A General Framework for the Precautionary and Inclusive Governance of Food Safety

Accounting for risks, uncertainties and ambiguities in the assessment and management of food safety threats*

by

Marion Dreyer**, Ortwin Renn***
Adrian Ely, Andy Stirling****
Ellen Vos, Frank Wendler*****

DIALOGIK gGmbH, Stuttgart

4 May 2007

* The research reported in this document is funded by the European Commission under the 6th Framework Programme and results from the fifth subproject (work package 5) of the Integrated Project SAFE FOODS, “Promoting Food Safety Through a New Integrated Risk Analysis Approach for Foods”. The governance framework as proposed in the present document is still work in progress and will be subject to revision in response to the insights that will be gained at the “Presentation Workshop” which will be held on 11 May 2007 in Brussels at the Fondation Universitaire.

** Dialogik gGmbH, Stuttgart, Germany
*** University of Stuttgart and Dialogik gGmbH, Germany
**** University of Sussex, Science and Technology Policy Research (SPRU), United Kingdom
***** University of Maastricht, Faculty of Law, The Netherlands
6.4 Approaches to management ..................................................................................... 61
6.4.1 Prevention ......................................................................................................... 62
6.4.2 Precaution-based approach ............................................................................... 62
6.4.3 Risk-based approach ........................................................................................ 63
6.4.4 Concern-oriented approach .............................................................................. 63

7. Legal and Institutional Aspects of the General Framework ...................................... 64
7.1 Introduction .............................................................................................................. 64
7.2 Proposal for institutional changes ............................................................................ 64
7.3 Capacity-building of EFSA: screening and concern assessment ............................. 66
7.4 Interface assessment – management ........................................................................ 67
7.4.1 Background of the proposal ............................................................................. 67
7.4.2 More transparency and participation ................................................................ 69
7.4.3 Institutionalising of food safety interfaces ....................................................... 70
7.5 Management: re-consideration of the comitology procedure .................................. 77
7.6 The General Framework and general principles of European law ............................ 79
7.6.1 Precautionary principle .................................................................................... 79
7.6.2 Proportionality principle .................................................................................. 80
7.6.3 Subsidiarity ....................................................................................................... 81
7.6.4 Good governance .............................................................................................. 81
7.6.5 Good administration ......................................................................................... 82
7.6.6 The principle of non-delegation of powers (Meroni doctrine) ............................. 84
7.7 The General Framework and WTO law ................................................................ 85
7.7.1 SPS and TBT agreement .................................................................................. 85
7.7.2 Added value of the General Framework .......................................................... 89
7.8 Conclusions .............................................................................................................. 89

8. A Structured Approach to Participation ..................................................................... 90
8.1 Introduction .............................................................................................................. 90
8.2 Participation through food safety interface institutions ........................................... 90
8.3 A structuring tool for additional processes of participatory deliberation ............... 92
8.3.1 Participation during framing ............................................................................ 93
8.3.2 Participation during assessment ....................................................................... 93
8.3.3 Participation during evaluation ........................................................................ 94
8.3.4 Participation during management ..................................................................... 95

9. Conclusions ..................................................................................................................... 97

Glossary.............................................................................................................................. 101

References.......................................................................................................................... 104

Figures
Figure 2.1 Risk, uncertainty, ambiguity and ignorance ................................................. 11
Figure 3.1 The ‘technocratic’ model ........................................................................... 24
Figure 3.2 The ‘decisionist’ model ............................................................................. 24
Figure 3.3 The ‘transparent’ model ............................................................................. 25
Figure 3.4 A simplified representation of the General Framework for food safety governance in Europe .......................................................... 26
Figure 3.5 The stages of framing in relation to the rest of the governance cycle .......... 29
Figure 3.6 The four approaches to assessment, and their relationship to screening and the other stages in the governance cycle ......................... 32
Figure 3.7 The primary features of management, and their relationship with the other stages in the governance cycle ........................................ 35
Figure 3.8  A detailed representation of the Governance Framework, including the institutional allocation of tasks 36
Figure 4.1  The General Framework with an emphasis on the stages and institutional settings of framing 38
Figure 5.1  The General Framework, with a focus on the stages of screening and assessment 49
Figure 6.1  The General Framework, with a focus on the stages of evaluation and management 55
Figure 6.2  Acceptable, tolerable, intolerable and borderline threats (Traffic Light Model) 57

Tables
Table 6.1  Generic management components 61
Table 6.2  Four management approaches 62
Table 7.1  Proposal for limited institutional changes 65
Table 7.2  Tasks and procedures of the platforms of the Internet Forum 73
Table 7.3  Size and composition of the Advisory Committee 75
Table 7.4  Three options for the institutional design of the food safety interface 76
Table 8.1  A structured approach to participation 97
Preface

This report aims to make a contribution to the reform process to which European food safety governance is currently being subjected. It provides suggestions for procedural and institutional reforms which focus on the challenges of the policy-science interface, precaution, and participation.

It is not the intention of this report to reinvent the wheel but rather to tie in with recent reforms at the EU-level and to build on previous studies in particular those carried out or commissioned by the European Commission and the European Food Safety Authority. The authors of this report have placed special emphasis on the compatibility of their suggestions with the existing EU regulations on food safety, the European Commission’s communications on governance and on precaution, and with the guidelines developed by Codex Alimentarius. With regard to the aspects of participation and deliberation in particular, the report is inspired by the 2005 International Risk Governance Council’s White Paper on Risk Governance1 and by the 1996 National Research Council’s report on risk characterization2 both in which science, politics, economic actors, and representatives of civil society are invited to play a role in both the assessment and the management of risks. The authors have made a special effort to keep the number of new terms to an absolute minimum and to use existing concepts and terms in a way consistent with these documents.

The General Framework for the Precautionary and Inclusive Governance of Food Safety is a product of the fifth subproject of the EU-funded Integrated Project ‘SAFE FOODS’ aimed at “Promoting Food Safety Through a New Integrated Risk Analysis Approach for Foods”. It feeds into the overall food risk analysis model which is being developed by the overarching (sixth) subproject of the SAFE FOODS project. Hence, the writing of this document would not have been possible without the collaboration of many persons involved in this overall project context. We are especially grateful to Harry Kuiper and Hans Marvin, the main coordinators of SAFE FOODS, and to Lynn Frewer, Ib Knudsen, Ariane Koenig, and Erik Millstone, all participants in this project, for scientific advice and input. We have received valuable feedback during several meetings of the project consortium and the two stakeholder conferences organised by the project. The whole endeavour would not have been possible without the financial support of the EU Commission for which we are especially grateful.

The major empirical activities that have been performed to date in order to inform the development of the governance framework presented in the report at hand include first, a comparative analysis of current institutional arrangements and recent reforms of food safety governance at the EU-level and in five EU Member States (Hungary, Sweden, France, United Kingdom and Germany) which was also carried out in subproject five of the SAFE FOODS project. One source from which this institutional study was derived is the result of a set of interviews conducted with relevant officials, policy-makers, and corporate and civil society actors in each of the countries and at the EU-level3. Second, the development of the framework has drawn on the insights gained at a number of deliberation-focused workshops employing a discussion technique based on sequences of plenary and break-out group sessions. The first

workshop brought together leading experts from the fields of risk and governance research and policy analysis for a discussion and review of a first draft of the framework concept (Pforzheim, Germany, 6-7 October 2004). The refined framework informed by the outcome of this academic expert review and the results produced by the comparative institutional account was then later presented and discussed at a series of four workshops with key actors in the field of food safety governance. The workshops were conducted through the Autumn of 2006 and involved, successively, industry representatives (Schloss Haigerloch, Germany, 18-19 September), representatives of non-governmental organisations (London, British Academy, 28-29 September), risk managers (Brussels, Fondation Universitaire, 23-24 October), and risk assessors (Brussels, Fondation Universitaire, 23 November) who were selected from across Europe⁴. Through this systematic feedback process insight was gained into the social and political viability of the suggestions for reform and these were revised in consideration of the knowledge, experience, and perspectives elicited through the deliberative exercises. Hence, last but not least we would like to express our special gratitude to the interviewees and the participants of the different workshops for their most valuable support of and engagement with our work.

The workshop-based review process will be completed on 11 May 2007: The governance framework as it was reworked in response to the four deliberative events with practitioners and concerned and interested parties will be presented at a fifth workshop in Brussels at the Fondation Universitaire. The objective of this Presentation Workshop will be to reflect the amended version with the views of those who contributed to the feedback processes so far and with the perspectives, insights and experiences of a wider audience in order to complement the final concept. This final concept aims to eventually inform the overall food risk analysis model that is being developed by the SAFE FOODS project.

Ortwin Renn
Marion Dreyer

---

⁴ In each case, a summary report was produced and circulated to the workshop participants to ensure accuracy and provide the opportunity for further feedback.
1. Introduction

Marion Dreyer and Ortwin Renn

Since the mid 1990s, following a series of food-related scares and debates with BSE and genetically modified foods as the most prominent issues, food safety institutions in Europe have been facing growing demands for a more effective, fairer, and more transparent and participatory regulation of food risks. These demands have been motivated by concerns that behind closed doors powerful industry interests would be 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 and thereby public health protection compromised. Another related underlying concern is 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 have been expressed relating to the independence of scientific advice, being put under much political pressure, as was the case during the BSE crisis.

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 and also 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”. Another prominent feature of reform of EU food safety regulation are efforts to advance the democratic quality throughout the risk regulation process mostly by improving transparency with a focus on increased documentation and by providing more opportunities for eliciting stakeholder viewpoints.

The current report ties in with these recent reforms and provides suggestions for carrying them forward through a set of additional procedural innovations and institutional modifications. The reforms envisioned pertain to a set of governance challenges which are considered by the authors of this report as deserving more attention and being in need of further improvement. These governance challenges include:

- the organisation of the relationship between risk assessment and risk management;
- dealing with scientific uncertainty;
- the handling of highly controversial food safety issues;
- establishing transparency during the entire food safety governance process;
- the provision of effective and legitimate mechanisms for stakeholder and public engagement.

These issues are all addressed - at least to some extent - by the recent EU-level reforms. Significant though these reforms are, they do not fully address prominent concerns and criticism. The results of the empirical research which was carried out to inform the development of the
General Framework for the Precautionary and Inclusive Governance of Food Safety (these results will be described in more detail in Chapter 2.2) suggest both the issues and the recent reforms that have an impact on them continue to be subjects of debate and controversy. The question of how to organise the relationship between scientific expertise and political decision-making in the governance of food risks which was brought high on the European policy agenda mainly through the BSE crisis is still not sufficiently solved in the view of many practitioners and concerned or interested observers. It is precisely the segregation of risk assessment responsibilities which highlights that scientific activities cannot be performed completely in isolation and a political vacuum. The National Research Council’s 1983 ‘Red Book’ already pointed to a central and well-founded criticism of “full organizational separation” which stated that “simply separating risk assessment from the regulatory agencies would not separate science from policy”\(^5\). How then to account for the inherent interlinkage between the scientific and the political aspects of food safety governance and at the same time not compromise the generally agreed functional differentiation between activities aimed at ‘understanding’ risks and activities aimed at ‘acting’ on risks?

The question of how to include both the knowledge and perspectives of both corporate and civil society actors in food safety governance especially in conditions of high levels of scientific uncertainty and social controversy (which gained prominence through both the BSE crisis and the persistent debate on GM crops and food) is also still a disputed issue. How to feed the valuable resources of social groups and also the wider public, which may be pertinent to effective and socially acceptable governance outcomes, into the process without an overkill of participatory procedures that would abuse the scarce resources of both the responsible institutions and actors of the ‘outside world’?

The governance framework which will be presented in the following chapters suggests procedures and structures for how to improve the treatment of these especially challenging governance issues by further implementing the principles of good governance enshrined in the General Food Law and the agenda on governance in the European Union.

Designed for this purpose the framework is aimed at offering, first, a truly interdisciplinary governance approach. It pursues this objective by envisioning that not only knowledge about the physical impacts of food substances, products and production techniques are elicited but also knowledge about the concerns that people associate with these issues. In addition to the natural scientific skills necessary to assess the risks, it identifies social scientific skills as highly pertinent to processes of diagnosing, understanding and including the concerns, expectations, and worries that individuals, groups or different cultures may link to a given food safety problem or the cause of the problem in the governance process.

A second key objective of the governance framework is to provide a concept for a more consistent application of the precautionary principle which is interpreted by the authors of this report as a general governance principle. This concept includes a specification of the conditions under which more extensive assessment and evaluation processes (including broader deliberation and participation) are required and provides some guidance on (generic) management measures especially suited under these conditions.

A third major objective is to provide suggestions for mechanisms to improve the coordination between assessment and management, and to address the concerns of corporate and civil society actors throughout the governance process. A set of options of food safety interface institutions destined for this purpose will be discussed which form part of the idea of inclusive governance that the General Framework promotes.

Before the general architecture and the individual components that make up the General Framework are presented both in an overview and in more detail, the following chapter will elaborate on the challenges that European food safety governance faces and point out the policy imperatives. This is done with reference to the current legal and policy framework and to viewpoints and experiences of key actors of food safety governance that were elicited in the empirical research. The chapter will in addition introduce the key conceptual ideas upon which the governance framework builds in order to respond to the policy imperatives.

2. The Need for Change

Adrian Ely, Andy Stirling, Marion Dreyer, Ortwin Renn, Ellen Vos and Frank Wendler

2.1 Fundamental challenges

As illustrated in the previous chapter, the governance of food safety presents a formidable series of challenges, both in general and more specifically within the context of the European Union. The purpose of this chapter is to outline and explore some of these challenges, bringing into focus the conceptual ideas upon which we may build in order to address them. The existing conditions that necessitate change in food safety governance arrangements within the EU will be discussed, and related to potential procedural and institutional responses. As such, this chapter introduces and defines the terms used to describe the various stages in the governance process, as well some of the specific problems encountered during each of these activities. These concepts will be further built upon in subsequent chapters, which will describe a general framework for food safety governance within the European Union that can address the challenges discussed here.

2.1.1 Conceptualising stages in the governance process

Here, as in discussions of other ‘technological risk’ issues, the 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.

Within this broad notion of governance, the framework outlined in Chapter 3 moves beyond the elements of risk analysis to account for the processes through which policy problems are identified as such, and the institutional and political influences that shape the ways in which these problems are perceived, conceptualised and prioritised by policy makers. This element of the governance process is here termed framing. Encompassing such activities as the identification of the scientific inputs that are required to inform policy, framing sets the terms of

---


reference for the next stage in the governance process: assessment. Assessment subsumes, with other methods which will be described in more detail in Chapters 3 and 5, the conventional procedures of ‘risk assessment’ as variously defined. Through gathering information on technical and socio-economic risks and benefits, as well as the concerns of stakeholders and citizens, assessment informs, substantiates and justifies governance decisions, policies and wider institutional practices and commitments. The framework proposed in this report proposes two further stages that contribute to the goals of food safety governance. Based on the outputs of the assessment, an evaluation exercise is undertaken. This exercise summarises the information gathered during the assessment phase and involves deliberation around divergent values associated with the threats under consideration. Following the evaluation exercise, intervention measures are identified, assessed and selected in a process of management. This process also includes the implementation of such measures and their follow-up through monitoring of existing threats and horizon-scanning for emerging threats.

2.1.2 Precaution as a response to lack of scientific certainty

One of the most significant challenges for risk governance relates to current and highly topical debates over the application of the precautionary principle. Variously defined in a multitude of different instruments, this embodies the central injunction that lack of scientific certainty should not be used as a reason to delay appropriate action. It is in this form that precaution has become a guiding principle of EU policy making and is recognised by the European Court of Justice and the European Commission to be a general principle of European law. Yet this raises a number of profound questions for its application in food safety governance. In particular, there is a question over whether precaution is applicable to assessment at all, or whether it is simply an approach to risk management. Alternatively, if precaution is applicable in the assessment, as well as in the management, stages of food safety governance then there follow a series of more detailed queries over the precise nature of the relationship between precautionary approaches to assessment and established practices based on conventional risk assessment. One central feature of this relationship follows from the formal scientific definition of the condition of risk itself.

Over many decades of intensive academic and policy activity, the term ‘risk’ properly refers to a situation in which it is possible confidently to quantify both the magnitudes and the probabilities for a defined range of outcomes (such as forms or degrees of harm in food safety). Indeed, it is this central reliance on probabilities that is a key diagnostic feature of conventional approaches to risk assessment. Variants of these probabilistic ‘risk-based’ methods offer sophisticated responses to different forms of ‘complexity’ in social, technological and natural systems. In the food safety realm, for example, probabilistic techniques might be applied to the characterisation of risks from a chemical additive with well-characterised toxicity and substantial long-term data on consumption levels. In a more complex case, probabilistic modelling might be used to investigate the potential synergistic activities between this

---

8 As expressed, for instance, in the classic definition at Principle 15 in the 1992 Rio Declaration on Environment and Development.
9 As in Article 174(2) of the EU Treaty.
12 F. Knight, Risk, Uncertainty and Profit, London, London School of Economics, 1921.
13 This is also a key element in the seminal formal understanding of risk assessment promulgated in the National Research Council’s 1983 ‘Red Book’, supra note 5.
14 O. Renn 2005, supra note 1.
chemical additive and a natural toxin existing in a traditional food product (again in which consumption patterns are well characterised). However it is defined, the precautionary principle addresses a set of more intractable circumstances - going beyond complexity - under which various forms of ‘incertitude’ render such quantification incomplete or problematic\textsuperscript{15}.

These more intractable circumstances can take three main forms, which are illustrated in figure 2.1 below. The first is referred to in the strict definition of the state of \textit{uncertainty}, under which the possible outcomes are clear, but it is difficult to quantify probabilities\textsuperscript{16}. As demonstrated in the figure, an example might be the appearance of a novel zoonosis associated with an unknown agent.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure2.1.png}
\caption{Risk, uncertainty, ambiguity and ignorance\textsuperscript{17}}
\end{figure}

The second is the condition of ‘\textit{ambiguity}’, where the problem lies not with probabilities, but in agreeing the appropriate values, priorities, assumptions, or boundaries that apply in defining the possible outcomes\textsuperscript{18}. Questions around the tolerability of a new form of battery hus-


\textsuperscript{16}F. Knight 1921, \textit{supra} note 12; J.M. Keynes, \textit{A Treatise on Probability}, London, Macmillan, 1921.

\textsuperscript{17}The general scheme here is taken from A. Stirling, ‘Risk at a Turning Point?’, \textit{Journal of Environmental Medicine} 1 (3), 1999, p. 119-126. Examples have been added for the purposes of this particular exercise.

bandry with animal welfare implications could produce a condition of ambiguity. Third, a condition of ‘ignorance’ exists where neither probabilities nor outcomes may be fully or confidently characterised. In this latter case, where “we don’t know what we don’t know”, we are seeking to mitigate our exposure to surprise. At the level of the UK in the early 1980s, when BSE was first appearing in cattle, ignorance existed as to the number of associated potential human deaths from vCJD and the probability that these deaths would emerge. Various forms of conventional risk assessment remain applicable under conditions of ‘complexity’. But uncertainty, ambiguity and ignorance are, by definition, states of knowledge under which conventional probability-based risk assessment is quite simply inapplicable. In such cases we look towards resilience, flexibility and diversity in agri-food systems in order to allow effective responses to areas of ignorance once they have been identified. Where conventional risk assessment leaves residual uncertainties unaddressed, then these must therefore be addressed by other complementary methods. It is in recognition of this challenge that we find the basis for reconciling conventional risk assessment and precaution in terms of their complementarity.

In short, the direct implication of the precautionary principle for assessment is to highlight the conditions under which it would be appropriate to apply what may be described as more comprehensive approaches to assessment. These are noted in Figure 2.1 above and will be discussed in much greater detail in Chapters 3 and 5.

These fundamental challenges to the stage of assessment raise some important implications for the current, conventional practice in the governance of food safety of opting by default for the application of conventional risk assessment. Unconstrained reliance on established risk assessment methods can sometimes seem to reflect a rather narrow and complacent view of uncertainty and an optimistic or expedient view of the depth and form of knowledge that is necessary in assessment. In governance terms, this can present problems of coherence, effectiveness, accountability and participation. On the other hand, recourse to more comprehensive but demanding ‘precautionary’ approaches to assessment can bring its own problems. To some, precaution can appear unduly pessimistic about the quality of the available knowledge. In particular there can be a lack of clarity over the ‘triggering’ of precaution and the consequent procedures may seem fuzzy, onerous, erratic or disproportionate in their effects. These can raise different challenges of timeliness, proportionality, predictability and consistency - as well as coherence in the articulation of conventional risk assessment and precaution. Chapter 5 will provide a detailed examination of these issues.

2.1.3 Resultant questions

In a field with the public profile and global importance of food safety, these challenges introduce very high political, economic and institutional stakes. Each side of the conventional risk assessment / precaution contrast is thus characterised in different ways by various actors for contending purposes. Whatever the details in specific instances, the general effect is to compound the prevailing state of confusion, polarisation and conflict over the appropriate approaches to assessment. Yet, despite the complexities, the central challenges seem quite clear. In short, any governance framework for food safety must address the following five questions:

---

21 General Food Law, *supra* note 6, Article 7.
a) How can governance address elements of ‘risk’, ‘complexity’, ‘uncertainty’, ambiguity’ and ‘ignorance’ in ways that are open, coherent, effective, accountable and participatory?

b) In particular, how can we articulate relatively narrow forms of conventional ‘risk assessment’ with more comprehensive forms of assessment suggested by the ‘precautionary principle’, in a fashion that is coherent, operational, proportionate and consistent with wider governance principles?

c) What are the appropriate roles for different specialist disciplines, technical procedures, institutional designs and modes of engagement under different forms of assessment and at different stages of the governance process and how should these relate to each other?

d) How can framing, assessment and evaluation reflect different forms of knowledge, contested political-economic interests and socio-cultural values in a balanced fashion, such as to provide those who manage a given threat with the broad-based knowledge necessary to yield feasible, timely, proportionate and consistent - as well as socially legitimate and robust - governance outcomes?

e) How do the proposals around risk governance outlined here relate to existing procedures and institutional arrangements in Member States and at the EU level? To what extent can the proposed framework be accommodated by current arrangements which are centred solely around conventional ideas of risk assessment and risk management?

Each of these questions will be addressed in forthcoming chapters. In order to provide further context for their treatment, the next section will outline the policy imperatives for improved food safety governance, drawing on empirical research into existing legal and institutional arrangements, and feedback received in a series of stakeholder workshops held between September and November 2006.

2.2 Policy imperatives

In order to set out the policy imperatives, this section will first highlight some of the major recent institutional re-arrangements and efforts into procedural reform in food safety regulation and sketch the legal and policy basis on which these changes and reform efforts build. In a second step, it will point out certain issues that emerge as essential to the task of changing food safety governance to the better. It will do so by reference to the policy imperatives identified in the legal and policy documents. In addition it will refer to policy imperatives which key stakeholders in the field emphasize on the basis of some years of experience since with the changes.

The exposition draws on the results of two empirical activities. First, it takes up the insights gained in a comparative study of institutional re-arrangements in food safety regulation that have taken place over the past decade in Europe. This study includes the EU-level and five European countries: Hungary, Sweden, France, the United Kingdom, and Germany. While the results on the EU case are of overriding importance for the purpose of the present exercise, insights gained from the country studies will be set forth where appropriate. Pertinent are empirical insights in relation to the challenges implied in the division of institutional responsibilities for risk assessment and risk management which characterise the EU food safety system as well as the French and German systems. The second source of empirical information

---

24 The results of this study which was also carried out within Work Package 5 of the SAFE FOODS project are presented in: E. Vos and F. Wendler 2006, supra note 3. At the EU-level and in each of the five countries semi-structured interviews were carried out with risk assessors, risk managers, and key stakeholders. A total of 13 interviews were conducted on the EU-level, 12 in Sweden, 16 in the United Kingdom, 23 in Hungary, 24 in France, and 25 in Germany.
on which the following subsections draw is a series of workshops with key stakeholders in the field of food safety governance at which a draft version of the governance framework presented in this report was put forward for discussion. The feedback events were conducted through the Autumn of 2006 and involved, successively, industry representatives, representatives of NGOs, risk managers, and risk assessors, all of whom were selected from across Europe.\textsuperscript{25}

\subsection*{2.2.1 Recent institutional and procedural reforms in food safety governance}

Over the past decade, food safety regulation at the EU-level and in several EU Member States represents a highly dynamic policy field, subjecting institutions to considerable pressure to demonstrate competence, credibility and fairness in the handling of risk problems. This pressure has resulted first of all from the experience of a gradual but substantial withdrawal of public trust in both food and those responsible for food safety following a series of food-related scares, most notoriously the BSE crisis of the mid 1990s. Since then, food safety institutions in Europe have faced a crisis of social legitimacy. Empirical research has shown that this crisis has triggered noticeable institutional responses designed to restore public trust and social legitimacy.

There are at least three responses that stand out: First, there is the use of procedural and structural mechanisms designed to assure a stricter separation of the risk assessment function from political decision making. Providing the public with a mainly independent and disinterested expert view about the magnitude of a risk through scientific analysis, and then explaining and justifying the regulatory actions that are based on these scientific assessments has come to be recognised as a major road to more transparency, accountability and, in particular, trustworthiness. In terms of loss of trust, the remedy resorted to in this approach is the trust-generating power of what is represented as 'independent risk assessment'.\textsuperscript{26} 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. This approach is especially pronounced at the EU-level and in those countries, including Germany and France, where responsibility for the functions of risk assessment and risk management has been allocated to different institutions.

This, as the STOA 2000 study points out, clearly contrasts with the practice prior to the ‘BSE-turning point’, when both EU institutions and EU Member States were neither systematically differentiating between activities of risk assessment and risk management, nor did they struc-

\textsuperscript{25} For each of the stakeholder workshops a summary report was produced and circulated to the workshop participants after the event to ensure accuracy and provide the opportunity for further feedback.

\textsuperscript{26} 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 even in theory is misleading: 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, does inevitably involve non-scientific considerations and value judgements, be they explicit or implicit; cp. E. Millstone, ‘Recent developments in EU food policy: Institutional adjustments or fundamental reforms?’, \textit{Zeitschrift für Lebensmittelrecht}, 2000, p. 818; E. Millstone and P. van Zwanenberg, ‘The evolution of food safety policy-making institutions in the UK, EU and Codex Alimentarius’, \textit{Social Policy & Administration}, 2002, p. 603; J.K.K. Jensen and P. Sandoe, ‘Food safety and ethics: the interplay between science and values’, \textit{J. Agric. and Env. Ethics}, 2002; see also the NRC’s ‘Red Book’ which argues that the description of risk assessment as a strictly scientific undertaking was a misconstruction; NRC 1983, supra note 5, p. 150.

\textsuperscript{27} In France, however, trust-building appears to rank behind improvement of effectiveness as a rationale for separation; cp. Dreyer et al., ‘Institutional re-arrangements in European food safety governance: a comparative perspective, in: E. Vos and F. Wendler 2006, supra note 3, p. 19.
urally separate organisational or institutional responsibilities\textsuperscript{28}. It was normal for the responsibility for assessment and management to be handled by a single institution, for those responsible for risk management to be closely involved in preparing and deciding scientific characterisations of risks, and for scientific advisors to be expected to provide specific advice on particular policy issues\textsuperscript{29}. Since that turning point, however, the appropriateness of this approach has been challenged in the scientific as well as policy communities. The BSE crisis was interpreted as a result, at least partly, of a regulatory regime marked by a non-transparent intermingling of the roles of assessment and management and of scientific and non-scientific considerations. The Committee of Inquiry into BSE, set up by the European Parliament, in its \textit{Medina Ortega} report deemed a blurred relationship between science and policy and a lack of transparency to have been major shortcomings of the EC’s policy (in the years before 1996) as well as of the British approach. It concluded that the EU institutions had given precedence to national interests of agriculture and industry at the expense of public health protection\textsuperscript{30}.

Suspected of abetting partiality and obscurity in dealing with food risk issues, the traditional approach of rather seamless scientific and political activities became a subject of intense debate, scrutiny, and reform. It is the \textit{primary feature} of the current institutional framework of EU food safety regulation that the responsibilities for assessment and management are divided between institutions, with the newly established European Food Safety Authority (EFSA) being located in Parma, and the European Commission being located in Brussels.

A policy of reassurance linked to a partial treatment of scientific information has been described as one of the principal shortcomings in the UK’s policy-making on BSE until the mid 1990s. It was pursued despite a lack of certainty that BSE posed no risk to humans, it undermined precaution, and it eventually produced a legitimisation crisis when in March 1996 UK government ministers announced that BSE had most likely been transmitted to humans\textsuperscript{31}. It seems reasonable to assume that the growing attention to and communication about \textbf{scientific uncertainties} at the EU-level is at least in some part a response to the UK’s critical experiences in terms of a ‘lesson learnt’.

Official EU statements increasingly declare scientific uncertainties to be an important subject of assessment, a component of transparency and public communication, and a matter of accountability in their own right. An EFSA Working Group has been set up which was asked to develop a framework for a guidance document dealing with transparency in risk assessment, including the way in which adequate information on the strengths and weaknesses of the data used could and should be provided\textsuperscript{32}. A recent discussion paper by the European Commission’s Health and Consumer Protection Directorate General (DG SANCO) critically notes that public debate would tend to over-sell science as a source of certainty. In order to achieve clearer risk perceptions and a better integration of risk into EU policy debate, according to the paper, it is of great importance that the limits on scientific certainty are more accurately un-

\textsuperscript{29} Ibid.
understood, and that the responsible authorities are able to highlight and communicate scientific uncertainties.\(^{33}\)

The more careful consideration of scientific uncertainties can be understood as a second resource employed to address a situation of low trust and legitimacy.\(^ {34}\) Just as the provisions for enhancing the independence of risk assessment, it can be described as a results-based legitimacy mechanism.

