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

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

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1. Introduction

1.1. Definitions and challenges

As reviewed in detail in a paper written for the present work package[1], the ***governance*** of food safety presents a formidable series of challenges[2]. Here, as in other 'technological risk' issues, the governance process includes, but extends beyond, the three conventionally recognised elements of ***risk analysis*** (risk assessment, risk management and risk communication)[3]. It 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.

The European Commission has identified five normative principles that are directly applicable to the ***good governance*** of food safety in this broad sense: openness, participation, accountability, effectiveness and coherence[4]. The principle of ***openness*** entails according to the Commission clear, accessible communication of the nature and rationale for decisions and other governance outcomes. ***Participation*** requires governance institutions actively to engage with other social groups, from the conception of strategic options right through to the implementation of decisions. ***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.

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

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[1] See E. Vos, C. Ni Ghiollarnath and F. Wendler, *European Food Safety Regulation under Review*, Report for workpackage 5 of the SAFE FOODS project, University of Maastricht, August 2005.

[2] As set out especially in Regulation (EC) No 178/2002 (*OJ* 2002, L31/1) as amended by Regulation (EC) No 1642/2003 (*OJ* 2003, L 245/4), hereinafter referred to as the *General Food Law*, but also by reference to other European Commission documentation, such as the White Papers on European Governance, European Commission, *European Governance: A White Paper*, COM (2001) 428, Brussels, Commission of the European Communities, 2001, and the Precautionary Principle, European Commission, *Communication from the Commission on the Precautionary Principle*, COM (2000)1, Brussels, Commission of the European Communities, 2000.

[3] National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC, National Academy Press, 1996; Codex Alimentarius Commission, *Procedural Manual* (fifteenth edition), Joint FAO/WHO Food Standards Programme, Rome, World Health Organization/ Food and Agriculture Organization of the United Nations, 2005; Regulation (EC) No 178/2002 (*OJ* 2002, L31/1) as amended by Regulation (EC) No 1642/2003 (*OJ* 2003, L 245/4).

[4] European Commission. *European Governance: A White Paper*, COM (2001) 428, Brussels, Commission of the European Communities, 2001, Section II.

The distinguishing characteristics of exactly what constitutes risk assessment tend to vary slightly between different intergovernmental and European Commission definitions. The particular stages of risk assessment recognised in European regulation of food safety comprise: hazard identification, hazard characterisation, exposure assessment and risk characterisation[5]. 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 – risk assessment does not present the only methodological approach to appraisal[6]. Indeed, depending on the context and conditions, a number of alternative or additional methods can offer more ***comprehensive*** approaches to appraisal 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 their effects on the outcomes of appraisal, than are usually addressed in conventional risk assessment.

Together with various forms of risk assessment itself, these techniques offer a rich and powerful array of possible approaches to appraisal. 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 framework 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. In short, what is lacking is an ***integrated governance framework***, under which these various forms of appraisal can be clearly articulated in order to satisfy contending governance principles.

The integrated governance framework proposed in this document proposes two further steps that contribute in this regard. Based on the outputs of the appraisal introduced above, an ***evaluation*** exercise is undertaken. This exercise, which will be described in more detail below, summarises the information and perspectives gathered during the appraisal 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 ***risk 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.

One of the most significant axes for contention on the issues of risk governance is found in 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

[5] *General Food Law*, Regulation (EC) No 178/2002 (*OJ* 2002, L31/1), Article 3.
[6] 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.

that lack of scientific certainty should not be used as a reason to delay appropriate action[7]. It is in this form that precaution has become a guiding principle of EU policy making[8] and is recognised by the European Court of Justice and the European Commission[9] to be a general principle of European law. Yet this raises a number of profound questions for its application to risk assessment and other forms of appraisal. In particular, there is a question over whether precaution is applicable to appraisal at all, or whether it is simply an approach to risk management[10]. Alternatively, if precaution is applicable in the appraisal, as well as in the management, of food safety then there follow a series of more detailed queries over the precise nature of the relationship between precautionary approaches to appraisal and established practices based on risk assessment. The resulting issues and implications remain unclear and contentious.

Any attempt definitively to resolve such questions must address a highly complex and wide-ranging set of considerations. Yet – for all the commotion – one central feature of the relationship between risk assessment and the precautionary principle remains quite robust, clear and simple. This follows from the formal scientific definition of the condition of ***risk***[11] 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)[12]. Indeed, it is this central reliance on probabilities that has already been identified as 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[13]. But – however it is defined – the precautionary principle, addresses a set of more intractable circumstances – going beyond complexity – under which various forms of 'uncertainty' render such quantification incomplete or problematic[14].

These more intractable circumstances can take three main forms. The first is referred to in the strict definition of the state of ***uncertainty***, under which the possible outcomes are clear, but it is difficult to quantify probabilities[15]. The second is the condition of '***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[16]. Third, a condition

[7] As expressed, for instance, in the classic definition at Principle 15 in the 1992 Rio Declaration on Environment and Development.
[8] As in Article 174(2) of the EU Treaty.
[9] European Commission, *Communication from the Commission on the Precautionary Principle*, COM (2000)1, Brussels.
[10] ESTO, *On Science and Precaution in the Management of Technological Risk*, Final Summary Report, Technological Risk and the Management of Uncertainty Project, A. Stirling and V. Calenbuhr (eds.), Seville, European Scientific Technology Observatory, 2000; EEA, *Late Lessons from Early Warnings: The Precautionary Principle, 1896-2000*, European Environment Agency, 2001; European Commission, *Communication from the Commission on the Precautionary Principle*, COM (2000)1, Brussels.
[11] F. Knight, *Risk, Uncertainty and Profit*, London, London School of Economics, 1921.
[12] This is also a key element in the seminal formal understanding of risk assessment promulgated in the National Research Council 'Red Book'; National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, Washington DC, National Academy Press, 1983.
[13] O. Renn, *White Paper on Risk Governance. Towards an Integrative Approach*, Geneva, International Risk Governance Council, 2005.
[14] WTO, *The Precautionary Principle: Protecting Public Health, the Environment and the Future of our Children*, M. Martuzzi and J. Tickner (eds.), World Trade Organisation, 2004; Public Health Reports, special issue on *The Precautionary Principle*, vol. 117, no. 6, November/December 2002.
[15] F. Knight, *supra* note 11; J.M. Keynes, *A Treatise on Probability*, London, Macmillan, 1921.
[16] Summarised in A. Stirling, Risk, uncertainty and precaution: some instrumental implications from the social sciences, in: F. Berkhout, M. Leach and I. Scoones (eds.), *Negotiating Change*, Cheltenham, UK, Edward Elgar, 2003, p. 33-76..

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[17]. Various forms of 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[18]. Where 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 risk assessment and precaution in terms of their complementarity. In short, the direct implication of the precautionary principle for appraisal is to highlight the conditions under which it would be appropriate to apply what are described above as more ***comprehensive*** approaches to appraisal.

From this account there follow some important implications for the current, conventional practice in the governance of food safety of opting by default for the application of 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 appraisal[19]. 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 appraisal 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[20]. These can raise different challenges of timeliness, proportionality, predictability and consistency – as well as coherence in the articulation of risk assessment and precaution.

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 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 appraisal. This does not assist in the practical business of developing clear and coherent frameworks for the articulation of risk assessment and precaution in appraisal for the governance of food safety.

Yet, despite the complexities, the central challenges seem quite clear. In short, any 'integrated governance framework' (in the terms discussed above) for food safety must address the following five questions:

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 appraisal suggested by the 'precautionary principle', in a fashion that is coherent, operational, proportionate and consistent with wider governance principles?

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[17] G.L.S. Shackle, *Uncertainty in Economics and Other Reflections*, Cambridge, Cambridge University Press, 1955; B.J. Loasby, *Choice, Complexity and Ignorance*, Cambridge, London, New York, Melbourne, Cambridge University Press, 1976.
[18] A. Stirling, *supra* note 16.
[19] ESTO, *supra* note 10.
[20] H.I. Miller and G. Conko, 'Precaution without Principle', *Nature Biotechnology*, 19, 2001, p. 293.

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

d) How can appraisal and evaluation reflect different forms of knowledge and contesting 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 around risk assessment and management?

1.2. Specific aims of the present exercise

A key objective of the present work package of the SAFE FOODS project[21] lies in developing a general framework by means of which to address these multiple challenges in the governance of food safety in the European Union. This is to be augmented by work under a parallel work package[22], in which these provisions will be linked with wider considerations emerging within the SAFE FOODS project[23]. Both exercises are closely interlinked and mutually complementary.

In seeking to address with this general framework the series of particular queries (a) – (e) plus other questions discussed above, a starting point must be made with the existing *status quo* in the governance of food safety in Europe[24]. This has been reviewed in detail for the EU in a paper produced under the present work package[25]. Here, the most specific and authoritative codification of current practice 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"[26]. Grounded in a wider regulatory literature[27], this rests on two key pillars. The first pillar is the application of principles of independence, objectivity and transparency in ***risk analysis*** (as defined in the last section). The second pillar is the application of the ***precautionary principle*** in the face of scientific uncertainty (as also defined in the last section). In codifying and defining the precautionary principle with particular reference to food safety, the General Food Law directly addresses the contentious nature of the relationship between risk assessment and

[21] Work package 5.4 in the SAFE FOODS project.
[22] Work package 6 in the SAFE FOODS project.
[23] At present this work is in a dynamic state of negotiation and development; see *Discussion Paper for a New Framework for the Governance of Food Safety*, based on draft papers by Ariane König, Harry Kuiper, Ib Knudsen and Ortwin Renn, March 2006.
[24] For a comparative analysis of recent institutional re-arrangements in food safety governance in five EU Member States and at the EU-level see E. Vos and F. Wendler (eds.), *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (Series Ius Commune), Intersentia Publishing, forthcoming 2006.
[25] E. Vos, C. Ni Ghiollarnath and F. Wendler, *supra* note 1.
[26] Regulation (EC) No 178/2002 (*OJ* 2002, L31/1) as amended by Regulation (EC) No 1642/2003 (*OJ* 2003, L 245/4); see discussion in E. Vos, C. Ni Ghiollarnath and F. Wendler, *supra* note 1.
[27] National Research Council, *supra* notes 3 and 12; EPA, G.S. Omen, A.C. Kessler, N.T. Anderson, et al., *Framework for Environmental Health Risk Management*, US Presidential/Congressional Commission on Risk Assessment and Risk Management, final report Volume 1,Washington, EPA, 1997; Codex Alimentarius Commission, *supra* note 3; European Commission, *Communication from the Commission on the Precautionary Principle*, COM (2000)1, Brussels.

precaution. Drawing on concepts that are discussed in the last section, the General Food Law characterises application of the precautionary principle in the following terms[28]:

> "*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 appraisal (as well as to the evaluation and 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 appraisal. To this extent, the discussion offered in the introduction of this document provides a strong basis of support for the otherwise rather under-specified reasoning and implications of the discussion in the General Food Law of the relationship between risk assessment and precaution. This said however, a number of serious questions remain to be addressed in any attempt to develop a truly integrated governance framework on the lines discussed above. In particular:

f) What is the operational definition of '***persistent scientific uncertainty***' and by what practical means can this be characterised in appraisal of food safety?

g) Which are the key operational features of '***more comprehensive risk assessment***' and how do these relate to current conventional and alternative available appraisal procedures?

h) How to decide what constitutes an appropriately '***high level of health protection'*** and exactly how does this relate to '***technical and economic feasibility and other factors'***?

i) How to ensure that the ***principle of proportionality*** is upheld in a procedurally consistent manner under different situations of persistent uncertainty?

Together with the earlier questions (a) – (e) set out under point 1.1, it is these issues that must be addressed by the present candidate design for an integrated general framework for the governance of food safety. To this end, the particular aims of the present paper are fourfold.

1) First, to provide an outline of the overall architecture for such an integrated governance framework. This must address, clarify and carry forward the main elements in current

[28] Regulation (EC) No 178/2002 (*OJ* 2002, L31/1) as amended by Regulation (EC) No 1642/2003 (*OJ* 2003, L 245/4); see discussion in E. Vos, C. Ni Ghiollarnath and F. Wendler, *supra* note 1.

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).

