation tasks to qualified entities in accordance with the guidelines to be adopted by the administrative board...' (Art. 46). This was changed in 2006 into 'the Agency *shall assist the Commission* in monitoring the application of this Regulation and its implementing rules, by conducting standardisation inspections of Member States' *competent authorities* as specified in Article 24(1)' (Article 53 on the working methods for inspections of Member States; emphasis added). This change not only brings the 'competent authorities' back in, but it also shows that the Member States prefer the Commission to be in the lead when it comes to actions on the basis of the inspections.

Further, when it comes to investigations by private sector bodies ('undertakings'), Member States were keen to reinsert their national aviation authorities. The relevant Article from the Commission's proposal to establish common rules in the field of civil aviation and creating a European aviation

safety agency (Article 48 Investigation of undertakings) reads: ‘...investigations of undertakings shall be undertaken by the Agency or by qualified entities’. This has been changed into: ‘The Agency may itself conduct or allocate to *national aviation authorities* or qualified entities (Article 46 2006).

The guidelines that the Board has to adopt – referred to in Article 46 – specify the conditions for when and how to inspect the NAAs, as well as the details of what to do with the inspection reports and how to financially compensate for experts from other national bodies that involved in the inspections (inspection as network activity). The investigations of Member States and undertakings have to be announced in good time and Member States are obliged to assist these inspections. As it now functions, the inspection reports go first to the Commission for follow up actions. The full reports are not made available to the public.

These changes had restored the general principles of subsidiarity and enforcement autonomy. Moreover, the individual articles had been diluted so that NAAs and other national bodies would remain involved and to ensure that responsibility for follow-up measures were attached to the more politically sensitive Commission. On the whole, what has emerged is a rather traditional inspection pattern with a central role for the Commission. More worryingly, with the inspection reports not being available to the public, the system lacks openness and transparency (Schout 2007a, 2008).

This was not enough for the Member States. The negotiations on EASA were, by the end of 2006, rather tense. The Member States wanted more reassurance that they would remain responsible for the inspection of planes. Hence, to prevent final problems in reaching a political agreement in the Council, the Commission issued a ‘Unilateral statement’ in the final document for the Council (13 December 2006) relating to EASA’s inspection

powers, which emphasises that EASA will not threaten national inspection responsibilities (emphasis added):

‘The Commission confirms that the text ... does not change the current role of Member States both as regards their primary oversight role over undertakings under their responsibility, and as regards ramp inspections including decisions on grounding of aircraft.

These provisions simply add the possibility for the Agency to carry out inspections of aircraft for the purpose of:

- Certification procedures carried out by the Agency...;
- Inspections of any undertaking ... in cooperation with Member States.

Article 7 explicitly limits the possibility to ground aircraft to Member States only. Under no circumstance can the Agency ground an aircraft.

The Agency's role – when a safety deficiency is found – is to inform the Member States concerned and the Commission of such a deficiency.

The Agency's power to act is limited to the withdrawal/suspension of certificates/authorisations it has issued.’

What these changes add up to is a series of compromises that have re-inserted maximum flexibility for the Member States. The Member States are to remain in charge of inspection and enforcement while the Commission – in this case through EASA – is to be the inspector of the inspectorates in accordance with the traditional division of inspection roles (Jans et al. 2007).

A Note on the Effectiveness of EASA’s Inspection Powers

Although the objective of the study is to understand the drift in agency design, the interviews also gave insights into how practitioners evaluate the effectiveness of the aviation inspection system. Evidently, an evaluation of the operations of a public sector body – including its efficiency – would require a much more in-depth analysis (e.g. Powell 1987). Nevertheless, the interviews give some indications of what the findings might be. The first finding in relation to the operation of EASA is that the JAA system that preceded it is in several ways still highly regarded. As regards rule-making, the current regulatory system is still largely based on JAA’s output.

Moreover, the experts from the NAAs that cooperated in the JAA now cooperate with EASA in rule-making and with inspections. Hence, as regards inspection, EASA resembles the JAA system. What is different is that the Commission can take decisions on the basis of the reports and if necessary plan follow up visits or take the NAAs to court. In addition, EASA has a department for supporting capacity building of NAAs.¹¹ Hence, it puts more effort into building up the capacities of the EASA network than the JAA was able to do.