The EU (and also very much the UK) has also resorted to reforms designed to hold up the procedural legitimacy of food safety governance by incorporating democratic norms in the risk analysis process.\(^ {35}\) Advancement of the democratic quality of the governance process forms the third major response to the situation of “contested governance”.\(^ {36}\) It is formulated on the DG SANCO’s website as follows: “Transparency of legislation and effective public consultation are essential elements of building this greater [consumer] confidence.”\(^ {37}\) There are three major modes by which this purpose was expected to be served in food safety regulation:

- by making the risk analysis process, including risk assessment, more transparent through wider public documentation (including the publication of EFSA’s opinions on the Authority’s website);
- by providing more 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 a prominent position);
- by offering more comprehensible and process-oriented information on risk to the public at large, specifically addressing major consumer concerns.

In short, the shift to procedurally-based legitimacy as a supplement to results-based legitimacy includes efforts to provide public access to documentation of both the outcomes and the procedures of both risk management and risk assessment, to consult with commercial and civil society actors on a more regular basis and in a more open manner (which contrasts with

---


\(^{34}\) Attention to and communication of scientific uncertainties seem to be rarely directly represented as trust-building measures. However, this point of emphasis usually forms part of official representations of the new approach to food safety governance, which typically include more or less specific references to the trust issue.

\(^{35}\) 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 legitimisation”; G. Skogstad, ‘Legitimacy and/or policy effectiveness?: Network governance and GMO Regulation in the European Union’, Journal of European Public Policy, 2003, p. 324. While the ‘test of appropriateness’ under output (or results-based) legitimation standards was the perceived merit of policy outcomes, this test under input (or procedure-oriented) legitimation standards was the conformity of decision-making procedures with democratic norms of public participation and control (p. 324-325).

\(^{36}\) 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.

\(^{37}\) C. Ansell and D. Vogel (eds.), What’s the Beef?: The Contested Governance of European Food Safety, MIT Press, Cambridge, 2006. 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” (p. 20) as “contested governance” and argue that European food safety regulation over the past decade exemplified such a case.

informal and confidential “behind closed doors” consultations), and to provide the public at large with more targeted information

2.2.2 Governance aspects in need of further improvement

At the EU-level, the most specific and authoritative codification of current structures and practice including the institutional re-arrangements and reform efforts set out above is provided in the new European Parliament and Council Regulation 178/2002 on general principles of food and setting up the European Food Safety Authority of 2002, better known as the “General Food Law”\(^40\). Grounded in a wider regulatory literature\(^41\), this rests on three key pillars. The first pillar is the application of principles of independence, objectivity and transparency in risk analysis (as defined in section 2.1.1), the second pillar is the application of the precautionary principle in the face of scientific uncertainty, and the third pillar is the resort to public consultation.

Public consultation directly relates to participation as one of the five normative principles of good governance that the European Commission has identified in its White Paper on European Governance. It requires governance institutions actively to engage with other social groups, from the conception of strategic options right through to the implementation of decisions. The four other principles are openness, accountability, effectiveness, and coherence\(^42\), all of them directly applicable to the good governance of food safety. The principle of openness entails according to the Commission clear, accessible communication of the nature and rationale for decisions and other governance outcomes. Accountability involves clarity over the nature of the reasoning and the allocation of responsibility in legislative and executive processes. Effectiveness relates to timeliness, delivering what is needed on the basis of clear objectives, and an impact evaluation. It includes issues of subsidiarity and proportionality in decision outcomes. Coherence concerns the degree of consistency that can be achieved by complex institutional frameworks in addressing even more complex technical, social and natural systems.

It is important to note that the revised European food safety governance system embedded in this legal and policy framework is an evolving system. Many specifications of the recent reforms are still very much developing. It is an inherent part of this embryonic stadium of change that the challenges of putting the reforms into practice in an effective and politically and socially acceptable manner are becoming increasingly visible. The following sections address some of these challenges. It will be argued that in order to further implement the principles of food safety governance enshrined in the General Food Law and the agenda on governance in the European Union several aspects deserve more attention and need further improvement.

Reconsideration of the relationship between risk assessment and risk management

As set out above, the division of responsibilities for risk assessment and risk management between institutions rests on one of the major pillars of the General Food Law which is the application of the principles of independence, objectivity and transparency in risk analysis. This substantial institutional re-arrangement is intended to ensure primarily the political inde-

---

\(^{39}\) Dreyer et al. 2006, \textit{supra} note 27.

\(^{40}\) General Food Law, \textit{supra} note 6; see discussion in E. Vos, C. Ni Ghiollarnath and F. Wendler 2005, \textit{supra} note 30.


\(^{42}\) COM (2001) (European Governance), \textit{supra} note 6, Section II.
dependence of the risk assessment authority and a disinterested scientific description of food safety issues. While separate responsibilities are generally seen as a welcome development, political decision makers, scientific experts, and economic and civil society actors increasingly realise that the institutional and geographical segregation of risk assessment creates new challenges in terms of organising the relationship with risk management.

In the first couple of years after EFSA’s establishment 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 presented practical reality in which interaction occurs and is deemed necessary. There exist obviously tensions between public legitimisation needs (insulating science from policy) and practical action requirements. Interviews with policy actors and expert advisors at the EU-level, in France, and also in Germany indicated that the experience with the new institutional divide has increasingly brought to light that problems might arise if the need for interaction is not accounted for at specific points in the risk governance process. The two main actors at the EU-level, EFSA’s Scientific Committee and the Commission’s DG SANCO, have recently explicitly recognised the need for an ‘efficient and transparent mechanism of interaction’ between risk assessment and risk management.

Interaction is deemed particularly relevant at the start of the risk governance process when a problem needs to be defined and the questions and tasks for the risk assessors need to be delineated. The interviewed Commission officials emphasized the need to be present during meetings of EFSA’s panels in order to explain their needs, to better understand the reflections of the scientists, to change the terms of reference if EFSA would feel that would be necessary to answer the question, and also to make sure that a panel is not stepping in risk management issues. Also in France, the stage of framing the issue and of setting the terms of reference has been identified as a critical issue in terms of interaction. The French food safety agency, AFSSA, has addressed this issue by introducing ‘quality procedures in referral handling’. These include training, ad hoc rather than systematic, of ministry personnel by assessors to assist those in the ministry in phrasing referrals properly.

A second interaction issue, brought to light by the comparative study, relates to the power of the risk assessment authorities to publish autonomously. From the interviews, it could be concluded that EU and also French and German risk managers have increasingly recognised the need for co-operation with the assessment authorities with regard to communicating food risks to the public. They expressed a preference for a buffer period before the publication of risk assessment opinions and related press announcements during which they could read and consider the opinion, and, if required, come back to the assessment authority for clarification or

---

43 Cp. Dreyer et al. 2006, supra note 27.
45 DG SANCO 2005, supra note 33. This 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 2005, supra note 7, p. 102. The NRC’s ‘Red Book’ is emphatic on that: “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, supra note 5, p. 6.
discussion of particularly important management issues. This would enable them to reflect on the management implications before being dragged into the limelight by the media and to provide both the media and the public with informed and coordinated responses. EFSA and the Commission, as well as the German Federal Institute for Risk Assessment (BfR) and the Ministry for Consumer Protection, have responded to this need by agreeing informally on timely information and consultation.

A third critical issue in terms of interaction was highlighted by German interviewees in particular. From the side of management it was described as a special challenge to tune expert evaluative advice along the lines of risks being ‘relatively low’ or ‘relatively high’ within the wider appreciation of political, economic and social conditions and requirements on which risk management decisions are based. To address this challenge of coordinating evaluative judgements would require improved interaction and communication between the BfR and the risk management authorities. Along similar lines, from the side of risk assessment an interest was expressed in establishing, in co-operation with the Federal Office of Consumer Protection and Food Safety (BVL, the main German risk management authority) ‘Best Practices in Evaluation’, which would define who – the BfR, the BVL, or both – should be given the task of performing evaluative judgments at the interface between assessment and management. Such a practice code could enable managers to implement similar or equivalent measures in dealing with similar risks and thus enhance consistency in decision-making on risk.

At the risk assessors’ workshop it was underlined that the existence of different cultures of risk assessment in the EU and different national perspectives of what constitutes an acceptable risk would render systematic and transparent evaluation performed jointly by assessors and managers both a necessity and a major challenge.

It was generally felt by EU-level assessors and managers whose views were elicited in the empirical research (and also by national policy makers and scientific experts) that there is still room for improving interaction, especially with regard to the aspects listed above. During interviews in the EU-level study it was suggested for example that opening up the interaction between EFSA and the Commission on the drafting of the terms of references could allow stakeholders to provide knowledge and comments. Most of the participants at the risk assessors’ and risk managers’ workshops underlined the need to promote and facilitate communication and co-ordination in these respects. In current practice, the interaction between EFSA and the Commission occurs mainly in an informal or semi-formal manner as part of an approach which is rather ad hoc and little targeted. Still, several of the workshop participants were sceptical of formalising interaction through permanent units or committees. They wor-

---

48 For France see C. Mays, M. Jahnich and M. Poumadère, supra note 47, p. 64.
53 In contrast with previous practice, where informal and pragmatic interaction was taken for granted, interaction is today more focused and subjected to restriction and scrutiny. Provisions for the involvement of risk managers in the assessment process are one example of this. The respective Article of the General Food Law (28/8) stipulates that, if invited to do so, representatives of the Commission may assist the discussion process for the purpose of clarification of information, but they should not attempt to influence the debate. The specific unit within DG SANCO that deals with the relations with EFSA (formerly unit 5) shall fulfil a ‘watchdog’ function in this respect and prevent Commission officials from overstepping the role of an observer who may supply information on request.
ried that this could end up in further complicating an already highly convoluted governance system.

Application of the precautionary principle in the face of scientific uncertainty

It was mentioned above, that official representations of EU food safety regulation increasingly express commitment to a more systematic recognition and communication of the scientific uncertainties that may be involved in the assessment of risks. Much more than in the past, the task of scientific expert advisors is seen as including both providing information about what is known and about what is not known. At the centre of a more systematic approach to dealing with the challenge of scientific uncertainty (as defined in section 2.1.2) lies the application of the precautionary principle, the second major pillar on which the General Food Law rests. In codifying and defining the precautionary principle with particular reference to food safety, the Law directly addresses the contentious nature of the relationship between risk assessment and precaution. Drawing on concepts that are discussed in section 2.1.2, the Law characterises the application of the precautionary principle in the following terms:

“1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.” [present authors’ emphasis]

In short, through its references to both more comprehensive risk assessment and provisional risk management measures under conditions of persistent uncertainty, the General Food Law acknowledges that the precautionary principle is of direct and important relevance to the assessment (as well as to the management) of food safety. Although little analysis is provided of the detailed rationale, and no examples are given fully to substantiate the concept of ‘more comprehensive risk assessment’, the injunction to greater comprehensiveness clearly reflects an understanding of the circumscribed status of conventional risk assessment as an approach to promote a broader understanding in assessment.

The empirical findings indicate that while precaution is generally acknowledged as a major EU policy making principle the concept continues to be contested in the actual regulation of risk which holds true also for the regulation of food risks. In particular, there is a lack of clarity over the ‘triggering’ of the precautionary principle and a related scepticism over the possibility of applying the principle in a consistent, predictable and non-arbitrary manner. The nature and extent of scientific uncertainty or evidence of the possibility of a serious risk required to justify a precautionary approach remains an open question. Another question which is deemed important, however unsettled, concerns the way in which the precautionary principle

54 This concern was expressed most strongly at the workshop with risk managers; E. Vos and F. Wendler, ‘A Summary Report of a Workshop with Risk Managers’, 2 November 2006, Maastricht, Maastricht University.
55 General Food Law, supra note 6; see discussion in E. Vos, C. Ní Ghíollarnáth and F. Wendler 2005, supra note 30.
56 E. Vos, C. Ní Ghíollarnáth and F. Wendler 2005, supra note 30, p. 82.
should and could be used in accordance with the principle of proportionality when deciding on management measures.\(^{57}\)

The information gained from the interviews with decision-makers and scientific advisory experts suggests that in current practice the concrete interpretation and application of the precautionary principle varies across countries and authorities, and appears highly contingent on the respective regulatory framework, on individual cases, and on the respective case assessors and managers. Both at EU-level and Member State level, the approach to identifying, characterising, and communicating scientific uncertainties and handling them on the basis of the precautionary principle is \textit{ad hoc} and \textit{case-specific}, rather than systematic and based on concrete guidelines. This may be at least partly due to the rather under-specified reasoning and implications of the discussion in the General Food Law of the relationship between risk assessment and precaution.

\textit{Opening up the governance process through public participation}

Public consultation is the third major pillar on which the General Food Law rests. It is represented as a response to the circumstance that “food safety and the protection of consumer interests are of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisation”\(^{58}\). 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”\(^{59}\). 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\(^{60}\). 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”\(^{61}\). 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\(^{62}\).

Up to now, one of the most notable changes to the traditional practice of involving interested and affected parties is that the risk assessment phase is being opened up to some degree to consultation. This new practice is not accepted unquestioningly. The findings of the empirical study show that the inclusion of stakeholders in the course of risk assessment is still very much disputed and has an exploratory character. By no means were all interviewees convinced about the necessity of having 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\(^{63}\). According to various Commission officials who were interviewed in the empirical study, 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 presentation of the assessment report\(^{64}\).

Another change from the \textit{status quo ante} in current consultation practice is that greater importance is attached to the representation of consumer interests. At the EU-level, it is institution-

\(^{57}\) C. Mays, M. Jahnich and M. Pounadère 2005, \textit{supra} note 47, p. 84.
\(^{59}\) General Food Law, \textit{supra} note 6, Art. 9.
\(^{60}\) General Food Law, \textit{supra} note 6, Art. 42.
\(^{61}\) General Food Law, \textit{supra} note 6, Art. 3 (12).
alised in the Advisory Group on the Food Chain and Animal Health and the Stakeholder Consultative Platform set up by EFSA. EFSA also provides for a formal representation of consumer interests at the management level, in the Authority’s Management Board. These provisions are generally welcomed by representatives of non-governmental organisations (NGOs). Various participants at the NGO workshop pointed, however, to the continuing challenges faced by NGOs around unequal power relations and access to resources between different actors in food safety governance in which informal contacts behind closed doors 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 early stage of the governance process when the problem is defined and the terms of reference are set and certainly at those stages at which action needs and ways of action are deliberated and concluded

At present, public consultation is mostly organised as stakeholder consultation, giving in particular the bigger and more prominent organisations a voice (within the framework of the Advisory Group on the Food Chain and Animal Health and the Stakeholder Consultative Platform). Several NGO representatives challenged this practice stressing 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 scarce resources of smaller NGOs or citizens to invest on a regular basis in the regulation of food safety. In a similar line of argument with regard to incorporating different views in society it was noted at the risk assessors’ workshop that decision making at the management stage would need to be informed by knowledge about risk perceptions, otherwise it was more likely to erode public trust.

2.3 Practical aims of the present exercise

Based on the policy imperatives identified in current legal and policy documents and highlighted by interviewees in the empirical studies and by stakeholders during the series of workshops described above, certain issues emerge as fundamental to the task of improving food safety governance across the European Union. It is these issues that will form the normative basis for the General Framework to be introduced in subsequent chapters.

In addition to those questions (a)-(e) outlined in Section 2.1.3 above, a number of further questions remain to be addressed in any attempt to develop a truly integrated governance framework that addresses the requirements of the General Food Law, the White Paper on Governance, the multiple forms of less tractable incertitude outlined above and the other issues raised by stakeholders. In particular:

f) How can framing be organised so as to engage stakeholders and the public and to allow different perspectives and priorities to be addressed in policy formulation, in a way that addresses ambiguity?

g) How can interactions and communications between the European Commission, EFSA and stakeholders be improved so that assessments are framed and evaluations concluded in an effective, open and transparent manner?

h) Within the activity of assessment, what is the operational definition of ‘persistent scientific uncertainty’ as defined in Article 7 of the General Food Law and by what practical means can this be characterised in the process of assessment?

66 To be sure, the Commission also organises regularly public consultations on several topics where everyone is invited to give comments.
68 M. Dreyer, O. Renn and K. Borkhart 2007, supra note 52.
i) Which are the key operational features of ‘more comprehensive risk assessment’ and how do these relate to current conventional and alternative available procedures?

j) How can we decide what constitutes an appropriately ‘high level of health protection’ and exactly how does this relate to ‘technical and economic feasibility and other factors’?

k) How can we ensure that the principle of proportionality is upheld in a procedurally consistent manner under different situations of persistent uncertainty?

l) How can the objectives of openness and participation be addressed in an effective and proportional way throughout the governance process, especially as regards assessment, evaluation and management?

Together with the earlier questions (a) – (e) set out in Section 2.1.3, it is these issues that must be addressed by the present candidate design for an integrated general framework for the governance of food safety. This report responds to each of these through the following chapters.

Chapter 3 will provide an outline of the overall architecture for such a food safety governance framework. This must address, clarify and carry forward the main elements in current EU law and policy on the governance of food safety (the 2002 General Food Law), the implementation of precaution (notably the 2000 CEC Communication on Precaution and the Nice EU Ministerial Resolution), its relationship with overarching principles of good governance (as discussed in the 2001 CEC White Paper on Governance) and with established international frameworks (notably IRGC and WTO -- the latter including TBT, SPS -- and Codex).

The subsequent three chapters will focus particular attention on the more detailed structure of the processes of framing (Chapter 4), assessment (Chapter 5) and evaluation and management (Chapter 6) within a wider governance framework. In particular, Chapter 4 will establish a basis for understanding the modalities for the implementation of the precautionary principle in assessment and the detailed implications for the role of conventional as well as extended risk assessment.

Chapter 7 will point out the legal and institutional conditions required to implement the proposed framework in EC food safety governance and make suggestions for institutional integration and adaptation.

Chapter 8 will outline in detail the proposed framework’s approach to citizen and stakeholder engagement, explaining the ways in which it can contribute to the governance principles of openness and participation.

Finally, conclusions will be put forward in Chapter 9 that will review the earlier chapters and relate their recommendations again to the challenges detailed above.

3. Overview of the General Framework

Adrian Ely, Andy Stirling, Marion Dreyer, Ortwin Renn, Ellen Vos and Frank Wendler

3.1 Historical precedents

Frameworks for food safety governance have evolved through a variety of forms since the mid-late 20th Century, and it is useful to reflect on these developments prior to introducing the General Framework adopted in this report. The simplistic ‘technocratic’ model, wherein objective science is seen to directly inform policy-making (shown in figure 3.1), gave way in the
late 20th Century to the less naïve ‘decisionist’ model (shown in figure 3.2)\textsuperscript{69}. This model, which corresponds closely to that illustrated by the NRC’s Red Book\textsuperscript{70}, recognised that policy making required inputs other than science in order to inform decisions, and that other legitimate factors (such as those relating to socio-political and economic objectives) needed to be taken into account in addressing risks. The Red Book in 1983 established the division between the scientific aspects (“risk assessment”) and political aspects (“risk management”) within the overall process of risk analysis. This division, and several other aspects of the “Red Book” model, have been adopted across a wide variety of risk management fields\textsuperscript{71}.

\begin{figure}[h]
\centering
\scalebox{0.6}{
\begin{tikzpicture}
  \node[rectangle,draw] (science) at (0,0) {Science};
  \node[rectangle,draw] (policy) at (3,0) {Policy Making};
  \node[rectangle,draw] (comm) at (6,0) {Risk Communication};
  \draw[->] (science) -- (policy);
  \draw[->] (policy) -- (comm);
\end{tikzpicture}}
\caption{The ‘technocratic’ model (from Millstone et al 2004)}
\end{figure}

\begin{figure}[h]
\centering
\scalebox{0.6}{
\begin{tikzpicture}
  \node[rectangle,draw] (assessment) at (0,0) {Risk Assessment};
  \node[rectangle,draw] (evaluation) at (3,0) {Risk Evaluation};
  \node[rectangle,draw] (management) at (6,0) {Risk Management};
  \node[rectangle,draw] (considerations) at (-3,-3) {Scientific considerations};
  \node[rectangle,draw] (information) at (0,-3) {Technical, economic and social information};
  \node[rectangle,draw] (outcome) at (6,-3) {Policy outcome and regulations};
  \draw[->] (assessment) -- (considerations);
  \draw[->] (considerations) -- (evaluation);
  \draw[->] (evaluation) -- (management);
  \draw[->] (management) -- (outcome);
\end{tikzpicture}}
\caption{The ‘decisionist’ model (from Millstone et al 2004)}
\end{figure}

The previous chapter (Section 2.2.1) has discussed how recent institutional and procedural reforms in European food safety governance have continued this trend. The objective of promoting “independent risk assessment” within EFSA, as legislated for under the General Food Law, has been seen as an important condition for re-building trust in the EU regulatory process, especially following the lessons from the BSE crisis. As has been discussed in Chapter 2 however, the strict separation of risk assessment and risk management laid down in the General Food Law is in practice somewhat blurred.

Since the widespread diffusion of the risk assessment/risk management distinction, careful analyses of the role of science in policy making have increasingly pointed to the importance of ‘framing assumptions’ in informing risk assessment. These insights have questioned the simple risk assessment/management boundary by pointing to politically-informed decisions around how risk assessment should proceed. Such decisions do not necessarily determine the outcome of the scientific assessment, however may often circumscribe the scope, or at least

\textsuperscript{69} The distinctions between the three models outlined in figures 3.1-3.3 are taken from E. Millstone, P. van Zwanenberg, C. Marris, L. Levidow and H. Torgersen, \emph{Science in Trade Disputes Related to Potential Risks: Comparative Case Studies}, Seville, Institute for Prospective Technological Studies, 2004.

\textsuperscript{70} National Research Council 1983, \emph{supra} note 5.

\textsuperscript{71} G.S. Omenn, ‘On the Significance of ”The Red Book” in the Evolution of Risk Assessment and Risk Management’, \emph{Human and Ecological Risk Assessment}, 9, 2003, p. 1155-1167. It is worth bearing in mind, however, as pointed out in the preceding chapter, that the view of risk assessment as a purely scientific process was also questioned within the ‘Red Book’.
the minimum scope, of the risk assessors’ deliberations. Millstone et al (2004)\textsuperscript{72} have borrowed from the terminology adopted by the Codex Alimentarius Commission to characterise these decisions as relating to “risk assessment policy”. According to them, such decisions concern issues such as:

- “which kinds of impacts are deemed to be within the scope of the assessment and which were outside it,
- which kinds of evidence to include and which to discount,
- how to interpret the available evidence,
- how to respond to uncertainties, and
- how much of different kinds of evidence would be necessary or sufficient to sustain different types of judgements.”

\[\text{Figure 3.3: The ‘transparent’ model (from Millstone et al 2004)}\]

Millstone et al (2004) have thus proposed a more sophisticated model for understanding policy that recognises the formulation of social framing assumptions based on socio-economic and political considerations. Based on research into science-related trade disputes over beef hormones, rBST and GM crops they argue that policy officials are increasingly articulating a co-evolutionary model that questions the over-simplicity of the decisionist model’s artificial distinction of a purely scientific up-stream risk assessment phase followed by a down-stream risk management phase. The ‘transparent’ model (Figure 3.3) views scientific and socio-political factors as intertwined throughout the process of policy-making and communication, with reciprocal links between science and policy, and recognises the input of various actors at each stage in the process. Millstone et al qualified their use of the word ‘transparent’ by stressing that if current practices in policy making around food risks were conducted transparently (which largely they are not), they would be seen as operating in accordance with this model. The authors of this report view ‘framing’ as an important aspect of risk governance. The governance concept they advocate aims to build transparency in decision-making around European food safety by explicitly recognising the function of framing.

While communication around risks, both with stakeholders and the public, has traditionally (at least within the technocratic model) been seen as a separate process, carried out following assessment and management, the governance approach adopted by the authors of the present

\footnote{E. Millstone et al 2004, \textit{supra} note 69.}
report views communication, more accurately referred to as *engagement* with stakeholders and the public, as integrated into every stage in the process. This corresponds with the relevant texts in Article 3(1), Article 9 and Article 42 of the General Food Law, as previously discussed in Section 2.2.2. Engagement and participation within the SAFE FOODS Work Package 5 governance framework will be covered in more detail in Chapter 8.

A simplified representation of the governance framework is illustrated in Figure 3.4 below (the complete and detailed framework is outlined in Figure 3.8), highlighting the successive stages of framing, assessment, evaluation and management. Each of these stages fulfil specific roles within food safety governance, engaging stakeholders in the ways most appropriate to ensure the principles of good governance outlined in Chapter 2 (as will be covered in more detail in Chapter 8). The following sections of this chapter will be dedicated to outlining the function and procedural aspects of each of these stages, before they are discussed in more detail in Chapters 4-6.

![Figure 3.4: A simplified representation of the General Framework for food safety governance in Europe](image)

### 3.2 The General Framework – a schematic picture

In broad terms, the proposed framework includes the well-established stages of risk analysis described above, here referred to as *Assessment* and *Management*. Moreover, as the representation in Figure 3.4 shows, the framework renders the established linear structure - in common with other contemporary conceptions of risk governance - into an *open, cyclical, iterative*...

---

and interlinked process. In this respect, there is particular resonance with the broad frameworks currently emerging under the auspices of the International Risk Governance Council. Furthermore, it includes two additional governance stages: firstly Framing which relates to risk assessment policy (in the terminology adopted by Codex Alimentarius and Millstone et al), 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 threat more explicitly in the governance cycle. These two stages act to promote efficient and transparent mechanism of interaction between risk assessment and risk management. All steps of the cycle are interlinked and involve multi-actor engagement processes that are specified in later parts of this document.

Several points are important to note at the outset, prior to the description of the advocated framework. The first is that this framework distinguishes between the precautionary principle, precautionary assessment and prevention. Section 2.1.2 focussed on the problem of the conditions under which the precautionary principle might be triggered by assessments of uncertainty. For the purpose of this report and in line with the definitions given by the European Court of Justice and the General Food Law (Article 7), we consider the precautionary principle to be a general governance principle employed in framing the overall process of framing, assessment, evaluation and management. In particular, as will be explained, precaution applies to the ‘screening’ of food safety ‘threats’ for the properties of seriousness or uncertainty in order to determine their subsequent treatment in assessment and management. Precautionary assessment consists of a ‘more comprehensive’ approach to assessment (as discussed in the previous chapter), adopted in cases where screening has identified a lack of scientific certainty of the kind referred to in the General Food Law. Prevention refers to the approach that is taken when a food safety threat is identified as being both serious and certain.

Secondly, it is important to note at the outset that the present integrated framework is primarily designed to address the regulation (including licensing) of food products, production methods, industrial processes and commercial practices. This is an extremely broad field. However, it does exclude certain important areas of regulatory activity, such as cases where developments are driven by urgent need directly to respond to particular emerging ‘food scares’. In this latter case assessment does not necessarily begin with a particular identifiable product, process or practice. Instead, attention starts with a less readily characterisable social or public health phenomenon, for which causal relationships with particular products processes or practices may be difficult to establish. Under such conditions - though the present framework will not be irrelevant - certain additional features will be necessary, which lie beyond the scope of the present exercise.

It is further important to note again that the implementation of the procedural provisions envisaged by the General Framework does not necessarily require institutional changes but could be effected through the currently existing institutional arrangements. While the General Framework outlined here introduces certain innovative elements, especially at the interface between risk assessment and risk management, it generally fits into the existing legal and institutional framework of European food safety regulation as defined by the General Food Law and other, more case-specific pieces of framework legislation (such as the regulations and directives setting out the procedures for the authorisation of GMO products) as well as the current structures and practices of food safety regulation at the European level. Against this background, it is the intention of the proposed General Framework to make recommendations especially for the improvement of practices and approaches within the conduct of risk regula-

74 O. Renn 2005, supra note 1.
tion, while complying with, and further implementing the key principles of the General Food Law and other relevant legislation and case law.

The limited institutional adaptations that will be suggested to address the interface between assessment and management would, however, facilitate the working of the proposed procedural reforms. In the following chapters, we refer to two specific adaptations: an Internet Forum (an online function, managed by the Commission that allows open and transparent communication between the Commission, EFSA, Member States and wider stakeholder groups) and an Interface Committee (which may take a number of forms, discussed in detail in Chapter 7).

The Internet Forum should act as a site for the dissemination of information associated with every stage in the governance process in order to promote the governance principles of openness and accountability. It should be designed in such a way as to facilitate proportionate deliberation between the core institutions of food safety governance with stakeholders and citizens. The modalities for ensuring effective, but proportionate deliberation through this route are outlined in Chapters 7 and 8. It should provide an outlet for framing (e.g. referring to the appropriate European and international frameworks at issue). It can act as a dissemination and deliberation mode for the outputs of EFSA’s engagement activities, particularly the Stakeholder Consultative Platform (formalized membership), annual colloquia (by invite/expressions of interest), technical meetings (by invite/expressions of interest), and science conferences and scientific colloquia (by invite). In addition, many of EFSA’s current practices for public consultations and requests for data should be made more easily available to risk managers and stakeholders through hosting on the Internet Forum. These include various activities linked to assessment, such as PRAPeR (40-day consultation for new pesticide draft assessment reports), public consultations on GMOs, additives, products and substances in animal feed, biological hazards, science committee consultations, requests for data on scientific issues, corporate events and “Porte Aperte” (engagement with the public in the Parma region)\(^76\). The forum would also act as a site where the Commission’s consultations and decisions could be relayed transparently to the European public, allowing accountable demonstration of effectiveness and coherence in decision-making.

### 3.3 An overview of framing: review, referral and terms of reference

#### 3.3.1 Review

‘Framing’ refers largely to what may be called the ‘meta-level’ of food safety governance, involving the whole range of processes concerning the iterative design and development of the framework conditions of regulation in the face of new learning and feedback between the various processes, both through binding rules and non-binding conventions. By explicitly including this as an element in the General Framework, it is acknowledged that the implementation of food safety governance takes place at a number of organizational, legal and discursive levels that lie outside the detailed focus of this project (for example within Codex Alimentarius or the WTO). ‘Framing’ is made up of three activities - ‘review’ of the technical and institutional conditions relating to food safety in its broadest sense, ‘referral’ of specific threats to EFSA for the process of screening, and the setting of ‘terms of reference’, upon which EFSA will base their assessment. These are represented diagrammatically in Figure 3.5.