2) Second, to focus particular attention on the more detailed structure of the process of appraisal, evaluation and management within a wider governance framework. In particular, to establish a basis for a coherent positive understanding of the modalities for the implementation of the precautionary principle in appraisal and the detailed implications for the role of conventional as well as extended risk assessment. This should be achieved in such a way as to allow effective communication and engagement between industry, regulators, legal practitioners and non-governmental organisations for the purpose of collecting and processing on a broad basis relevant knowledge, and promoting consistency, facilitating predictability and limiting the scope for arbitrariness and special pleading.

3) Third, to establish a basis for a coherent positive understanding of the modalities for the implementation of the precautionary principle in evaluation and management, the two steps which follow appraisal and are performed on the basis of its outcomes. Both steps, evaluation and management should be assisted by effective communication and engagement between the different 'interested parties' for the purpose of making a judgement on the levels of adequate protection and selecting appropriate management measures on the basis of this judgement.

4) Fourth, to point out the legal and institutional conditions to implement the proposed framework in EC food safety regulation and make suggestions for institutional integration and adaptation.

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 appraisal 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 right from the start that the implementation of the procedural provisions envisaged by the governance framework does not necessarily require institutional changes but could be effected through the currently existing institutional arrangements. The limited institutional adaptations that will be suggested and address the interface between appraisal and management would, however, *facilitate* the working of the proposed procedural reforms.

The following sections will point out how the proposed framework addresses the questions, issues and aims as outlined above. First, the ***overall architecture*** of the framework will be outlined and the major elements to the process it envisages be summarised. This synopsis chapter includes an overview of the ***legal and institutional aspects*** which sets out how these major components relate to existing arrangements of food safety regulation and to what extent institutional changes would be required to put them into practice. The following four sections

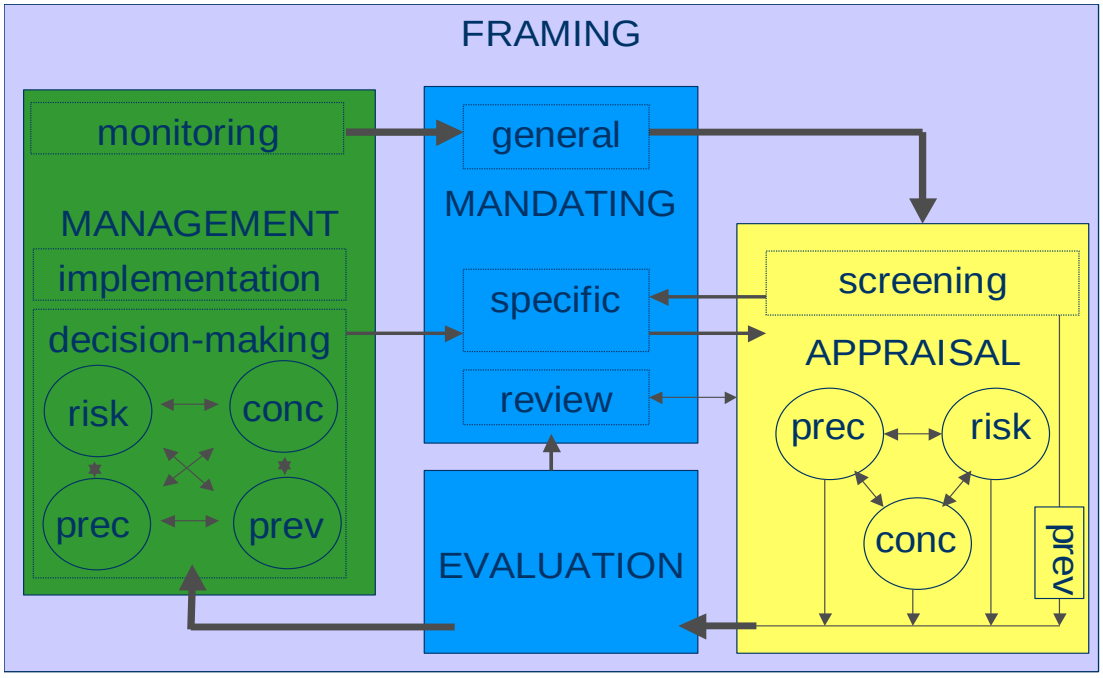
will discuss in ***more detail*** issues of the components of 'framing', 'screening', 'appraisal' and of the two steps of 'evaluation' and 'management'. The subsequent section will provide an outline of the ***participatory process*** that the framework envisages. This distinguishes between different purposes (subject to the respective governance stage) and different levels of intensity of engagement (subject to the particular features of the food safety threat under consideration). The concluding section will summarize the ***suggestions*** for procedural innovations and institutional adaptations put forward by the General Framework[29].

2. An Overview of the General Framework

2.1. A schematic picture

Figure 1.0 presents a schematic representation of a general framework for addressing the governance challenges in the field of food safety identified in the preceding section. There are five main elements to the process envisaged: 'framing', 'mandating', 'appraisal', 'evaluation', and 'management'.

Figure 1.0. ***A framework for the precautionary and inclusive governance of food safety***
Four approaches to appraisal and management: ***prev****ention,* ***prec****aution-based,* ***risk****-based,* ***conc****ern-oriented*



In broad terms, the proposed framework includes the well-established three stage process of conventional risk analysis: ***Screening*** includes the activity referred to in the General Food Law as hazard identification. ***Appraisal*** then, includes the processes referred to there as hazard characterisation (for example dose-response relationships), exposure assessment and risk characterisation. ***Management***, together with the preceding step of ***Evaluation***, include the process determined by the General Food Law as a weighing of policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, followed by implementation and monitoring of management measures. '***Framing***' is the over-

[29] The task of *empirical illustration* of the operation of the proposed framework will be performed as part of a later Deliverable. It will provide a series of snapshot illustrative case studies and, in addition, a detailed investigation of the particular case of Bt11 genetically modified maize.

arching term used to describe the given 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. In contrast to the structural conditions under which regulation takes place, the step referred to as 'mandating' focuses on the concrete processes and procedures by which food safety problems are formulated and delivered to screening and appraisal.

In order to address the challenges outlined in section 1, our framework added three ***novel appraisal approaches*** in addition to the conventional risk assessment procedure. These approaches address the threats which are certainly and unambiguously serious calling for a presumption of prevention, threats subject to scientific uncertainty calling for a precautionary appraisal, 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.) Moreover, as the representation in Figure 1.0 shows, the framework renders the established linear structure – in common with other contemporary conceptions of risk governance[30] - 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[31] and the related initiatives underway as part of another work package in the SAFE FOODS project[32]. Furthermore, it includes ***two additional governance stages***: First '*mandating*' which provides instructions of how to handle the specific threat in appraisal and consecutive steps, and, second, '*evaluation*' which gives the necessary judgement about tolerability or acceptability of a given threat more prominence in the governance cycle. All steps of the cycle are interlinked and overseen by multi-actor processes that are specified in later parts of this document.

Each step is summarised here before more detailed discussion in the following subsections. One point that is important to note at the outset, is that this framework distinguishes between the ***precautionary principle***, ***precautionary appraisal*** and ***prevention***. For the purpose of this document 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 screening, appraisal, evaluation and management. In particular, precaution applies to the screening of food safety 'threats' for the properties of seriousness or uncertainty in order to determine their subsequent treatment in appraisal and management. Precautionary appraisal consists of a 'more comprehensive' approach to appraisal 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.

2.2. An overview of Framing

As in the existing governance of food safety, the framing of safety governance processes is subject to various institutional and legal requirements and settings concerned with the assignment of responsibilities, the articulation of rights and obligations with respect to all organisations involved in the regulatory process, rules concerning the division of labour,

[30] Prime Minister's Strategy Unit/ UK Cabinet Office, *Risk: Improving Government's Capability to Handle Risk and Uncertainty*, London, 2002; National Research Council, *supra* note 3; EPA, Gilbert S. Omen et al., *supra* note 27; RCEP, *Twenty-first report: Setting Environmental Standards*, London, Royal Commission on Environmental Pollution, 1998.
[31] O. Renn, *supra* note 13.
[32] See *Discussion Paper for a New Framework for the Governance of Food Safety*, based on draft papers by Ariane König, Harry Kuiper, Ib Knudsen and Ortwin Renn, March 2006.

prescribed procedures and oversight activities. Framing 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 integrated framework is spelled out and changes and progresses 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 the Member States exercise an influence.

'Framing' hence refers 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). The crucial role of framing is represented by its position at the top of Figure 1.0. Issues related to framing are discussed in more detail in section 3.

2.3. An overview of Mandating

As has already been specified above, 'Mandating' focuses on the concrete processes and procedures by which food safety problems are formulated and delivered to screening and appraisal. The activity of 'Mandating' can be further distinguished into general and specific mandating. ***General Mandating*** refers to 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 being a (possible) 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 further screening. General mandating 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. With regard to a particular product or process, general mandating hence entails the *identification of a problem and the applicable legislation and referring the matter to EFSA for screening*. It is understood that in cases of self-tasking by EFSA, which is 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.

Against the background of the results from the screening, it is the task of ***Specific Mandating*** to *draw up the detailed terms of reference* (based on an exchange of opinions by the Commission as the manager, EFSA as the appraisal actor and the relevant stakeholders) which forms the basis for the appraisal process. It is here 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 for the appraisal. 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 appraisal. Specific mandating is intended to establish a more interactive procedure for the drafting of the terms of reference, which is currently undertaken either by a specific unit of DG SANCO (in cases of a request by the Commission), or the originator of a request. However, it is the

intention of the proposed framework that this step should involve both appraisal actors and managers in conjunction with representatives of key stakeholder groups.

2.4. An overview of Appraisal

During the ***screening*** stage, which follows after 'general mandating' key features of the food safety threat in question are identified and pre-classified in advance of actual 'appraisal'. 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 appraisal 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 appraisal approach to which the threat should be submitted. The outcome of the screening process informs, as already explained above, 'specific mandating'.

The use of the term ***'threat'*** in this framework is important for purposes of consistency and coherence. It was explained in section 1.1 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) may be characterised. The term threat, which is also used in influential governance instruments and documents[33], 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 appraisal 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 appraisal approaches that are discussed in more detail in section 4.

Four different approaches to appraisal were developed and are shown in figure 2. Each appraisal 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 appraisal.

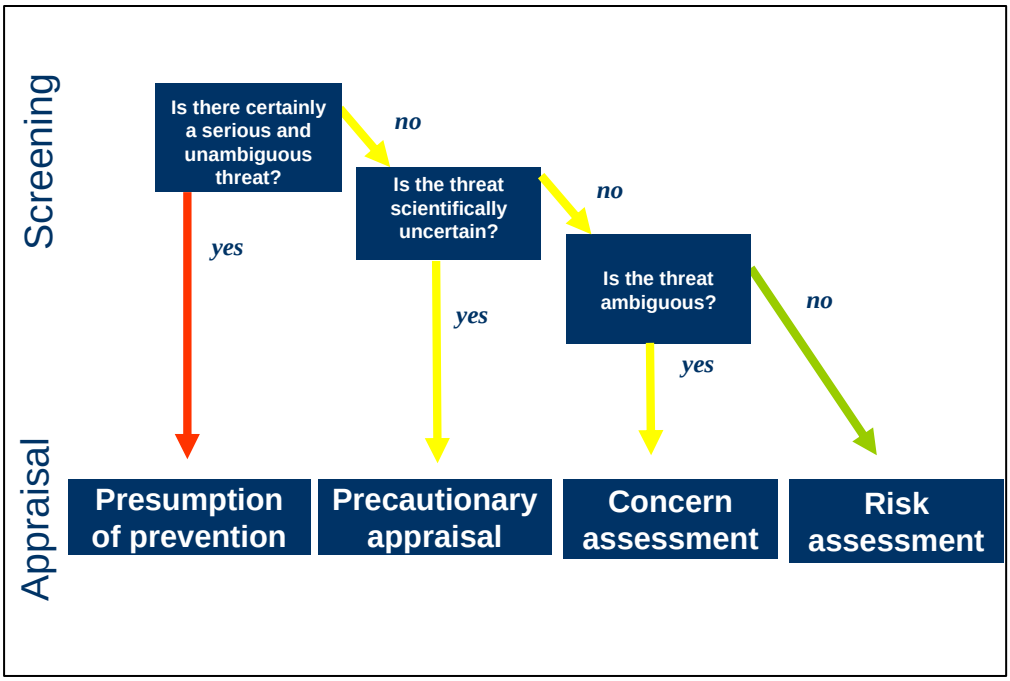
If the threats in question are certainly and unambiguously serious, i.e. significant harm is to be expected with almost certainty, then, subject only to consideration of any over-riding justification, they are assigned directly to ***preventive measures***. If the threats in question are minor and quantitative data about probabilities and magnitudes is either available or easy to produce, then they are assigned directly to ***risk-based appraisal***. Here there may be a

[33] For example, Principle 15 of the Rio Declaration on Environment and Development.