Thus, there has been considerable continuity in terms of expertise and the networks involved. EASA's success is mainly the success of integrating the non-binding JAA rules into the EU legal system. This, as such, has little to do with EASA. What is different is that the Commission has a stronger organising voice within the network of NAAs and it can take Member States to court.

As regards openness and transparency, one of the arguments for creating EU agencies, EASA shares characteristics with its predecessor (JAA). The inspection reports remain unavailable to the public. They are addressed to the Commission for decisions on follow-up actions. This compares poorly to the Commission's good governance principles (CEC 2001), as well as to ICAO's inspection system.

Therefore, following the distinction between risk assessment and risk management, EASA does not seem to be an improvement on the JAA system in relation to risk assessment – which was always rather effective. It is the same experts working together, and they have always been highly focused on safety and independence. The big difference is that aviation safety is a Community competency with binding legal force, which moves enforcement beyond soft power. Hence, risk management has improved by being brought under the Commission's authority. Risk management has also improved because the Commission now operates with a Database in which the NAAs

have to report the results from their inspections of the planes.¹² This system allows the Commission to spot problems with operators on an EU scale. This helps to identify the weak players and, because it is a tool of the Commission, it prevents inspection becoming an issue of one Member States against another country. In other words, the gains relate to the Commission and less to EASA. However, transparency of inspections has not improved.

In sum, the main advantages relate to the Communitarisation of aviation safety and not primarily to the agencification. EASA has found its niche. It organises and provides expertise, and it manages the inspections. The system as a whole functions rather well – although transparency could be improved – and it shares characteristics with the previous JAA system.

Conclusions

Following regulatory theory, EU agencies can undertake major functions leading to better policies: more consistency between policies, evidence-based policies, greater transparency, and better consultations. Agencies could support the EU administration with specialised expertise and flexible and professional management (CEC 2001). Their independence and expertise may lead to the de-politicisation of policy-making and contribute to better risk assessment and risk management. Clearly, the trend towards agencification is visible in the EU and there are signs that agencies are becoming ever stronger. The European Aviation Safety Agency (EASA) is a case in point, with its in deep involvement in both hard and soft regulation and in enforcement.

In several ways, this development is remarkable given that agencification has been one of the more sensitive issues in the EU as it relates to the distribution of tasks and powers between the Commission and the Member States. Moreover, in relation to rule-making and enforcement,

agencies are not just more of the same but potentially change the administrative–political landscape by depoliticising rule-making and enforcement. In relation to enforcement, this can have major consequences as the Commission could be much more inclined towards acknowledging political sensitivities than an agency that is driven by expert judgements. Moreover, enforcement in the EU is strongly based on the principles of subsidiarity and administrative autonomy. EASA, as initially conceived, would have meant a leap away from these EU traditions.

In general, EU agencies have so far not acquired the position as foreseen in regulatory theories. Majone (1996) posited that the expert power organised in and around the agency will lead to a growing power of the agencies, akin to spill-over predictions derived from functionalist theories. Dehousse (2007), however, notes that the current positioning of agencies has already existed for quite some years and that any rationalisation of the disorganised position of EU agencies is likely to meet strong resistance (see also Craig 2007). As it has turned out, EU agencies are kept on a leash. On the other hand, those in favour of traditional majoritarian policy-making find EU agencies too powerful.

Presumably, the debate on EU agencies reveals some tendency towards image building. Some see major EU failures and call for independent agencies. Others regard agencies as a threat to traditional power positions. EASA was first *assumed* to be needed due to failures in the previous more intergovernmental way of working. Our assessment, however, is that the previous system was not that bad. In rule-making it was quite effective. Enforcement was the JAA's greatest weakness but EASA's inspection regime simply repeated the weaknesses of the previous system. What actually improved inspections were the powers of the Commission and much less the creation of EASA *per se*.

EASA turned out to be weaker than originally planned. It has been developed through the elaboration of its tasks by the adaptations in its Basic Regulation and through the decisions taken in the Board. A pattern can be seen in these developments. In relation to inspection, the original plans of the Commission to centralise tasks in Köln have been watered down and opportunities have been opened up for NAAs and national qualified entities to remain involved in the inspection process.