Figure 3.5 The stages of framing, in relation to the rest of the governance cycle

‘Review’ sets the structure of the legal and institutional design with respect to responsibilities, rights, obligations, division of labour, prescribed procedures and oversight activities. It also includes the dynamic aspect of incorporating structural changes over time and is closely related to the underlying philosophy of food safety governance. Review thus involves activities such as the development and enactment of laws and regulations (such as the Community’s General Food Law and its regulations on genetically modified food), the generation and use of legal principles (such as the Precautionary Principle), the determination of scientific conventions (such as statistical procedures), the establishment of predominant procedural perspectives (such as the three-step risk analysis process) and also the review of the conduct of the safety governance process as a whole. All of these activities have an impact on how the concrete design of the governance framework is spelled out and changes over time. The European Community bodies are obviously highly influential in these framing activities, but also global organisations, the World Trade Organisation and the Codex Alimentarius Commission, in particular, and also the Member States exercise an influence.

3.3.2 Referral

In contrast to the structural conditions under which regulation takes place, the step referred to as ‘referral’ focuses on the concrete processes and procedures by which food safety problems are identified, formulated and initially referred to EFSA for screening and assessment. Referral is based upon the legally prescribed regulatory framework of a product, a production method, an industrial process or a commercial practice. Once such a substance, process or outcome is identified as possibly being subject to regulatory actions on the basis of the general legislative provisions (on the basis of Article 29, GFL), and has to be submitted to specific licensing, certification, or testing whether all standards are met, it is forwarded to EFSA.
for screening. Referral may hence be performed by applying existing laws or regulations or by initiating preliminary regulatory procedures resulting possibly in modifications of existing or even the drafting of news acts by the European institutions. The process of referral will often fall to the Commission or to Member States, however the establishment of the Internet Forum and Interface Committee will also allow the opening up of referral to wider stakeholders. It is understood that in cases of self-tasking by EFSA, which are prescribed by Article 29, 1 (b) of the General Food Law, this step is omitted and the food safety governance cycle starts at the stage of screening.

3.3.3 Terms of reference

Screening, which is carried out by EFSA and is thus described further in the following section on Assessment, involves the preliminary characterisation of the threat in question in order to select the most appropriate form(s) of assessment. This assessment must be based on specific and detailed terms of reference (which is formulated based on an exchange of opinions by the Commission as the manager, EFSA as the assessor and the relevant stakeholders). It is during this process of setting terms of reference that residual uncertainties or data gaps in relation to a threat may be identified, or specific participatory procedures or consultations with external experts may be requested to form part of assessment. The terms of reference will be informed by the insights gained through the screening exercise in relation to what constitutes the most appropriate, efficient and proportionate form of more detailed assessment. While the drafting of the terms of reference is currently undertaken either by a specific unit of DG SANCO (in cases of a request by the Commission), or by the originator of a request, it is the intention of the proposed framework that this step should involve both assessment actors and managers in conjunction with representatives of key stakeholder groups. While DG SANCO may retain the overall responsibility for the drafting process, the Internet Forum and the Interface Committee will allow these other actors the opportunity to influence and monitor the process.

3.4 An overview of assessment

A key element in the broader process of food safety governance lies in the assessment of risks and benefits from alternative products, processes, investments, standards, regulations and strategies. In this document, we consistently use the broad term assessment (as opposed to “risk assessment” or “conventional risk assessment”) to refer to the process of gathering, eliciting, synthesising and deliberating over information and perspectives that are pertinent to governance decisions. Assessment therefore subsumes, with other methods which will be described in more detail below, the conventional procedures of risk assessment as variously defined. It is foremost assessment that informs, substantiates and justifies governance decisions, policies and wider institutional practices and commitments. As such, assessment helps ensure coherence, inform openness and provide accountability.

3.4.1 Screening

EFSA will receive its initial mandate to assess a given food safety threat through the process of referral outlined above. The first stage in the subsequent assessment is that of screening, in which the most appropriate approach to assessment is identified. During the screening stage, which follows after ‘referral’, key features of the food safety threat in question are identified and pre-classified in advance of actual ‘assessment’. In the interests of openness, effectiveness and proportionality, the attributes of seriousness, uncertainty, and ambiguity are used to identify the most appropriate approach to a more detailed assessment and to help prioritise attention to different threats. This essential activity relates to established notions of ‘preliminary risk assessment’ in discussions under the auspices of the WTO and elsewhere, which can be either quantitative or qualitative in form. Through its identification with the task of hazard
identification, it is intended that this task should be undertaken by a specific unit of EFSA, in cooperation between the Scientific Committee or Panel and the scientific expert services. The screening process collects what is already known about the substance, process or activity (i.e., about the source of threat under consideration), characterizes the main hazard properties and suggests the appropriate assessment approach to which the threat should be submitted. The outcome of the screening process informs, as already explained above, the terms of reference.

In order to address the challenges outlined in Section 2.1 (surrounding uncertainty, ambiguity and ignorance), assessment within our framework includes three novel approaches in addition to the conventional risk assessment procedure. These approaches address threats which are certainly and unambiguously serious calling for a presumption of prevention, threats subject to scientific uncertainty calling for a precautionary assessment, and threats subject to socio-political ambiguity calling for a concern assessment (in which systematic knowledge is collected about risk perceptions by individuals and groups, socio-economic impacts and other information related to the threat source). We propose that the process of screening threats to identify which of these (or conventional risk assessment) is most appropriate should be carried out within EFSA, by individuals who have expertise not only in technical risk assessment but also in issues relating to public concerns (usually associated with the social sciences).

Based on the screening process and drawing upon stakeholder perspectives sought through the Internet Forum and Interface Committee, the terms of reference will be drafted (as mentioned above). These will include a detailed description of which approach to assessment should be followed by EFSA in order to address various aspects of the threat in question.

### 3.4.2 The four approaches to assessment

The four different approaches to assessment are shown in figure 3.6 below. Each assessment approach is designed to gather the information necessary for making adequate and prudent governance decisions in different contexts. Where a given threat displays a number of different attributes, these different aspects may be allocated to parallel treatment by different types of assessment.

If the threats in question are certainly and unambiguously serious (illustrated by the question “serious?” in the screening stage of the diagram below), i.e. significant harm is to be expected with almost certainty, then, subject only to consideration of any over-riding justification, they are assigned directly to preventive measures. If the threats in question are minor and quantitative data about probabilities and magnitudes is either available or easy to produce, then they are assigned directly to risk-based assessment. Here there may be a presumption in favour of approval, subject to evaluation and management considerations around the complexity and scale of the threat in question.

If screening is unable to allocate threats to straightforward preventive measures or to risk-based assessment, then more comprehensive assessment procedures are recommended. If a lack of scientific certainty has been identified in screening (illustrated by the question “uncertain?” in the same diagram), then the subsequent approach to assessment is precautionary. If socio-political ambiguity (illustrated by the question “ambiguous?”) has been identified, then a process of concern assessment is adopted in subsequent assessment. Both conditions (uncertainty and ambiguity) can apply at the same time and for the same assessment candidate. In this case both approaches, i.e. the precautionary assessment approach and the concern assessment approach, need to be combined. Each of the four assessment approaches are discussed in more detail in Chapter 5.
3.5 An overview of evaluation

The step of ‘Evaluation’ which follows after the assessment stage is undertaken on the grounds of provisions of the GFL requiring risk managers to consider “other legitimate factors” (i.e., wider societal and economic concerns) in addition to the results of the scientific risk assessment. Evaluation serves two main purposes:

- first, to reach a balanced, value-based judgment on the tolerability/acceptability of a given food safety threat, or to perform a trade-off analysis of a set of functional equivalents (of the product, process, or practice which is the threat source under consideration);

- second, to initiate (if deemed necessary) a management process and make preliminary suggestions for the most suitable management approach.

The term ‘tolerable’ refers to an activity that is seen as warranted on the grounds of associated benefits, yet which requires additional measures in order to reduce the threat below reasonable limits. The term ‘acceptable’ refers to an activity where any residual threat is so low that additional measures for mitigating the threat are not seen as necessary. To draw the line between ‘intolerable’ and ‘tolerable’ as well as ‘tolerable’ and ‘acceptable’ is one of the most difficult tasks in the governance of food safety.

77 General Food Law, supra note 6, Art. 3 (12).
The tolerability or acceptability judgement is informed by the results of the assessment process but it is not determined by it. Other important considerations on wider social and economic factors may be included transparently in the balancing process. The main elements of this process are:

- summarizing of the results of the assessment process in terms of the likely consequences for food safety or other relevant endpoints (such as environmental quality, nutrition etc.) if no management measures were taken;
- deliberation over these results in consideration of wider social and economic factors (e.g. benefits, societal needs, quality of life factors, sustainability, distribution of risks and benefits, social mobilization and conflict potential), legal requirements and policy imperatives;
- weighing of pros and cons and trading-off of different (sometimes competing or even conflicting) preferences, interests and values.

While assessment deals with knowledge claims (around what are the causes and what are the effects), evaluation deals with value claims (around what is good, acceptable and tolerable). Defined as a tolerability/acceptability judgement evaluation takes up and at the same time specifies what the General Food Law refers to as the task of “weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors” \(^78\). While the General Food Law determines this task as an element of risk management alongside “if need be, selecting appropriate prevention and control options” \(^79\), the General Framework, as it is presented here, refers to it as a separate step in the overall safety governance process mediating between the two stages of assessment and management \(^80\). Ideally, this step should, like the setting of terms of reference, involve both assessment actors and managers in conjunction with representatives of key stakeholder groups. This is best accomplished through the application of the Internet Forum in order to open up evaluation to the widest possible values base, and the Interface Committee to enable direct co-ordination between managers, assessors and stakeholders.

### 3.6 An overview of management

As in conventional understandings of the governance of food safety, the final major stage envisaged by the General Framework is ‘Management’. As a part of the framework presented here, it has essentially the same meaning as the definition given in the General Food Law \(^81\) and is therefore conducted by both the Commission and the Member States. Based on the output of the evaluation exercise, it is at this point that decisions on management measures are taken. This requires the consideration of policy choices among contending possible management measures. Such measures may include numerical limits for concentrations of substances in food items, standards for production and consumption, performance control, food preparation...
tion guidelines, monetary incentives, labels, and others. In some ways, this is analogous to the process already undertaken in assessment and evaluation. Here, however, the information is based on the positive and negative implications of a series of different regulatory interventions and not of particular threats. Depending on the context, the relevant information might best be gathered through assessment, by reference to the most relevant measures. In other cases, it will be necessary to undertake this information-gathering process at the management stage in addition - and as a complement - to the evidence gathered during assessment.

Either way, the series of steps involved in the decision-making process around management measures is as follows:\textsuperscript{82}:

- Identification of possible measures (with special consideration of the suggestions made during the evaluation stage);
- Assessment of measures (with respect to predefined criteria);
- Evaluation of measures;
- Selection of one or more appropriate measures.

As in the assessment stage, there are various approaches to management which may be more or less appropriate in dealing with decision-making around specific measures. These broadly follow similar themes to the assessment approaches outlined in Section 3.4 above, however the assessment approach for a specific threat that was identified in screening does not automatically determine the most appropriate management approach. The process of evaluation, especially through eliciting value preferences around tolerability/acceptability from stakeholders, will play a large part in determining the appropriate management approach. The finer details of this process are discussed in Chapter 6 on evaluation and management.

In the broader understanding of management, this stage involves two more steps:

- Implementation of measures, and
- Monitoring of how these measures perform in practice.

Note that monitoring of the outputs and effectiveness of management may lead to problems to be reframed, thus completing the food safety governance cycle.

The stage of management, along with its institutional base (primarily the European Commission and Member States) and the relationship to other stages in the governance process, is illustrated in Figure 3.7 below.

\textsuperscript{82} O. Renn 2005, \textit{supra} note 1, p. 40-48.
Figure 3.7: The primary features of management and their relationship with the other stages in the governance cycle

3.7 Summary

As has been stressed throughout this document, it is important within an open, iterative governance cycle that the system can adapt in the event that new uncertainties or ambiguities are identified. In certain cases this may require feedback from later stages of the governance cycle to earlier stages, so that improvements can be made and problems averted. Specific examples of where this may be appropriate include:

- the possibility of reframing assessment (through the formulation of additional or altered terms of reference) following evaluation;
- the identification of gaps in knowledge about threats at the stages of evaluation or management, which will require further assessment to be carried out. In these cases terms of reference will need to be drawn up afresh through consultation and discussion within the Interface Committee;
- the identification of gaps in knowledge about management measures, which will necessitate targeted assessment by EFSA of the possible implications of these measures. Again, this will require the formulation of new terms of reference by the Interface Committee, with the opportunity of input from the Internet Forum.

Figure 3.8 below illustrates the entire General Framework for food safety governance that has been presented above, including the various components of framing, assessment, evaluation and management, the full set of possible interactions and feedback between all of these stages and the institutional bases to which the various tasks are allocated. The following chapters
will take each of these in turn and discuss their associated procedures and practices in more
detail.

Figure 3.8: A detailed representation of the General Framework,
including the institutional allocation of tasks

4. The Process of Framing

Adrian Ely, Andy Stirling, Frank Wendler and Ellen Vos

4.1 Introduction

The previous chapter discussed various studies\(^{83}\) which have highlighted the importance of
risk assessment policy in influencing decisions around food and environmental safety. Risk
assessment policy is the term used by the Codex Alimentarius Commission to describe
“documented guidelines on the choice of options and associated judgements for their application
at appropriate decision points in the risk assessment such that the scientific integrity of
the process is maintained”\(^{84}\). Codex views this as an activity that guides the scope and
purpose of the risk assessment, for example by setting out the remit, who should participate, the
questions that need to be addressed, how uncertainties should be dealt with, the factors that
the assessors need to consider, the output form and possible alternative outputs. From the
point of view of Codex, risk assessment policy is a task to be carried out by risk managers.
However, as set out in previous chapters, empirical insights into current practice of EU food

\(^{83}\) E.P. Millstone et al 2004, supra note 69.

\(^{84}\) Codex Alimentarius Commission 2005, supra note 7.
safety governance have shown that risk assessment policy is a task already de facto shared
between risk managers and risk assessors, with various initiatives of EFSA to take the lead to
develop common approaches towards risk assessment and to make risk assessment more har-
monised and transparent. Therefore, it appears that EFSA has started to play a role in develop-
ing its own risk assessment policy, which is driven less by requests of risk managers than by
its own priorities and insights\(^{85}\). Against the background of these insights, the General
Framework recommends that risk assessment policy should be understood as a task to be un-
dertaken \textit{jointly} by risk assessors and risk managers, taking into account also the input of
stakeholders. Risk assessment policy, according to the General Framework proposed here,
therefore falls within the \textit{interface process of framing}, which is carried out as a cooperative
exercise within an interface institution (the details of which will be discussed in Chapter 8).
The General Framework also recognises that this process of setting EU risk assessment policy
involves (either directly or indirectly) supranational organisations like Codex, as well as a
variety of actors at national and EU levels.

The food safety governance activities represented by the framework in Figure 3.8 are subject
to various institutional and legal arrangements concerned with the assignment of responsibili-
ties and the articulation of rights and obligations. As illustrated by the cyclical nature of the
framework, these structures are open to \textit{design}, iterative \textit{development} in the face of new
learning and to feedback between various stages in the process in response to regulatory \textit{over-
sight} activities. The design and development of the process itself is guided by Directives, De-
cisions, Regulations, and other European legal instruments and principles (which themselves
can all become subject to change) and is moreover shaped by non-binding frames such as
conventions, prominent perspectives and orientations, as well as by international influences.
By explicitly including this as an element in the proposed framework within \textit{framing}, it is
acknowledged that the application of the precautionary principle as a general governance
principle takes place at a number of organisational, legal and discursive levels, including insti-
tutional structure, process implementation and the exercise of administrative discretion.

Scholars in the fields of sociology and in particular science and technology studies (STS)
have adopted the analytic term “frame” or “framing” to describe the ways in which individu-
als’ or social groups’ worldviews or the conditions under which they operate can influence the
production and/or interpretation of data or knowledge\(^{86}\). More recently scholars have applied
the concept to empirical studies of science in policy-making\(^{87}\).

Within the process of \textit{framing} described here, we identify a number of stages, which are de-
scribed briefly below and illustrated in Figure 4.1:

- \textbf{Review} - the ongoing process of adapting and improving the arrangements for food
  safety governance within the EU to respond to the dynamic global contexts in which
  they are situated. These contexts are made up not only of developments in scientific un-
derstanding (based in part on monitoring the effectiveness and consequences of existing
  management measures, but also on emerging upstream/basic research findings) but also


\(^{86}\) P. van Zwanenberg and E. Millstone, \textit{BSE: Risk, Science and Governance}, Oxford, Oxford University Press,
“framing assumption” was first used by the sociologist Erving Goffman in E. Goffman, \textit{Frame Analysis: an
Northeastern University Press.

\(^{87}\) P. van Zwanenberg and E. Millstone 2005, \textit{supra} note 86; S. Jasanoff 2005, \textit{supra} note 86; L. Levidow, S.
Carr, D. Wield, R. von Schomberg, ‘European Biotechnology Regulation: Framing the Risk Assessment of
on shifting socio-political, legal and institutional contexts at the national, EU and supranational levels. Review does not apply to specific cases as much as to the regulatory structures within which these cases are dealt with.

- **Referral** - the process of referring a specific case (be it a new food product, production method, industrial process or commercial practice) to EFSA for screening, and later assessment. This may be carried out by the European Commission, by individual Member States, or in the case of self-tasking by EFSA itself.

- **Terms of Reference** - the process of setting detailed terms of reference, including information on the most appropriate assessment approaches for a specific case, upon which EFSA should act.

Each of these will now be dealt with in turn in order to outline the associated procedural arrangements and the salient aspects of their design.

![Figure 4.1: The General Framework with an emphasis on the stages and institutional settings of framing](image)

### 4.2 Review

Within the process of framing - which hence refers to both collectively binding rules and non-binding conventions and prominent perspectives - we first identify and define the stage of “review”. Review describes the constant vigilance of regulators to new scientific evidence, technological developments, changing socio-political conditions or altered international regulatory frameworks and, subsequently, aims to produce timely responses to these dynamics. Thus one aspect of review involves the European Parliament, Council and the European
Commission in the formulation of binding rules in the form of European Directives, Decisions and Regulations which form the basis for the design of arrangements for handling specific products or processes (e.g. in terms of setting the rules for comitology procedures, defining the division of roles between Commission/EFSA, and setting out the respective functions and responsibilities of stakeholders and Member States). As such, the actors involved in the process of review are primarily the European Parliament, the Council, and the Commission (as the main actors responsible for legislative procedures), but also EFSA as the main responsible actor in the field of risk assessment. All of these actors are furthermore required to consider the input from a wide variety of European stakeholders.

The influence of international institutions such as the WTO (and the Codex Alimentarius Commission) on this process must be recognised and should not be underestimated, as these are also recognised in the relevant legislation as one of the sources of European food law. The main point of reference for this influence is the requirement set out in the GFL that international standards shall be taken into consideration in the development or adaptation of food law (Article 5,3 GFL). According to this requirement, a derogation from this general obligation is only possible in cases where such standards would constitute an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law, where there is a “scientific justification” for such a derogation, or where the application of international standards would result in a different level of protection from the one determined as appropriate in the Community. Therefore, the establishment of legal acts that are not in full compliance with either existing or imminent international standards would require a strong scientific justification and would need to be firmly grounded on the general principles and standards of food law set out in the GFL. Against this background, requirements established especially in the context of WTO rules and agreements (such as the TBT and the SPS agreements) have a direct influence on the framing of food safety governance procedures as set out in the General Framework. The compatibility of the framework with these agreements is discussed in more detail in Chapter 7 on legal and institutional aspects.

Apart from questions of compatibility of European food law with international standards, the GFL also establishes the obligation for the Community and Member States to contribute to the development of international technical standards for food, feed and sanitary and phyto-sanitary standards, and to promote the co-ordination of work on food and feed standards undertaken by international organisations such as the Codex Alimentarius Commission (Article 13 GFL). Review therefore includes an international aspect not just by “downloading” provisions and requirements established in international standards, but also by “uploading” new developments and insights into the discussions and decision-making procedures at the international level, and to ensure the compatibility between European and international developments. This aspect also refers to the practical operation of EFSA, which is obliged to contribute to the co-operation between the Community and international organisations through scientific and technical assistance (Article 23, I GFL) and to work in close cooperation with international bodies in the field of data collection (Article 33, 2 GFL). This aspect underlines the relevance of emerging new scientific evidence or technological developments on the international level for the conduct of tasks under review.

Review encompasses certain elements of risk assessment policy in that it influences or frames the forms of knowledge that are gathered in the assessment process. Within the General Framework, assessment is further framed by a process (covered in detail in the next chapter) termed screening. Screening identifies the salient qualities of the products, processes

89 In the sense used by S. Jasanoff 2005, supra note 86, and P. van Zwanenberg and E. Millstone 2005, supra note 86.
around which knowledge needs to be gathered in order that the most appropriate approach(es) of assessment can be followed. This not only ensures that resources allocated to assessment are proportionate to the threats in question, but also helps to reduce the possibility of ignorance (as defined in Chapter 2.1) by ensuring that the necessary levels of attention are paid, especially where these are required to understand uncertain and/or ambiguous threats. As will be discussed further in Chapter 5, screening proceeds on the basis of set criteria, and the associated outcome will determine the approach to assessment taken. EFSA already has procedures and arrangements akin to this (although these may not be codified as such) that prioritise between threats and allocate responsibility for their assessment to different Scientific Panels serving the authority.

Within the framework being presented here, the process of review includes those activities that govern the selection, characterisation, implementation of the threat criteria employed in screening. This stage involves assuring that the right criteria are being selected and applied in an appropriate fashion to the relevant threats. The General Framework allocates the responsibility for this part of review mainly to EFSA, on the basis of its task to promote and coordinate the development of uniform risk assessment methodologies (thus taking the lead on the definition of questions asked at the stage of screening), to collect, analyse and summarise scientific and technical data in the field within its mission (thus to gain knowledge about limitations and gaps in existing data), and to undertake action to identify and characterise emerging risks (thus assuming a lead function in the identification of novel serious risks). However, it is suggested that the criteria applied at the stage of screening should be included in the discussions taking place within the Interface Committee, thus allowing for inputs from risk managers and stakeholders.

Furthermore, review specifies the relative priorities attached to different threats and ensuring that a justifiable and proportional balance is being struck in the allocation of resources to different aspects of screening, assessment, evaluation and management. In current practice, this set of tasks is also undertaken by a variety of actors: Whereas the annual work programme of EFSA, which is essential for the prioritisation of threats, is adopted by the Management Board on a proposal from the Executive Director, the Management Board is required to make sure that both the annual work programme and the revisable multi-annual work programmes of EFSA are consistent with the Community’s legislative and policy priorities in the area of food safety. Moreover, in drawing up the proposal for the annual work programme of EFSA, the Executive Director is required to consult with the Commission (Articles 25, 8, and Article 26, 2). The prioritisation of threats is therefore influenced by both EFSA and the Commission. This is confirmed by the information collected through interviews held with Commission officials. This revealed that increasingly the Commission consults with EFSA on the prioritisation of threats instead of consulting with the Member States within the framework of the Standing Committee on the Food Chain and Animal Health. With regard to the allocation of resources to different aspects of food safety governance, however, the European Parliament (in co-operation with the Commission and Council) has significant influence through its control over the general budget of the European Union, on which the budget for EFSA depends (cp. Article 43 GFL).

The governance principles of participation, openness and accountability, and commitments outlined in the General Food Law require transparent communication and the involvement of relevant stakeholders in each stage in the food safety governance process. The objective of fulfilling these principles during review could be served by making communications at each

---

90 cp. Articles 23 and 34 of the General Food Law, supra note 6.
93 General Food Law, supra note 6.
stage available to the public through a web-based forum (described in the preceding chapter), managed by the Commission but providing a space for transparent input from risk managers, assessors, stakeholders and citizens.

The review function will necessarily involve a range of complex processes and a wide variety of institutions. It addresses any unforeseen difficulties that may arise and ensures that the overall framework is robust to changes in circumstances. It also ensures that the process as a whole allows effective social learning to take place at every level, from the individual criteria to the architecture of the process as a whole. This allows for greater efficacy and efficiency, and in particular for the screening process to benefit from cumulative experience gained in assessment itself. The process should remain sensitive to wider evaluative and contextual issues and be open from the outset to engagement with the views and experience of different public constituencies and all interested and affected parties. In this context, consultations with interested parties during the preparation, evaluation and revision of food law (as required by Article 9 GFL) may also constitute a part of review. At the current state, there are indications that some of the discussions taking place at the level of the EFSA Stakeholder Consultative Platform fall within this distinction. Examples include discussions about the general procedures and requirements for the provision of scientific advice (meeting of 9 March 2006), debates about risk communication strategies, transparency in risk assessment, and the identification and characterisation of emerging risks (meeting of 21 July 2006), or discussions about the working method of the Stakeholder Platform, the organisation of the interface with Member States and stakeholders, or EFSA’s future work and priorities (meeting of 6 December 2006). Similar observations can be made at the level of the Advisory Group on the Food Chain and Animal Health of the Commission. Within this forum, debates were held on the new comitology procedures, the use of impact assessment, and the potential establishment of fees for EFSA (meeting of 12 January 2007), on labelling, developments in the Rapid Alert System (meeting of 19 May 2006), or a report by the Commission on the state of the art on food policy, and general food safety legislation (meeting of 5/6 July 2005). However, further empirical research appears necessary to evaluate these debates and exchanges.

With regard to institutional arrangements, it is therefore clear that the factors affecting review cannot be identified with a single procedure or set of institutions, but refers to a range of existing processes and institutions that are relevant for setting the framework conditions of food safety governance. Above all, this is the adoption of framework legislation both of a general scope and acts setting out procedural requirements for a specific policy-area. Most of these legislative acts specifying the general rules and procedures of food safety governance are adopted through the co-decision procedure as defined by the European Community Treaty (Article 251), which strongly involves the European Parliament and the Council in the decision-making process, illustrating the significance of both actors for the conduct of framing. Examples for such framing decisions include the General Food Law (Regulation 178/2002) and its amendment through Regulation 1642/2003 EC, the European Regulation 1829/2003 specifying the authorisation procedure for genetically modified food and feed products, the European Directive 2001/18 on the deliberate release of genetically modified organisms into the environment, or the European Regulation 1935/2004 on food contact materials. However, some of the general rules of decision-making in the conduct of food safety governance are also set by legislative acts without the participation of the European Parliament, such as in the Council Decision 1999/468 specifying the comitology procedure applied at the stage of risk management. Therefore, it must be pointed out that not all legislative acts with a prescriptive  

---

94 The agendas and minutes of the meetings of the Stakeholder Consultative Platform can be viewed online at: http://www.efsa.europa.eu/en/stakeholder_stakeholder/consultative_platform.html.

95 The agendas and minutes of the three meetings of the Advisory Group on the Food Chain can be viewed online at: http://ec.europa.eu/food/committees/advisory/index_en.htm.
function for the general conduct of procedures of food safety governance are adopted with the same degree of involvement by the European Parliament.

Furthermore, other relevant procedural arrangements are created not through full legislative procedures, but by single executive acts. Especially legal acts specifying the details of requirements and obligations set out in the GFL are often adopted through Commission Regulations. Examples for such decisions include Commission Regulation 2230/2004 EC on the networking of organisations operating within the field of mission of EFSA, which specifies the general requirements of Article 36 (3) of the GFL, or Commission Regulation 1304/2003 specifying the procedure for the handling of requests for scientific opinions by EFSA, prescribed in Article 29 of the GFL. Furthermore, many decisions concerning the involvement of stakeholder organisations and the realisation of principles of good governance are adopted through executive acts without the participation of the European Parliament, mainly on the basis of the requirements about the consultation of interested parties in the General Food Law (Articles 9 and 42 GFL). For example, the creation of consultative bodies like the Advisory Group on the Food Chain was established through a Commission Decision, and the creation of EFSA’s Stakeholder Consultative Platform, or the adoption of the Code of Good Administrative Behaviour of EFSA was made through a decision of the Authority’s Management Board. Furthermore, not all decisions affecting the conduct of review necessarily have a legal character, but are adopted in the form of declarations, guidance documents, or communications. For example, efforts undertaken by EFSA (partly through self-tasking) to achieve a harmonisation of approaches towards risk assessment (in accordance with its tasks as defined in Article 23 (b) in the General Food Law), which are more procedural in character and communicated through guidance documents and communications of the Scientific Committee, can be considered as part of the governance design and therefore the review process. On a broader scale as mentioned above, the setting of international food safety standards by the Codex Alimentarius Commission (CAC) must be considered as a part of the activities referring to the design of food safety governance.

To sum up, ‘review’ refers largely to what may be called the meta-level of food safety governance. As such it is - to limit the scope of the current exercise - excluded from the considerations of procedural and institutional challenges and possibilities for innovation. It deserves, however, to be addressed in this respect in a further exercise.

4.3 Referral

The second stage in framing, referral, involves the forwarding of a particular case for assessment by EFSA, usually with reference to a particular law under which the associated threat should be assessed and managed. The General Framework proposes that details of the referral, including the legal jurisdiction under which the case is referred to EFSA, should be placed transparently on the Internet Forum (for specifications, see Chapter 7) and space made available for comment, which can be taken into account during the stage of screening (carried out by EFSA) and the final stage of framing, the setting of terms of reference. In current practice, the task of referring cases to EFSA is already structured by a variety of legal requirements and provisions. The main requirements for the referral of cases to EFSA are set out in Article 29 of the GFL, which entitles the Commission, the Member States, and the European Parliament to request scientific opinions, and EFSA to issue opinions on its own initiative. The exact procedures to be applied in the handling of such requests are set out in Commission Regulation 1304/2003, which inter alia, requests that such requests are made in an objective, transparent and functional manner. The proposal of the General Framework to make the referral of

96 Commission Regulation 1304/2003 EC of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, OJ L 185/6, Recital 5.
cases to EFSA more transparent through the publication of draft terms of reference in the Internet Forum builds on this objective. Furthermore, Regulation 1304/2003 stipulates that in all requests for scientific opinions, it is essential for the applicant to remain responsible for the substance of the question posed and to agree to any amended request before it is forwarded to the scientific committee. It is therefore clear that even if screening adds additional insights to a case referred to EFSA and the exact terms of reference are only agreed on after the results of screening have been discussed by risk assessors, risk managers, and stakeholders, the applicant for a request must participate in the drafting of the terms of reference and agree to the final version passed on to EFSA. The question of which actor is responsible for the referral of cases may therefore have some significance for the setting of terms of reference in the case of dissenting views.