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 appraisal, then more comprehensive appraisal procedures are recommended. If a lack of scientific certainty has been identified in screening, then the subsequent approach to appraisal is ***precautionary***. If socio-political ambiguity has been identified, then a process of ***concern assessment*** is adopted in subsequent appraisal. Both conditions (uncertainty and ambiguity) can apply at the same time and for the same appraisal candidate. In this case both approaches, i.e. the precautionary appraisal approach and the concern assessment approach, need to be combined. Each of the four appraisal approaches are discussed in more detail in section 5 below.

Figure 2. Key features of screening and appraisal



2.5. An overview of Evaluation

The step of 'Evaluation' which follows after the appraisal 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[34]. Evaluation serves two main purposes:

- First, to reach a balanced, value-based judgement 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

[34] General Food Law, Art. 3 (12).

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.

The tolerability or acceptability judgement is informed by the results of the appraisal 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 appraisal 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 of 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 appraisal 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"[35]. While the General Food Law determines this task as an element of risk management besides "if need be, selecting appropriate prevention and control options"[36], 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 appraisal and management[37]. Ideally, this step should involve, like 'specific mandating' both appraisal actors and managers in conjunction with representatives of key stakeholder groups.

2.6. 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[38] 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

[35] Regulation (EC) No 178/2002 (*OJ* 2002, L31/1) as amended by Regulation (EC) No 1642/2003 (*OJ* 2003, L 245/4).
[36] *Ibid.*
[37] Handling threats will inevitably be directed by evidence claims *and* normative claims. It is true that providing evidence is always contingent on existing normative axioms and social conventions. Likewise, normative positions are always enlightened by assumptions about reality; cp. J. Ravetz, 'What is Post-Normal Science', *Futures*, vol. 31, no. 7, 1999, p. 647-653. The fact that evidence is never value-free and that values are never void of assumptions about evidence does not compromise the need for a functional distinction between the two. For handling threats one is forced to distinguish between what is likely to be expected when selecting option x rather than option y, on one hand, and what is more desirable or tolerable: the consequences of option x or option y, on the other hand. It is hence highly advisable to maintain the classic distinction between evidence and values and also to affirm that justifying claims for evidence versus values involves different routes of legitimisation and validation. This is one of the main reasons for making an analytical distinction between appraisal, evaluation and management.
[38] General Food Law, Art. 3 (12).

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 appraisal 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 the specific mandating of appraisal 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 appraisal.

Either way, the series of steps involved in the decision-making process on management measures is as follows[39]:
- Identification of possible measures (under special consideration of the suggestions during the evaluation stage)
- Assessment of measures (with respect to predefined criteria)
- Evaluation of measures
- Selection of one or more appropriate measures

In the broader understanding of management, this stage involves two more steps:
- Implementation of measures, and
- Monitoring of how these measures perform in practice.

Issues related to evaluation and management are discussed in more detail in section 6.

2.7. An overview of legal and institutional aspects

On the level of legal and institutional arrangements, the General Framework addresses mainly three specific challenges. The first of these refers to the *separation between risk assessment and risk management*, which can be considered as one of the most central principles of the General Food Law. However, the research undertaken in the framework of work package 5 of SAFE FOODS shows that this separation is not so clear-cut in the practical conduct of food safety regulation, both on the national and the EU level. Although the idea of a separation between risk assessment and risk management is very broadly accepted in principle, in practice a grey zone between both spheres is acknowledged to exist, and some actors actually speak of interaction between both areas rather than a strict separation. Moreover, the results of the research undertaken show that risk assessors like to frame their findings in a rather prescriptive manner, and that risk managers like to have some guidance from these opinions for the decisions they have to adopt. This would mean that to some extent the concept of strict separation of risk assessment and risk management laid down in the General Food Law is blurred. Against this background, the General Framework seeks to find more systematic, transparent and inclusive procedures for the conduct of tasks of risk analysis on the interface between risk assessment and risk management, while recognizing the need for a certain degree of interaction between both. This issue is addressed particularly by the consideration of the steps of mandating and evaluation.

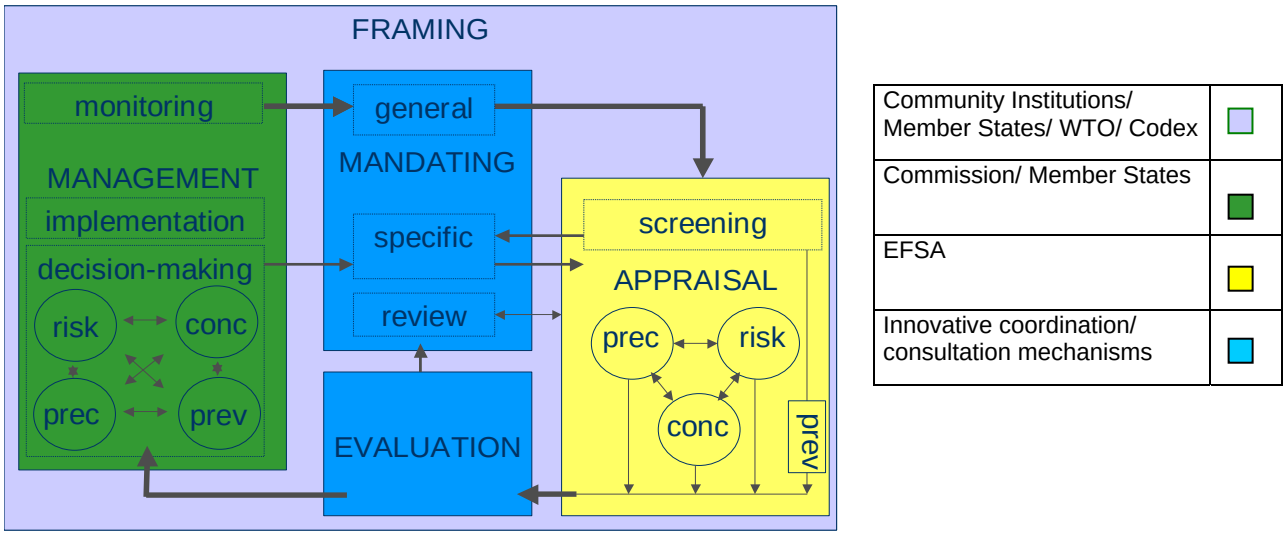
Second, the General Framework seeks to further improve the *application of the principles of "good governance"* of the Commission White Paper – participation, openness, transparency, accountability, coherence, and effectiveness. While all of these criteria are discussed as a cross-cutting issue throughout the Framework, a particular emphasis is put on the creation of engagement procedures for key stakeholders and civil society groups, in order to achieve a higher degree of inclusiveness of risk governance and establish the necessary link between

[39] O. Renn, *supra* note 13, p. 40-48.

risk regulators and civil society actors, as well as the wider public. Procedures for the engagement of stakeholders will be discussed with regard to all steps of risk analysis (both the main steps of appraisal and management, but also the innovative procedures of specific mandating and evaluation), and be elaborated in chapter 7.

Third, whereas the framework of food safety governance outlined here introduces innovative elements especially on 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 on the European level[40]. Against this background, it is the intention of the proposed framework to make recommendations especially for the improvement of *practices* and *approaches* within the conduct of risk regulation, while complying with, and further implementing the key principles of the General Food Law and other relevant legislation and case law. The proposed general allocation of tasks is shown in figure 1.1. below.

Figure 1.1. The General Framework: Allocation of tasks



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[41]. 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* judgements related to the ECSC Treaty, their applicability to the EC Treaty has been generally accepted[42].

[40] See E. Vos, C. Ni Ghiollarnath and F. Wendler, *supra* note 1.
[41] Case 9/56, *Meroni & Co., Industrie Metallurgische S.p.A.* v *High Authority* [1957-58] ECR 133 and Case 10/56, *Meroni & Co., Industrie Metallurgische S.p.A.* v *High Authority* [1957-58] ECR 157.
[42] See, e.g., Lenaerts, 'Regulating the regulatory process: 'delegation of powers' in the European Community', 18 *ELR* 41, 1993.

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[43].

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

- ***Specific Mandating***: 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. Four specific options for the possible form of this forum will be examined in detail in section 4.7. As will be explained in this section, this proposed change is not seen to infringe the doctrine, as the setting of the terms of reference does not predetermine the outcome of appraisal, 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, several options are discussed for the conduct of specific mandating that take account of such concerns. It is therefore also up to the interpretation of the *Meroni* doctrine which of the four options presented below is chosen for this step.
- ***Appraisal***: The doctrine clearly has strong implications for the conduct of appraisal, 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. As will be discussed in more detail in section 4.7., 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

[43] See C. Joerges, H. Schepel and E. Vos, 'The law's problems with the involvement of non-governmental actors in Europe's legislative processes: the case of standardisation', *EUI Working Paper*, Law 99/9, Florence, European University Institute, 1999.

management), precautionary appraisal (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 appraisal 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.

- ***Evaluation***: Finally, 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, appraisal actors and stakeholders, in an external body that is independent from the Commission. However, the General Framework takes account of this concern in defining the task of that external body 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. Again, should the creation of an external body still be the basis of concern in relation to the doctrine, the Framework presents several options for undertaking evaluation as a cooperative task (see section 6.5.).
- ***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.

Table 1 summarises the different steps of food safety governances as identified in the General Framework with regard to their main function, their relation to existing arrangements of food safety regulation, and with regard to the question whether these require institutional changes to the present state.

Table 1. Institutional points of reference and implications of the main framework components

	Main Functions Within the General Framework	Point of Reference in Existing Structures of Food Safety Regulation and the GFL	Responsible Actor(s) in Current Arrange-ments	Institutional Changes Required?
Governance Framing	General development and oversight of food safety governance	Variety of arrangements and procedures	EP, Council, Commission	No
General Mandating	Identifying problem and applicable legislation and referring the matter to EFSA for screening	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.	Commission, EP, Member States	No
Screening	Identification and basic characterisation of threats	Definition of risk assessment in Article 3, 11 GFL, description of tasks of EFSA in Article 22,4 and 23 (f) GFL	EFSA	Yes: Creation of Screening Board within EFSA, consultation of external experts
Specific Mandating	Specification of the terms of reference for the appraisal	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	Commission, EP or Member States	Yes: Creation of (Advisory) Operational Committee, Interface Working Group or consultation procedure (proposed as alternatives)

Appraisal	Applying the four approaches to appraisal identified in the framework	Definition of risk assessment in Article 3, 11 GFL and related articles	EFSA	To some extent: increase transparency and re-consider participation structures
Evaluation	Conducting an acceptability /tolerability judgement	Definition of risk management in Article 3, 12 GFL, consideration of "other legitimate factors" in authorisation procedures (Article 7, Reg. 1829/2003 EC)	Commission, Member States	Yes: Creation of Advisory Operational Committee, Interface Working Group or consultation procedure (proposed as alternatives)
Management	Identify, assess, select and implement measures	Definition of risk management in Article 3, 12 GFL and related articles	Commission, Member States	To some extent: increase transparency and re-consider voting requirements in comitology procedure, and re-consider participation structures

3. Framing: Design, Development and Oversight

It is important to note that the process portrayed in this general framework is itself subject to an iterative approach to ***design***. Activities are subject to various institutional and legal requirements and settings concerned with the assignment of responsibilities, the articulation of rights and obligations with respect to all organisations involved in the regulatory process, rules concerning the division of labour, prescribed procedures and oversight activities. These structures are open to ***development*** in the face of new learning and to ***feedback*** between various stages in the process. The process design needs to abide by framing rules with collectively prescriptive power as they are set by laws, regulations and legal principles (which themselves can all become subject to change) and is moreover shaped by non-binding frames such as conventions, prominent perspectives and orientations. By explicitly including this as an element in the General Framework, it is acknowledged that the implementation of precaution takes place at a number of organisational, legal and discursive levels, including ***institutional structure, process implementation*** and the exercise of ***administrative discretion***.