The explanation for this dilution includes, firstly, the fact that Member States were initially happy to drop some tasks in relation to aviation safety, particularly where it concerned the certification of aircraft design. However, when the Member States realised that this agencification would set a pattern for the subsequent phases of EASA's task expansion including inspection, the earlier enthusiasm for an agency diminished. Secondly, the Member States feared the independence of EASA in relation to inspection and enforcement. The Member States were more at ease with keeping inspection as a national task and ensuring that the Commission – through EASA – would take charge of inspecting the inspectors.

Thirdly, the interviews showed that the agency concept was not clear to those involved in the negotiations. Most of the negotiators and the dossier managers in the capitals were not familiar with what an agency is, how it operates and what consequences it might have for policies and inspections. Hence, establishing an 'agency' as such was not part of the negotiations so that the hundreds of footnotes that the Member States inserted to the various Commission proposals all brought EASA back to a situation that was quite close to how aviation safety had always operated. Related, the Member States regarded the agencification of aviation safety apparently not as a positive sum game in which new structures were created to *change* the polity by giving independent expertise a bigger role, but as a negative sum game.

Theorising on the basis of this N=1 case study about the institutionalisation of EU agencies, our conclusion is that the negotiations can only very partly be termed 'rational'. On the one hand, the negotiations were rational as Member States tried to preserve powers, discretion and employment. The Commission – not in the position to absorb the tasks related to aviation itself – tried to bind the hands of the Member States by creating a strong agency.

On the other hand, the negotiations were far from rational. Firstly, there was very little hard analysis of what the problems with the JAA system were and what alternatives were available. The plans to centralise tasks in an agency were quickly written. The overall ambition was, initially, to remove the competences from Member States and to depoliticise the decision-making process. The step-by-step approach of the creation of EASA, with a first phase in which EASA would take care of type approval – an expensive task for countries individually – made Member States willing to give up certain roles. However, the realisation that other powers would follow suit eroded the enthusiasm. Moreover, the incremental article-by-article negotiations in the Council were not linked to an overall objective or model, and the motives at play during the negotiations were conflicting. Furthermore, such an incremental approach was not needed to dilute EASA's inspection powers. Had a few general enforcement principles been agreed upon, such as the principles of subsidiarity and the institutional autonomy, then the responsibility of Member States to ensure their own implementation and enforcement systems would have been guaranteed.

These sometimes idea-less negotiations can be seen throughout EASA's short history; for example, the way in which prices and fees for experts were determined so that EASA became highly loss-making. Moreover, the result of the negotiations is an inspection system that is not too different from what existed. EASA has not been the innovation that could have been expected

from an agency. Given the fact that other agencies have similar problems (Monda et al, forthcoming) and are created in much the same way by negotiations between officials not schooled in creating independent agencies, the conclusions of this case study may have wider relevance.

Notes

¹ CEC, Commission of the European Communities, *Commission working document in view of the discussions within the Council on the creation of the European Aviation Safety Authority in the Community framework*, COM(2000) 144 final, 21 March 2000, Brussels; CEC, Commission of the European Communities, *Proposal for a regulation in the European Parliament and of the Council on establishing common rules in the field of civil aviation and creating a European aviation safety agency*, COM(2000) 595 final, 4 December 2000, Brussels.

² Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on Common rules in the field of civil aviation and establishing a European Aviation Safety Agency, *OJL* 240/1.

³ There is mostly sketchy information on the effectiveness and efficiency of EU agencies. Each EU agency has a website on which evaluation reports can be found. Evaluations are however hardly comparable due to a lack of shared methodology. The Commission has begun initiatives to arrive at more systematic agency evaluations.

⁴ See the principle of national institutional autonomy; Case C-8/88 *Commission v. Germany* [1990] ECR I-2321.

⁵ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004, *OJL* 165.

⁶ Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999, *OJL* 136.

⁷ See Schout 1999b in which this point is elaborated for the difference between Eurostat and the Eurostat system.

⁸ Article 20.1.e from the final version of the negotiations that was agreed in December 2007 (emphasis added).

⁹ Article 15.1.c in the working document from November 2006.

¹⁰ Article 24 in the legislative act from December 2007 (emphasis added).

¹¹ The Directorate for Approval and Standardisation, which has *inter alia* a budget for training.

¹² Known as a system of ‘collective oversight’ on how operators ensure the safety of their planes.

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