In addition, many cases are referred to EFSA on the basis of case-specific legislation prescribing the submission of cases to EFSA, such as in the authorisation procedures for genetically modified food and feed (specified in Regulation 1829/2003 EC) or the authorisation procedure for food contact materials (specified in Regulation 1935/2003 EC). In both instances, cases are referred to EFSA within a specifically prescribed authorisation procedure and accompanied by full technical and scientific dossiers prescribed in the relevant legislation and specific guidance documents. Therefore, these cases may differ from cases which are referred to EFSA to ask for a scientific opinion about an emerging threat or a question of a more general nature, such as the request by the European Parliament for a scientific opinion on wild and farmed fish. In practice, a large part of the cases referred to EFSA from one of the Member States is made on the basis of these authorisation procedures, i.e. following the request of a private applicant (mostly enterprises wishing to place their products on the markets) in one of the Member States instead of questions from a national food safety authority.

Therefore, the conditions (e.g. legal context) under which referral takes place can also frame the way in which the assessment will be carried out. EFSA then proceeds with the screening of the threat, informing the most appropriate form of assessment, which is then specified further by the setting of “Terms of Reference”.

4.4 Setting of the terms of reference

Once screening has identified the most salient characteristics of the threat at hand, it is the role of the Interface Committee to define a detailed terms of reference upon which the assessment should be based. Usually written by the Commission, this subproject has identified a potential need for enhanced co-ordination between managers and assessors in the setting of terms of reference. In addition, the proposed framework would see the draft terms of reference displayed in the Internet Forum in order for assessors and stakeholders to offer input (for specifications about the tasks and structure of the Internet Forum, see Chapter 7). In the present state, EFSA is legally required to establish a register of requested opinions which is accessible to the public, allowing the progress of requests for opinions to be followed from the date on which they are received. Although this register of scientific opinions is accessible on the EFSA website, the terms of reference of ongoing risk assessments cannot be retrieved from this register and are only made public as part of established opinions of EFSA.

---

97 Ibid., Recital 6.
99 Commission Regulation 1304/2003 EC of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, OJ L 185/6, Article 2.
100 See: http://www3.efsa.europa.eu/register/qr_panels_en.html
which are made public in the register. Making the draft terms of reference public and allowing stakeholders and interested parties to comment on them would allow the Commission to make use of this input, and to respond to it. The institution taking responsibility for the final terms of reference should justify the text chosen, based on a summary of the various points made on the Internet Forum and including any constraints or requirements emanating from the stages of review or referral, discussed above. This summary/justification should be published on the Internet Forum as an accompanying document to the final terms of reference. Following the issuing of the final terms of reference by the Commission or the Interface Committee (see Chapter 7), which have been formulated through interface communication between the different parties, EFSA continues with its established role of assessment. This process is the subject of the following chapter.

5. The Process of Assessment

Adrian Ely and Andy Stirling

5.1 Introduction

This chapter is dedicated to those activities carried out solely by assessors, largely EFSA focusing on the work of EFSA under the proposed General Framework. As has already been mentioned, the first activity, screening involves the identification of the most appropriate assessment approach for the threat in question. The process of screening was mentioned briefly in the previous chapter but will be treated in more detail in section 5.2, below. The various aspects of the actual assessment process, how they relate to the legal and institutional requirements of good governance outlined in Section 2.2.2 and how they can help to overcome the challenges outlined in Section 2.3, will then be addressed in Section 5.3.

Prior to addressing the function of screening, it is necessary to introduce the different approaches to assessment that are understood within the proposed framework. The distinguishing characteristics of exactly what constitutes conventional risk assessment tend to vary slightly between different intergovernmental and European Commission definitions. The particular stages of conventional risk assessment recognised in European regulation of food safety comprise: hazard identification, hazard characterisation, exposure assessment and risk characterisation. In common with similar understandings throughout the field of safety regulation worldwide, this embodies the central understanding that risk assessment involves the use of probabilistic techniques to address incertitude over the likelihood of different possible outcomes.

Despite its prominence - in the field of food safety as elsewhere - conventional risk assessment does not present the only methodological approach to assessing different products, processes or policy options. Indeed, depending on the context and conditions, a number of alternative or additional methods can offer more comprehensive approaches to assessment than is achievable using conventional risk assessment. For instance, procedures such as horizon scanning, sensitivity analysis, interactive modelling and scenario workshops provide more comprehensive means to represent and examine the range of possible outcomes without aggregating them together. Likewise, analytic-deliberative processes of decision analysis, multi-criteria mapping, stakeholder engagement and citizen participation can identify a more comprehensive range of questions, options, assumptions and values and allow fuller exploration of

---

101 General Food Law, supra note 6. Art. 3.
102 C. Yapp, B. Rogers and A. Klinke, A Review of Institutional Arrangements for Food Safety Regulation in the UK, Report for Work Package 5 of the SAFE FOODS project, King’s College London, August 2005.
their effects on the outcomes of assessment, than are usually addressed in conventional risk assessment.

Together with more quantitative approaches focussed on risk, these techniques offer a rich and powerful array of possible approaches to assessment. Each individual approach - and a host of variants, composites and hybrids - displays contrasting characteristics in relation to different principles of good governance. There can be significant tensions and trade-offs between qualities such as timeliness and proportionality (on the one hand) and accessibility and effectiveness (on the other), or between the imperatives for participation and accountability and those for coherence and consistency. Different approaches are favoured under divergent institutional, disciplinary and socio-political perspectives. It is clear that no one assessment approach offers a panacea for all possible empirical contexts or governance conditions. But it remains unclear how best to go about reconciling the tensions, trade-offs and perspectives in order to identify the most appropriate approach to take under any given context or condition.

The use of the term ‘threat’ in this framework is important for purposes of consistency and coherence. It was explained in section 2.1.2 that the scientific definition of the term ‘risk’ implies conditions under which both probabilities (exposures, frequencies) as well as magnitudes may lend themselves to quantification. As such, it is conventionally distinguished from a ‘hazard’, for which only magnitudes (in terms of potential for damage, without considering exposure or probability) may be characterised with confidence. The term threat, which is also used in influential governance instruments and documents, is chosen because it covers both risk and hazard and admits interpretation either in terms of probabilistic risk or intrinsic hazard properties, depending on the context. Screening is therefore focused on threats including hazards and/or risks depending on knowledge and context. For many regulatory purposes such as determining maximum daily intakes empirical data on exposure is not important so that hazard information is sufficient for the assessment and management process to follow.

In the field of food safety, examples of intrinsic hazard properties may relate to endpoint effects (such as cancer, genetic disorders or allergies) or to exposure potentials (like bioaccumulation, persistence and ubiquity). Either way, the screening of threats involves attention to the basic elements of precaution (seriousness and lack of scientific certainty) as well as additional considerations concerning the socio-political ambiguity of the threats in question. This requires sets of operational criteria for triggering the different assessment approaches that are discussed in more detail in section 5.3.

5.2 Screening

5.2.1 Screening criteria

What is here termed the ‘screening’ of threats corresponds approximately to established notions of hazard identification, basic characterisation and ‘preliminary risk assessment’, as featuring (for instance) in discussions under the auspices of the WTO and elsewhere. This requires that a systematic and transparent approach, which can be either quantitative or qualitative, be adopted to the achieving of two main aims. First, to guide the allocation of different broad types of threat to the most appropriate, efficient and proportionate form(s) of assessment. Second, to inform the prioritisation of attention and resources in assessment to different instances of threat within these broad types. The two tasks are closely interlinked, since information gained during screening for the first aim is also likely to be useful in addressing the second.

103 For example, Principle 15 of the Rio Declaration on Environment and Development.
In order to meet the challenges identified in Chapters 1 and 2, a number of further specific attributes of a threat must be clearly addressed in the screening process. In particular, the following elements must all be systematically scrutinised in this process: the level of seriousness of a threat; the extent to which it is subject to scientific uncertainty and the levels of socio-political ambiguity with which it is associated. Each implies the necessity of different kinds of information in the subsequent assessment process. In the General Framework, efficient and effective allocation to these different assessment processes is achieved by means of a series of explicit criteria, against which each threat in question is examined. The adoption of particular criteria will depend in part on the legal and regulatory context (included within the review stage of framing) and will be subject to normal provisions for design, development and oversight.

Under each criterion, some threshold level or characteristic is established, which identifies this threat as registering under that criterion. This is then taken as a basis for assigning this threat to a particular form of attention in subsequent assessment. In this way, the application of successive criteria serves clearly and consistently to allocate particular types of threat to particular forms of regulatory treatment. Additional information gained in this screening process will be very useful in the prioritisation of attention to the different types of threat within the different assessment procedures.

Of course, the application of the criteria that inform the screening process is not purely mechanical. There are typically close inter-relationships between criteria, requiring that they be applied as part of an integrated, reflective, deliberative process, accountable to the appropriate institutions of design oversight. A general working sequence is suggested from seriousness to precaution with ambiguity being somewhat separate and considered in parallel to precaution. In other words, in the interests of effectiveness and proportionality, the question as to whether a given threat is ‘certainly and unambiguously serious’ is clearly prior to the other considerations. Only in the event that the response to this question is ‘no’, does attention turn in sequence to the various reasons why this might be the case.

A negative response to this initial question of seriousness may variously be because the threat in question is scientifically uncertain, socio-politically ambiguous, or is certainly and unambiguously not in excess of the chosen criteria of seriousness. Of course, where a particular threat displays multiple attributes, for example conforming to screening criteria for both ambiguity and uncertainty, then these different aspects may be treated in parallel by different forms of assessment.

5.2.2 Criteria of ‘seriousness’

The first step in the screening process is therefore to identify whether the threats in question are ‘certainly and unambiguously serious’. Subject to further findings in the parallel review of existing institutional practice the Work Package 5 team has developed a number of specific exposure-based hazard criteria for general application to food safety threats. These include carcinogenicity, mutagenicity and reprotoxicity in food components or residues (as already embodied in existing regulatory initiatives in this field, such as the 2001 CEC Chemicals White Paper). Beyond this, attention may extend to further health threat criteria such as endocrine disruption, neurotoxicity, asthmagenicity or sensitising potential. In other contexts, threat criteria might be formulated in terms of other types of food safety hazard, such as the presence of certain particularly virulent pathogens or the inclusion of those antibiotic resistance marker genes that were opposed in genetically modified organisms by the EFSA Scien-
tific Panel on Genetically Modified Organisms in 2004\textsuperscript{104}. Alternatively, in areas where there exist robust applicable data, threat criteria may be formulated in terms of risk-based thresholds, such as \textit{concentrations} for certain less hazardous pathogens or toxicants.

As has been noted, these criteria are all subject to discussion as part of the review stage of the framing exercise. Prevention is then chosen when examination of the threat based on these criteria leads to the conclusion that it violates an existing legal requirement, exceeds a threshold of previously established standards or norms (based on a legal or institutional requirement to act) or is highly likely to exceed such a threshold. In addition, if a new threat is found where analogies to existing intolerable threats can be drawn, the presumption of prevention is justified. Such a judgement may be obvious in many cases and uncontested; in other cases there may be dissenting views or differences in opinions. If that is the case, one of the other three assessment approaches has to be taken. The first criterion combines two qualifiers: the threat has to be serious and the judgement has to be univocal. When both conditions apply, then \textit{preventive measures} are triggered.

\textbf{5.2.3 Criteria of ‘scientific uncertainty’}

In considering whether a threat is certainly serious under criteria such as those identified above, an accompanying step in the screening process is to identify specific criteria for what constitutes ‘scientific uncertainty’. A crucial issue here concerns the applicability of probabilistic risk assessment techniques. As outlined in section 2.1.2 above, difficulties in this respect may lie not only in addressing \textit{uncertainty} (where, by definition, we cannot confidently derive probabilities for at least some sub-set of outcomes), but also \textit{ignorance} (where some outcomes themselves may be entirely unanticipated).

The Work Package 5 team has developed a series of candidate criteria for identifying all these forms of scientific uncertainty which are not fully characterisable by probabilistic techniques. The first two address different aspects of ignorance, insofar as this is possible, by focussing on sensitivities to the prospect of surprise. The remaining criteria address different aspects of uncertainty. Taken in logical sequence, the criteria are as follows:

\begin{itemize}
  \item[a)] Are there scientifically founded questions concerning the status of the theoretical foundations of the disciplines bearing on the characterisation of the threat?
  \item[b)] Are there features of the food or food component in question which are substantively novel, in the sense that they involve characteristics or properties that are in some sense unprecedented?
  \item[c)] Are there scientifically founded questions concerning the completeness or sufficiency of the particular scientific models bearing on the characterisation of the threat?
  \item[d)] Are there scientifically founded questions concerning the applicability to the context in question of the particular scientific models used to characterise the threat?
  \item[e)] Are there scientifically founded questions concerning the applicability to the context in question of the data sets bearing on the characterisation of the threat?
  \item[f)] Are there scientifically founded questions concerning the quality of the data sets bearing on the characterisation of the threat of a kind that is not susceptible to probabilistic treatment?
  \item[g)] Do there exist any indirect, interactive or synergistic causal mechanisms of a kind that may not fully and confidently be characterised by probabilistic techniques?
\end{itemize}

\textsuperscript{104} Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants (Question N° EFSA-Q-2003-109), \textit{The EFSA Journal}, 48, 1-18.
Where a consensus does not emerge between the EFSA personnel responsible for screening as to the presence or absence of uncertainty (as defined by the above criteria), it is assumed that the high level of protection would lead to an assumption of uncertainty, as if one of the above criteria was triggered. Where they are held to be acceptable in principle, such criteria can be elaborated further by reference to an extensive existing literature. Where any one of them exceeds predefined quality criteria (pertaining to deficits in theory and modelling) or limits of foreseeable variability (pertaining to data analysis and interpretation, for example by using Monte Carlo simulation techniques), then the threat in question is assigned to precautionary assessment.

5.2.4 Criteria of ‘socio-political ambiguity’

In addition to the initial screening question over scientific uncertainty, the other reason why threats may be identified not to be definitely serious is where they are socio-politically ambiguous. This focuses on the degree to which a given threat may be subject to strongly divergent cultural attitudes, political perspectives or economic interests. There are four types of criteria that can be used to identify these kinds of ambiguity.

a) At the level of individual constituencies, is there a perceived threat of harm on a catastrophic scale (individual criterion)?

b) Where there is disagreement between regulatory agencies and/or Member States, are there aspects of these institutional conflicts ostensibly unrelated to scientific uncertainty (institutional criterion)?

c) With regard to the news media, are there signs that the threat in question is subject to a pronounced degree of amplification (amplification criterion)?

d) At the level of society as a whole, are there signs of adverse effects in terms of social justice in the distribution of threat or in terms of manifest political mobilisation on the part of particular public constituencies (social criterion)?

Where any one of these criteria apply, then the threat in question is assigned to a process of concern assessment.

5.2.5 Threats not addressed by above screening criteria

Where a threat is found not to be serious, uncertain, or ambiguous under any of the screening criteria described so far, then it will by definition trigger criteria for the applicability of conventional risk assessment (meaning that probabilistic techniques are applicable). Such threats are best addressed by drawing on a variety of risk assessment techniques, depending on the nature of the problem at hand.

Under circumstances where an extensive epidemiological record of safe use exists, then standard risk assessment may be appropriate. This usually involves the simple combination of hazards (as characterised through dose-response relationships, for example) and exposures (as evident from established data-sets). At other times, a more extended risk assessment may be required. In these cases, conventional probabilistic techniques may still be applicable, but need to be applied in a more wide-ranging and elaborate fashion than is normally the case. The third subproject of the SAFE FOODS project (Work Package 3) has adopted probabilistic techniques to model the health impacts on European populations to pesticide, mycotoxin and natural toxin exposures. Where probabilistic risk assessment is applied, it should not be used inappropriately as an aggregative tool exclusively to justify or enforce ostensibly definitive monolithic claims to safety or to the unitary sufficiency of intervention measures. Sensitivity analysis (both analysing the effect of data and model uncertainty on the assessment) is an essential part of such quantitative techniques and is recognised as such by other Work Packages.
in SAFE FOODS. While Work Package 3 has reported adequate data in relation to pesticides, data on mycotoxins and natural toxins have been poor both in availability and quality. Especially under such circumstances, where the scarcity of data means that assessment must be assumption- (rather than data-) driven, uncertainty criteria may in addition be triggered (necessitating a precautionary approach to assessment).

The kinds of threats necessitating extended risk assessment are complex (if the threat is subject to complex cumulative or additive causal mechanisms) or large in scale (if a number of people exposed exceed a certain threshold). In addition extended risk assessment may be required if the maximum possible harm exceeds a certain threshold magnitude or if the time lapse between the policy decision in question and the manifestation of the resulting impacts exceeds a certain threshold time period (for example in the case of intergenerational effects). If the response to any of these questions is uncertain, then this should already have been picked up in applying the uncertainty criteria specified above. However, the finding of particular reasons for uncertainty at this stage might prompt re-application or re-interpretation of the earlier uncertainty criteria in light of the new evidence.

5.3 Assessment

The purpose of assessment is to gather the information necessary to inform and substantiate a particular governance outcome.

---

Figure 5.1  The General Framework, with a focus on the stages of screening and assessment

---

The type, scope and quality of information relevant to this decision making will vary from context to context and from threat to threat. Depending on the context and magnitude of the threats in question it may be necessary to include assessment of socio-economic as well as health factors. In the interests both of efficiency and effectiveness, it is desirable for the terms of reference (informed by screening, above) to be as specific as possible about the most appropriate form to be taken by the assessment process in any given context.

Instead of a single undifferentiated notion of ‘risk assessment’, then, the present framework distinguishes four different approaches to assessment (corresponding with the four potential outcomes of screening). In the terms alluded to in the existing General Food Law as reviewed in Chapter 2, the four more elaborate forms of assessment detailed here each represent a different specific way in which assessment might be ‘more comprehensive’ than standard risk assessment. The four different approaches to assessment, and their relationship with framing and with the screening process described above, are illustrated in Figure 5.1.

5.3.1 Presumption of prevention

Where threats are identified in the screening process certainly and unambiguously to be serious (illustrated by the question “serious?” in Fig 5.1 above), then the presumption is that they are assigned directly to preventive measures. Here, assessment simply involves consideration of whether there exist any mitigating factors that justify conditional relaxation of restrictive regulatory instruments. Such mitigating factors may take the form of countervailing risks, over-riding benefits or unavoidable constraints on control.

In those rare cases where prevention is argued to be counter-balanced by such mitigating factors, then this effectively implies that the triggering of criteria of ‘certain and unambiguous seriousness’ is, in this particular instance, correspondingly qualified. Depending on whether the qualification takes the form of uncertainty or ambiguity, the threats in question will be assigned for further attention either (respectively) to precautionary assessment or concern assessment. In either case, the presumption of prevention will be augmented by critical examination of such potential mitigating factors or grounds for conditional relaxation as part of a comprehensive and inclusive deliberative process, involving relevant interested and affected parties. Such rare instances should also be subject to particular attention as part of the overarching ‘framing’ process.

Under a presumption of prevention, assessment of socio-economic factors is included alongside more direct issues of hazard and risk as a means to inform judgements over the nature of any ‘countervailing risks, over-riding benefits or unavoidable constraints on control’.

5.3.2 Key features of precautionary assessment

Where the identification of a threat displays a lack of scientific knowledge about probability distributions and/or the magnitude of harm (illustrated by the question “uncertain?” in Figure 5.1), then the presumption is that the product, process or practice in question will be subject to precautionary assessment. This does not automatically imply the implementation of preventive measures. A wide variety of regulatory measures may result.

In essence, precautionary assessment involves more detailed and broader-based consideration of the factors bearing on the threat in question and a comparative review of a set of functional equivalents to the product/process/practice in question.

Here (recalling the discussion of different forms of incertitude in Section 2.1.2), a practical distinction can be made between institutional ignorance (located specifically at the point of decision-making) and societal ignorance (a generic property of the state of knowledge extant in society as a whole). The former can be addressed by ‘broadening out’ the assessment proc-
ess in the ways detailed in the criteria below. This ensures that as much pertinent knowledge and experience as possible is brought to bear on decision-making. Beyond this, a number of other provisions can directly address the more intractable latter forms of societal ignorance. A series of key characteristics can be identified:

a) Extension of the scope of assessment to include a range of indirect forms of exposure, additive, cumulative and synergistic effects occurring throughout the food chain, addressing mixtures, derivatives and reaction products that may be present in final foodstuffs as well as considering institutional trends and compliance issues. These aspects are part of a precautionary assessment if the causal connections are not well understood and cannot be modelled with a high degree of confidence in an extended risk assessment.

b) Address aspects of institutional ignorance by engaging a full range of technical disciplines and stakeholders right at the outset in assessment, in order to elicit the pertinent prioritisation, conceptualization and interpretation of the different questions that may be posed of the scientific data and the comprehensive exploration of the resulting sensitivities.

c) The systematic examination of the potential adverse effects for public health associated with the products, processes or practices presenting the threats in question at the earliest stages in the innovation process.

d) Subject to the terms of reference, the detailed and balanced comparison of contending merits and drawbacks of a series of strategic options which present alternatives (in the sense of functional equivalents) to the product, process or practice in question, including inaction and the status quo and better ways to provide the goods or services in question. This includes the eliciting of the knowledge and also the concerns and preferences of stakeholders regarding the different alternatives and their social and economic implications.

e) A shift in the burden of persuasion, such that it is those who wish to implement the technology or product in question who must resource the acquisition of relevant data and sustain an argument as to the acceptable nature of the associated threat, subject to an appropriate level of proof.

f) An explicit focus on the extent to which the technologies or products under scrutiny display properties of flexibility, adaptability, reversibility and diversity - all of which offer different ways of hedging against exposure to any residual societal ignorance that has not been addressed by the other elements in precautionary assessment.

These elements of precautionary assessment are best addressed by taking into account all relevant bodies of knowledge, including that available from different natural and social scientific disciplines, as well as experiential knowledge on the part of different organised interests and groups such as workers, consumers or local residents. Where socio-economic, as well as scientific uncertainty exists (for example, when the potential outcomes for the livelihoods of various sections of society, or the impact on the broader economy cannot be predicted with confidence), similar techniques to those listed above may be applied to the assessment of socio-economic risks and benefits. This generally relates to a broadening out of the assessment process to wider disciplines and stakeholders, a shift in the burden of persuasion to those who wish to implement the technology or product in question, and a balanced comparison of strategic options in order to gather information on the relative benefits and risks of various functional equivalents.

Precautionary assessment is based on knowledge (systematic and experiential) not on beliefs or value judgments. That is why participation in the resulting analytic-deliberative exercise
should be limited to *knowledge acquisition*. Examples of processes for eliciting stakeholder knowledge might include hearings, focus groups or surveys.

### 5.3.3 Key features of concern assessment

Where a threat is identified not to be definitely serious under the chosen criteria, nor subject to scientific uncertainty, but where screening has identified socio-political ambiguity (illustrated by the question “ambiguity?” in figure 5.1), then the choice of appropriate management measures will be subject to a process of concern assessment designed to clarify and so help resolve this ambiguity. The available methods for concern assessment take a variety of forms:

a) The commissioning of large scale quantitative surveys, focusing as appropriate on representative, weighted or particular relevant groups.

b) The conduct of qualitative social scientific procedures such as focus groups, examining the perspectives of specific sensitive or exposed groups.

c) The design of extensive expert Delphi procedures in which a diverse array of interdisciplinary specialisms are focused on resolving the relevant questions.

d) The direct retaining of wider social science expertise to observe, engage with and explain processes of social mobilisation.

e) The holding of formal hearings with relevant social interest groups or targeted at relevant public constituencies as a means to elicit their concerns (such as affected local communities).

f) The convening of deliberative bodies such as trans-disciplinary commissions to elicit as wide a range of concerns, visions, and mental associations as possible.

The above methods may be applied to the assessment of ambiguous socio-economic impacts as well as those dealing directly with human health issues. Relevant examples might include instances in which certain outcomes deliver disproportionate benefits to certain sectors of society but impose risks on other groups who do not stand to gain. In any event, the choice of appropriate methods for the process of concern assessment will itself be a matter for careful deliberation on a case by case basis. This will necessarily be closely interlinked with the activity of review (involving design, development and oversight of the food safety governance structures within which these cases are attended to) and the setting of the terms of reference.

### 5.3.4 Conventional risk assessment

Where threats are identified in the screening process as neither characterised by unresolved uncertainty nor ambiguity, the presumption is that they are subject either to deterministic or (in the case of modelled uncertainties) probabilistic risk assessment procedures. In cases of standard risk assessment, assessment takes a *straightforward form*, based simply on *probabilities* and *magnitudes*, and is performed by panels of independent experts, assisted by staff from the regulatory bodies concerned. There is no particular need for involvement by external actors. If this routine process identifies any residual uncertainties, ambiguities or complexities that may have been missed in screening, then the threats are referred to one of the more comprehensive assessment procedures, as appropriate. Of course, this assessment process, as are the others, is subject to general political oversight and accountability.

Extended risk assessment involves *detailed consideration* of *all aspects* of the threat in question, including *systematic modelling* of different *exposure pathways*, with their *associated probabilities*. This allows the determination of appropriate safety margins. The process is undertaken in a fully *transparent and accountable* fashion by *interdisciplinary groups* of specialists, with *full independence* from special interests and *external to the regulatory bodies*.
concerned. Particular attention is directed at the factors identified under the criteria discussed above: the complexity of the causal mechanisms, the number of people exposed, maximum extent of possible harm, and the time lapse between the commitment and manifestation of effects. If uncertainties remain beyond the level of acceptable confidence intervals, then the risk is referred to a precautionary approach. Where justified by the relevant expertise, conventional risk assessment may also involve scientific engagement by experts from stakeholder groups.

Under conventional risk assessment, the priority attached to consideration of socio-economic factors will depend on the context and magnitude of the threats in question. Where assessment reveals risks to be low in magnitude, then - as at present - it would not be efficient or proportionate to include detailed assessment of socio-economic factors. However, as the magnitudes of risks are recognised to increase, there will be a corresponding necessity to provide subsequent evaluation and management stages with information concerning the nature and scale of any socio-economic benefits or justifications for the toleration of what might otherwise be seen as relatively high levels of risk.

A scientific colloquium held by EFSA last year suggested that a favoured basis for future practice under such conditions might incorporate the definition of a common scale of measurement (e.g., disability-adjusted life years or DALYs, quality-adjusted life years or QUA-LYs, or even more simply Euros) for comparing the risks and the benefits of particular risk management measures\textsuperscript{106}. It remains for EFSA\textsuperscript{107} formally to adopt an approach for this purpose. The complexities involved in assigning unitary measures to outcomes which may be subject to divergent evaluations by differing stakeholder groups make this approach particularly vulnerable as a tool on which to base policy. Bearing in mind the weaknesses of such reductive quantitative approaches, the appropriateness of alternative analytic-deliberative processes should not be understated. Decision analysis, multi-criteria mapping, stakeholder engagement and citizen participation (which may be drawn upon alongside other social scientific elicitation techniques in the process of concern assessment) can help to open up assessment to some of the socio-economic dimensions of food safety decisions whilst avoiding the over-simplification of aggregative techniques.

5.4 Potential opportunities for inter-linkages between different forms of assessment

Potential inter-linkages exist between the approaches of precautionary assessment, concern assessment and conventional risk assessment. The opportunities for inter-linkages between different forms of assessment will of course depend on the specific features of the case in point. One specific threat may have impacts that demand extended risk assessments (for example health risks) and other types of impacts that would suggest a precautionary or concern approach (for example looking into environmental impacts or ethical implications). The different approaches are not mutually exclusive but can be combined depending on the nature of the threat and the different types of impacts under review. The opportunity for inter-linking different forms of assessment may be specified in the terms of reference, or alternatively may be initiated by the assessors themselves.

It is important to stress that the assessment process may also reveal errors resulting from the screening process. For example, a threat may have been routed to the extended risk assessment approach but, during the assessment, it may become obvious that a precautionary ap-


proach is more suitable. It is therefore essential that during the assessment process checks about the need for re-routing to another approach are incorporated in the assessment process.

5.5 Outputs of assessment

Following the principle of transparency put forward in the other stages in the food safety governance cycle, the outputs of assessment and the supporting documentation should be made available on the Internet Forum, to allow comment and feedback (and where necessary challenge) by stakeholders and citizens. Where such deliberation uncovers issues that were not adequately addressed in assessment, these issues can be referred back to the EFSA for screening, after which new terms of reference can be formulated in order to address them adequately.

Following the process of assessment, in which knowledge in various forms is accumulated in order to inform decision-making, the governance framework proposes the two processes of evaluation and management. It is here that the knowledge is assimilated, and stakeholders’ values brought to bear on the outputs of the assessment process so that scientifically informed, and democratically accountable decisions can be made. The next chapter addresses both the processes of evaluation and management.

6. Evaluation and Management

Ortwin Renn and Marion Dreyer

6.1 Introduction

The main purpose of the ‘evaluation’ stage is to judge the tolerability or acceptability of a given threat and, if deemed necessary, to initiate a management process. The chief purpose of the stage of ‘management’, closely related to the stage of evaluation, is to decide on intervention measures which will range in each case from strict prohibition (such as bans and phase-outs) to unrestricted permission. In between, there lies a wide range of measures, including legal requirements (such as exposure standards, engineering regulations and best practice), financial instruments (such as mandatory insurance, assurance bonds or tradable licenses), private self-regulations such as in-house quality control and information and educational strategies (such as consumer information, labelling and class room curricula). Following a regulatory impact assessment of the possible measures, investigating their feasibility and acceptability to stakeholders, one or more appropriate measures are selected and implemented, and enforcement details and options for review are determined. The various key features of evaluation and management are illustrated in Figure 6.1 below.