It is the process of framing – which hence refers to both collectively binding rules and non-binding conventions and prominent perspectives - that governs the ***selection, characterisation, implementation*** and ***review*** of the threat criteria employed in screening and of the various elements in the different approaches to subsequent appraisal. This role involves assuring that the right criteria are being selected and applied in an appropriate fashion to the relevant threats. In particular, framing specifies the conditions and rules that govern the processes for determining the ***relative priorities*** attached to different agents and threats and ensuring that a ***justifiable*** and ***proportional*** balance is being struck in the allocation of resources to different aspects of screening, appraisal, evaluation and management.

The framing 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 process 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 appraisal 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. It is subject to principles of good governance, including ***competence, transparency, efficiency, legitimacy*** and ***accountability***.

With regard to institutional arrangements, it is therefore clear that framing 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 (such as the General Food Law) and acts setting out procedural requirements for a specific policy-area (such as the definition of GMO authorisation procedures through European Directives and Regulations). Many of these acts 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.

However, other relevant procedural arrangements are created not through full legislative procedures, but by single executive acts. 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, 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 mostly not defined by legal acts, can be considered as part of the governance design. Furthermore, on a broader scale 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. Whereas the governance design is therefore not a single, identifiable step or procedure, it remains to be specified how its elements relate to different elements of the General Framework (e.g., the adaptation of screening through requirements for the harmonisation of risk assessment as defined in the General Food Law).

To sum up, 'framing' refers 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. Screening

4.1. Screening criteria

What is here termed the 'screening' of threats corresponds simply 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 appraisal. Second, to inform the prioritisation of attention and resources in appraisal 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.

In order to meet the challenges identified in the introduction to this document (section 1), 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 the screening 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 appraisal

process. In the General Framework, efficient and effective allocation to these different appraisal 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 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 appraisal. 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 appraisal 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 appraisal.

4.2. 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 project 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, which were opposed in genetically modified organisms by the EFSA Scientific Panel on Genetically Modified Organisms in 2004. Alternatively, in areas where there exist robust applicable data, threat criteria may be formulated in terms of risk-based thresholds, such as ***concentrations*** for certain less hazardous pathogens or toxicants.

As has been noted, these criteria are all subject to discussion as part of the framing exercise. Prevention is then chosen when the framing exercise comes to the conclusion that the threat 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 appraisal 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 ***preventive measures*** are triggered.

4.3. 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 1.1 above, difficulties in this respect may lie not only in addressing ***uncertainty*** (where, by definition, we cannot confidently derive probabilities for at least some sub-set of outcomes), but also ***ignorance*** (where some outcomes themselves may be entirely unanticipated).

The project 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:

i) Are there scientifically founded questions concerning the status of the theoretical foundations of the disciplines bearing on the characterisation of the threat?

ii) 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?

iii) Are there scientifically founded questions concerning the completeness or sufficiency of the particular scientific models bearing on the characterisation of the threat?

iv) Are there scientifically founded questions concerning the applicability to the context in question of the particular scientific models used to characterise the threat?

v) Are there scientifically founded questions concerning the applicability to the context in question of the data sets bearing on the characterisation of the threat?

vi) 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?

vii) Do there exist any indirect, interactive or synergistic causal mechanisms of a kind that may not fully and confidently be characterised by probabilistic techniques?

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 appraisal*** in the subsequent governance framework.

4.4. 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.

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

ii) 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***)?

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

iv) 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*** in subsequent appraisal.

4.5. 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 risk-based appraisal (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 risk-based appraisal may take the form of ***standard risk assessment***. 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[44]. Especially under such circumstances, where the scarcity of data means that assessment must be assumption- (rather than data-) driven, precautionary criteria may in addition be triggered.

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).

[44] Work package 3 report-back session, SAFE FOODS Consortium Meeting, Pretoria, South Africa, 25 May 2006.

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.

4.6. Legal and institutional aspects of screening

As stated above, 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 usually 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 ***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)).

Within EFSA, specific units of the Scientific Expert Services appear best equipped to undertake the tasks of screening, especially the departments on data collection and networking, assessment modelling, and hazard characterisation. In their work, these services could be assisted by the scientific units of EFSA that work in thematic areas parallel to the subjects of the Scientific Panels. Furthermore, for specific subjects, screening could also be undertaken by the external Expert Working Groups that have been established in various areas, including Geographical BSE risk, TSEs, Zoonoses Data Collection, pesticide peer review, and the setting of MRLs for pesticides. The General Framework recommends, however, that a specific screening board of those responsible for appraisal should be formed in the administrative structure of EFSA, which is in a position to co-ordinate the procedures of hazard identification and to consult external experts and potentially stakeholders wherever this is considered necessary.

Within the conduct of tasks before appraisal, screening fulfils an intermediate function between general mandating – the identification of a problem and applicable legislation- and the definition of the terms of reference which is undertaken through the step of specific mandating by the requesting authority, mostly the Commission. In this intermediate function, the foremost task of screening is to establish guidance for the committee defining these terms, and to prepare the approaches to appraisal that appear most appropriate for the assessment of a given threat. It is, however, understood that in the screening stage no compulsory choice for a specific approach to appraisal is made. Instead of an automatism, it is therefore up to the body responsible for specific mandating to define the way in which a question is asked to EFSA. The actors responsible for screening, however, can assist this process in providing the scientific information which is requested as a background for such questions (Article 29, 2 GFL).

4.7. Linking screening and appraisal: legal and institutional aspects of Specific Mandating

Specific Mandating corresponds strongly with the setting of the specific terms of reference for a question asked to EFSA. In the current institutional framework of EU food safety regulation, this is one of the main fields of risk analysis where an interaction between risk managers and risk assessors can be observed. The specification of the terms of reference occurs by the 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 EFSA and is always involved whenever terms of reference are drafted and to be submitted. It coordinates 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 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' where it is to ensure that Commission officials who attend the meetings do not transgress their role as observers.

Whereas DG SANCO ensures a sufficient degree of coordination between the process of risk assessment and risk management, one of the shortcomings of the current practice appears to lie in the fact that this is often done in a rather opaque manner, and that no systematic coordination between the requests of risk managers and the perspectives of risk assessors and stakeholders can be achieved. Against this background, the General Framework seeks to establish the innovative step of specific mandating in order to establish a ***more inclusive and transparent solution*** for the coordination between risk assessment and risk management.

Therefore, in order to give expression to the existence of strong interaction effects between risk assessment and risk management, and with the aim of rendering these more transparent and inclusive as well as to achieve better coordination between both spheres of risk analysis, the General Framework proposes different institutional solutions to improve the current practice. The options proposed vary with regard to their degree of formalisation, thus leaving the choice between more strongly institutionalised and more informal solutions. Four options are proposed:

Option 1: Adoption of terms of reference by an Operational Committee

A first option of ensuring a higher degree of transparency and coherence while ensuring the direct cooperation between those responsible for appraisal and those responsible for management would be to transfer the setting of the terms of reference to an "Operational Committee" composed of appraisal actors, policy-makers, and stakeholder representatives. This is envisaged as a relatively strongly institutionalised solution, as the operational committee is set up as a permanent body and subject to rules of "good governance" as the body responsible for the adoption of the terms of reference. In order to achieve the objective of an enhanced coordination between appraisal and management, it is intended that this body should adopt the terms of reference by consensus in principle. To create more visibility, this option would also require the publication of the terms of reference on their own 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). Although this Committee would be responsible for the task of specific mandating (and thus, the definition of the terms of reference), this activity is not associated with the adoption of binding decisions and hence would not infringe with the current thinking on delegation of powers, derived from the *Meroni* doctrine.

Option 2: Establishment of an opinion on the Terms of reference by an Advisory Operational Committee

However, it may be felt that the *Meroni* doctrine still interferes with the possibility of having a new organ deciding on the terms of reference, as it would take away powers of foremost the Commission to independently decide on issues of risk management. In this case, a second option would be to emphasise the purely advisory nature of the Operational Committee and leave the authority that requested the opinion (i.e., mostly the Commission) with the ultimate responsibility to decide on the specific terms of reference. The composition of the committee and the requirement of adopting the advisory opinion in principle by consensus would therefore be the same as in Option 1; the difference being that this Committee adopts an advisory opinion, addressed to the Commission or the other authorities requesting for a scientific opinion by EFSA. Given that the primary aims of the exercise described here are to

achieve a better coordination between those responsible for appraisal and those responsible for management and more transparency, it is intended to maintain this body as a forum comprising all three groups of actors, although it is conceptualised as an advisory procedure for the managers. If it is felt that this creates a duplication, a proposal for a consultation procedure comprising only appraisal actors and stakeholders is also set out (see Option 4).

Option 3: Discussion of the terms of reference in an Interface Working Group

A more flexible and informal structure (which however compromises partly the objective of a coordination of appraisal actors and managers as well as the objective of transparency) would be to require a consultation procedure between the Commission, appraisal actors and stakeholders in relation to the task of specific mandating within an institutional setting, the so-called 'Interface Working Group'. This Working Group would be a platform where views can be openly exchanged, and more specifically, where the terms of reference can be discussed between the three actor groups, without however formalising these discussions with a view of adopting decisions or opinions. The authority responsible for the definition of the terms of reference could then use these discussions to define the specific terms of reference asked to EFSA for an appraisal process. This option would also require the publication of the draft terms of reference and the agenda of consultation procedures in advance (in the current system, the terms of reference are revealed only after the completion of an opinion).

Option 4: Establishment of a mandatory consultative procedure in the setting of terms of reference

The general option of organising a mandatory consultative procedure could also be realised without specifying a particular institutional setting. The most flexible and informal option would therefore simply require the Commission (or the authority that requests a scientific opinion) to consult those responsible for appraisal and stakeholders on questions addressed by specific mandating. It would in this case be up to the Commission to organise its own consultation procedure (e.g. through the adoption of a Communication specifying the procedures and working principles), on the basis of the Code of Good Administrative Behaviour and the Communication on the general principles and minimum standards of consultation with civil society[45]. The choice of the participants of the consultation procedure could then be taken relatively freely; it is however, recommended that it should comprise a relatively broad range of stakeholder organisations (representing industry, consumer, agricultural and environmental interests), as well as the appraisal actors.

The four options outlined here are summarised once more with regard to the organisation, participants, tasks, and working procedures in table 2. Our proposal to introduce a more coherent and transparent step of specific mandating coincides with various ideas that have been circulated especially by EFSA to work towards a more transparent and inclusive approach to defining the terms of reference in the process of risk assessment. These ideas came also to the fore during the interviews with some Commission officials[46]. An EFSA information note to the Advisory Forum on increasing the transparency of risk assessment[47] refers therefore to the clearer definition of the terms of reference – including explanations about underlying uncertainties and assumptions – as a major task in the achievement of more

[45] Communication of the European Commission, *Towards a Reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM (2002) 277 final, Brussels, 5.6.2002.
[46] See E. Vos, C. Ni Ghiollarnath and F. Wendler, *supra* note 1.
[47] EFSA document, *Making Risk Assessment More Transparent – Information Note to the Advisory Forum*, AF 08.04.2004 – 5.

transparency in risk assessment[48]. Furthermore, it sets out that in 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. Our proposal developed here therefore builds on and extends existing ideas among risk assessors, managers as well as stakeholders to create more transparency and introduces a more coherent approach at this crucial step of food safety analysis.

Table 2. Options for a formal organisation of the interface of mandating

	Composition/ Participants	Tasks/Mandate	Working and Decision-Making Procedures
Operational Committee	Equal number of appraisal actors and managers, and a smaller number of stakeholders (however not below 2); e.g. 4+4+2 members; in cases of an opinion requested by the EP or a Member State, one additional representative of the respective institution	Definition of the terms of reference for the conduct of a specific appraisal, on the basis of the request made in the stage of general mandating and the results of screening	Adoption of terms of reference by consensus in principle
Advisory Operational Committee	See above	Adoption of an advisory opinion on the definition of terms of reference, to be specified by the actor requesting the opinion (i.e., mostly the Commission, but less frequently also EFSA, EP or Member States)	Adoption of advisory opinion by consensus in principle
Interface Working Group	See above	Discussion of the terms of reference for a specific appraisal, to be specified by the actor requesting the opinion	Conduct of an open exchange between appraisal actors, managers and stakeholders, with no formal conclusions or decisions adopted at the end of the meeting
Consultation Procedure	Flexible	Advisory consultation procedure with appraisal actors and stakeholders by a specific unit of DG SANCO	No specific institutional setting; establishment of consultation procedure on the basis of the Code of Good Administrative Behaviour and the Communication on consultation with civil society

5. The Process of Appraisal

5.1. Introduction

The purpose of appraisal is to gather the information necessary to inform and substantiate a particular governance outcome. The type, scope and quality of information relevant to this

[48] 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, formulation of the „terms of references“ should be considered as an iterative process involving dialogue with stakeholders, where appropriate.“, EFSA document, *supra* note 47, p. 3.

decision making will vary from context to context and from threat to threat. Depending on the context and magnitude of the threats in question (as detailed below) it may be necessary to include appraisal of socio-economic as well as health factors. In the interests both of efficiency and effectiveness, it is desirable to be as specific as possible about the most appropriate form to be taken by the appraisal process in any given context. Instead of a single undifferentiated notion of 'risk assessment', then, the present framework distinguishes ***four different approaches to appraisal*** and shows how they fit together and articulate with the wider governance process. In the terms alluded to in the existing General Food Law as reviewed in section 1, the four more elaborate forms of appraisal detailed here each represent a different specific way in which appraisal might be more 'comprehensive' than standard risk assessment. The details of the institutional and procedural modes of implementation will be discussed in a final sub-section.