There is no necessary correlation between each respective approach to assessment and particular evaluation and management procedures or management measures adopted. However, depending on whether a given threat is characterized as certainly serious that cannot be justified by any mitigating factors, as a scientifically uncertain threat, or as socio-politically ambiguous threat, certain procedures and measures are especially suited to handling the threat in evaluation and management.
6.2 Value-based evaluation

The step of evaluation, which follows after the assessment stage, implies that the insights of the assessment exercise are summarised and deliberated in consideration of wider social and economic factors in order to inform a decision on the necessity of intervention measures and the selection of appropriate management measures.

While assessment deals with knowledge claims (around what are the causes and what are the effects), evaluation deals with value claims (around what is good, acceptable and tolerable). Assessment is about collecting and summarising all relevant evidence necessary for making an informed choice on the threat’s tolerability or acceptability, evaluation means to apply societal values and norms to the judgement on tolerability and acceptability and, consequently, determine the need for management measures. The tolerability or acceptability judgement is informed by the results of the assessment process but they do not determine it. It will be based on balancing pros and cons, testing potential impacts on quality of life, discussing different strategic options for the economy and society, and weighing the competing arguments and evidence claims in a balanced manner.

If deemed necessary, evaluation might conclude that further systematic scientific assessments (i.e. beyond the assessment of health effects), for instance with respect to other endpoints deemed relevant (such as environmental quality, nutrition, animal welfare, or specific economic factors etc.) are commissioned, possibly to be provided by ‘external’ institutions with the required special expertise.

The main elements of the evaluation process can be described as follows:
- Summarizing of the results of the assessment process in terms of the likely consequences for human health or other relevant endpoints and the concerns that individuals, groups or different cultures may link to a given food safety problem both under the condition that not management measures were taken;

- Deliberation over these results in consideration of wider social and economic factors (e.g. benefits, societal needs, quality of life factors, sustainability, distribution of risks and benefits, social mobilization and conflict potential) legal requirements, and policy imperatives;

- Weighing of pros and cons and trading-off of different (sometimes competing or even conflicting) preferences, interests, and values with regard to a given threat; or a trade-off analysis of a set of functional equivalents of the substance, product, process, or practice under consideration (the framework envisions such a broader trade-off analysis under the condition of scientific uncertainty and as the step following a precautionary assessment);

- Conclusion on whether the given threat is acceptable, tolerable, unacceptable or ill-defined (if the threat is ill-defined, the assessment process needs to be repeated or augmented), or on what is the most appropriate functional equivalent;

- If the conclusion is that management measures are required, recommendation for the most appropriate management approach (the details of which will be discussed in Section 6.4.).

The term ‘tolerable’ refers to an activity that is seen as worth pursuing (for the benefit it carries) yet it requires additional efforts for threat reduction within reasonable limits. The term ‘acceptable’ refers to an activity where the remaining threats are so low that additional efforts for threat reduction are not seen as necessary. If tolerability and acceptability are located in a threat diagram (with probabilities on the y-axis and extent of consequences on the x-axis), the well known traffic light model emerges (Figure 6.2 below). In this variant of the model the red zone signifies intolerable threat, the yellow one indicates tolerable threat in need of further intervention actions and the green zone shows acceptable or even negligible threat. The grey area illustrates the border lines: the first border identifying the area where one gets close to certainty (probability = 1) and the second where one gets close to indefinite losses. In both cases the framework suggested here would recommend preventive actions.

To draw the line between ‘intolerable’ and ‘tolerable’ as well as ‘tolerable’ and ‘acceptable’ is one of the most difficult tasks of safety governance. Yet such a judgement is required in order to proceed with decisions on management requirements. Arriving at a balanced judgement means that the assessed product, process or technology will deliver sustainable added value for society, economy and industry only if it is possible to control and manage the associated threats in a way acceptable to society. It is not sufficient only to include the ‘physical-risk’ approach, although undoubtedly important, because it addresses only part of what is at

---

108 The UK Health and Safety Executive developed an evaluation procedure for chemical risks based on risk-risk comparisons (cp. R.E. Löfstedt, ‘Risk evaluation in the United Kingdom: legal requirements, conceptual foundations, and practical experiences with special emphasis on energy systems’, Working Paper no. 92, Stuttgart, Akademie für Technikfolgenabschätzung, 1997). Some Swiss cantons such as Basle County experimented with Round Tables as a means to reach consensus on drawing the two lines, whereby participants in the Round Table represented industry, administrators, county officials, environmentalists, and neighbourhood groups (cp. RISKO, Mitteilungen für Kommission für Risikobewertung des Kantons Basel-Stadt: Seit 10 Jahren beurteilt die RISKO die Tragbarkeit von Risiken, Bulletin, 3, June 2000, p. 2-3). Irrespective of the selected means to support this task, the judgement on acceptability or tolerability is contingent on making use of a variety of different knowledge sources.
stake within culturally plural, morally concerned and educated societies. Stakeholders play an important role in defining what is acceptable or intolerable by considering among others the balance between risk and benefits and the probability of extreme events. Therefore the General Framework proposes to involve them as formal members of the Interface Committee, the proposed body with the mandate to present advice to the Commission with regard to evaluation decisions, and/or to involve them through the Internet Forum (the third baseline for a food safety interface institution) where stakeholders would be invited to deliberate on the evaluation advice or decision (see Chapter 7 for a detailed discussion of the options proposed).

![Figure 6.2: Acceptable, tolerable, intolerable and borderline threats (Traffic Light Model)](image)

Figure 6.2: Acceptable, tolerable, intolerable and borderline threats (Traffic Light Model)

After the evaluation exercise has been conducted by the Interface Committee or the Commission, management is presented with three potential outcomes:

- **Intolerable situation**: this means that either the threat source (such as a technology or a chemical) needs to be abandoned or replaced or, in cases where that is not possible, vulnerabilities need to be reduced and exposure restricted.

- **Tolerable situation**: this means that the threats need to be reduced or handled in some other way within the limits of reasonable resource investments (ALARP, including best practice). This can be done by private actors (such as corporate risk managers) or public actors (such as regulatory agencies) or both (public-private partnerships).

- **Acceptable situation**: this means that the threats are so small – perhaps even regarded as negligible – that any threat reduction effort is unnecessary. However, threat sharing via insurances and/or further threat reduction on a voluntary basis present options for action which can be worthwhile pursuing even in the case of an acceptable threat.

The distinction in intolerable, tolerable, and acceptable may appear (too) simple but it reflects the actual need for a judgement at the end of the assessment and evaluation processes. This

---

final judgement on the given food safety problem allows for only three alternatives: either to do nothing, to ban the threat, or to initiate threat-modifying actions. There is no other alternative at this point. The governance framework as it is presented here emphasises that this important judgement is made as transparent as possible to all interested individuals and parties and that the organisations responsible for this judgement have the skills, the assets, the background knowledge and the sensitivity with respect to the corresponding values and socio-cultural preferences to derive at an informed, balanced, and fair judgement.

With regard to the three evaluation outcomes the managers may either face a situation of unanimity, i.e. all relevant actors agree with how a given threat should be qualified, or a situation of conflict in which major actors challenge the classification undertaken by others. The degree of controversy is one of the drivers for selecting the appropriate instruments for the type of participation procedure needed to resolve these controversies. The use of additional participation processes which reach beyond the inclusion of stakeholders through the respective food safety interface institution(s) will depend on the case in hand and be considered by the Interface Committee or, if this interface institution is not established, by the Commission solely.

The prima facie default is as follows: If there is hardly any ambiguity and controversy, it is likely that participation and deliberation through the Interface Committee and/or the Internet Forum would be sufficient as a means to elicit the evaluation criteria, risk-benefit ratios, and tradeoffs of a diversity of social groups. If the topic raises strong controversy and evaluation is highly ambiguous, a full fledged participation process might be appropriate. Deliberation through the Internet Forum could be complemented by face-to-face participatory deliberation processes such as stakeholder roundtables, citizen forums, citizen juries or consensus conferences. In this situation face-to-face deliberation of citizens in processes in which a randomised or deliberately stratified group of individuals work to scope and explore the issues and options in contention could be part of the exercise.

### 6.3 Decision-making in management

As in conventional understandings of the governance of food safety, the final major stage in the General Framework is management. As a part of this framework, it has essentially the same meaning as the definition given in the General Food Law and is therefore conducted by both the Commission and the Member States. It starts with a review of all the relevant information gained in the assessment process and the tolerability/acceptability judgement and the recommendation for the most appropriate management approach with which the evaluation exercise concluded. On that basis management measures are identified, selected, and implemented.

Hence, it is at this point of the governance cycle that decisions on management measures are taken. This requires the consideration of policy choices among contending possible management measures. Such measures may include numerical limits for concentrations of substances in food items, standards for production and consumption, performance control, food preparation guidelines, monetary incentives, labels, and others. In some ways, this is analogous to the process already undertaken in assessment and evaluation. Here, however, the information is based on the positive and negative implications of a series of different regulatory interventions and not of particular threats (i.e. specific substances, products, processes, or practices). Depending on the context, the relevant information might best be gathered through the terms of reference for assessment itself, by reference to the most relevant measures. In other cases, it will be necessary to undertake this information-gathering process at the management stage in addition - and as a complement - to the evidence gathered during the assessment. Either

---

110 General Food Law, supra note 6, Art. 3 (12).
way, the series of steps involved in the decision-making process on management measures is as follows:\textsuperscript{111}

1) \textbf{Identification of possible management measures (under special consideration of the suggestions made during the evaluation stage):} Generic management measures include the avoidance, the reduction and the transfer of a given threat and - also a measure to take into account - self retention. Whereas to avoid a threat means either selecting a path which prevents exposure (e.g. by abandoning the development of a specific technology) or taking action in order to fully eliminate a certain threat, threat transfer deals with ways of passing the threat on to a third party. Self retention as a management measure essentially means taking an informed decision to do nothing about the threat and to take full responsibility both for the decision and any consequences occurring thereafter. Management by means of threat reduction can be accomplished by many different means. Among them are:

- technical standards and limits that prescribe the permissible threshold of concentrations, take-up or other measures of exposure;
- performance standards for technological and chemical processes;
- governmental economic incentives including taxation, duties, subsidies and certification schemes;
- third party incentives, i.e. private monetary or in kind incentives;
- compensation schemes (monetary or in kind);
- insurance and liability;
- co-operative and informative measures ranging from voluntary agreements to labelling and education programs.

All these measures can be used individually or in combination to accomplish even more effective threat reduction. Measures for threat reduction can be initiated by private and public actors or both together.

2) \textbf{Assessment of management measures (with respect to predefined criteria):} Each of the measures will have desired and unintended consequences which relate to the threats that they are supposed to reduce. In most instances, an assessment should be done according to the following criteria:

- \textit{Effectiveness}: Does the measure achieve the desired effect?
- \textit{Efficiency}: Does the measure achieve the desired effect with the least resource consumption?
- \textit{Minimisation of external side effects}: Does the measure infringe on other valuable goods, benefits or services such as competitiveness, public health, environmental quality, social cohesion, etc.? Does it impair the efficiency and acceptance of the governance system itself?
- \textit{Sustainability}: Does the measure contribute to the overall goal of sustainability? Does it assist in sustaining vital ecological functions, economic prosperity and social cohesion?
- \textit{Fairness}: Does the measure burden the subjects of regulation in a fair and equitable manner?

\textsuperscript{111} O. Renn 2005, supra note 1, p. 40-48.
- **Political and legal implementability**: Is the measure compatible with legal requirements and political programmes?

- **Ethical acceptability**: Is the measure morally acceptable?

- **Public acceptance**: Will the measure be accepted by those individuals who are affected by it? Are there cultural preferences or symbolic connotations that have a strong influence on how the risks are perceived?

3) **Evaluation of management measures**: This step integrates the evidence on how the measures perform with regard to the assessment criteria with a value judgement about the relative weight each criterion should be assigned. Ideally, the evidence should come from experts and the relative weights from politically legitimate decision makers including stakeholder input. In practical management, the evaluation of measures should be done in close cooperation between experts and decision makers.

4) **Selection of one or more appropriate management measures**: Once the different measures are evaluated, a decision has to be made as to which measures are selected and which rejected. This decision is obvious if one or more measures turn out to be dominant (relatively better on all criteria). Otherwise, trade-offs have to be made that need legitimisation. A legitimate decision can be made on the basis of formal balancing tools (such as cost-benefit or multi-criteria-decision analysis), by the respective decision makers (given this decision is informed by a holistic view of the problem) or in conjunction with participatory procedures.

In the broader understanding of management, this stage involves two more steps:

5) **Implementation of management measures**: It is the task of management to oversee and control the implementation process. In many instances implementation is delegated, as when governments take decisions but leave their implementation to other public or private bodies or to the general public. However, the management team has at any rate the implicit mandate to supervise the implementation process or at least monitor its outcome.

6) **Monitoring of how these measures perform in practice**: The last step refers to the systematic observation of the effects of the measures once they are implemented. The monitoring system should be designed to assess intended as well as unintended consequences. Often a formal policy assessment study is issued in order to explore the consequences of a given set of management measures on different dimensions of what human beings value. In addition to generating feedback for the effectiveness of the measures taken to reduce the threats, the monitoring phase should also provide new information on early warning signals for both new and old threats viewed from a new perspective. It is advisable to have those responsible for performing the risk and concern assessments and the precautionary assessment participate in monitoring and supervision so that their analytic skills and experience can be utilised in evaluating the performance of the selected management measures.

These steps follow a logical sequence but can be arranged in different orders depending on both situation and circumstance. It might be helpful to visualise the steps not as a linear progression but as a circle forming an iterative process in which reassessment phases are intertwined with new measures emerging, new situations arising or new demands being placed on managers. Similarly, sometimes the assessment of different measures causes the need for new measures to be created in order to achieve the desired results. In other cases, the monitoring of existing rules impacts on the decision to add new criteria to the portfolio. Measure identifica-

---

tion, information processing, and measure selection should indeed be seen as a dynamic process with many iterative loops.

<table>
<thead>
<tr>
<th>Management Components</th>
<th>Definition</th>
<th>Examples / Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Identification</td>
<td>Identification of potential measures, in particular threat reduction, i.e. prevention, adaptation and mitigation, as well as threat avoidance, transfer and retention</td>
<td>- Standards&lt;br&gt; - Performance rules&lt;br&gt; - Restrictions on exposure or vulnerability&lt;br&gt; - Economic incentives&lt;br&gt; - Compensation&lt;br&gt; - Insurance and liability&lt;br&gt; - Voluntary agreements&lt;br&gt; - Labels&lt;br&gt; - Information/education</td>
</tr>
<tr>
<td>2 Assessment</td>
<td>Investigations of impacts of each measure (economic, technical, social, political, cultural)</td>
<td>- Effectiveness&lt;br&gt; - Efficiency&lt;br&gt; - Minimisation of side effects&lt;br&gt; - Sustainability&lt;br&gt; - Fairness&lt;br&gt; - Legal and political implementability&lt;br&gt; - Ethical acceptability&lt;br&gt; - Public acceptance</td>
</tr>
<tr>
<td>3 Evaluation and Selection</td>
<td>Evaluation of measure (multi-criteria analysis) and decision-taking</td>
<td>- Assignment of trade-offs&lt;br&gt; - Incorporation of stakeholders and the public</td>
</tr>
<tr>
<td>4 Implementation</td>
<td>Realisation of the most preferred measure</td>
<td>- Institutional accountability&lt;br&gt; - Organisational efficiency&lt;br&gt; - Cost-effectiveness of implemented measures</td>
</tr>
<tr>
<td>5 Monitoring and feedback</td>
<td>- Observation of effects of implementation (link to early warning)&lt;br&gt; - Ex-post evaluation</td>
<td>- Investigation of intended impacts&lt;br&gt; - Investigation of non-intended impacts&lt;br&gt; - Policy impacts</td>
</tr>
</tbody>
</table>

Table 6.1: Generic management components

Table 6.1 above provides a summary of the management steps. The list of examples and indicators represents the most frequently used heuristic rules for selecting input and for measuring performance.

6.4 Approaches to management

In analogy to assessment, the framework also distinguishes between four management approaches. These are prevention, a precaution-based approach, a concern-oriented approach, and a risk-based approach. Each of these approaches lends themselves to a set of suitable risk management measures (as shown in table 6.2). There is no automatic correlation in the allocation of assessment and management approaches, yet there is a preliminary assumption that the appropriate assessment approach is subsequently pursued during the phase of management.
### Table 6.2: Four management approaches

<table>
<thead>
<tr>
<th>Management Approach</th>
<th>Suitable Measures Include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>- Bans (substitution possible?)</td>
</tr>
<tr>
<td></td>
<td>- Phase-outs (substitution possible?)</td>
</tr>
<tr>
<td></td>
<td>- (tolerance only when benefit is overwhelming)</td>
</tr>
<tr>
<td>Precaution-Based</td>
<td>- Containment in space and time</td>
</tr>
<tr>
<td></td>
<td>- Close monitoring of potential adverse effects</td>
</tr>
<tr>
<td></td>
<td>- (More) stringent provisions for compensation and liability</td>
</tr>
<tr>
<td></td>
<td>- Selecting the functional equivalent with a significantly lower risk and/or less uncertainty</td>
</tr>
<tr>
<td></td>
<td>- Bans (substitution possible?)</td>
</tr>
<tr>
<td></td>
<td>- Phase-outs (substitution possible?)</td>
</tr>
<tr>
<td>Risk-Based</td>
<td>- Technical standards</td>
</tr>
<tr>
<td></td>
<td>- Economic incentives</td>
</tr>
<tr>
<td></td>
<td>- Labeling and information</td>
</tr>
<tr>
<td></td>
<td>- Voluntary agreements</td>
</tr>
<tr>
<td>Concern-Oriented</td>
<td>All of the above: Choice is highly dependent on the outcome of participatory procedures of stakeholder and public engagement</td>
</tr>
</tbody>
</table>

### 6.4.1 Prevention

This approach applies where threats have been identified in the assessment process as certainly and unambiguously to be serious. Existing preventive approaches yield a wide variety of instruments and measures appropriate for the reduction, phasing-out or banning of the activities or products in question. The only management objective here is to eliminate the threat-causing activity in a fashion that is as economically efficient and socially acceptable as possible. If the assessment process has brought to light any mitigating factors that justify conditional relaxation of restrictive regulatory instruments, evaluation may, however, address the possibility that the threat may nonetheless be tolerated if the benefits or justifications were sufficiently overwhelming. Whilst depending intrinsically on the case in question, the criterion of sufficiency must, however, itself be extremely rigorous. Subject to the governance principle of participation, such a criterion could only be determined and applied through a broad-based process of participatory deliberation which might include both internet-based and face-to-face deliberation, and would need to be further legitimated through dedicated procedures of democratic accountability.

### 6.4.2 Precaution-based approach

A precaution-based approach is required under the condition of unresolved scientific uncertainties. These imply that the (true) dimensions of the threats are not (yet) known. Therefore, it is vital to pursue a cautious strategy that allows learning by restricted errors. This manage-

---

113 The containment approach allows small steps in implementation that enable the managers to stop or even reverse the process as new knowledge is produced or the negative side effects become visible. It finds application in European regulation of GM crops. Principally, for each case a risk assessment is carried out and the likelihoods of characterized hazards are determined by successively larger-scale experiments (case-by-case step-by-step approach).
ment strategy needs to be informed by processes of precautionary assessment (detailed in Section 5.3) and a trade-off analysis of a set of functional equivalents of the product, process, or practice under consideration performed at the stage of evaluation. This trade-off analysis requires a more extensive reflection on and deliberation over the effects that the different choices would imply in different dimensions. The consideration of wider social and economic factors is here of particular relevance (as in the case of high degrees of socio-political ambiguity, see the concern-oriented approach) and the resort to ‘trans-disciplinary’ deliberation involving specialists from ethics, humanities and social (as well as natural) sciences alongside active engagement by a diversity of interested and affected parties through the Internet Forum and possibly also through face-to-face participatory deliberation processes (for more detail see Chapter 8). Specifically precautionary management measures may include, for example, small steps in implementation (containment approach) and close monitoring of potential side effects that enable managers to stop or even reverse the process as new knowledge is produced or the negative side effects become visible. They may also be associated with enhancing the resilience of threat bearing systems so they can better cope with surprises. Strategic options for resilience include diversification of the means for approaching identical or similar ends and reducing overall catastrophic potential or vulnerability. They may further include an emphasis on the substitution of those products, processes or technologies presenting the greatest threats and more stringent provisions for compensation, including strict and absolute liability regimes, mandatory insurance requirements and product-withdrawal schemes.

6.4.3 Risk-based approach

For those threats, which can be adequately described by the two classic components probability and extent of harm (on the basis of more or less sophisticated data modelling depending on the complexity of the given threat), management measures may include, for example, the setting of technical standards, economic incentives, education, labelling and voluntary agreements. Measures to deal with more complex risks where it is more difficult to establish the cause-effect relationship between the risk agent and its potential consequences, may further include additional safety factors or redundancy and diversity in the design of safety devices. Evaluation can be done on the basis of traditional methods such as risk-risk comparison (for instance, does the new activity replace an established activity with a greater risk to human health or would an established activity be substituted by an activity implying a greater risk to human health), cost-effectiveness and cost-benefit analysis or balancing of risks and benefits with a clear priority on human health effects. Certainly, the proper use of these instruments requires transparency over subjective ‘framing assumptions’, sensitivities and limits to applicability and their implications for the shaping of parameters on both sides of the cost-benefit equation. Participatory processes beyond the Interface Committee and/or the Internet Forum at the stages of evaluation and management would not be required.

6.4.4 Concern-oriented approach

This strategy applies to situations in which there is intense controversy among key stakeholders and also different parts of the affected and/or observing wider public over the framing of the food safety problem, the appropriate ways to interpret the assessment results, and/or the need and requirements for management. The stakeholders on the Interface Committee, the concern assessment, and also the deliberations via the Internet Forum are major sources of information about whether these conditions are given: Are there strongly divergent viewpoints on the type of problem given, the relevance, meaning and implications of factual explanations and predictions for deciding about the acceptability or tolerability of a given threat, and the values and priorities of what should be protected? As pointed out above, in such circumstances of high socio-political ambiguity there is the need to organise a broad societal discourse in which issues of fairness, visions of future technological developments and societal
change, and preferences about desirable lifestyles and community life play a major role, preferably at the stage of evaluation. Compared with the situation of scientific uncertainty, it is even of higher relevance that under this condition management is informed by the conclusions of a broad ‘trans-disciplinary’ deliberation at the evaluation stage. As will be described in more detail in Chapters 7 and 8, the Internet Forum is a means to generally assure that all stakeholders and also representatives of the wider public can question and collectively consider all major elements of the governance process including evaluation and management decisions. When food safety problems are subject to strongly divergent cultural attitudes, political perspectives, or economic interests, it might be required to organise in addition face-to-face participatory deliberation processes involving all relevant stakeholders and/or representatives of the wider public. If also the choice of the appropriate management measures is highly contested, both stages evaluation and management might need to be subjected to extended participation (for a discussion of this approach to broadened participation see Chapter 8). Applicable methods include randomly selected citizens’ panels or juries, voluntary advisory groups, consensus conferences, and other face-to-face participatory techniques aimed at resolving ambiguities and value conflicts. The aim of this more extensive participatory deliberation is to ‘close down’ on the most robust basis for consensus or common ground in decision making (informed by processes of concern assessment, which as outlined above, ‘open up’ the salient features of the ambiguities in question and the particular divergences of perspective). At the end, in management, discrete measures need to be selected and implemented.

Following this approach to management, the intervention measures to be adopted may include any of those listed above as appropriate to prevention, precaution or risk-based approaches. The significant difference with the concern-oriented approach is that measures will be highly dependent on the outcome of procedures of stakeholder and public engagement.

### 7. Legal and Institutional Aspects of the General Framework

#### 7.1 Introduction

As stated in previous chapters, one of the primary objectives of the General Framework is to be fully compatible with the existing legal requirements of EU food safety regulation and possible to implement with as few institutional changes as possible. Following this objective, it is stressed that the General Framework could be put into practice without any major structural changes, taking into account its procedural and methodological recommendations within the current system. However, this chapter aims to set out a proposal for some limited institutional changes which would facilitate the realisation of the innovative steps of risk governance established by the General Framework, especially the tasks of screening, the setting of terms of reference and evaluation, and the reconsideration of participation procedures. These recommendations are summarised in table 7.1 below, together with the legal and institutional points of reference of the main components of the General Framework (for more detailed explanations, compare the overview in Chapter 3).

#### 7.2 Proposal for institutional changes

The recommendation for limited institutional changes proposed by the General Framework consists of mainly three components. These include:

a.) The creation of a Screening Unit and Panel on Concern Assessment as parts of a proposal for capacity-building of EFSA to fulfil the functions foreseen in the General Framework;
b.) the establishment of *food safety interface institutions* to improve the inclusiveness, transparency and coherence of the setting of terms of reference and evaluation; and finally,

c.) the better application of *existing rules*, both with regard to stakeholder involvement and decision-making procedures in the framework of the comitology procedure.

<table>
<thead>
<tr>
<th>Main Functions Within the General Framework</th>
<th>Point of Reference in Existing Structures of Food Safety Regulation and the GFL</th>
<th>Responsible Actor(s) in Current Arrangements</th>
<th>Institutional Changes Recommended?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framing - Review</td>
<td>General development and oversight of food safety governance</td>
<td>EP, Council, Commission</td>
<td>No (although comments made through the Internet Forum may refer to review)</td>
</tr>
<tr>
<td>Framing - Referral</td>
<td>Identifying problem and applicable legislation and referring the matter to EFSA for screening</td>
<td>Consultation of EFSA as required by Article 29 GFL or specific procedures; e.g. according to Reg. 1829/2003 EC; Dir. 2001/18 EC et al.</td>
<td>Commission, EP, Member States</td>
</tr>
<tr>
<td>Framing - Terms of Reference</td>
<td>Specification of the terms of reference for a risk assessment</td>
<td>Setting of terms of reference by the originator of the request for an opinion; Coordination by DG SANCO when opinion is requested by the Commission</td>
<td>Commission, EP or Member States</td>
</tr>
<tr>
<td>Screening</td>
<td>Identification and basic characterisation of threats</td>
<td>Definition of risk assessment in Article 3, 11 GFL, description of tasks of EFSA in Article 22,4 and 23 (f) GFL</td>
<td>EFSA</td>
</tr>
<tr>
<td>Assessment</td>
<td>Applying the four approaches to assessment identified in the framework</td>
<td>Definition of risk assessment in Article 3, 11 GFL and related articles</td>
<td>EFSA</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Conducting an acceptability/ tolerability judgement</td>
<td>Definition of risk management in Article 3, 12 GFL, consideration of “other legitimate factors” in authorisation procedures (Article 7, Reg. 1829/2003 EC)</td>
<td>Commission, Member States</td>
</tr>
<tr>
<td>Management</td>
<td>Identify, assess, select and implement measures</td>
<td>Definition of risk management in Article 3, 12 GFL and related articles</td>
<td>Commission, Member States</td>
</tr>
</tbody>
</table>

Table 7.1: Proposal for limited institutional changes

In the design of the proposed institutional changes, the General Framework seeks to implement the following objectives and principles, which are also used to revisit some of the existing structures of food safety governance, especially the procedures of participation at the steps of assessment and management and the comitology procedure:
a.) the objective of introducing more transparency into the conduct of risk governance procedures, in particular the drafting of terms of reference, evaluation, and decision-making at the stage of comitology. This objective builds on efforts by both EFSA and the Commission to increase the transparency of risk assessment and achieve a better understanding of the limitations of science by risk managers, key stakeholders and the public, as expressed in various working documents of both institutions already discussed in Chapter 2. Furthermore, this objective builds on the request by the Commission that the application of the precautionary principle in the area of food safety requires decision-making procedures that are transparent\textsuperscript{114};

b.) building on the objectives of the Commission’s White Paper on Governance, the aim of achieving a better involvement of stakeholder organisations and the wider public, particularly in relation to the scientific uncertainty and socio-political ambiguity involved in a given threat. This objective was also called for by the Commission in its communication on the precautionary principle, where it requested that all interested parties should be involved in the decision-making process around its application at the earliest possible stage\textsuperscript{115};

c.) ensuring the effectiveness and flexibility of procedures of risk governance and avoiding bureaucratic overload, an objective established especially with regard to the feedback received from policy practitioners at the workshops and the principle of effectiveness also enshrined in the CEC White Paper;

d.) embedding the innovative procedures of screening, setting the terms of reference and evaluation as much as possible within the existing structures, in order to make the General Framework as easily applicable as possible and reduce the costs of institutional innovations to the minimum;

e.) providing procedures for the handling of threats involving scientific uncertainty and socio-political ambiguity that comply with both legal requirements and principles at the European level and international agreements in the framework of the WTO and SPS agreement, as these represent fundamental obligations on the conduct of food safety regulation at the European level.

The proposed institutional changes mentioned above - in relation to the capacity-building of EFSA and the design of the food safety interface institutions - are outlined in more detail in the following sections.

### 7.3 Capacity-building of EFSA: screening and concern assessment

The General Framework recognises EFSA as the central actor for risk assessment and does therefore not alter the distribution of tasks between EFSA and the Commission established by the GFL. However, it proposes two limited innovations with the objective of increasing the capacity of EFSA to take on the functions foreseen for it in the General Framework. These recommendations relate to the conduct of screening through a specifically designed unit and the creation of a panel for concern assessment, which are set out below.

**Screening Unit**

The tasks of hazard identification and characterisation undertaken through screening are part of risk assessment as defined in the General Food Law (GFL, Article 3, 11). Therefore, the task of screening should be fulfilled by EFSA. This is underlined by the enumeration of the tasks of EFSA in the GFL, which includes the duty to „collect and analyse data to allow the

\textsuperscript{114} COM (2000) (Precautionary Principle), supra note 6, p. 18.

\textsuperscript{115} Ibid.
characterisation and monitoring of risks which have a direct or indirect impact on food safety” (Article 22, 4). Similarly, the GFL establishes the task of EFSA to „undertake action to identify and characterise emerging risks, in the field within its mission“ (Article 23 (f)).