5.2. Presumption of Prevention

Where threats are identified in the screening process certainly and unambiguously to be serious, then the presumption is that they are assigned directly to preventive measures. Here, appraisal 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 appraisal 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 over-arching 'framing' process.

Under a presumption of prevention, appraisal 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'. The institutional means to achieving this are discusses in the final sub-section.

5.3. Key features of Precautionary Appraisal

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

In essence, precautionary appraisal 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 1), 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 appraisal process 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:

i) Extension of the scope of appraisal 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 appraisal if the causal connections are not well understood and cannot be modelled with a high degree of confidence in an extended risk assessment.

ii) Address aspects of ***institutional ignorance*** by engaging a full range of technical ***disciplines*** and ***stakeholders*** right at the outset in appraisal, 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***.

iii) 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***.

iv) Subject to the provisions of specific mandating, 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.

v) 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***.

vi) 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 appraisal.

These elements of precautionary appraisal 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 appraisal of socio-economic risks and benefits. This generally relates to a broadening out of the appraisal 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 appraisal is based on knowledge (systematic and experiential) not on beliefs or value judgments. That is why participation in the resulting analytic-deliberative appraisal exercise should be limited to ***knowledge acquisition*** and systematic ***knowledge appraisal***.

Examples of processes for eliciting stakeholder knowledge might include hearings, focus groups or surveys.

5.4. 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, 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 transdisciplinary commissions to elicit as wide a range of concerns, visions, and mental associations as possible.

The above methods may be applied to the appraisal 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 framing (involving design, development and oversight of the food safety governance process as a whole) and the activity of specific mandating, the step at which the terms of reference are set.

5.5. Risk-based Appraisal

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, appraisal 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 elaborate appraisal procedures, as appropriate. Of course, this appraisal 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, risk-based appraisal may also involve scientific engagement by experts from stakeholder groups.

Under risk-based appraisal, the priority attached to consideration of socio-economic factors will depend on the context and magnitude of the threats in question. Where appraisal 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. The institutional means to achieving this are discussed in the final sub-section.

However, recent statements by EFSA indicate 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, or even more simply Euros) for comparing the risks and the benefits of particular risk management measures. It remains for EFSA[49] 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 appraisal to some of the socio-economic dimensions of food safety decisions whilst avoiding the over-simplification of aggregative techniques.

5.6. Potential opportunities for inter-linkages between different forms of appraisal

Potential inter-linkages exist between the approaches of precautionary appraisal, concern assessment and risk-based appraisal. The opportunities for inter-linkages between different forms of appraisal 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.

It is important to stress that the appraisal 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 appraisal, it may become obvious that a precautionary approach is more suitable. It is therefore essential that during the appraisal process checks about the need for re-routing to another approach are incorporated in the assessment process.

[49] http://www.safefoods.nl/Lists/News/DispForm.aspx?ID=35, accessed 21 May 2006.

5.7. Legal and institutional aspects of appraisal

Before elaborating on the institutional specifics of appraisal, it should be stressed that for years, the Community institutions have adhered to the so-called 'anti-delegation' doctrine and only allowed for transferring very limited, defined powers to existing agencies. In doing so, the institutions follow arguably the so-called *Meroni* doctrine inspired by the case law of the European Court of Justice of the late 1950s[50]. 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* judgements related to the ECSC Treaty, their applicability to the EC Treaty has been generally accepted[51]. So we can observe that it is true that the strict separation between risk assessment and risk management as laid down in the General Food Law is a response to the failures of risk regulation by the EU institutions that came to the fore during the BSE crisis; it is also true that this separation is a direct result from the adherence to the *Meroni* doctrine. Hence, this explains that the delegation of powers to Community agencies has generally proved to be quite restrictive. Now ***appraisal*** is defined in this document as subsuming conventional risk assessment, but providing also for the use of broader methods of a kind that might serve to make this "more comprehensive" in the sense set out in the General Food Law (Article 3,11). We can therefore conclude that this broader process of appraisal is an appropriate task for EFSA, the allocation of which is not controversial in terms of the *Meroni* doctrine.

On the level of institutional requirements, the four approaches towards appraisal outlined above have reference to the practices in the conduct of risk assessment as described by the General Food Law (GFL). These can be summarised as follows:

- Presumption of prevention: This approach is reflected mainly in Article 50-57 GFL on rapid alert and crisis management. The main function of EFSA in this context is defined to acting as a contact point in the rapid alert network; it may therefore supply scientific or technical information to other actors in the network after the notification of a risk but cannot decide on crisis management measures.
- Precautionary appraisal: This approach is recognised in a general form by Article 7 GFL on the precautionary principle, although it is related mainly to "provisional measures of risk management". Other applicable means for EFSA in the field of risk assessment are measures to reduce the degree of institutional and societal ignorance about risks and to reduce uncertainty; relevant provisions of the GFL on societal ignorance are the Articles 32-24 on the commissioning of scientific studies and data collection, and on the identification of emerging risks. Provisions related to the reduction of institutional ignorance are the Article 30 on divergent scientific opinions, which demands an exchange of data and information in cases of divergence of scientific views, and to reduce uncertainty, and the mandate given to EFSA by the GFL to build networks with relevant national authorities and work towards a harmonisation of risk assessment (Article 23).
- Concern assessment: This approach is recognised also in a very general form by Article 42 GFL requiring EFSA to "develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties". This article may be taken as a basis for the strengthening of efforts to give all interested parties the opportunity to bring relevant matters to the attention of the Scientific Committee or Panels, also through public hearings (as requested by stakeholders during the first

[50] Case 9/56, *Meroni & Co., Industrie Metallurgische S.p.A.* v *High Authority* [1957-58] ECR 133 and Case 10/56, *Meroni & Co., Industrie Metallurgische S.p.A.* v *High Authority* [1957-58] ECR 157.
[51] See, e.g., K. Lenaerts, *supra* note 42.

Stakeholder Colloque at Ostend). Furthermore, on a more general level, Article 9 GFL requires that there shall be open and transparent consultation during the preparation, evaluation and revision of food law.

- Risk-based appraisal: This follows the standard procedure of risk assessment as set out in the GFL, especially in Article 29 on the request and issue of a scientific opinion by EFSA.

6. Evaluation and Management

6.1. Introduction

The main purpose of evaluation is to judge the ***tolerability or acceptability*** of a given threat and, if deemed necessary, to initiate a management process. The chief purpose of management 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.

There is no necessary correlation between each respective approach to appraisal 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 (detailed in section 6.4 below).

6.2. Value-based Evaluation

Evaluation implies that the insights of the appraisal exercise are summarised, aggregated 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 appraisal 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 risk management measures. This judgement 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.

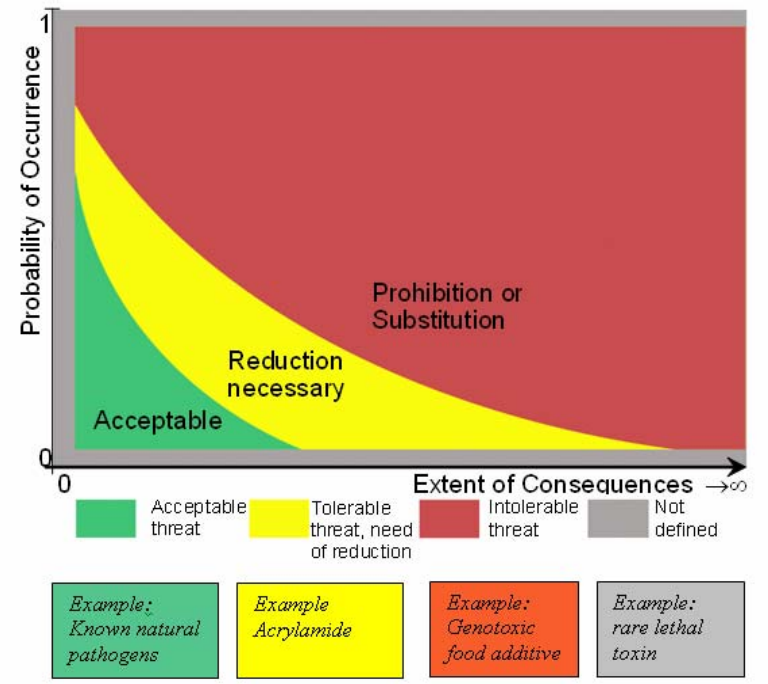
If deemed necessary, evaluation might conclude that further assessments (i.e. beyond the appraisal of health effects), for instance with respect to other endpoints deemed relevant (such as environmental quality, nutrition, animal welfare, or specific economic factors etc.) are commissioned, possibly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

The evaluation process can be structured in ***four consecutive steps***:

- Summary of the appraisal results focused on the four different appraisal approaches;
- Societal (value-based) balancing of benefits and risks (including consideration of legal requirements, societal needs, contributions to quality of life, contribution to sustainability, potential for substitution and compensation, policy imperatives, choice of technology, and overall risk-benefits balance);
- Conclusion on whether the given threat is acceptable, tolerable, unacceptable or ill-defined. If the threat is ill-defined, the appraisal process needs to be repeated or augmented.
- If the conclusion is that management measures are required, recommendation for the most appropriate management approach (for this point cp. sub-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 3 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.

Figure 3. Acceptable, tolerable, intolerable and borderline threats (Traffic Light Model)



To draw the line between 'intolerable' and 'tolerable' as well as 'tolerable' and 'acceptable' is one of the most difficult tasks of safety governance. The UK Health and Safety Executive developed a procedure for chemical risks based on risk-risk comparisons[52]. Some Swiss

[52] 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.

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[53]. 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.

Arriving at a ***balanced judgement*** means that the appraised 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 stake within culturally plural, morally concerned and educated societies[54]. 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 members of the "interface group", i.e. the Operational Committee (in one of its forms), across all cases (for a detailed discussion of this point see sub-section 6.5.).

When evaluation has been performed by the "interface group", 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.

With regard to these 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 more comprehensive engagement involving stakeholders beyond the Operational Committee (in one of its forms) or also the wider public will depend on the case in hand and be considered by this Committee. The *prima facie* default is as follows: If there is hardly any ambiguity and controversy, it might not be necessary to involve more actors in the evaluation process. If there is little ambiguity and controversy, it could be sufficient to hold formal hearings with relevant social interest groups or targeted at relevant public constituencies as a means to elicit their evaluation criteria and risk-benefit ratios. If the topic raises more concerns or if the appraisal process resulted in higher degrees of ambiguity, it could be advisable to convene deliberative bodies such as trans-disciplinary commissions to elicit as wide a range of evaluative criteria and tradeoffs as possible. If the process faces strong controversy and evaluation is highly ambiguous, a full fledged participation program might be appropriate such as stakeholder roundtables, citizen forums, citizen juries or consensus conferences which

[53] 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.
[54] R. Grove-White, P. Macnaghten and B. Wynne, *Wising up: The Public and New Technology*, Lancaster, CSEC, 2000.

might be accompanied by internet feedback rounds and other means of gaining public input. In this situation more open processes of citizen participation 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[55] and is therefore conducted by both the Commission and the Member States. It starts with a review of all relevant information gained in the appraisal process and of the tolerability/ acceptability judgement and the recommendation for the most appropriate management approach made in the evaluation phase. 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 appraisal 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 the specific mandating of appraisal 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 appraisal. Either way, the series of steps involved in the decision-making process on management measures is as follows[56]:

1) ***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 does not touch on the threat (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;

[55] General Food Law, Art. 3 (12).
[56] O. Renn, *supra* note 13 p. 40-48.

- 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) ***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:
   a. *Effectiveness:* Does the measure achieve the desired effect?
   b. *Efficiency:* Does the measure achieve the desired effect with the least resource consumption?
   c. *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?
   d. *Sustainability:* Does the measure contribute to the overall goal of sustainability? Does it assist in sustaining vital ecological functions, economic prosperity and social cohesion?
   e. *Fairness:* Does the measure burden the subjects of regulation in a fair and equitable manner?
   f. *Political and legal implementability:* Is the measure compatible with legal requirements and political programs?
   g. *Ethical acceptability:* Is the measure morally acceptable?
   h. *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?

   The EU parliament has been pushing a proposal to make such policy impact assessments mandatory for all EU regulations with significant impact on the economy or society.

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[57]. 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

[57] J.D. Graham and J.B. Wiener, *Risk versus Risk*, Cambridge, Harvard University Press, 1995.

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 the institutions performing the risk and concern assessments and the precautionary appraisal participate in monitoring and supervision so that their analytic skills and experience can be utilised in evaluating the performance of the selected management measures.

Table 3. Generic management components

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

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

Table 3 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 appraisal, 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 lend themselves to a set of suitable risk management measures (as shown in table 4). There is ***no automatism*** in allocation between the appraisal and management approaches of the same label, yet there is the *prima facie* presumption that the appropriate appraisal approach is subsequently pursued during the phase of management.

Prevention

This approach applies where threats have been identified in the appraisal 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 appraisal 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 again to the governance principle of participation, such a criterion could only be determined and applied through a broad based process of participatory deliberation of the kind applicable under ambiguity, and further legitimated through dedicated procedures of democratic accountability.

Precaution-based approach

Since unresolved scientific uncertainties imply that the (true) dimensions of the threats are not (yet) known, it is vital to pursue a cautious strategy that allows learning by restricted errors. Informed by processes of precautionary appraisal, detailed earlier in this document, specifically precautionary management measures may hence 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.

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, 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, i.e., the overall judgement for defining the threat as acceptable, tolerable or intolerable, can be done on the basis of traditional methods such as risk-risk comparison (does the new activity replace another more harmful risk or would it be substituted by a more harmful activity), cost-effectiveness and cost-benefit analysis or risk-benefit balancing. 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.

Concern-oriented approach

This strategy applies to situations in which information about a threat is interpreted in varying ways by different stakeholders and also different parts of the affected and/or observing wider public – i.e. there are different viewpoints about the relevance, meaning and implications of factual explanations and predictions for deciding about the tolerability of a threat as well as management actions - and/or if the values and priorities of what should be protected or reduced are subject to intense controversy. Evaluation and management, in such circumstances, need to address the causes of conflicting views[58]. Where managers are confronted with such ambiguities, however, it is not enough to demonstrate that evaluation and management are open to public concerns. As in the case of precaution, the governance principle of participation here requires 'trans-disciplinary' deliberation in the process of decision making itself – involving specialists from ethics, humanities and social (as well as natural) sciences alongside active engagement by wider interested and affected parties.

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, the aim of a broader societal discourse destined to enable participative decision making is to 'close down' on the most robust basis for consensus or common ground in decision making. At the end discrete measures need to be selected and implemented. The discursive process is aimed at finding appropriate conflict resolution mechanisms capable of promoting consensus or tolerance for evaluation results and the evaluation and selection of management measures. The main effort of concern-oriented management is hence the organisation of a suitable discourse combined with the assurance that all stakeholders and also representatives of the wider public can question and critique the framing of the issue as well as each element of the entire food safety governance process. Issues of fairness, visions of future technological developments and societal change, and preferences about desirable lifestyles and community life play a major role in such a broader societal discourse. Applied techniques include randomly selected citizens' panels or juries, voluntary advisory groups, consensus conferences, and other participatory techniques aimed at resolving ambiguities and value conflicts.

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.

[58] D. von Winterfeldt and W. Edwards, 'Patterns of conflict about risk debates', *Risk Analysis*, 4, 1984, p. 55-68.

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.

Table 4. Four management approaches

Management Approach	Suitable Measures Include:
Prevention	– Bans (substitution possible?) – Phase-outs (substitution possible?) – (tolerance only when benefit is overwhelming)
Precaution-Based	– Containment in space and time[59] – Close monitoring of potential adverse effects – (More) stringent provisions for compensation and liability – Selecting the functional equivalent with a significantly lower risk and/or less uncertainty – Bans (substitution possible?) – Phase-outs (substitution possible?)
Risk-Based	– Technical standards – Economic incentives – Labeling and information – Voluntary agreements
Concern-Oriented	All of the above: Choice is highly dependent on the outcome of participatory procedures of stakeholder and public engagement

6.5. Legal and institutional aspects of evaluation and management

The tasks conducted in the step of evaluation include 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 (GFL, Article 3, 12). With regard to the general provisions set out in the GFL, the General Framework proposed here introduces a differentiation of the tasks defined as „risk management"[60] (Article 3, 12) into ***two separate steps***: ***evaluation*** and ***management***. Whereas the consideration of risk assessment and other legitimate factors is considered as a task of evaluation, management is used in a narrower sense to refer mainly to the tasks of selecting and implementing management measures.

This close connection between evaluation and management is also explained by other elements of the legal and institutional framework: Evaluation, which consists mainly of the conduct of a tolerability or acceptability judgement, is closely related to the consideration of

[59] 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).

[60] The full definition of risk management in the General Food Law is: „'Risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options" (Regulation 178/2002, Article 3, 12).

„other legitimate factors“ (.i.e., wider social and economic concerns) in addition to the scientific assessment of risks. The GFL defines the consideration of such factors as part of risk management (Article 3, 12). A similar provision exists in the legislation defining the authorisation procedure for GMOs (Regulation 1829/2003), which assigns the Commission the task of considering the opinion of EFSA, any relevant aspect of Community law and „other legitimate factors relevant to the matter“ in its draft decision (Article 7).

As the consideration of such factors has been identified as one of the main fields in the interaction between risk managers and risk assessors, it is intended that evaluation should be conducted in a similar structure as in the task of specific mandating, thus involving both actors from appraisal and management as well as stakeholder organisations. Therefore, basically the same options for engagement procedures are proposed as for specific mandating. Given that the task of evaluation is a part of management, however, it is understood that the status of this committee in this task is ***purely advisory*** and hence in line with the prevailing view on the delegation of powers (*Meroni* doctrine, see section 5.7.), and that the Commission takes on the full responsibility for its decision-making in the field of management. The options proposed, therefore, do not include the first variant of an operational committee with the competence to adopt an act as was proposed for the stage of specific mandating in relation to the adoption of the terms of reference (see section 4.7.).

Therefore, ***three options*** are proposed for the conduct of evaluation which are summarised in table 5 below.

Option 1: Establishment of an opinion on the tolerability and acceptability judgement by an Advisory Operational Committee

As explained before, it must be assumed that the *Meroni* doctrine could interfere with the possibility of having a new organ deciding on evaluation (i.e., taking a decision on the consideration of “other legitimate factors” as a part of risk management), as it might be seen to take away powers of the Commission to independently decide on management issues. Therefore, at this step the purely advisory nature of the Operational Committee is emphasised, leaving the Commission with the ultimate responsibility to decide on the tolerability or acceptability of threats. However, the objective of this engagement procedure is also to achieve a better coordination between appraisal and management and more transparency with regard to the process of evaluation. The composition of the committee and the principle of adopting the advisory opinion in principle by consensus would therefore be the same as in the Operational Committee proposed for the task of specific mandating. Therefore, this body is also envisaged as a forum comprising both groups of actors, although it is conceptualised as an advisory procedure for managers. If it is felt that this creates a duplication, a proposal for a consultation procedure comprising only appraisal actors and stakeholders is also set out (see Option 3).

Option 2: Discussion of the tolerability/ acceptability judgement in an Interface Working Group

A more flexible and informal structure (which however compromises partly the objectives of coordination between appraisal actors and managers and transparency) would be to require a consultation procedure between the Commission, appraisal actors and stakeholders in relation to the task of evaluation. The objective of this option would therefore be to create an “interface working group” in which an open exchange of views can be organised and more specifically, where the outcome of a tolerability or acceptability judgement can be discussed between the three actor groups, without however formalising these discussions with a view of adopting decisions or opinions. To ensure a certain degree of continuity of discussions and to create appropriate conditions of access, it is envisaged that this discussion process should take

place within the framework of a body with fixed membership (notwithstanding the possibility of additional consultations where these are considered necessary), giving equal representation to appraisal actors and managers and including at least 2 stakeholder representatives.

Option 3: Establishment of a mandatory Consultative Procedure in the conduct of evaluation

The general option of organising a mandatory consultative procedure could also be realised without specifying a particular institutional setting. The most flexible and informal option would therefore simply require the Commission to consult appraisal actors and stakeholders on questions related to evaluation. It would in this case be up to the Commission to organise its own consultation procedure (e.g., through the adoption of a Communication specifying the procedures and working principles), on the basis of the Code of Good Administrative Behaviour and the Communication on the general principles and minimum standards of consultation with civil society[61]. The choice of the participants of the consultation procedure could then be taken relatively freely; it is however, recommended that it should comprise a relatively broad range of stakeholder organisations (representing industry, consumer, agricultural and environmental interests), as well as appraisal actors.

Table 5. Options for a formal organisation of the interface of evaluation

	Composition/ Participants	Tasks/Mandate	Working and Decision-Making Procedures
Advisory Operational Committee	Equal number of appraisal actors and managers, and a smaller number of stakeholders (however not below 2); e.g. 4+4+2 members	Adoption of an advisory opinion on the tolerability / acceptability of a given threat under the premise of approval by the Commission	Adoption of advisory opinion by consensus in principle
Interface Working Group	See above	Discussion of the tolerability/ acceptability judgment of a given threat	Conduct of an open exchange between appraisal actors, managers and stakeholders, with no formal conclusions or decisions adopted
Consultation Procedure	Flexible	Advisory consultation procedure with appraisal actors and stakeholders by the Commission	No specific institutional setting; establishment of consultation procedure on the basis of the Code of Good Administrative Behaviour and the Communication on consultation with civil society

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 difference, however, is that the Framework envisages the consideration of appraisal results and other legitimate factors (i.e., evaluation) as a task in which appraisal actors and stakeholders should be involved in an advisory function. It is clear, however, that the final responsibility for the consideration of such factors rests with the managers.

With regard to 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

[61] Communication of the European Commission, *supra* note 45.

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[62]. 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 strong mechanism for deliberative decision-making, advancing consensus and part of a regulatory network with a strong role of the Commission in practice, 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 about 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[63]. Although especially transparency rules are still largely excluded in these regulations, principles of good governance have therefore 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[64], stakeholders in the field[65] as well as Member States[66]. This calls for stricter rules on transparency. With regard to the procedures of decision-making, an element of concern which has gained particular importance in the field of GMO authorisation is that the adoption of implementation measures (or the approval of authorization 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. Particularly in the field of GMO authorizations 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.[67]

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*

[62] see R. Dehousse: 'Comitology: who watches the watchmen?', *Journal of European Public Policy*, 10:5, 2003, p. 798-813, and C. Joerges and E. Vos (eds.), *EU Committees: Social Regulation, Law and Politics*, Oxford, Hart Publishing, 1999.
[63] European Commission, Standard Rules of Procedure – Council Decision 1999/468 EC, 2001/C 38/03, 6.2.2001
[64] 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.
[65] Cp. E. Vos, C. Ni Ghiollarnath and F. Wendler, *supra* note 1.
[66] EU Food Law Weekly, no. 247, 10 March 2006, p. 4.
[67] *Ibid.*

to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure[68].”

Against this background, the General Framework therefore makes the recommendation that in areas such as the authorisation of genetically modified 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. A Structured Approach to Participation

As described above, the General Framework advocates participatory processes at each of the major phases of the governance cycle. This section sets out in more detail the design of the participatory process that is proposed. This design distinguishes between ***different purposes*** and ***different levels of intensity*** of participation (illustrated in a schematic form in table 6 below). The different purposes of participation are served at different stages in the governance process. 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 scientific uncertainty and socio-political ambiguity. While the proposed governance framework intends to provide the “interface group”, i.e. the Operational Committee in one of its forms, a prominent role in decision-making on the design of participation in a concrete case (at the stages of Specific Mandating and Evaluation), the considerations which follow present the *prima facie* default for organising stakeholder and public engagement in a more or less comprehensive form depending on whether managers and appraisal actors face the key challenges of uncertainty and ambiguity.