In the present state, it appears that while EFSA may be scientifically equipped to undertake the task of screening, there is currently no specific department or unit that could co-ordinate the referral of screening questions to the Scientific Panels and expert services. Therefore, it is recommended that a new structure should be created with a specific responsibility for the conduct of this task, acting as a coordination point for the referral of questions and the collection of the corresponding answers from the responsible scientific units. This implies the creation of a Screening Unit, established as a small structure which would mainly have the task of acting as secretariat for the conduct of screening. It would therefore not conduct the investigation of the questions asked through screening itself, but have the task of passing on requests for screening to the different scientific panels or EFSA’s Scientific Expert Services (such as in the fields data collection, pesticides, zoonoses, and further units that are currently being established), and potentially also the various Working Groups established under the auspices of various Scientific Panels. Within the organisational structure of EFSA, the Screening Unit would be inserted as part of the department on “risk assessment” and would be conceived as a structure co-ordinating and overseeing the permanent scientific units of EFSA, which exist with parallel mandates to the Scientific Panels.

Concern Assessment

With regard to concern assessment, it was noted in the discussions at the stakeholder workshops that EFSA lacks the social scientific expertise to undertake this task, and that concern assessment could best be undertaken through a specific structure that works in parallel to and in interaction with the existing Scientific Panels. The General Framework thus envisions the creation of a Concern Assessment Panel to serve EFSA, in combination with a specific unit with social scientific expertise within EFSA’s scientific expert services. The creation of a new Scientific Panel would require a decision by the Commission in the framework of the comitology procedure, made on request by EFSA (Articles 28 (4) and 58 (2) of the General Food Law). The last adjustment of the number and names of EFSA’s Scientific Panels was undertaken through Commission Regulation 575/2006, which added the Panel of Plant Health (PLH). The creation of an additional unit of the scientific expert services would require action by the Management Board of EFSA, which has the task of ensuring that EFSA carries out its mission and the tasks assigned to it (GFL, Article 25 (7)).

7.4 Interface assessment – management

7.4.1 Background of the proposal

A large part of the innovative proposals set out in the General Framework refer to the ‘interface’ between the spheres of risk assessment and risk management. First, this ‘interface’ refers to the task of the setting of the terms of reference, during which under the current institu-
tional framework of EU food safety regulation interaction between risk managers and risk assessors can be observed. In current practice, the specification of the terms of reference occurs by the institution or authority that requests an opinion (Commission, Parliament or Member State). Currently that is mostly the Commission. A specific unit of DG SANCO deals with the relations with science and stakeholders and is always involved whenever terms of reference are drafted and submitted. It co-ordinates all requests to EFSA for scientific opinions. This unit examines all mandates as to their background, tries to understand the type of answer the mandates are looking for, ensures the coherence with the other questions, sets the priority of the questions to be asked and establishes the legal basis under which to act. Here the exact phrasing of the question is spelled out, on the basis of the drafts made by the Commission officials dealing with the specific dossiers. The unit also functions as a ‘watchdog’ in that it is charged with ensuring that Commission officials who attend meetings of the Scientific Panels of EFSA do not transgress their role as observers. While DG SANCO ensures co-ordination between the process of risk assessment and risk management in this way, one of the shortcomings of the current practice appears to lie in the fact that this is often done in a rather opaque manner, leading to calls by the Commission for more transparent communication and interaction. The General Framework thus aims to make this part of the ‘interface’ more transparent and more inclusive.

Second, the ‘interface’ relates to the step of evaluation which refers mainly to the consideration of the results of “risk assessment and other legitimate factors” relevant to the matter under consideration, which are defined as a part of risk management by the General Food Law. Also here, our empirical research revealed that evaluation is currently part of risk management and as such it is often done in a rather opaque manner, and that there is no systematic involvement of stakeholders. Here too in order to avoid an overburdening with new structures, the General Framework considers that evaluation should be conducted in the same structure as the setting of terms of reference, thus involving actors from assessment and management as well as stakeholder organisations. Against this background, the General Framework seeks to establish an innovative structure to achieve a more inclusive, transparent and systematic co-ordination between risk assessment and risk management.

In an earlier version of the General Framework we proposed both the establishment of an ‘Operational Committee’ (proposed in two slightly different forms) composed of risk assessors, risk managers and stakeholder representatives with the task of discussing terms of reference and evaluation, and a more flexible, ad-hoc consultation procedure under the auspices of the Commission. These proposals for institutionalising the “interface“ between risk assessment and risk management were discussed in much detail at the expert workshops that we held between September and November 2006. The overall reaction by the participants of the workshops was mixed, with many positive reactions about the principal idea of in some way institutionalising the risk assessment - risk management interface and improving its transparency and participation, but also various critical remarks about the proposed institutional design. Two primary problematic issues were brought up during the workshops, 1) the bureaucratic overload of the proposed institutional and procedural changes, and 2) the difficulty or impossibility to select representatives of stakeholders to be present on the ‘Operational Committee’.

---

120 Ibid., p. 121.
121 General Food Law, supra note 6, Art. 3 (12).
- **Bureaucratic overload:** While the idea of developing procedures for more systematic communication and interaction between risk assessors and risk managers was endorsed by most participants, risk managers especially expressed some reservations towards the idea of creating a standing committee to deal with all interface issues, creating thus yet another bureaucratic layer. In this context, it was stressed that such an innovative structure should deal especially with those cases highlighted as particularly problematic or in need of additional input from stakeholders. It was stressed that the new structure should be able to deal with the great number of cases of risk governance efficiently, i.e., by „bundling“ together cases and leaving out those that do not need any in-depth discussion between risk assessors, managers, and stakeholders. With regard to the options proposed, no clear preference was expressed at the workshops, although representatives of NGOs and risk assessors appeared to be slightly more inclined to the establishment of an Operational Committee than risk managers and representatives of industry, who expressed preferences for a more flexible solution.

- **Selection of stakeholder representatives:** Many participants of the workshops (especially the ones from NGOs) expressed doubts and scepticism about the possibility of appointing a limited number of stakeholder representatives for the proposed committee that would be recognised as legitimate, while keeping them sufficiently few in number as not to overstretch the size of the new structure. It was argued by some participants that stakeholders should not just participate in discussions that are dominated by risk assessors and risk managers (i.e., on terms of reference), but also be able to make requests and comments in a more independent function. Therefore, they should be able to alert risk managers and assessors to issues they consider problematic, and to highlight concerns with regard to particular cases of risk governance. Various solutions were discussed to address this problem, such as appointing independent representatives with a professional background in fields relevant to stakeholder interests / appointing representatives from stakeholder fora like the EFSA Stakeholder Consultative Platform or Commission Advisory Group.

### 7.4.2 More transparency and participation

The feedback gathered from the stakeholder workshops highlights the need to avoid an overburdening of procedures and the addition of unnecessary bureaucratic layers in the attempt to introduce more transparency and participation. The General Framework supports that position. Yet, where advocating more transparency and participation in the interface procedures, the General Framework addresses current problems in the risk governance process and answers to various proposals by both EFSA and the Commission to increase the transparency of risk assessment: An EFSA guidance document to the Advisory Forum on increasing the transparency of risk assessment calls for a close information exchange between the EFSA Scientific Committee or Panel and the originator of a request for a scientific opinion, recognising that while the General Food Law “provides for a clear distinction between risk assessment and risk management, … an efficient and transparent mechanism of interaction is obviously needed to ensure that appropriate exchanges may satisfactorily take place, particularly in more complex cases”.

---

123 For details, E. Vos and F. Wendler 2006, supra note 54.
125 The relevant passage of the document reads as follows: „A clear formulation of the question (i.e. „terms of reference“) is another important step before carrying out any risk assessment. These „terms of reference“ should include a clear definition of the concern and a plan for characterising and assessing the risk. Ideally,
tive of these interactions should be to ensure that the terms of reference of questions asked to EFSA are clearly drafted, and that opinions provided by EFSA are clearly formulated with the underlying science, indicating uncertainties in the assessment, so that “the information given in the opinion can be well understood and used by the originator of the request”126. This guidance document follows an earlier information note by EFSA to the Advisory Forum on increasing the transparency of risk assessment127 which points out that in the future the setting of terms of reference would include a description of the strengths and limitations of the data used and the underlying assumptions, criteria for inclusion or exclusion of available scientific information for a given risk assessment, considerations about appropriate stakeholder engagement and other process-related issues, consistent documentation, and science-based statements about the need of additional studies for the conduct of a risk assessment. Similarly, as already mentioned, DG SANCO of the European Commission published a discussion paper on the contribution of science to European Health and Safety in July 2005, in which it requested good interaction and communication between risk assessors and risk managers, and suggested a formal procedure through which scientific groups in charge for a risk assessment should designate two representatives to meet risk managers before the start of an assessment and again after the establishment of a draft scientific opinion128.

In order to address the problem of selecting representatives of civil society organisations and their representativeness, the General Framework proposes to make use of online procedures for the involvement of stakeholders at the stage of setting terms of reference and evaluation through a specific Internet Forum, allowing for a broad input from a wide variety of interest groups, civil society organisations and the wider public (see below).

### 7.4.3 Institutionalising of food safety interfaces

Therefore the General Framework recommends to create food safety interface institutions to improve both the transparency and consistency of the interaction between risk assessors and risk managers and the involvement of stakeholders. In this way it advocates a participatory process which goes beyond mere consultation and allows for more genuine engagement.

The General Framework thus proposes:

a.) to create an Internet Forum to increase the transparency of interface communication and documentation, and to allow for the broader engagement of stakeholders and the public with these communications; and

b.) optionally, to create an Interface Committee, either in the form of an (flexible and non-binding) Advisory Committee or in the form of a (more compulsory, binding) Steering Committee.

Whereas the establishment of the Internet Forum is recommended unconditionally as a means to increase the transparency and openness of interface communications to stakeholders and the wider public, the General Framework offers three options with regard to the possible formalisation of direct, face-to-face debates between risk assessors and risk managers in an institutionalised structure. These options are proposed as follows:

---

126 Ibid.
a.) a ‘minimal’ proposal, consisting only of the Internet Forum and leaving the direct interaction between risk assessors and risk managers to current practice without any further formalisation;

b.) a ‘maximal’ proposal, consisting of the Internet Forum combined with the compulsory discussion of all cases in an Interface Steering Committee; or

c.) an ‘intermediate’ proposal, consisting of the Internet Forum combined with a more flexibly applicable Interface Advisory Committee. As this proposal takes into account both the objective of establishing a more formalised setting for the interaction of risk assessors and risk managers, and the wish to keep the innovative structures sufficiently flexible, this variant is proposed as the favourite option for the implementation of the General Framework.

Before explaining these options into more detail, we will first explain what in our view the composition and tasks of the Internet Forum and the Interface Committee in its two variants should be.

7.4.3.1 Internet Forum

As explained above, the conduct of the “interface” tasks (terms of reference, evaluation) builds on the objective of eliciting the views of a wide range of assessors, policy actors, stakeholders and the public. Against this background, a mode of engagement proposed by the revised proposal is to establish a web-based deliberation and consultation forum, which could work as a way to generally involve the wider constituencies than those being part of the Interface Committee: a wider diversity of civil society groups, but also risk managers and scientific experts, including the Member States’ risk managers, and scientific experts affiliated to the Competent Authorities at the national level. Hence, the Internet Forum would be a good response to the points raised by several workshop participants concerning issues of inclusion, selection, and representation. It would also respond to the feedback from the workshop participants that the Member States are not represented in the Interface Committee.

The General Framework therefore proposes to launch a website under the auspices of DG SANCO (to be managed by the Unit of Science and Stakeholder Relations), on which contributions of (both European and national) risk assessors, stakeholders and also the wider public could be posted. It is envisaged that the Internet Forum should be organised in four platforms, relating to the main elements of the revised General Framework (Framing/ Assessment/ Evaluation/ Management).

The Internet Forum would be used to increase transparency, especially through the publication of the draft terms of reference, but also to engage its participants in a debate and open exchange of views. With regard to the logic of involvement, the Internet Forum could serve as a platform both for the targeted consultation of interest groups and civil society organisations by the Commission, EFSA and potentially the Interface Committee (“top-down”), and the more spontaneous and open elicitation of views and concerns of participants in the forum (“bottom-up”).

A “bottom-up” logic of involvement (i.e., one that follows the initiatives and concerns of interest groups, civil society organisations and the public) could be used to identify issues of concern to the widest possible variety of stakeholders and the public. This method could be applied to questions of a general nature such as the discussion of the membership in the Interface Committee, the exchange of views about suggestions for referral and review (including the prioritisation of threats), and the exchange of views on the choice of management instruments and monitoring results. This implies that participants could take the initiative by suggesting which cases should be taken up for discussion, and could therefore make contributions
to potentially every case of risk governance. Importantly, these debates would not be mediated by the Commission or another institution, and hence contributions of participants are posted on the website as they are, instead of being submitted to the Commission and then summarised in a report\textsuperscript{129}. Furthermore, this kind of involvement would be open to all interested stakeholders and also the wider public. Given the potential problem of overcrowding, it is clear that this form of involvement could only be applied to a limited number of functions of the Internet Forum, which will be specified further below.

In cases where more specific responses of stakeholders and the public are sought with regard to particular cases of risk governance the Internet Forum could also make use of involvement techniques with a „top-down“ logic. The debate in these cases would be more strongly pre-structured (i.e., consultation documents would be posted on the website of the Forum with specific questions to be discussed), and the submission of comments would be restricted to a selected number of accredited stakeholder groups, to be chosen by the Commission (for example, all members and associated members of the main stakeholder consultation bodies of EFSA and the Commission, the Stakeholder Consultative Platform and the Advisory Group on the Food Chain, and a selection of interest groups and civil society organisations to which contacts have been established by EFSA and the Commission through specific consultations, e.g. the partners of the PRAPeR consultations on pesticides or organisations participating in debates on GMO with EFSA). This involvement technique could be applied to questions of a more specific nature, such as the exchange of views about the draft terms of reference, screening results, the application of terms and reference and assessment results, and proposals for risk management options. It is however stressed that the contributions of the participants should be directly visible on the website (and thus not just be submitted to the Commission for consideration and summary), thus allowing for an exchange of views between the participants, and the evolution of genuine debate on the topics under discussion.

As mentioned above, the General Framework suggests that the Internet Forum could be combined with one of the two variants of the Interface Committee (i.e., either the Steering Committee or the Advisory Committee). Therefore, one of the main tasks of the Internet Forum would in this case be to communicate with, and comment on the work of the Interface Committee. In this context, it is stressed that the discussions in the Internet Forum would not directly determine the agenda of the committee, but serve as an additional input to be considered by its members. However, not taking into account concerns expressed in the Internet forum could lead to infringement of the principle of good administration, in particular, the obligation for the Commission to examine carefully and impartially all the relevant elements of the individual case\textsuperscript{130}.

Therefore, the Internet Forum would involve a variety of involvement procedures in relation to the main tasks of interface communication, structured by the four platforms in relation to

\textsuperscript{129} Obviously, variations to these two points could easily be developed if this is desired (i.e. by restricting the range of cases that are up to discussion, and by introducing elements of summarising and mediation, i.e. through the establishment of contact points reporting from stakeholders and citizens to the website (as envisaged in existing IPM initiatives of the Commission), or by introducing the existing technique of the Commission of gathering comments by e-mail and reporting them back to the website.

\textsuperscript{130} Cp. the European Court of Justice in Agraz: The Commission enjoys a discretion, while being required, by virtue of the principles of a duty of care and of sound administration, to gather the factual elements necessary for the exercise of its discretion. According to a consistent line of decisions, where a Community institution has a wide discretion, observance of the procedural guarantees conferred by the Community legal order is of even more fundamental importance. Those guarantees include, in particular, the obligation for the competent institution to examine carefully and impartially all the relevant elements of the individual case. Only in that way is the Community judicature able to ascertain whether the elements of fact and of law on which the exercise of the discretion depends were present. We will leave outside the scope of this Chapter the problematic issue of access to justice for individuals for Community acts.
the four main elements of the General Framework. These include the following tasks, indicating whether a procedure is applied with a bottom-up (BU) or top-down (TD) logic:

<table>
<thead>
<tr>
<th>Platforms</th>
<th>Tasks / Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRAMING</td>
<td>- Publication and exchange of views on the (draft) terms of reference (TD);</td>
</tr>
<tr>
<td></td>
<td>- Exchange of views and suggestions about referral and review (BU);</td>
</tr>
<tr>
<td></td>
<td>- Discussion of memberships in the Steering Committee or Advisory Committee if present (BU).</td>
</tr>
<tr>
<td>ASSESSMENT</td>
<td>- Exchange of views on the results of screening (TD);</td>
</tr>
<tr>
<td></td>
<td>- Exchange of views on the application of terms of reference and assessment results (TD).</td>
</tr>
<tr>
<td>EVALUATION</td>
<td>- Exchange of views on evaluation advice and evaluation decisions (TD).</td>
</tr>
<tr>
<td>MANAGEMENT</td>
<td>- Consultation on proposals for risk management options (TD);</td>
</tr>
<tr>
<td></td>
<td>- Exchange of views on the choice of instruments and monitoring results (BU).</td>
</tr>
</tbody>
</table>

Table 7.2 Tasks and procedures of the platforms of the Internet Forum

7.4.3.2 Interface Committee

Apart from this web-based forum of involvement and debate, the General Framework also proposes a structure for the direct, face-to-face discussion between risk assessors, risk managers, and stakeholders. The two options for this structure are outlined in the following paragraphs.

a) Interface Advisory Committee (IAC)

A first option of ensuring the direct co-operation between those responsible for assessment and those responsible for management would be to establish an Interface Advisory Committee (IAC) composed of risk assessors (i.e., members of EFSA Panels and scientific services), risk managers (i.e., members of responsible units of DG SANCO), and stakeholder representatives (i.e., representatives of the key European consumer, industry and farmer organisations). The committee would be established through a Commission Decision specifying its tasks and composition. The IAC would adopt advisory opinions on the terms of reference of given cases and on the evaluation of cases addressed to the Commission. The institution or authority responsible for the definition of the terms of reference could then use these discussions to define the specific terms of reference forwarded to EFSA for a risk assessment. In this option the draft terms of reference would be published as soon as they have been submitted to EFSA (in the current system, the terms of reference are revealed only after the completion of an opinion by EFSA).\(^\text{133}\)

The Advisory Committee would not be expected to deal with all cases of risk governance, but only address those cases considered to be particularly problematic or requiring further discussion between risk assessors, risk managers, and stakeholders. In practice, this would mean that the Commission would convene meetings of the Advisory Com-

---

\(^{131}\) This point needs to be specified with regard to whether one of the Interface Committees has been set up, as these play a major role in the setting of terms of reference; see table 7.4 which provides an overview of the three options proposed below for further specifications.

\(^{132}\) As in the setting of terms of reference, this task differs slightly when either the Steering Committee or the Advisory Committee has been established; see the discussion of the three options proposed for the food safety interface institutions for further specifications.

\(^{133}\) In current practice, the terms of reference are published in the register of requested opinions on the website of EFSA after an opinion has been established; for ongoing risk assessments, no terms of reference can be found on this website. See: http://www3.efsa.europa.eu/register/qr_panels_en.html
mittee where this was seen to be necessary, especially in cases where the results of screening have indicated sources of uncertainty or ambiguity. As indicated above, the Internet Forum would also have the possibility of making suggestions about cases to be dealt with by the Advisory Committee. Furthermore, the Commission would also be free to use the Advisory Committee as a forum for an exchange of views about questions of a more general nature. Therefore, it is envisaged as a structure that operates remotely from individual decision-making procedures in single cases of risk governance. It would deal with only those cases which either risk assessors, risk managers or stakeholders would like to discuss in the framework of the Committee. In this vein, the Advisory Committee would also be free to combine or “bundle” cases in a way that appears conducive to the effectiveness of procedures and the avoidance of overload.

It is envisaged that the IAC would work in a flexible setting, with its composition depending on the case in question around a core of permanent members (see table 7.3). To this end, the Commission would appoint a group of core members of the IAC consisting of an equal number (2-4) of risk assessors, risk managers, and stakeholder representatives (suggesting a size of the core group between 6 and 12 committee members). These should include members of the „horizontal“ units of EFSA and the Commission (i.e., those units responsible for non case-specific issues as science and stakeholder relations, risk assessment, food law, and the food chain), and stakeholders with a background in the representation of the general interests of consumers, industry, farmers, and other interests involved in the food chain.

Furthermore, in order to be able to deal with cases from different fields, the IAC should be convened in different constellations for each major field of food safety governance (suggesting 6-9 different IAC constellations). These constellations could be established in correspondence with the eight Scientific Panels of EFSA. Therefore, in addition to the core committee members, each constellation of the IAC should include an equal number (2-4) of risk assessors, risk managers and stakeholder representatives with case-specific expertise for a specific field. These committee members would be appointed by the core committee members and could be recruited from the Scientific Panels and scientific expert services of EFSA, the units of DG SANCO with responsibility for a specific field of food safety governance (pesticides, GMOs, etc.), national food authorities, and stakeholder representatives with a case-specific interest.

Moreover, for particularly problematic cases, the committee would be allowed to invite further experts with specific interests or expertise on an ad-hoc basis, depending on the case in question. For example, if the originator of a request to EFSA is a Member State or the European Parliament, a representative of the respective institution should be invited to the committee session as an ad-hoc member. Although no fixed number of participants is prescribed for the IAC, it is clear that it should remain a sufficiently small structure to work effectively and therefore not include too many participants. The size of the committee could therefore vary between 6 and 24 and be kept flexible, with the objective of bringing together the risk assessors and risk managers with specific expertise and responsibility for a given field of risk governance (i.e., GMOs, pesticides, or animal health). The size and composition of the Interface Advisory Committee is summarised once more in table 7.3 below.
Table 7.3: Size and composition of the Advisory Committee

### Core Committee Members

<table>
<thead>
<tr>
<th>Risk Managers</th>
<th>Risk Assessors</th>
<th>Stakeholder representatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-4 persons representing “horizontal” units of DG SANCO (e.g., on science and stakeholder relations, food law, food chain and labelling)</td>
<td>2-4 persons representing “horizontal” EFSA bodies (e.g. Scientific Committee, units on science and risk assessment)</td>
<td>2-4 persons having their background in the representation of general interests of consumers, industry, farmers or other interests of the food chain</td>
</tr>
</tbody>
</table>

### Case-specific Committee Members

<table>
<thead>
<tr>
<th>Risk Managers</th>
<th>Risk Assessors</th>
<th>Stakeholder representatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-4 persons representing case-specific units of DG SANCO (e.g. on pesticides, GMOs or animal health)</td>
<td>2-4 persons representing case-specific bodies of EFSA (e.g. members of the Scientific Panels or of the scientific services)</td>
<td>2-4 persons with a background in the representation of case-specific stakeholder interests</td>
</tr>
<tr>
<td>➔ to be appointed by the core committee members for all major fields of food risk governance (i.e., 6-9 different constellations of case-specific committee members)</td>
<td>➔ to be appointed by the core committee members for all major fields of food risk governance (i.e., 6-9 different constellations of case-specific committee members)</td>
<td>➔ to be appointed by the core committee members for all major fields of food risk governance (i.e., 6-9 different constellations of case-specific committee members)</td>
</tr>
<tr>
<td>plus: may invite ad-hoc members for particular cases if considered necessary</td>
<td>plus: may invite ad-hoc members for particular cases if considered necessary</td>
<td>plus: may invite ad-hoc members for particular cases if considered necessary</td>
</tr>
</tbody>
</table>

### Interface Steering Committee (ISC)

As a second option of ensuring deliberations between risk assessors, risk managers and stakeholders the creation of an Interface Steering Committee (ISC) could be envisaged. This option would be a more strongly formalised solution. The ISC would have the same size and composition as the Advisory Committee and also serve as a platform where the terms of reference and risk evaluation can be discussed between the three actor groups. However, contrary to the Advisory Committee, the Steering Committee would be able to adopt the terms of reference instead of issuing only an advisory opinion. The tasks of the ISC with regard to evaluation, however, would still be restricted to the adoption of advisory opinions\(^\text{134}\). Furthermore, the tasks of the ISC could be defined as dealing with all cases of risk governance, instead of a selection of only the more problematic cases. This could take account of the view that not just the deliberation about the terms of reference, but also the more fundamental decision on the selection of critical cases requires an open exchange between assessors, managers, and stakeholders. From this point of view, it could be argued that it would be less laborious to deal with all cases (albeit at different intensities) than to organise a meeting of the Interface Committee in each case where assessors or stakeholders flag up critical issues. Moreover, the decision-making process on the selection of critical or special issues would also be subjected to full transparency. Therefore, whereas this option may appear as

---

\(^{134}\) For further explanations on this point, see Section 7.6.6 in this Chapter on the principle on the non-delegation of powers („Meroni doctrine“).
more burdensome at first sight, it clearly has its advantages in carrying forward the objectives of openness, transparency and stakeholder involvement in a very obvious manner. It is therefore proposed as the „maximal“ option for the design of the food safety interface institutions in the General Framework.

### 7.4.3.3 The three options compared

The General Framework thus proposes three options (as presented in table 7.4 below):

1) the creation of the Internet Forum only (‘*Minimal Option*’)
2) the creation of the Internet Forum and the Advisory Committee (‘*Intermediate Option*’)
3) the creation of the Internet Forum and the Steering Committee (‘*Maximal Option*’).

<table>
<thead>
<tr>
<th>Internet Forum only</th>
<th>Internet Forum and Interface Advisory Committee</th>
<th>Internet Forum and Interface Steering Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>(‘Minimal Option’)</td>
<td>(‘Intermediate Option’)</td>
<td>(‘Maximal Option’)</td>
</tr>
</tbody>
</table>

**ADVISORY COMMITTEE:**

**Composition:**
- **Core Members:** Equal number of assessors, managers, and stakeholder representatives, to be appointed by the Commission
- **Case-specific members:** assessors, managers and stakeholders with specific expertise for different fields of food safety governance, to be appointed by the core members
- **Ad-hoc members:** may be invited by IAC for specific cases

**Tasks:**
- Gives advice on the Terms of Reference and Evaluation to the Commission

**Working Procedures:**
- Deals with only a selection of cases
- Advisory Committee is convened by the Commission for particular cases, especially when screening has found uncertainty and/or ambiguity

**STEERING COMMITTEE:**

**Composition:**
- as in the Advisory Committee

**Tasks:**
- Adopts Terms of Reference
- Gives advice on Evaluation to the Commission

**Working Procedures:**
- could deal with all cases of risk governance

**INTERNET FORUM**

<table>
<thead>
<tr>
<th>Framing:</th>
<th>INTERNET FORUM</th>
<th>INTERNET FORUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Publication of Terms of Reference</td>
<td>(in addition to the tasks of the IF listed for the „Minimal Option“):</td>
<td>(same tasks as in case of the Advisory Committee)</td>
</tr>
<tr>
<td>- Exchange of views about referral and review</td>
<td>- Discusses proposals for the appointment of stakeholder representatives in the Advisory Committee</td>
<td></td>
</tr>
<tr>
<td><strong>Assessment:</strong></td>
<td>- Makes suggestions for cases to be discussed by the Advisory Committee</td>
<td></td>
</tr>
<tr>
<td>- Exchange of views on application of terms of reference in assessment procedures</td>
<td>- Discusses Evaluation results and the advice on Terms of Reference by the Advisory Committee</td>
<td></td>
</tr>
</tbody>
</table>
Table 7.4: Three options for the institutional design of the food safety interface

Comparing these three options, we feel that the objectives of the General Framework are best expressed through an option that also includes a structure for the direct interaction between risk assessors and risk managers, in particular the Advisory Committee. The „minimal“ option is proposed mainly as one that is relatively easy to implement and flexible in its application. When reflecting upon these proposals, it is important to repeat that the proposal to introduce a more coherent and transparent step of setting terms of reference - as expressed in the proposals for an Advisory or a Steering Committee - coincides with the ideas by both the Commission and EFSA to work towards a more transparent and inclusive approach to defining the terms of reference in the process of risk assessment. These ideas were also put forward during the interviews with some Commission officials. These ideas are consistently taken up through the proposal for an interface committee bringing together all involved actors with the aim of improving communications at the interface of risk assessment and risk management. Our proposal therefore builds on and extends existing ideas among risk assessors and managers as well as stakeholders to create more transparency, and introduces a more coherent approach at this crucial step of food safety analysis.

7.5 Management: re-consideration of the comitology procedure

Management as a part of the General Framework presented here has essentially the same meaning as the definition given in the General Food Law (Article 3, 12). One of the main recommendations of the General Framework with regard to this step of risk governance refers to the re-consideration of procedures for the involvement of stakeholder organisations. It is important to stress, however, that the participation procedures (both at the stages of management and assessment) should be implemented without institutional changes, e.g. without the creation of another consultation body or forum, but by making use of existing arrangements and procedures. This point will be considered in greater detail in Chapter 8 on participation procedures.

Furthermore, with regard to the institutional requirements, a particularly important and sensitive question in management refers to the application of the comitology procedure in the adoption of measures or the approval of authorisations. The development of comitology has been subject to intensive debates both in the legal and social scientific field, especially with regard to questions related to the internal procedures of committees, transparency, and oversight of committees by the European Parliament and access for external actors such as experts and stakeholders. One of the key findings of this debate is the apparent paradox that whereas comitology committees were initially created to serve as a control mechanism for the fulfilment of implementation tasks by the Commission, they mostly appear to work as a

---

135 E. Vos, C. Ní Ghiollarnáth and F. Wendler 2005, supra note 30, p. 120 ff.
strong mechanism for deliberative decision-making, advancing consensus as part of a regulatory network with a strong role for the Commission, therefore raising questions about the transparency, control and oversight of the committees themselves. It therefore appears as one of the key institutional challenges in the field of risk management to ensure the compliance of comitology procedures with principles of good governance (especially transparency and accountability) while preserving this procedure as a pragmatic and powerful mechanism for deliberative decision-making and the creation of consensus around the adoption of measures in risk management.

In this context, an important development is that the comitology procedures were revised in 1999 by a Council decision, requiring committees, *inter alia*, to adopt rules of procedure from a template adopted by the Commission, including a commitment to keep the European Parliament informed of activities of committees and ensuring access to documents equivalent to those of the Commission\(^ {137}\). Principles of good governance have been introduced to a stronger degree into the work of comitology committees, a fact also underlined by annual reports drafted by the Commission on the work of committees\(^ {138}\), stakeholders in the field\(^ {139}\) as well as Member States\(^ {140}\). This calls for stricter rules on transparency. With regard to the procedures of decision-making, an element of increasing concern in the field of GMO authorisation is that the adoption of implementation measures (or the approval of authorisation of novel food products) is legally possible in the absence of a political agreement among the Member States to support such a decision by the Commission\(^ {141}\). Particularly in the field of GMO authorisations the Commission has frequently made use of this possibility. The background for this problem is that several authorization procedures have not resulted in a vote with a required qualified majority either for or against the adoption of a Commission proposal in both the Standing Committee and the Council, thus leaving the possibility open for the Commission to authorize a product. Recently Member States have severely criticized this practice.

This practice of adopting authorizations even in the absence of a positive vote by the Member States has met intensive criticism both by the Member States and a number of stakeholder organisations. In this context, it is noteworthy that in a declaration attached to the 1999 Comitology decision, the Commission committed itself to avoid situations in which measures are adopted against a strong expressed opinion of the Member States, especially in sensitive areas:

> "In the review of proposals for implementing measures concerning particularly sensitive sectors, the Commission, in order to find a balanced solution, will act in such a way as to


\(^{138}\) The first of these reports is: European Commission: Report from the Commission on the working of committees during 2000, 2002/ C 37/02, 9.2. 2002.


\(^{140}\) EU Food Law Weekly, no. 247, 10 March 2006, p. 4.

\(^{141}\) This possibility results from the requirements established in Council Decision 1999/468 EC for the comitology procedure. According to Article 5 of this Decision, the regulatory procedure prescribes that in cases where the comitology committee (in the case of GMOs the responsible section of the Standing Committee on the Food Chain and Animal Health) has not endorsed a measure proposed by the Commission (i.e., a proposal for the authorisation of a GMO product) or no opinion was expressed, the measure is forwarded to the Council. In cases where the Council does not oppose the measure with a qualified majority or no vote is taken, the Commission is authorised to adopt the measure even in the absence of a positive vote supporting the proposed measure (cp. Article 5,6 of Council Decision 1999/468 EC).
avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure."

Against this background, the General Framework therefore recommends that in areas such as the authorisation of GM food products, implementation decisions by the Commission should not be adopted in the absence of a qualified majority vote expressing the political support of a majority of the Member States for the adoption of such a decision. This recommendation could already be realised without the requirement for changes in the institutional framework, as it would actually follow existing commitments expressed by the EC institutions. However, as the Commission does not seem to adhere to this, an amendment of the Comitology decision in this sense seems necessary.

7.6 **The General Framework and general principles of European law**

Importantly, any decision adopted on the basis of the General Framework should comply with general principles of Community law, in particular the precautionary principle, the proportionality principle, and the subsidiarity principle.

7.6.1 **Precautionary principle**

Today the precautionary principle is an important pillar of food safety regulation. The application of this principle is a source of much debate and controversy in Europe and its application leaves much to be desired in terms of consistency and clarity. The GFL labels the precautionary principle as a general principle of food safety and is defined in Article 7 of the GFL. Notwithstanding this definition, there is nevertheless, still much unclarity about the precise significance of the precautionary principle. In its landmark National Farmer’s Union case the European Court of Justice gave a broad definition to the precautionary principle stating that

> ‘[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent’.

---


Whilst other projects have already studied the precautionary principle in much detail\textsuperscript{145}, this project aims to give the precautionary principle a place in the process of risk governance, recognising that the principle needs to be applied throughout the whole process. The Commission in its Communication on the precautionary principle of 2000 emphasised its view that the precautionary principle should be regarded as a risk management principle\textsuperscript{146}. It argued that ‘the precautionary principle is particularly relevant to the management of risk. The principle, which is essentially used by decision-makers in the management of risks should not be confused with the element of caution that scientists apply in their assessment of scientific data’\textsuperscript{147}. Also the ECJ seems to see the principle foremost as a principle of risk management, although phrased in more flexible wording and referring to it as being ‘an integral part of the decision-making processes leading the adoption of any measure for the protection of human health’\textsuperscript{148}. Recent thinking in legal circles point out moreover that from a legal point of view, nothing precludes that the risk assessment stage has to be carried out in accordance with the obligations stemming from the precautionary principle. It is thus argued that in order to deal effectively with uncertainty, ambiguity, and ignorance, assessors should apply precaution at an early stage\textsuperscript{149}.

### 7.6.2 Proportionality principle

The proportionality principle says that “any action of the Community shall not go beyond what is necessary to achieve the objectives of the Treaty” (Article 5 (3) EC Treaty)\textsuperscript{150}. In this way, it has particular relevance for risk governance measures, protecting human health. The proportionality principle has been developed in the case law of the European Court of Justice in the context of trade hindering measures adopted by the Member States. In particular the ECJ developed a threefold test to examine the validity of the measures adopted by the Member States and in a later stage the measures adopted by the Community institutions. The proportionality of the measures is thus judged by looking at the aim and nature of the measure. Questions to examine include whether:

1. a measure is necessary to protect one of the recognised interests (amongst which protection of health and the environment),
2. the measure is the least restrictive of trade, and
3. the imposed restrictions are proportionate to the aim pursued\textsuperscript{151}.

Examination of the early case law of the Court of Justice has revealed that in the field of free movement of goods the proportionality principle as developed by the Court already included a kind of precautionary principle long before the precautionary principle appeared in the Community context as a ‘true’ principle\textsuperscript{152}. It can thus be said that the precautionary principle

---


\textsuperscript{146} COM (2000) (Precautionary Principle), \textit{supra} note 6.

\textsuperscript{147} Ibid., \textit{Summary}, para 4.

\textsuperscript{148} Case C-236/01, \textit{Monsanto Agricoltura Italia}, ECR [], para 133.

\textsuperscript{149} N. de Sadeleer 2006, \textit{supra} note 143, p. 148.

\textsuperscript{150} See e.g. Protocol on the application of the principles of subsidiarity and proportionality.


‘grew out’ of the proportionality principle, before it was finally recognised by the ECJ as an autonomous principle applying also to health issues 153.

### 7.6.3 Subsidiarity

The principle of subsidiarity too is a very much debated principle. It is laid down in the EC Treaty in Article 5 (2) that says ‘In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community’. The importance of this principle for the general risk governance is clear: the Community institutions should clearly not exercise their powers in a way detrimental to the Member States. Yet, it will be clear that in view of the objective of free movement of foods, it will be likely that the Community will legitimately exercise its powers ensuring free circulation of those goods in the whole Community market. Furthermore, an interesting feature of the General Framework is that it actually provides for an extra possibility of the Member States to participate in the deliberations within the Advisory Committee. This may also be viewed as a means of engaging subsidiarity. As we know the subsidiarity principle clearly dictates that Member States should not be excluded from the process of creating a European Union based upon the rule of law, democratic principles and solidarity. In this manner, one could say that observing carefully the procedural element of decision-making taking into consideration the level at which decisions are taken, how and in what way they are drafted, is also a means of implementing the philosophy of subsidiarity 154. Therefore mechanisms which provide for co-operation between all the levels concerned might address Member States’ concerns for unnecessary Community activities and hence respect the subsidiarity principle 155. Where the Advisory Committee proposed by the General Framework provides for the possibility to include also Member States, this can thus be regarded as implementing the subsidiarity principle.

### 7.6.4 Good governance

The General Framework directly addresses the five principles of good governance identified in the 2001 CEC White Paper. With regard to the principle of openness, the paper prescribes that EC institutions “should work in a more open manner” and “actively communicate about what the EU does and the decisions it takes” 156. As has been made clear in the course of this chapter, one of the primary objectives of the innovations proposed by the General Framework is to increase the transparency of risk governance especially during the crucial steps at the ‘interface’ of scientific assessment and political decision-making, requiring that all relevant interface communications should be made accessible to interested parties and the wider public through the Internet Forum. This applies equally to the principle of participation, which is addressed as a major objective of all steps of risk governance outlined in the General Framework, and specifically supported through the creation of the Internet Forum and an Interface Committee that involves stakeholder representatives. By rendering the interaction of risk assessment and risk management less opaque and more open to critical observation and debate,

---


156 COM (2001), supra note 6, p. 10.
the General Framework also helps to realise the principle of **accountability**, requiring that “each of the EU institutions must explain and take responsibility for what it does in Europe”. Through the recommendation to re-consider decision-making practices at the stage of the comitology procedure, the Framework also follows the objective of increasing the clarity and responsibility of decisions made by the Member States, required by the accountability principle. Furthermore, the General Framework takes account of the principles of **effectiveness** and **coherence** by proposing a more effective and appropriate distinction of threats through screening, and by establishing an interface structure to render the co-ordination between risk assessment and risk management more systematic and effective.

### 7.6.5 Good administration

Finally, the General Framework builds on the principle of good administration as one of the basic rights of citizens protected by European law. The principle has its background in Article 41 on the right to good administration of the Charter of Fundamental Rights of the European Union, which was formally proclaimed by the Heads of State and Government at the Nice European Council and later enshrined in Part II of the (still non-ratified) Constitutional Treaty. Although still formally non-binding, the Charter of Fundamental Rights may have visible effects, as its provisions can be used by national and European courts to interpret national and Community legislation in conformity with the Charter, especially with regard to provisions directly concerning the behaviour of public authorities such as Article 41\(^\text{157}\). Furthermore, the right to a good administration may be called upon by citizens by referring cases of maladministration in the activity of Community institutions or bodies to the European Ombudsman, a right set out by Article 43 of the Charter of Fundamental Rights. The right to good administration is also remarkable through the fact that it applies not just to EU citizens, but is recognised to every person coming into contact with the Union’s institutions and bodies. The principle of good administration is established as guidance to the administrative behaviour of Community institutions and bodies and obliges their relations with the public. The first two paragraphs of Article 41 set out the content of the principle of good administration, establishing the principles of impartiality, fairness, and reasonable time limits, giving every person the right to be heard before any measure which would affect him or her adversely, and establishing the obligation on Community institutions and bodies to give reasons for its decisions (also enshrined in Article 253 of the Treaty\(^\text{158}\)). The third and fourth paragraphs of the Article concern the compensation of damages caused by the EU institutions and the right to make written inquiries and receive answers in one of the languages of the Treaties.

Departing from this legal principle, various attempts have been made to give substance to the exact meaning and application of the right to good administration. In this vein, the contents of this article have been spelled out in a European Code of Good Administrative Behaviour, drafted by the European Ombudsman and approved through a resolution of the European Parliament on 6 September 2001. The code details the rules of good administrative behaviour that EU institutions and bodies, their administrations and officials should respect and abide by. Apart from imposing general principles of lawfulness, proportionality, objectivity, fairness, impartiality, and absence of discrimination and abuse of power, the Code prescribes in its Article 16 the Right to be heard and make statements. The article prescribes that in cases where the rights or interests of individuals are involved, officials of European Institutions shall ensure that the rights of defence are respected, allowing every member of the public the

---


\(^{158}\) Article 253 EC sets out that „Regulations, directives and decisions adopted jointly by the European Parliament and the Council, and such acts adopted by the Council or the Commission, shall state the reasons on which they are based and shall refer to any proposals or opinions which were required to be obtained pursuant to this Treaty“.
right to submit written comments in cases where a decision affecting his or her rights or interests are affected. Furthermore, Article 18 on the duty to state the grounds of decisions obliges the European institutions to state the grounds of decisions that may adversely affect the rights or interests of a person, indicating the relevant facts and the legal basis of a decision. In addition, officials of European institutions are obliged to provide citizens who expressly request it with an individual reasoning for decisions.

In addition to the general rights and obligations, the European Commission has also specified its own rules of good administrative behaviour in relations with the public (adopted on 13 September 2000), following on initiatives to improve its administrative practices triggered by its White Paper on Administrative Reform adopted after the resignation of the Santer Commission in 1999. Adding to the general obligations on European institutions and their officials outlined above, the Code prescribes that in cases where Community law provides that interested parties should be heard, Commission staff shall ensure that an opportunity is given to them to make their views known. Furthermore, the obligation is established that a Commission decision should clearly state the reasons on which it is based, requiring full justification for decisions as a general rule. Moreover, Article 3 of the Code sets out that any interested party who expressly requests a detailed justification shall be provided with it.

Many of these obligations of ‘good’ or ‘sound’ administration have been developed by the ECJ. Important for the General Framework is in particular the duty for the Community institutions ‘to examine, carefully and impartially, all the relevant aspects of the individual case’159. This means for example that the scientific assessment must be made on the basis of scientific advice founded on the principles of excellence, transparency and independence in order to guarantee the scientific objectivity of the measures adopted and preclude any arbitrary measures160.

The significance of the principle of good administrative behaviour and the codes of conduct presented above for the General Framework is twofold: First, by establishing the right to persons to be heard and the obligation on Community institutions to state reasons for their decisions, these documents provide a guidance for the interaction between the expression of views in the Internet Forum and reactions by the Community institutions, in particular the Commission and EFSA. As mentioned above, these provisions establish the obligation to take into account the views expressed in the forum and to give reasons for decisions in relation to these views, especially in cases where the interests of individual persons can be seen to be affected. Whereas there would be no formal reporting mechanism from the Internet Forum to EFSA or the Commission and the Internet Forum would not be able to directly determine the agenda of the Interface Committee, an obligation is therefore established to take into account and discuss interests and concerns expressed by stakeholder groups and individual citizens through the Internet Forum. Therefore, secondly, the proposed institutional innovations can also be seen to further implement the objectives established by the right to good administration and the codes of good administrative behaviour, by giving both civil society actors and individual citizens an accessible instrument to make their views known, and to provide a forum for the Commission and EFSA to state reasons behind decisions through the increased transparency of communications at the interface between risk assessment and risk management.


7.6.6 The principle of non-delegation of powers (Meroni doctrine)

In this context, specific attention is also given to the principle of non-delegation, as expressed in the so-called “Meroni” doctrine. The doctrine is still the dominant argumentation framework both in legal and political debates for restricting tendencies of functional decentralisation in the institutional structure of the EC to the degree of giving only very specific and limited powers to independent agencies (such as EFSA) and other bodies that are independent from the Commission. This doctrine was inspired by the case law of the European Court of Justice of the late 1950s. In the Meroni cases, the Court rejected the transfer of sovereign powers to subordinate authorities outside the EC institutions and ruled that only “clearly defined executive powers” could be delegated, the exercise of which was to remain at all times subject to Commission supervision. Although the Meroni judgments related to the ECSC Treaty, their applicability to the EC Treaty has been generally accepted.

This case law would suggest that the following conditions apply to the admissibility of transferring sovereign powers to subordinate authorities outside the EC institutions:

- the Commission cannot delegate broader powers than it enjoys itself;
- only strictly executive powers may be delegated;
- discretionary powers may not be delegated;
- the exercise of delegated powers cannot be exempted from the conditions to which they would have been subject, had they been directly exercised by the Commission, in particular the obligation to state reasons for decisions taken, and judicial control of decisions;
- the powers delegated remain subject to conditions determined by the Commission and subject to its continuing supervision; and
- the institutional balance between the EC institutions must not be distorted.

The Court justified its reasoning by referring to the balance of powers, “characteristic of the institutional structure of the Community”, which would be distorted if discretionary powers were delegated to bodies other than those established by the Treaty. The underlying concern about the distinction between “clearly defined executive powers” and “discretionary powers” and the concern about the prohibition to delegate the latter to “outside structures” seems to lie in the Court’s understanding of democratic legitimacy, in which it must be possible to eventually trace the powers of any rule-making body to the authority of a democratically elected parliament. Although over the years some pro-delegation voices have been heard in the Commission, it is currently still the prevailing opinion that no discretionary powers can be delegated to agencies.

The Meroni doctrine is relevant for the application of the General Framework with regard to the following aspects:

---

- **Terms of Reference/Evaluation**: The doctrine may have implications for this step of the General Framework, as the intention is to transform the specification of the terms of reference from a closed process within the Commission into a co-operative exercise that is shared with risk assessors and stakeholders, and which may be transferred to an external forum composed of these three actor groups. This proposed change is not seen to infringe the doctrine, as the setting of the terms of reference does not predetermine the outcome of assessment, and even less of the decision taken later on at the step of management. Nevertheless, if it should be felt that the Meroni doctrine interferes with the setup of a new organ deciding on the terms of reference, as this takes away relevant functions of risk analysis from the Commission, the intermediate and minimal options take account of such concerns. It is therefore also up to the interpretation of the Meroni doctrine which of the options is chosen for this step. Equally, the doctrine needs to be considered in relation to the step of evaluation, which is also recommended as a task to be undertaken in cooperation between managers, assessors and stakeholders, in the Interface Committee that is independent from the Commission. However, the General Framework takes account of this concern in defining the task of the Interface Committee as a purely advisory one, which does not interfere with the full responsibility of the Commission for the decision about the outcomes of evaluation and the eventual conduct of management.

- **Assessment**: The doctrine clearly has strong implications for the conduct of assessment, as tasks within this stage of food safety governance can only be allocated to EFSA as far as they fall within the sphere of risk assessment as defined by the General Food Law and can thus be separated from functions of risk management falling under the responsibility of the Commission. This requires clarifications in some cases such as the presumption of prevention (in which the application of crisis management mechanisms is understood as a function of risk management), precautionary assessment (which is understood not to interfere with the final responsibility of risk managers to apply the precautionary principle), and concern assessment (which refers to the gathering of information about socio-economic concerns, but not to their evaluation). Furthermore, it is understood that the choice of one of the approaches to assessment for a particular case of food safety governance does not preclude the choice of a particular management strategy and does therefore not interfere with the autonomous decision of risk managers of selecting, ranking, choosing, and implementing particular options to deal with a given food safety threat.

- **Risk Management**: This step does not pose a particular problem in the light of the non-delegation doctrine, as decision-making is fully left as a responsibility assigned to the Commission (and the Member States), as set out in the General Food Law.

### 7.7 The General Framework and WTO law

As stated in the introductory remarks, one of the primary objectives of the General Framework is to achieve a full compatibility of risk governance procedures with requirements at the international level, especially in the framework of WTO agreements. The General Framework now, we argue, and in particular the way in it proposes to carry out assessment, might be interesting for the EC as it offers potentially a way to make decisions which are adopted according to the General Framework ‘WTO compatible’.

#### 7.7.1 SPS and TBT agreement

The relevant agreements are the GATT 1994, the TBT Agreement and the SPS Agreement. GATT 1994 deals with trade-restrictive measures imposed by countries. The goal of GATT is to encourage trade between WTO members by reducing tariffs and preventing trade barriers.
The Agreement on Technical Barriers to Trade (‘TBT’) lays down rules for the general category of technical barriers to trade. The Agreement on the Application of Sanitary and Phytosanitary measures (‘SPS’) deals with more specific types on barriers to trade, namely those protecting human or animal life and health, as provided for by Annex A of the SPS Agreement. The SPS Agreement is, to a certain extent, to be regarded as an expansion and clarification of Article XX of GATT, that allows Member States to deviate from the general prohibition to create trade barriers for specific reasons, such as the need to protect human, animal or plant life or health, provided that such national measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail. However, the link between GATT and SPS is not a necessity: no violation of GATT needs to be shown before the SPS Agreement can be relied upon. Both the SPS Agreement and the TBT Agreement are co-equal sources of WTO law, since Article II:2 of the WTO Agreement defines these agreements as integral parts of the WTO Agreement, thus binding all Members.

The substantive scope of application of the different WTO Agreement differs, but does not exclude the possibility of overlapping application. The GATT agreement has the widest substantive scope, while SPS has the most closely defined scope and is thus to be seen as a *lex specialis* to both GATT and the TBT Agreement. This is also clarified by the rules on mutual exclusivity in the relationship between the SPS Agreement and the TBT Agreement. The SPS Agreement is the sole applicable in cases of measures protecting human or animal life against risks arising from pests, food, or feedstuffs. The relevant article for risk assessment in the SPS Agreement is Article 2.2, which reads:

“Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.”

Furthermore, Article 5.1 specifies that:

“Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”

Finally, Article 5.7 deals with the exception to Article 2.2 and provides to some extent for the possibility to take precautionary action:

---

166 1. Sanitary or phytosanitary measure — Any measure applied:
(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

167 See *Hormones* (Panel) para. 8.41 and *Salmon* (Panel), paras. 8.38-8.39.

168 Article 1.5 of the TBT Agreement emphasizes that the TBT Agreement is not to be applied where the SPS Agreement is applicable. As seen before, broadly speaking, this means that the TBT Agreement is not applicable to trade barriers seeking to protect the human or animal life and health from pests of food-related risks. Article 1.5 of the TBT Agreement emphasizes that the TBT Agreement is not to be applied where the SPS Agreement is applicable. As seen before, broadly speaking, this means that the TBT Agreement is not applicable to trade barriers seeking to protect the human or animal life and health from pests of food-related risks.
“In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.”

Annex A.5 defines risk assessment, and makes a distinction between assessment of measures intended to protect against pests and those intended to protect against food- and feedstuffs:

“Risk assessment — The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”

Risk management is not mentioned explicitly under SPS. One could generally read the notion of risk management into Article 2.1, which stipulates that:

“Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.”

The Appellate Body in EC Hormones stretched the notion of risk assessment so as to avail Members of the possibility to include risk management (i.e. policy) decisions in the risk assessment phase. The influx of these policy decisions, however, is possible through Article 2.1 SPS, which allows the Members to decide the level of SPS measures taken to protect human life, provided that these measures are not inconsistent with the SPS Agreement.

The use of science as a benchmark in the SPS Agreement marks a ‘radical departure from the pre-dominantly discrimination based approach of the GATT’ J. Scott, The WTO Agreement on Sanitary and Phytosanitary Measures, A Commentary, OUP, 2007, Chapter 3. Its influence is not to be underestimated. As seen above, many of the most important SPS Articles revolve around the use of science. Importantly, Article 2.2 sets science as ‘the touchstone against which SPS measures are judged for validity’. As can be seen from the above citation, Article 2.2 requires SPS measures taken to be (1) necessary, (2) based on scientific principles, and (3) not to be maintained without sufficient evidence. In all three criteria, the concept of ‘rational relationship’ has evolved and plays an important role, implying that there should be such a relationship between the science being relied upon and the measure taken by the Member. This ‘rational relationship-test’ has evolved to include a proportionality test.

As for the first criterion, the requirement of necessity, case law has clarified that the measure must be necessary for the protection of human or animal life and health. Moreover, the Appellate Body has clarified that the measure need not be indispensable, but rather able to achieve the objective sought. As seen above, the requirement of rational relationship does also play a role in the assessment of the criterion of necessity.

Concerning the second and most important criterion, which requires the measure to be based on scientific principles, the Appellate Body in EC-Hormones has defined the requirement of ‘based on’ as meaning simply derived from. In this context the rational relationship test is extremely important. In Japan Apples, the Panel required more than the existence of a ‘negligible risk’ for the imposition of an SPS measure. Moreover, it established that where no rational relationship exists between the measure and the risk, the imposition of the SPS meas-

---

170 Japan Apples (Appellate Body), para. 146.
ure is to be seen as disproportionate to the risk and therefore not valid. This may seem to imply a sort of balancing exercise, with the Panel comparing the risk with the ‘nature of the measure’.

As for the third criterion, the requirement of ‘sufficient evidence’, the WTO judicial bodies have defined the notion of ‘sufficient’ to imply a ‘sufficient or adequate relationship’ between the measure and the evidence involved. Moreover, a minority scientific opinion, if stemming from qualified and respected sources, can amount to ‘sufficient evidence’. Especially when the risk is greater and the threat more imminent, governments may ‘proceed down the spectrum of minority opinion’.

The integrated approach of Articles 2.2 and 5.1 leads to the fact that a risk assessment is required for any SPS measure taken. The requirement of risk assessment boils down to a two-step approach. The Member assessing the risk must identify the adverse effects and must evaluate the potential of occurrence of such risk. There has to be an objective relationship between the assessment and the measure taken. The crucial question is not whether the assessment was taken into account, but whether the measure was taken based on the risk assessment. Importantly, for an SPS measure to be allowed, the underlying risk assessment must show ‘more than theoretical uncertainty’. In fact, positive evidence is required. Even though not yet explicitly supported by the Appellate Body, there seems to be some leeway in the assessment of this positive evidence-obligation.

Members are to take inter alia scientific evidence, production methods and economic aspects into account when assessing the risk posed by a disease of food- and feedstuffs. The question then arises as to whether other factors may be taken into account by the Members in their risk assessments. The Appellate Body in *EC Hormones* seems to support the inclusion of non-scientific factors. However, it struggled with the absence of a textual reference in the SPS Agreement which posed a problem for the formal recognition of risk management. Since the absence of the notion of ‘risk management’ in the SPS Agreement limits the role of policy choices and value-based considerations, the Appellate Body ‘tried to build in some capacity for risk management considerations into the process of risk assessment under the SPS Agreement’. The most explicit example of this was the Appellate Body’s ruling in *EC Hormones*, where it stressed that risk assessment included: “not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die”. Furthermore, it contended that “the object and propose of the SPS Agreement justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be”.

This ruling seems to support a more integrated approach to risk analysis that recognizes the scope for policy choices and policy options. The necessity of examination of non-scientific

---

171 Japan Apples (Panel), para. 8.181.
172 J. Scott 2007, supra note 169, Chapter 3.
173 Japan Varietals (Appellate Body), para. 73.
174 Hormones (Appellate Body), para. 194.
175 J. Scott 2007, supra note 169, Chapter 3.
176 Ibid.
177 Hormones (Appellate Body), para. 186.
180 Hormones (Appellate Body), para 206.
risk is to be addressed on a case-by-case basis. However, closer investigation of the position of scientific and non-scientific factors in the SPS risk assessment shows that this role is largely curtailed by a rigorous demand of scientific proof. Members have ‘little discretion to stray too far from a scientific assessment of risk’. Similarly, in Japan Apples, the Panel and Appellate Body strongly relied on ‘specific’ or ‘direct’ scientific evidence in order to link the measure with the risk. WTO Panels ‘rely on the advice of independent scientific experts in assessing factual matters of a scientific or technical nature, rather than deferring to the Members’ interpretation of the scientific evidence’.

Against this background, it seems the WTO Panels have factually closed all possibilities for the inclusion of non-scientific factors in risk assessment that were created by the Appellate Body in EC Hormones. The stronger adherence to science is understandable, as it is the sole tool which can claim to have universal application but may be seen as regrettable in regard to the democratic deficit in global governance and the rights of defence in these cases which are highly dependent upon the opinion of scientific experts. There is also strong critique on the adequacy of judicial review of risk assessment and the capacity of the WTO panels to find a middle ground between politics and science. By permitting the Members to make qualitative assessments of the risk and not quantitative, there however seems to be still scope for the inclusion of non-scientific aspects in the evaluation of risks.

7.7.2 Added value of the General Framework

In this context, the added value of the General Framework is demonstrated through its objective or rationalisation of non-scientific values. As has been shown in previous chapters, these are subjected to a rigorous test through scientific principles first at the stage of screening, and then addressed through the setting of terms of reference and assessment, taking into account in a systematic manner the sources of scientific uncertainty and socio-political ambiguity recognised by risk assessors, risk managers and stakeholders. Seen in this light, the concern assessment proposed in the General Framework which is about gathering evidence about concerns through scientific methods, could fall under the concept of ‘scientific evidence’ as interpreted by the WTO Appellate Body in Japan Apples, where it found scientific evidence to be: ‘evidence gathered through scientific methods, excluding by the same token information not acquired through a scientific method’. In this manner, measures based on concern assessment and drawing on non-scientific values could potentially be regarded as science-based in the WTO context.

7.8 Conclusions

The General Framework proposes a limited set of optional institutional innovations referring mainly to the capacity-building of EFSA and the better co-ordination of risk management and risk assessment. These proposals are in line with insights gained from empirical research and

---

181 *Hormones* (Appellate Body), para 206.
183 *Japan Apples* (Appellate Body), para. 165.
184 Ibid.
185 See J. Scott, ‘European Regulation of GMOs: thinking about judicial review in the WTO’ (Jean Monnet Working Paper 04/04).
189 *Japan Apples* (Panel) para. 8.92.
documents from both EFSA and the Commission calling for improved communication and transparency at this interface. In this sense, three options for the design of interface organs have been presented, one of which – the “intermediate” option combining the Internet Forum with an Interface Advisory Committee – is proposed as the preferred option. As outlined above, these options have grown out of discussions with risk managers, risk assessors, and representatives of both industry and NGOs in a series of workshops in which initial proposals were presented and afterwards revised in the light of the comments and suggestions received. These proposals are therefore not just the product of a purely academic exercise, but reflect and integrate the viewpoints of policy practitioners both from the European and the Member State level.

It was stated from the outset that one of the major aims of the General Framework is to be fully compatible with the existing institutional structures EU food safety regulation, the general principles of European law, and requirements established through international agreements especially in the framework of the WTO. As shown in the latter parts of this chapter the General Framework is based on the objectives of improving the application of the principles of good governance and good administration, while being fully compatible with the principles of subsidiarity and proportionality. Furthermore, it is important to stress that the General Framework proposals are not just compatible with international requirements, but can be used to establish more solidly the compliance of risk governance decisions with requirements established through the SPS agreement. Finally, as stated in previous chapters, the General Framework contributes to the understanding of scientific uncertainty and the clarification of the suitability and necessity of measures and thus constitutes a major step forward in the consistent and transparent application of the precautionary principle in European food safety governance.

8. A Structured Approach to Participation

Marion Dreyer and Ortwin Renn

8.1 Introduction

All previous chapters have already touched on the topic of participation. Chapter 7 has pointed out the core of the participatory design of the food safety governance framework that this report proposes: This consists of food safety interface institutions which are destined to function as intermediaries between science, policy, and civil society. The present chapter will provide a condensed presentation of the envisioned participatory design of the governance of food safety. Firstly, it will highlight the special value that is assigned to the interface institutions as formal mechanisms for putting the idea of inclusive governance that this report advocates into practice. Secondly, this chapter will present a structuring tool that is designed to assist the Interface Committee or the Commission solely (if no Interface Committee would be set up) to specify whether it is required to resort to more extensive participation in a given case, that is, to select additional participatory processes. This structuring tool, which will be set out in more detail below, distinguishes between different purposes of participation, specific to the respective governance stage, and different levels of intensity of participation dependent on the levels of uncertainty and ambiguity.