In the literature many classification systems for stakeholder engagement and public discourse are to be found[27]. One can argue about factual issues, assessments, action requirements or about aesthetic concepts. For the purpose of classifying types of discourse in the General Framework a distinction into ***four discourse categories*** seems helpful[28]. These will be discussed in the sequence in which they were covered in the General Framework above.

7.1. Stakeholder engagement during specific mandating

The first type of discourse that can be located in the governance framework is called the ***design discourse*****.** At the stage of Specific Mandating this discourse is aimed at setting the terms of reference including the scope, focus and design of appraisal and at specifying the way (degree, concrete procedures) in which stakeholders and/or the wider public are included in the appraisal process. In each case stakeholders will contribute to this task as members of the Operational Committee (in one of its forms). Whether further, ‘external’ stakeholders should be given a voice will depend on the case at hand and be considered by the Operational Committee. If one expects a high degree of controversy it seems advisable to call all relevant commercial and civil society groups in, for example through formal hearings. Further procedures that could be used in a design discourse include open space conferences, stakeholder interviews, and public forums.

[68] Declarations of 17th July 1999 on Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 C203/1), Commission Statement (ad Article 5).

7.2. Stakeholder and public engagement during appraisal

The second type of discourse allocated in the appraisal phase is called ***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 characterising threats and alternative strategic options as part of the appraisal stage. The more complex, interdisciplinary and uncertain the given threat is, the more a communicative exchange among experts 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. stake the claim where dissent can still be founded by methodical or empirical factors.

Subject to the provisions of Specific Mandating, stakeholders may contribute to the broadening and refining of the infrastructure of ***knowledge*** and information upon which evaluation and management outcomes are based. In terms of intensity, one can distinguish three levels that correspond with the appraisal approaches:

- If the threat is complex because it is, for instance, subject to known cumulative or additive causal mechanisms, the cause-effect relationship between a threat and its potential consequences may only be established by more elaborate probabilistic techniques (which would be part of an extended risk assessment approach). Such threats that are complex in nature require *external expertise and experience in the appraisal process*. Different science camps and knowledge carriers which may come from academia, government as well as from industry or civil society should participate in the epistemic discourse designed to finding the best estimates for characterising the risk under consideration. The major goal of this discourse is to resolve cognitive conflicts. Methods such as classical Delphi and Group Delphi could serve this goal.
- When a given threat is approached by a precautionary appraisal, stakeholders could be asked to administer their specific knowledge regarding the likely consequences of the product/process/practice in question that carries a certain threat and also a range of *alternative strategic options*. The realm of knowledge that is needed to characterise uncertain threats expands the scope of traditional risk analysis and includes expertise about social benefits associated with the threat or its alternatives, about possible substitution pathways, potential for using "foregiving" 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 concern assessment, engagement with stakeholders is vital to elicit as widely as possible the *concerns* that the social groups, on the basis of their specific knowledge and information, have regarding the threat under review. The concern assessment should elicit the values, concerns, and preferred options by all relevant stakeholder groups and, if the appraisal concludes that there is a major debate even in the wider public, should conduct surveys among different groups and the public at large. 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 at the appraisal 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 strategic 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.

7.3. Stakeholder and public engagement during evaluation

The third type of discourse is called ***reflective discourse*** and is located within the evaluation phase. 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. In each case the stakeholders that form part of the Operational Committee (in one of its forms) would contribute also to this task. The idea behind the link established between the engagement mechanisms for Specific Mandating and Evaluation is that those who were involved in the drawing up of the terms of reference are best suited to assess whether the mandate has been properly fulfilled and to re-assess it on the basis of the information that the appraisal process has produced (and to advise on a revision, if required). Again, more comprehensive engagement involving more stakeholders and specific participatory procedures such as round tables, consensus conferences or citizen juries at this stage and/or the management stage will depend on the case in hand and be considered by the Operational Committee.

In terms of intensity, one can again distinguish three levels that correspond with the appraisal approaches:

- When the threat is complex but not uncertain or ambiguous, it is probably sufficient to compare potential benefits to society with the risks identified in the appraisal process. Stakeholder participation could be consultative, i.e. one could ask the most relevant stakeholder groups to suggest a tolerability/ acceptability judgement and explain the reasoning and justification behind their stated preference. The Operational Committee (in one of its forms) could then carry out this balancing act and suggest a judgement to the management side. The major goal on the first level of intensity is to make sure that the complex issues of the decision are well understood by all actors and that the major preferences and values are well represented. Since these are not contested, a consultation process seems sufficient. Methods such as a classic hearing or written comments could serve this goal.
- When the threat has gone through a precautionary appraisal, a second level of intensity is reached. At this level, it might not be sufficient to consult stakeholders but advisable to organise a more elaborate participation program. 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, risk evaluators need to include the main stakeholders and ask them to find a consensus on the extra margin of safety 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 it is opted for 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, representatives of major stakeholder groups, and scientists take part in this type

of 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. The second level reflective discourse can take different forms: round tables, open space forums, negotiated rule-making exercises, mediation or mixed advisory committees including scientists and stakeholders.

- When a given threat has gone through a concern assessment, the third level of intensity is reached. At this level, engagement with stakeholders would be directed towards a fair representation of all the conflicting values and preferences that are associated with the threat under review. 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 risk 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. 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, citizen advisory committees, and similar participatory instruments which might be accompanied by internet feedback rounds and other means of gaining public input. In addition, classic stakeholder engagement processes might accompany the public participation program.

7.4. Stakeholder and public engagement during management

The fourth type of discourse is called ***practical discourse*** and is located within the step of management. It comprises communication processes aiming 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 General Framework intends that the Operational Committee (in one of its forms) would advise on the need for and the form of stakeholder and public engagement in this discourse. 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.

In terms of intensity, one can again distinguish three levels that correspond with the appraisal approaches:

- If the threat is complex but not uncertain or ambiguous, it is probably sufficient to use classic measures such as standards or incentives to reduce the risks to tolerable and then acceptable levels. The selection of these measures should be driven by the criteria of effectiveness and efficiency. Stakeholders can assist here in pointing out the potential cost of risk reduction measures or other side effects that may be associated with the different measures. The process should be consultative as neither the science behind the appraisal results nor the values are contested.
- When the threat has gone through a precautionary appraisal, a second level of intensity could be activated. At this level, it is advisable to have stakeholders perform a pro and con balancing act 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 this second level discourse. Methods for this purpose include negotiated rule-making exercises, mediation or mixed advisory committees including scientists and stakeholders.

- When a given threat has gone through a concern assessment, the third level of intensity is reached. This level requires an inclusive strategy for participation. High ambiguity may lead to very different visions of social groups of how to address these ambiguities in form of management measures. If only the threat itself is contested but not the measure to deal with it, one can resort to level 1 or level 2 discursive action. If the ambiguities extend, however, to the selection of measures, it seems advisable to organise a broad societal discourse about the appropriateness of these measures and a debate about the best way to find a consensus or an agreement on the measures to be taken. However such a discourse may be 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. Available sets of deliberative processes on this third level 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. The framework provides a map that locates the most appropriate discourse format in each phase of the governance cycle and distinguishes between three levels of intensity for each location. Each of these discourses produces different types of outcomes that are fed into the next stage and enlighten the legitimate decision makers. While all participants should have equal rights in the deliberation processes themselves, the responsibility for the final decision should lie with the managers.

In order to sum up: The General Framework advocates that stakeholder engagement is institutionalised at the stages of Specific Mandating and Evaluation through the Operational Committee (in one of its forms) which brings together appraisal actors, managers and key stakeholders. It further advocates that there are food safety issues that require more or less intense engagement of further, ‘external’ stakeholders and the wider public. ***Procedurally***, the intensity and form of engagement (participatory tools) are specified during the processes of Specific Mandating and Evaluation by the Operational Committee where the given context and the overall socio-political climate can be taken into account. The Framework envisages, however, that there is a *prima facie* default that ***the precautionary approach and the concern-oriented approach require a higher degree of engagement***, i.e. involvement of a

diversity of stakeholders, and – as the case may be - also of representatives of the wider public, in terms of two-way dialogue and in depth-deliberation which goes beyond mere consultation.

Table 6. A structured approach to participation

Governance stage	Purpose: as a contribution to:	Style of discourse	Degree and form of engagement
Specific Mandating	Drawing up a blueprint of the appraisal process (including participatory tools)	Design	Procedurally, context dependent and decided at Specific Mandating and Evaluation *Prima facie* default: The precautionary and concern-oriented approach require more intense engage-ment, the latter approach also the involvement of the wider public
Appraisal	Gathering of knowledge and information	Epistemic	
Evaluation	Value-based balanced judgements on acceptability/ tolerability	Reflective	
Management	Selection of appropriate measures	Practical	

7.5. Legal and institutional aspects of stakeholder and public engagement

A number of provisions in the General Food Law (GFL) and other relevant pieces of legislation establish the principle of a high degree of stakeholder engagement in all parts of the policy-making process. In its preamble, the GFL states that it is necessary to „ensure that consumers, other stakeholder and trading partners have confidence in the decision-making process underpinning food law“ (Rec. 9), and its Article 9 requests that „there shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it“. Furthermore, the GFL states in its Article 42 that EFSA shall „develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties“. Further documents of reference are the White Paper on Governance, in which the Commission committed itself to opening up the policy-process, and the Commission's Communication on the „General Principles and Minimum Standards for consultation of interested parties by the Commission“[69].

Therefore, there is ample room for the realisation of the demands of the General Framework with regard to the engagement of stakeholder organisations and the wider public at least in principle. Against this background, the proposed governance framework seeks to build partly on a number of initiatives for the consultation of interested parties which have been pursued both by the Commission and EFSA, whereas some parts are introduced as fully innovative

[69] Communication by the Commission, COM 2002 704 final, Brussels, 11.12.2002.

procedures. With regard to the different steps of food safety analysis as proposed by the General Framework, these can be summarised as follows:

- With regard to ***appraisal***, the General Framework seeks to build on several initiatives which EFSA has undertaken in recent years for a closer engagement of stakeholders, both with a rather wide-ranging agenda covering the overall conduct of appraisal, and more case-specific initiatives. These include especially the conduct of colloques on the involvement of stakeholders in the conduct of risk governance (Ostende 2003 and Berlin 2004), two further scientific colloquia in 2004, a number of public consultations in the area of GMOs and feed additives and smaller meetings with interested parties on numerous occasions. After the first meeting with stakeholder organisations in Ostende, the Management Board of EFSA has established that it is desirable to give all interested parties the opportunity to bring relevant matters to the attention of the Scientific Committee or Panels. This meeting also revealed support to hold public hearings to enable stakeholder views to be put to the Scientific Committee or Panel[70]. Furthermore, the colloque established the principle that the Chairs of the respective Scientific Committee or Panel should be responsible and encouraged to experiment with the participation of civil society actors, instead of establishing a single procedure of involvement. The current framework of institutions and procedures of risk assessment therefore leaves room to undertake the participatory approaches as outlined above in an appropriate measure to the subject in question.

  A further major initiative is the creation of the EFSA Stakeholder Consultative Platform, which has been established in June 2005 by the Management Board of EFSA and reunites 24 stakeholder organisations representing industry, farmers, consumers, and broader environmentalist and public health interests[71]. Within its terms of reference, the Committee has set itself the task of alerting "EFSA to key issues of current or emerging stakeholders concern", as well as advising on the topics for consultations and the best way to organize such contributions[72]. The commitment to these goals was also confirmed at the first meeting of the Stakeholder Consultative Committee on 6 and 7 October 2005[73]. Apart from consultation in individual cases of food safety governance, a forum therefore exists for a broader input of stakeholders into the prioritisation of threats and the setting of the agenda for self-tasking activities of EFSA. Furthermore, there are also examples of stakeholder consultations about the conduct of risk assessment in specific areas, such as the Guidance Document for the Risk Assessment of GMOs, which was adopted after consultations with a broad range of stakeholder groups[74].

- With regard to ***evaluation***, no specific procedure of stakeholder engagement exists so far at the European level. The proposal for the creation of an advisory body or consultative procedure therefore aims at the establishment of an innovative mechanism of consultation.

- With regard to ***management***, a relevant recent initiative was undertaken through the creation of the Advisory Group on the Food Chain, which serves as the major forum of exchange with stakeholder organisations in the realm of risk management. Its mandate, as

[70] Note by the EFSA Management Board: EFSA Ostend Colloque: Outcome and Proposed Follow-Up Action, MB 03.12.2003 – 8.

[71] http://www.efsa.eu.int/stakeholder_stakeholder_consultative_platform/consultative_platform/catindex_en.html.

[72] EFSA Stakeholder Consultative Committee: Terms of Reference, MB 20.06.2005 - 8.

[73] EFSA document: "Key issues emerging from EFSA´s Stakeholder Consultative Platform and from the 3rd annual Colloque with stakeholders, MB 5 15.12.2005 – 5.

[74] Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, adopted 24 September 2004, final, edited version of 8 November 2004.

set out in the Decision establishing the Advisory Group, refers mostly to the discussion of concrete risk management measures (such as labelling and presentation of food products), but may be extended to include more general questions of food and feed safety and "any measure which the Commission has to take or propose". Its discussions may therefore include wider questions of risk governance only in cases in which the Commission seeks advice, therefore fitting the intention of "closing down" rather than "opening up" debates at this stage. It therefore fits the description of the 'practical discourse' as set out in the General Framework. An innovation proposed here, however, is that the discussions within this forum should take more account of the outcomes of appraisal, especially with regard to the occurrence of complex risks, scientific uncertainty and socio-political ambiguity. This, however, should be understood as a procedural recommendation and not be made subject of any institutionalised rules.

- With regard to the design of the ***overall food safety governance process***, no specific procedure exists so far for the engagement of stakeholder organisations. However, various tasks of both the Advisory Group and the Stakeholder Consultative Committee can be related to this task, especially with regard to the prioritisation of risks and the discussion of future developments of food law. Against this background, the General Framework seeks to establish an innovative element especially with regard to the step of ***specific mandating*** which is conceptualised as an inclusive procedure through the creation of a new engagement mechanism (operational committee/advisory group/consultation procedure). The General Framework does not advocate to create one overarching stakeholder forum responsible for the entire task of conducting a design discourse, but envisages several fora at different points of the food safety governance cycle where specific elements related to the design of food safety analysis can be discussed.

The different levels of stakeholder engagement as proposed by the General Framework are summarised in table 7, indicating their function within the conduct of food safety governance, their point of reference in the current system of food safety regulation, and the innovations proposed by the General Framework.

Table 7. Institutional points of reference and implications of stakeholder engagement

	Function Within the General Framework	Point of Reference in Existing Arrangements	Innovations Proposed by the Framework
Design Discourse	Selecting appropriate policies, defining priorities and organising engagement procedures and food safety governance process during ***mandating***	No specific forum so far; discussions are undertaken on two levels: – Setting of priorities and discussion of self-tasking are envisaged as a task of the EFSA Stakeholder Platform – Debating proposals about the development of food law are envisaged as task of the Advisory Group in the Food Chain	Establishment of an engagement procedure at the stage of specific mandating (operational committee/advisory operational committee/interface working group/consultation procedure)
Epistemic Discourse	Broadening and refining the infrastructure of knowledge about evaluation and management outcomes during ***appraisal***	Involvement procedures established by EFSA (Stakeholder Platform, annual colloquia, consultations on specific issues)	Distinction of three levels of discourse, according to the complexity, uncertainty, and ambiguity of a given threat

Reflective Discourse	Interpretation of factual issues, clarification of preferences and normative judgement of tolerability/acceptability during ***evaluation***	No specific forum in place so far	Establishment of an engagement procedure at the stage of evaluation (advisory operational committee/interface working group/consultation procedure)
Practical Discourse	Generation and assessment of options in the conduct of ***management***	Consultation on a range of management measures[75], as well as "any measures which the Commission has to take or propose" in food and feed safety defined as task of the Advisory Group on the Food Chain	Distinction of three levels of discourse, corresponding with the outcomes of appraisal (i.e., in relation to complex, uncertain and ambiguous threats)

8. Conclusions

As mentioned above, the present exercise has been informed by the results of a comparative analysis of the systems of food safety regulation in five European countries and at the EU level, which was undertaken as part of the fifth subproject (work package 5) of the SAFE FOODS project which deals with institutional challenges and innovations with regard to food safety governance. Against the background of a number of observations and empirical findings from these studies, the exercise undertaken here has sought to identify key challenges in the conduct of food safety regulation on the European level, and to develop a set of specific recommendations to tackle these challenges. Whereas the 'General Framework for the Precautionary and Inclusive Governance of Food Safety' as presented here is designed to fit into the existing structure of EU food safety regulation as defined by the General Food Law (GFL), it seeks to complement and modify the conduct of a number of practices within the existing institutional framework by proposing a number of innovative elements and procedures, all of which can be introduced without major institutional changes. These recommendations are made in relation to three main challenges, which are set out below:

1.) Increasing the coherence and transparency of the interaction between appraisal and management

On the institutional level of food safety governance, the primary feature of the current institutional framework of EU food safety regulation as established by the GFL is the rigorous separation between risk assessment and risk management. However, the findings of the empirical investigation undertaken by work package 5 of SAFE FOODS show that this separation is not so clear-cut in practice. Although the idea of a separation between risk assessment and risk management is very broadly accepted by risk assessors, regulators and stakeholders in principle, in practice a grey zone between both spheres is acknowledged to exist, and some actors actually speak of an *interaction between both areas* rather than a strict separation. Moreover, the findings show that risk assessors like to frame their findings in a rather prescriptive manner, and that risk managers like to have some guidance from these opinions for the decisions they have to adopt. This would mean that to some extent the

[75] The Commission Decision 2004/613 of 6 August 2004 on the creation of the Advisory Group on the Food Chain enumerates the following issues as tasks on which a consultation can take place by the Commission (Article 2): food and feed labelling and presentation, as well as matters relating to crop protection, plant protection, products and residues thereof, and conditions for the marketing of seed and propagation material, including biodiversity, and including matters pertaining to industrial property.

concept of strict separation of risk assessment and risk management laid down in the GFL is blurred.

It is therefore one of the key intentions of the framework presented here to identify mechanisms and procedures to make the two main steps of food safety analysis which are most affected by this interaction – the definition of the terms of reference of an appraisal of a given threat and the conduct of its evaluation – ***more coherent, structured and transparent***. To achieve this objective, the General Framework proposes to make these steps more explicit, and to identify procedures that address both the requirements of an integrated approach to food safety analysis, and the principles of good governance as set out in the Commission's White Paper on Governance and the General Food Law.

To achieve this objective, the General Framework makes the following specific recommendations:

- the establishment of the tasks of ***mandating*** and ***evaluation***, which were identified as the tasks most affected by the interaction between risk assessment and risk management, as a cooperative procedure that involves actors from both sides as well as stakeholders;
- the establishment of a ***cooperative procedure*** (through the establishment of an operational committee or one of the other options proposed) involving appraisal actors, managers and key stakeholders as an innovative working procedure in the step of specific mandating;
- the conceptualisation of ***governance framing*** as an overarching mechanism for the adjustment of the risk analysis functions and their interaction;
- the conceptualisation of food safety governance as an ***open, cyclical, iterative and interlinked process***, in line with the framework of risk governance currently emerging under the auspices of the International Risk Governance Council.

2.) Reconciling scientific risk assessment with wider forms of appraisal, especially the recognition of scientific uncertainty and socio-political ambiguity

Whether explicit or implicit, a key element in this broad process of food safety governance lies in 'appraisal', which informs, substantiates and justifies governance decisions, policies and wider institutional practices and commitments. As such, appraisal helps ensure coherence, inform openness and provide accountability. These are key aims of conventional risk assessment in risk analysis. However, scientific risk assessment – in the field of food safety as elsewhere – does not present the only methodological approach to appraisal and faces a number of specific challenges. These more intractable circumstances can occur in the form of 'uncertainty', under which the possible outcomes are clear, but it is difficult to quantify probabilities, through '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, and through 'ignorance' where neither probabilities nor outcomes may be fully or confidently characterised.

Where risk assessment leaves residual uncertainties unaddressed, then these must therefore be addressed by other complementary methods. It is in recognition of this challenge that the General Framework seeks to establish a basis for reconciling risk assessment and precaution in terms of their complementarity. In short, the direct implication of the precautionary principle for appraisal is to highlight the conditions under which it would be appropriate to apply what can be described as a more ***comprehensive*** approach to appraisal.

Against this background, the General Framework makes the following specific recommendations:

- The establishment of ***screening*** as a separate step of food safety governances, which is specifically targeted at the identification and characterisation of threats at a very early stage of the governance process;
- The establishment of a clearer and more systematic distinction between ***four approaches to appraisal*** in correspondence to different types of threats (specifically taking into account the handling of scientific uncertainty, and socio-political ambiguity), and a corresponding distinction of ***four different approaches to management***, which are suitable for taking into account the different possible outcomes of appraisal and evaluation;
- The establishment of stronger efforts and better mechanisms for the collection and use of ***external expertise*** and a better consideration of ***stakeholder concerns*** (through the stronger use of socio-economic analysis in food safety governance and a more intensive engagement of stakeholder groups through concern assessment and other mechanisms).

3) ***Evaluating and managing the outcomes of appraisal***

Following the step of appraisal, furthermore, a challenge of risk regulation lies in the task of summarising the results obtained from this procedure with regard to the likely consequences which might result from a given threat for human health or other relevant endpoints (environmental quality, etc.), and to organise an exchange about the appropriate value judgements with regard to these impacts. This task is therefore strongly influenced by the results of appraisal, but constitutes a separate step in referring not to the discussion of *knowledge claims* (such as in appraisal) but the deliberation about ***value claims*** in relation to judging the tolerability or acceptability of a given threat. This is the main task of evaluation, which is introduced as an intermediate step between appraisal and management into the General Framework. Due to the relevance of wider societal concerns in this step of the process, this task requires the establishment of participatory and deliberative procedures that are appropriate to identify and elaborate such concerns. At this point, the General Framework again refers to elements already present in current structures and procedures of EU food safety regulation: Whereas the idea of considering wider societal concerns in the framework of evaluation and management is reflected in the requirement of the General Food Law to weigh “policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors”, the Framework tries to specify and systematise the realisation of this requirement. To this end, it proposes the following innovative elements:

- The explicit weighing of pros and cons and trading-off of different (sometimes competing or even conflicting) preferences, interests and values in order to come to a balanced judgement on the ***tolerability or acceptability*** of a given food safety threat; this is the task to be performed at the evaluation step;
- the establishment of evaluation as a ***cooperative procedure*** (through an operational committee or the other options proposed) between appraisal actors, managers and key stakeholders, in order to ensure a better coordination between the actors responsible for the results of appraisal on the one hand, and those responsible for the choice of management measures, on the other, and civil society organisations relevant to the matter;
- the distinction of different approaches to management – prevention, precaution-based, concern-oriented, risk-based - in analogy to appraisal.

4.) Implementing principles of good governance

The European Commission has identified five normative principles that are directly applicable to the ‘Good Governance’ of food safety in this broad sense: *openness*, which entails clear,

accessible communication of the nature and rationale for decisions and other governance outcomes; *participation*, which requires governance institutions actively to engage with other social groups; *accountability*, which involves clarity over the nature of the reasoning and the allocation of responsibility in legislative and executive processes; *effectiveness* as an expression for what is needed on the basis of clear objectives; and finally, *coherence* as the degree of consistency that can be achieved by complex institutional frameworks in addressing even more complex technical, social and natural systems.

To achieve the best possible degree of realisation of these objectives, the General Framework makes the following specific recommendations:

- The establishment of a number of additional requirements for the ***transparency*** of food safety governance and the ***engagement of stakeholder organisations***, especially (but not only) with regard to tasks on the interface of appraisal and management (i.e., through the publication of the draft terms of reference during specific mandating, and the continuous involvement of stakeholders in the steps of mandating and evaluation through the cooperative procedures proposed here with different options);
- the conceptualisation of a variety of ***participatory and deliberative procedures*** to establish a more intensive and effective engagement of stakeholder organisations and the wider public into the different steps of food safety governance;
- the achievement of a higher degree of ***coherence*** and ***effectiveness*** of food safety governance through the more systematic interaction of appraisal and management, and the establishment of a differentiated approach to the handling of different types of threats through the introduction of screening and different approaches to appraisal and management.

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