8.2 Participation through food safety interface institutions

The present report recognizes the idea of inclusive governance as a necessary (although not sufficient) prerequisite for tackling food safety problems in both a sustainable and acceptable manner and, consequently, imposes an obligation to ensure the early and meaningful in-
volvement of a diversity of social groups. Inclusive governance is based on the assumption that affected and interested parties have something to contribute to the process of food safety governance, and that mutual communication and exchange of ideas, assessments, and evaluations improve the final decisions rather than impede the decision-making process or compromise the quality of scientific input and the legitimacy of legal requirements. As the term ‘governance’ implies, analysing and managing food safety threats cannot be confined to private companies and regulatory agencies. Rather it involves a wider array of actors: political decision-makers, scientists, economic actors, and civil society actors.

As set out in detail in Chapter 7 the General Framework advocates the setting up of ‘food safety interface institutions’ in order to improve the co-ordination between these key actors in the governance of food safety. These interface institutions present platforms for deliberation on major elements of the governance process. The Internet Forum is the most inclusive of the proposed interface institutions as it offers a deliberation platform with open public access (however, in order to keep the appraisal of the Forum’s discussions practical detailed posting should be conceded only to accredited stakeholders). Not only corporate and civil society actors, but also those responsible for management at Member State level and scientific experts affiliated to the national Competent Authorities could use this deliberation forum to engage with the different subjects. The Internet Forum is inclusive also in that it provides the possibility to deliberate on all of the major elements underlying governance outcomes including the referral details, the screening results, the terms of reference, the assessment results, and the evaluation conclusions (Chapter 7 provides a detailed discussion of this).

To create transparency on these elements means to subject the reasons of decision-making on food safety problems to public scrutiny. By inviting and expecting participants to not merely state their opinions but to also exchange views, i.e. to discuss each others’ standpoints and arguments, the Internet Forum extends beyond a mere consultation process: it is designed to provide the 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 through the Internet Forum can be expected to vary greatly very much depending on the potential for conflict that might be implied in the cases. In that sense, the Internet Forum could act as 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.

The suggestion of this report is to complement the Internet Forum by a food safety interface institution which brings managers, assessors, and key stakeholders together in a committee structure at two stages in the governance process: at the framing stage and the evaluation stage. Both framing and evaluation are distinct hybrid activities in the sense that they draw on both political and socio-economic considerations and scientific knowledge in order to conclude on the design of the assessment process respectively on the acceptability of a given threat which is informed (however not determined) by the assessment results. Therefore, a direct face-to-face exchange between the Commission, EFSA, and selected stakeholders is of particular relevance at these two stages. The deliberations of the Steering Committee or the Advisory Committee would draw upon stakeholder perspectives sought through the Internet Forum in order to account for a broader range of viewpoints (unlike the Steering Committee.

---

the Advisory Committee would not be convened for every case but only for cases identified as specifically challenging and act solely in an advisory function; see Chapter 7 on this difference).

8.3 A structuring tool for additional processes of participatory deliberation

As was already mentioned above, specific cases might require that participation through the interface institution(s) is complemented by additional participatory processes. The proposed governance framework envisions a proceduralisation of decision-making over any possible extension of the scope of participation and about the selection of appropriate processes: If an Interface Committee is set up, it is part of the mandate of this body to advise on this matter at the stages of framing and evaluation in consideration of the specific case and the given context and the overall socio-political climate. In all cases it will be the responsibility of the Commission to take the decision over the necessity for additional participatory processes.

Aspects that could inform this decision-making process may derive from the Internet Forum and from the stakeholders who sit on the Steering Committee who can act as ‘sensitivity sensors’ for highly controversial issues which call for broader participation. In addition, those consultative stakeholder bodies which 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. The primary task of these bodies is, however, to consult on broader policy and strategic issues and not on the individual case. Hence, they will deal with individual food safety problems only in exceptional cases.

While these sources of information already have a great potential for facilitating decision-making around the need for broader participation, the General Framework offers in addition a default assumption for decision guidance: It proposes as a preliminary assumption that under the conditions of high levels of scientific uncertainty and socio-political ambiguity also a higher degree of participation is required. This corresponds with the central institutional idea that the Advisory Committee is not convened for every case at the stages of framing and evaluation (in contrast to the Steering Committee) but only for specifically challenging cases, including those cases where screening has identified the conditions of scientific uncertainty and/or socio-political ambiguity.

In short, the structuring tool it offers for deciding on more extensive participation distinguishes between different levels of intensity and also different purposes of participation (illustrated in a schematic form in table 8.1 below). Intensity is linked to the likelihood of major societal debate or conflict surrounding the threat under review which is assumed to be higher under the circumstances of high levels of scientific uncertainty and socio-political ambiguity (on which the screening stage provides preliminary information, see Chapter 5.2). The different purposes of participation are served at the different stages in the governance process and need to be taken into account in the selection of appropriate participation processes.

In what follows the requirements for extended participation will be discussed with regard to each of the four major governance stages. The purpose of participation will be discussed in terms of the type of discourse which is identified as being generic to each respective stage
different discourse types were first introduced by O. Renn, ‘Diskursive Verfahren der Technikfolgenabschätzung’, in: T. Petermann and R. Coenen (eds.), Technikfolgenabschätzung in Deutschland. Bilanz und Perspektiven, Frankfurt/M., Campus, 1999, p. 115-130.
8.3.1 Participation during framing

The type of discourse that is generic to the framing stage is called design discourse. This discourse (involving the Interface Committee, if set up) 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 beyond the formalized engagement mechanisms (i.e. the Internet Forum). Only in those cases where screening identifies high degrees of scientific uncertainty and/or socio-political ambiguity would it be advisable to complement stakeholder participation through the Internet Forum (where the referral details and the screening results are documented) and the Interface Committee (if set up) by additional participatory processes. Appropriate procedures that could be used in a design discourse include formal hearings of relevant commercial and civil society groups, open space conferences, and public forums.

8.3.2 Participation during assessment

The type of discourse that is generic to the assessment phase is entitled epistemic discourse. It comprises communication processes, where 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 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 also beyond the Internet Forum (where the terms of reference would be documented) through face-to-face methods of consultation and/or deliberation-based interactive elicitation. The conditions of high levels of scientific uncertainty and socio-political ambiguity in the first place would suggest such extended participation:

- When a given threat is approached by a precautionary assessment, stakeholders should be asked to administer their specific knowledge 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 can only show the range of the still methodically justifiable knowledge, i.e. define 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. 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, poten-

---

tial for using ‘forgiving’ technologies, etc. Methods such as stakeholder surveys, qualitative interviews, focus groups and public hearings are most appropriate for this task.

When a given threat is approached by a concern assessment, engagement with stakeholders is vital to elicit 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 the assessment drawing on the contributions and deliberations in the Internet Forum reveals that there is major debate even in the wider public and a high potential for social conflict involved, it might be required to also 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.

It is important to note, that it is not the task of stakeholders and representatives of the wider public at the assessment stage 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’.

8.3.3 Participation during evaluation

The type of discourse that is generic to the evaluation phase is named reflective discourse. This discourse comprises communication processes dealing with the interpretation of factual issues, the clarification of preferences and values and a normative judgement of tolerability or acceptability. Reflective discourses are 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 purpose of stakeholder engagement here is to assure 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 stakeholders sitting on the Interface Committee (if set up) would reconvene with the managers and assessors during this phase and use the new knowledge from the assessment to draw normative conclusions about the threat in consideration. Part of the evaluation process would be to draw on the Internet Forum (where the assessment results and the (draft) evaluation conclusions would be documented) to judge the need for more comprehensive engagement involving additional stakeholders and/or the wider public. Again, the conditions of high levels of scientific uncertainty and socio-political ambiguity in the first place would suggest a more elaborate participation programme:

- When scientific uncertainty is implied with a given threat, the central question is: How can one judge the severity of a situation when the potential damage and its probability are unknown or highly uncertain? In this dilemma, the Interface Committee or the Commission solely (if the Interface Committee was not set up) may need to include all of the relevant stakeholders in a face-to-face participatory deliberation and ask them to find a consensus on the extra margin of safety (or alternative measure) in which they would be willing to invest in exchange for avoiding potentially catastrophic consequences. This type of deliberation relies on a collective reflection about balancing the possibilities for over- and under-protection. If too much protection is sought, innovations may be prevented or stalled; if too little protection, society may experience unpleasant surprises. The classic question of ‘how safe is safe enough’ is replaced by the question of ‘how much uncertainty and ignorance are the main actors willing to accept
in exchange for some given benefit’. It is recommended that policy makers, scientists, and representatives of all relevant social groups (including the Interface Committee if set up) take part in this type of extended face-to-face discourse. It is also essential that the discourse is not just preoccupied with the threat under review but also considers potential alternatives, social benefits, sustainable practices, and other related aspects. Methods for this type of extended involvement include round tables, open space forums, negotiated rule-making exercises, or mediation.194

Threats characterised by high ambiguities require the most inclusive strategy for participation since not only directly affected groups but also those indirectly affected have something to contribute to this debate. Resolving ambiguities in food safety debates necessitates a platform where 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. Under the condition of high levels of socio-political ambiguity and a great potential for social conflict and mobilisation it is recommended to complement the deliberation through the Interface Committee (if set up) and the Internet Forum by face-to-face participatory deliberation with citizen involvement. 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.195 In addition, classic stakeholder engagement processes such as hearings might accompany the public participation program.

8.3.4 Participation during management

The type of discourse that is generic to the management phase is called practical discourse. It comprises 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. The term practical refers to the nature of decision-making, i.e. the different steps outlined in section 6.3. The practical 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. If set up, the Interface Committee would give advise on participation procedures in this discourse with the Commission taking the decision. It is recommended that participatory deliberation reaching beyond the Internet Forum (where the evaluation outcome including the most appropriate management approach would be documented) is employed at the stage of management when a high level of scientific uncertainty surrounds a given case, and/or under the condition that not only the threat itself is contested but that socio-political ambiguities extend to the selection of management measures.

- For highly uncertain threats, it is advisable to have stakeholders involved in an exercise to balance pros and cons associated with each of the potential measures. Measures that increase resilience or robustness (as advocated by a precautionary approach) are often inferior to cost-minimization strategies when cost-benefit analysis or other formal balancing techniques are applied. Therefore the question of what methods to use when balancing pros and cons for evaluating a variety of measures should be a major topic of the stakeholder discussions. It is recommended that policy makers, representatives of major stakeholder groups, and experts on the impacts of each measure take part in the discourse. Methods for this purpose include negotiated rule-making exercises, mediation, or mixed advisory committees including scientists and stakeholders.196

- High socio-political ambiguity may lead to very different visions between social groups of how to address these ambiguities in form of management measures. If also the measures are highly contested, it seems advisable to organise a broad societal discourse about the appropriateness of these measures and the best way to find a consensus or an agreement on the measures to be taken. However such a discourse is conducted, the design of the participatory procedure should allow for a high degree of representativeness on the part of participants in relation to interested and affected parties in the wider society. The methods for addressing ambiguity in the evaluation process are also appropriate for handling ambiguity in the selection of management measures and hence include citizen forums, citizen panels, citizen juries, consensus conferences, ombudspersons, citizen advisory commissions, and similar participatory instruments in addition to classic stakeholder engagement processes.

All four forms of discourse require that the design of the participatory procedures displays these basic features:

- A good level of transparency from the point of view of third parties, in documenting how specific inputs relate to the decision on one or more management measures;

- A freedom from constraints on the way in which participants may express themselves;

- A high degree of reflection over the different conditions and perspectives bearing on the threat in question;

An effective level of communication between participants concerning the different factual and value issues involved.

The combination of the four discourse types forms the fabric of the envisioned political culture in food safety governance. Each of these 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.

To sum up: the General Framework advocates that public participation is institutionalised throughout the governance cycle through the Internet Forum with open public access, and at the stages of framing and evaluation through an Interface Committee (in one of its two forms) bringing together assessors, managers and key stakeholders. It further holds that a subset of food safety issues requires more extensive stakeholder and public engagement. The recommendation is that procedurally, the intensity and form of engagement (participatory processes) are specified during the processes of framing and evaluation by the advocated Interface Committee in consideration of the given context and the overall socio-political climate. The Framework recommends, however, to proceed on the preliminary assumption that under the conditions of high levels of scientific uncertainty and socio-political ambiguity more extended participation which includes face-to-face participatory deliberation processes is of particular importance.

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

Table 8.1: A structured approach to participation

9. Conclusions

Marion Dreyer and Ortwin Renn

The empirical starting point of the research presented in the report at hand are the dynamics to which food safety governance in Europe since the mid 1990s is being subjected. Shaken by a series of food-related scares and controversies the governance system has been undergoing a process of review and reform. The General Framework for the Precautionary and Inclusive Governance of Food Safety that was portrayed in the preceding chapters is designed to contribute to configuring this process which will presumably still last for some time. European
Food safety governance is an evolving system with the challenges of implementation beginning to show and with many specifications of the recent reforms still shaping up.

This is the main argument that was brought forward in the discussion of the framework’s main elements: In order to improve both the effectiveness and the democratic legitimacy of food safety governance in Europe it is crucial to apply an approach that systematically distinguishes between dealing with ‘routine’, ‘prohibitive’, and ‘intractable’ food safety threats (with the latter characterized by scientific uncertainty and socio-political ambiguity), and to establish interface institutions designed to facilitate the co-ordination between knowledge experts, political decision-makers, and corporate and civil society actors in putting this approach into practice.

The authors of this report have paid special attention to the compatibility of the proposed procedural and institutional reforms with the current European Union legal and policy framework. In what follows the key features of the proposed General Framework will be summarized, and the way in which these seek to further the implementation of the principles of food safety governance enshrined in the General Food Law and the agenda on governance in the European Union will be highlighted.

The General Framework builds upon the logical structure of four consecutive phases called framing, assessment, evaluation, and management. The structure reproduces the separation of assessment and management activities as specified in the General Food Law. However, it adds two more phases, framing and evaluation, which are designed for constituting intermediaries 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. Framing provides guidance for the conduct of assessment; during this phase the problem is defined and the terms of reference are specified. This task needs 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 as well as a judgmental competence for making the necessary trade-offs between risk, benefits and other relevant impact categories.

Hence, framing and evaluation are distinct hybrid activities in the sense that they draw on both political and socio-economic considerations and scientific knowledge. This hybrid character is likely to explain at least in part the need for improved interaction between assessors and managers in activities related to framing and evaluation that was expressed by several of the stakeholders whose views were elicited in order to inform the development of the governance framework. In the current governance system these activities are mostly implicit and lie outwith the view of political accountability. The authors of this report suggest structuring them through establishing a formal institution bringing together managers, assessors, and key stakeholders in a committee structure (in the form of an Advisory Committee or a Steering Committee).

The four-stage-design proposed by the General Framework 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-design promises 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 accountability by clarification of the responsibilities for essential governance activities.
By providing a structuring tool (the screening procedure) designed to tailor the governance process to key attributes of food safety threats, the proposed framework promises to contribute to the governance principle of coherence. The structuring tool is the distinction between the attributes of seriousness, uncertainty, and ambiguity. It guides the selection of the appropriate approach(es) to assessment, the adequate design of the evaluation process, and the most suitable measures of management, and also assists in the decision-making on whether extended participation is required and if so, in the choice of appropriate participation methods. This structuring tool forms the basis on which “more comprehensive risk assessment” as stated in the General Food Law is developed as precautionary assessment and its relation to other forms of assessment including quantitative risk assessment and concern assessment is specified. Scientific uncertainty, calling for precautionary assessment, and socio-political ambiguity, calling for a concern assessment, are more intractable circumstances under which the conditions for using a quantitative risk-based approach do not apply. It is these conditions that essentially shape more intense and persistent conflicts between regulators and corporate and civil society actors over new and emerging food production technologies. They are of special relevance in contemporary societies which are characterized by plural worldviews and visions of a ‘quality of life’ (including deeply held beliefs about what constitutes ‘good’ food) as well as by plural knowledge claims. The precaution-based governance approach and the concern-oriented governance approach are designed to address with more analytical rigour and more deliberative effort, if required by the respective cases, the limits of scientific knowledge and evidence and the breadth of possible harms and losses that different social groups may be concerned with. The four-approach-design (risk-based, precaution-based, concern-oriented, prevention), which is based on a conceptualisation of the precautionary principle as a general governance principle, promises to contribute to achieving a higher degree of transparency and consistency in addressing the multiple challenges (extending beyond morbidity and mortality) that may be associated with food safety threats.

It is during the initial step of screening, which precedes the setting of the terms of reference and is carried out at the assessment stage, that the attributes of seriousness, uncertainty, and ambiguity are used in the form of a preliminary assessment to identify the most appropriate approach to a more detailed assessment and to help prioritise attention to different threats. The provision of this step shows promise for contributing to the timeliness of food safety handling and hence to honour the principle of effectiveness. It is proposed that a Screening Unit within EFSA is established which would mainly have the task of acting as a secretariat and coordination point for the conduct of screening.

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” but raises the more exigent question of how to incorporate the perspectives and specialized knowledge of interested and affected parties into the governance process. The proposed food safety interface institutions and the guidance tool for deciding on the need for an extended participatory programme proposed in the report at hand are designed as a response to this challenge and as a more structured approach to honouring the principle of participation. The interface institutions are intended to improve the co-ordination between the key actors - political decision-makers, expert advisors, and corporate and civil society actors - in the governance of food safety. They present platforms for deliberation on major elements of the governance process with the Internet Forum being the most inclusive in terms of both the governance elements that it opens up for deliberation and the voices which it invites for engaging in this deliberation. The Interface Committee is suggested as an additional interface

---

institution which allows for the hybrid character of framing and evaluation activities. The selection of a few ‘key stakeholders’ to sit on the Interface Committee will inevitably provoke questions of representativeness, power, and fairness. However, the existence of a second interface institution, the Internet Forum, which is more inclusive, as well as the recognition of the default assumption that threats associated with high levels of uncertainty and/or ambiguity warrant more broad participatory procedures might allay to some extent the concerns linked with these questions. The overall participatory design envisioned by the General Framework can help to achieve a broader and more structured engagement of EFSA and the Commission with a diversity of social groups in a way which maximises valuable input (knowledge, interest, value preferences) into the governance process while avoiding overburdening the process caused by excessive participation on every food safety issue. The Internet Forum, in particular, through documentation of the major elements of the governance process, is established to increase transparency from the point of view of third parties and hence honours the governance principle of openness. Moreover, the more structured approach to participation that this report suggests has the potential for creating more accountability for contesting political-economic interests and socio-cultural values and plural knowledge claims that underpin food safety governance processes within contemporary pluralistic societies.

The Internet Forum and the Interface Committee designed to improve the politics-science-society coordination throughout the governance process present two of the four institutional innovations that are proposed to put the procedural reforms that the General Framework envisions into practice. In addition to these two food safety interface institutions we suggest to establish a Screening Unit within EFSA, also already mentioned above, which would act as secretariat and co-ordination point for the conduct of screening. Finally, we propose to complement EFSA’s scientific panels by a Concern Assessment Panel. These four institutional reforms are deemed essential for facilitating the envisioned procedural reforms. There are good reasons to assume that they do not overtax the adaptability of the current governance system. The Internet Forum ties up to the increasing use of the Internet for documentation and for eliciting stakeholder feedback by EFSA and the Commission. While the Internet Forum could also be set up as the sole interface institution, it is recommended to establish in addition the Interface Committee (in form of a Steering Committee or an Advisory Committee). This Committee is designed to provide framing and evaluation activities which are already performed in the current system (however are largely implicit and ad-hoc) with a formal footing. The Screening Unit would not address the screening questions itself but pass requests for screening to the different scientific units and could hence be easily integrated into EFSA’s current structure. The same applies to the Concern Assessment Panel. It would extend EFSA’s scientific panels by a panel comprised of experts with a background in the social and economic sciences, and in further disciplines such as psychology and consumer research in order to establish EFSA’s capacity for carrying out concern assessments.

The procedural innovations themselves include provisions to not overburden the food safety governance system and unacceptably increase resources for making decisions. These provisions are key to making the proposed framework practical. The proposed differentiated approach to assessment expands the assessment process by a precautionary assessment or a concern assessment only as appropriate to specified conditions. Also, the assessment of health effects is not expanded for every case by a wholesale scientific analysis of social, economic, and ethical impacts. Instead, the ‘endpoints’ for which a thorough analysis is required are specified at the stage of framing and revisited and possibly revised at the stage of evaluation. Furthermore, our recommended approach to participation implies the need for an extensive participatory programme (extending beyond the Internet Forum and the Interface Committee) only for particular food safety threats, namely those characterized by high levels of scientific uncertainty and socio-political ambiguity. That said, quantifiable risks still need to be as-
sessed, evaluated and managed. The efforts to conduct these activities which will follow well-established procedures are minimal compared to the handling of uncertain and ambiguous threats. No major effort is implied to collect concerns, include stakeholders, or organise a sophisticated assessment of management measures under such circumstances. It is the firm conviction of the authors of this report, however, that for some of the most challenging food safety threats the more extensive process including assessment techniques beyond quantitative risk assessment and a broad participatory programme can lead to governance outcomes that are better informed, better balanced, and socially more robust.

**Glossary**

**Ambiguity** – a state of knowledge under which incomplete information or divergent informed understandings preclude full confidence in the bounding, partitioning, characterising or prioritising of the possible outcomes.

**Assessment** – the process of gathering relevant information for the purpose of informing decision making concerning the relative merits and drawbacks of a range of different possible decision options.

**Certainty** – a state of knowledge under which there exists no incertitude. In other words, knowledge is judged to be definitive and complete concerning both the nature and the eventuation of the outcome in question.

**Concern Assessment** – a systematic, scientific process of gathering knowledge about individual and group risk perceptions, socio-economic impacts and other specific cognitive (rather than value-based) characteristics related to the source of a threat.

**Dose** – the magnitude of exposure to a potentially hazardous agent or property.

**Dose-Response Assessment** – a step in risk assessment involving the determination of the magnitudes of the causal relationships between the dose and the response.

**Exposure** – the magnitude, likelihood or frequency of contact between a (human or environmental) system of interest and a potentially hazardous agent or process.

**Exposure Assessment** – a step in risk assessment involving determination of qualitative forms or quantitative magnitudes of possible types of contact between human or environmental systems and potentially hazardous agents or processes.

**Flexibility** – a property of an individual decision option relating to the degree to which this is subject to deliberate intervention in order to effect structural or functional change in the face of changing circumstances.

**Hazard** – a possible source of harm to human beings or the environment.

**Hazard Characterisation** – a stage in risk assessment involving the qualitative and/or quantitative evaluation of the possible magnitudes of hazards.

**Hazard Identification** – a step in risk assessment involving the determination of biological, chemical, and physical agents or properties capable of causing adverse health or environmental effects.
**Ignorance** – a state of knowledge under which there exists both *uncertainty* about *probabilities* and *ambiguity* over possible *outcomes*. In particular, ignorance involves exposure to the possibility of surprise.

**Incertitude** – a term used in a precise and specific fashion to refer collectively to real-world combinations of states of *risk, uncertainty, ambiguity* and *ignorance*.

**Indeterminacy** – a particular set of conditions contributing to a state of *ignorance*, under which relevant causal processes of the phenomena in question are open, dynamic, recursively linked to the observer or otherwise incompletely understood.

**Interface Institution** – a collective term that refers to the innovative mechanisms allowing communication and co-ordination between assessment and management activities (specifically the Internet Forum and the Interface Committees). In this regard, the word “institution” is used in a broad sense and does not relate to the formal EU institutions of the European Parliament, Council, Commission and Court of Justice.

**Interface Committee** – a food safety governance committee made up of assessors, managers and stakeholders that serves to act as an interface between assessment and management governance stages. The two variants of such a committee highlighted in this report are named the Interface Advisory Committee and the Interface Steering Committee.

**Stakeholders** – the full range of social actors who stand to be affected by decision making or who perceive themselves to hold an interest in its *outcome*.

**Intrinsic property** – a quality that is intrinsic to a potentially *hazardous* agent or process and is of relevance in the *assessment* of the agent, but which is not necessarily of itself in any way *hazardous*.

**Irreversibility** – an *intrinsic property* of a potentially *hazardous* agent or process or its derivatives arising where one or more of the consequences of its use are not readily subject to restoration to the state preceding this use.

**Likelihood** – the frequency or plausibility of the chance that a defined outcome will in fact eventuate. Where this is expressed in quantitative terms, it is a *probability*.

**Option** – a particular possible course of action that may be adopted in decision or policy making, either individually or as part of a *portfolio*.

**Outcome** – the consequences of a particular course of action or state of the world.

**Persistence** – an *intrinsic property* of a potentially *hazardous* agent or process or its derivatives arising from the propensity to be retained in the environment in an active form over long periods of time.

**Portfolio** – a mix of different decision *options* pursued concurrently.

**Precaution** – an approach to *assessment* and *management* prompted by the *precautionary principle*, under which deliberate attention is afforded as much to *uncertainty, ambiguity* and *ignorance* as to the narrower condition of *risk*. 
**Precautionary Assessment** – the use of a wide variety of broad-based approaches at the earliest stages in an innovation or policy making process, extending beyond conventional quantitative, expert-based techniques of **risk assessment**.

**Precautionary Principle** – a legal and policy principle adopted in various forms under many national and international instruments, which holds important implications for the conduct of **assessment** and decision making under **uncertainty**.

**Presumption of Prevention** – the appropriate response to a certainly and unambiguously serious threat, in which **assessment** is bypassed and preventative **management** measures are prioritised.

**Probability** – a quantitative expression of the **likelihood** of some defined **outcome** in terms of a numerical value between 0 and 1, where 0 indicates impossibility and 1 indicates **certainty**.

**Resilience** – a property of a **portfolio** (or individual decision **option**) relating to the capability of sustaining functional value despite short term episodic shocks arising in the external environment.

**Response** – the severity and/or frequency of adverse environmental or health effects associated with an **exposure** to a potentially **hazardous** agent or property.

**Risk** – a state of knowledge under which the range of possible **outcomes** has been well characterised and there exists sufficient information confidently to determine the **probabilities** associated with these outcomes.

**Risk Analysis** – a term used (especially in the USA) to refer to the entire process of **hazard identification**, **risk assessment**, **risk management** and **risk communication**.

**Risk Assessment** – a range of **assessment** techniques involving systematic characterisation of **likelihoods** and **outcomes** (usually through the determination of **probabilities**) in order to inform the prioritising of different decision **options**.

**Risk Characterisation** – a step in **risk assessment** involving the collection and analysis of all relevant evidence deemed necessary for informed decision making on the tolerability or acceptability of a particular **risk**.

**Risk Communication** – the process of two-way communication with **stakeholders** and the public in order to frame, inform and convey the rationale and outcomes of **assessment**, **evaluation** and **management**.

**Evaluation** – the application of socio-economic values and norms to judgements over tolerability and acceptability, as informed by **assessment** and as necessary for **management**.

**Management** – a term used to refer to the process informed by **assessment** of decision making and implementation of measures.

**Robustness** – a property of a **portfolio** (or individual decision **option**) relating to the capability of sustaining functional value despite long term enduring change in circumstances.

**Threat** – a term that may be used in a general sense such as to include reference to both **hazard** and **risk** depending on the context.
**Transparency** – a quality and principle of good *governance* such that the natures of motivating reasons and priorities, analytic-deliberative processes and *outcomes* are readily accessible to detailed scrutiny by *interested and affected parties*.

**Ubiquity** – an *intrinsic property* of a potentially *hazardous* agent or process or its derivatives arising from the quality of being widely distributed in space, across ecological systems, or throughout different environmental media.

**Uncertainty** – a state of knowledge under which the range of possible *outcomes* has been well characterised, but there exists insufficient information confidently to determine the *probabilities* associated with these outcomes.

**Vulnerability** – a propensity on the part of environmental or human systems, ecological taxa or social groups of being exposed to possible harm from a potentially *hazardous* agent or process.

**References**


EFSA document, Key Issues Emerging From EFSA’s Stakeholder Consultative Platform and From the 3rd Annual Colloque with Stakeholders, MB 5 15.12.2005.


R. Gregory, T. Mc丹nies and D. Fields, ‘Decision aiding, not dispute resolution: a new perspective for environ-


R. Hagendijk and A. Irwin, ‘Public deliberation and governance: engaging with science and technology in con-


P. Harremoes et al. (eds., European Environment Agency), *Late Lessons from Early Warnings: The Precautionary

Health and Safety Executive (HSE), *Reducing Risks, Protecting People: HSE's Decision-Making Process*, Lon-


J.K.K. Jensen and P. Sandoe, ‘Food safety and ethics: the interplay between science and values’, *J. Agric. and Env.

1999.

C. Joerges and J. Neyer, ‘Politics, risk management, World Trade Organisation governance and the limits of

C. Joerges, H. Schepel and E. Vos, ‘The law’s problems with the involvement of non-governmental actors in
University Institute, 1999.

C. Joerges, H. Schepel and E. Vos, ‘The law’s problems with the involvement of non-governmental actors in
University Institute, 1999.

S. Joss, ‘Public participation in science and technology policy- and decision-making: ephemeral phenomenon or

B. Kasemir, W.C. Clark, M.T. Gardner, C.C. Jaeger, J. Jaeger and A. Wokaun, *Public Participation in Sustain-

L. Kathlene and J. Martin, ‘Enhancing citizen participation: panel designs, perspectives, and policy formation’,

R. Keeney, *Value-Focused Thinking. A Path to Creative Decision Making*, Cambridge, Harvard University Press,


2003, 40 CMLR 6, p. 1455.

K. Lenaerts, ‘Regulating the regulatory process: ‘delegation of powers’ in the European Community’, 18 ELR 41,
1993.

L. Levidow, S. Carr, D. Wield and R. von Schomberg, ‘European Biotechnology Regulation: Framing the Risk


J. Scott, ‘European Regulation of GMOs: thinking about judicial review in the WTO’ (Jean Monnet Working Paper 04/04).


J. Stilgoe, A. Irwin and K. Jones, *The Challenge is to Embrace Different Forms of Expertise, to View them as a Resource rather than a Burden... The Received Wisdom. Opening up Expert Advice*, London, Demos, 2006.


