Chapter 2
Overview of the General Framework

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2.1 Historical Precedents

Frameworks for food safety governance have evolved through a variety of forms since the mid-late twentieth century, and it is useful to reflect on these developments prior to introducing the General Framework adopted in this book. The simplistic *technocratic* model, wherein objective science is seen to directly inform policy making (shown in Fig. 2.1), gave way in the late twentieth century to the less naïve *decisionist* model (shown in Fig. 2.2).[1] This model, which corresponds closely to that illustrated by the National Research Council's (NRC) "Red Book" (NRC 1983), recognised that policy making required inputs other than science in order to inform decisions, and that other legitimate factors (such as those relating to socio-political and economic objectives) needed to be taken into account in addressing risks. The Red Book in 1983 established the division between the scientific aspects (*risk assessment*) and political aspects (*risk management*) within the overall process of risk analysis. This division, and several other aspects of the Red Book model, have been adopted across a wide variety of risk management fields (Omenn 2003).[2]

Chapter 1 (Sect. 1.2.1) has discussed how recent institutional and procedural reforms in European food safety governance have continued this trend. The objective of promoting "independent risk assessment" within EFSA, as legislated for under the General Food Law, has been seen as an important condition for re-building trust in the EU regulatory process, especially following the lessons from the BSE crisis. As has been discussed in Chap. 1, however, the strict separation of risk assessment and risk management laid down in the General Food Law is in practice somewhat blurred.

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[1] The distinctions between the three models outlined in Figs. 2.1–2.3 are taken from Millstone et al. (2004).

[2] It is worth bearing in mind, however, as pointed out in Chap. 1, that the view of risk assessment as a purely scientific exercise was also questioned within the "Red Book" (NRC 1983).

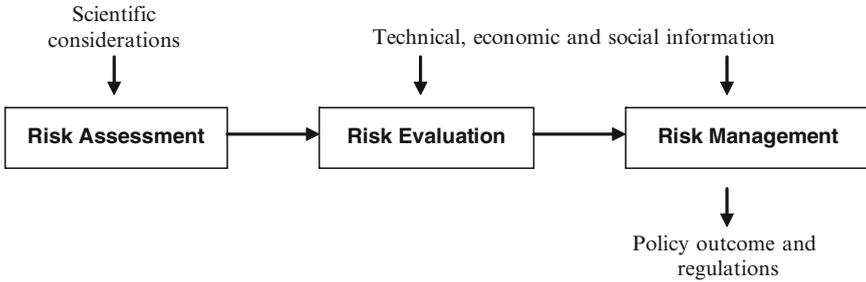**Fig. 2.1** The *technocratic* model (from Millstone et al. 2004)

Fig. 2.2 The *decisionist* model (from Millstone et al. 2004)

Since the widespread diffusion of the risk assessment/risk management distinction, careful analyses of the role of science in policy making have increasingly pointed to the importance of "framing assumptions" in informing risk assessment. These insights have questioned the simple risk assessment/management boundary by pointing to politically informed decisions around how risk assessment should proceed. Such decisions do not necessarily determine the outcome of the scientific assessment, but may often circumscribe the scope, or at least the minimum scope, of the risk assessors' deliberations. Millstone et al. (2004) have borrowed from the terminology adopted by the Codex Alimentarius Commission to characterise these decisions as relating to "risk assessment policy". According to them, such decisions concern issues such as:

– Which kinds of impacts are deemed to be within the scope of the assessment and which were outside it,
– Which kinds of evidence to include and which to discount,
– How to interpret the available evidence,
– How to respond to uncertainties, and
– How much of different kinds of evidence would be necessary or sufficient to sustain different types of judgements (Millstone et al. 2004: 1).

Millstone et al. (2004) have thus proposed a more sophisticated model for understanding policy that recognises the formulation of *social framing assumptions* based on socio-economic and political considerations. Based on research into science-related trade disputes over beef hormones, recombinant bovine growth hormones (rBST) and GM crops they argue that policy officials are increasingly articulating a co-evolutionary model that questions the over-simplicity of the decisionist model's
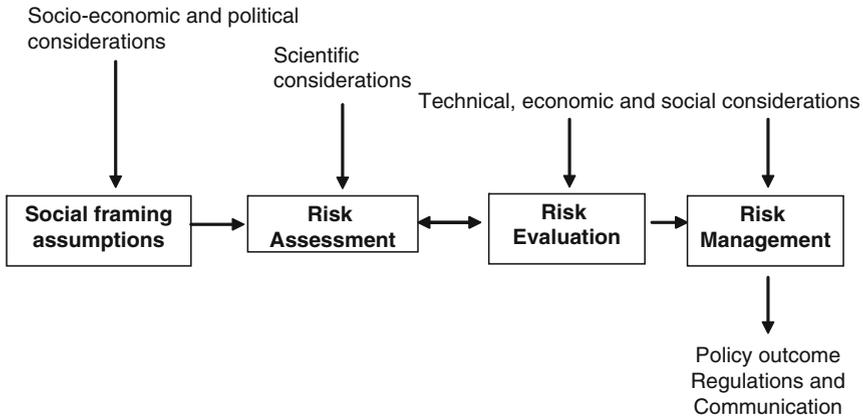
Socio-economic and political
considerations

Scientific
considerations

Technical, economic and social considerations

Social framing assumptions	Risk Assessment	Risk Evaluation	Risk Management

Policy outcome
Regulations and
Communication

Fig. 2.3 The *transparent* model (from Millstone et al. 2004)

artificial distinction of a purely scientific up-stream risk assessment phase followed by a down-stream risk management phase. The *transparent* model (Fig. 2.3) views scientific and socio-political factors as intertwined throughout the process of policy making and communication, with reciprocal links between science and policy, and recognises the input of various actors at each stage in the process. Millstone et al. qualified their use of the word "transparent" by stressing that if current practices in policy making around food risks were conducted transparently (which largely they are not), they would be seen as operating in accordance with this model. We view *framing* as an important aspect of risk governance, advocating a governance concept that aims to build transparency in decision making around European food safety by explicitly recognising the function of this step.

While communication around risks, both with stakeholders and the public, has traditionally (at least within the technocratic model) been seen as a separate process, carried out following assessment and management, the governance approach adopted by us views *communication* as well as *engagement* with stakeholders and the public, as integrated into every stage in the process. This corresponds with the relevant texts in Articles 3 (12, 9) and 42 of the General Food Law, as previously discussed in Sect. 1.2.2. Communication and engagement within the advocated governance framework will be covered in more detail in Chaps. 7 and 8.

A simplified representation of the governance framework is illustrated in Fig. 2.4 below (the complete and detailed framework is outlined in Fig. 2.8), highlighting the successive stages of framing, assessment, evaluation, and management. Each of these stages fulfils specific roles within food safety governance, engaging stakeholders in the ways most appropriate to ensure the principles of good governance outlined in Chap. 1 (as will be covered in more detail in Chap. 7). Sections 2.3 to 2.6 of this chapter will be dedicated to outlining the function and procedural aspects of each of these stages, before they are discussed in more detail in Chaps. 3–5. The section subsequent to this stage-related outline (Sect. 2.7) will provide an overview of the major aspects of the cross-cutting activities of communication and participation.
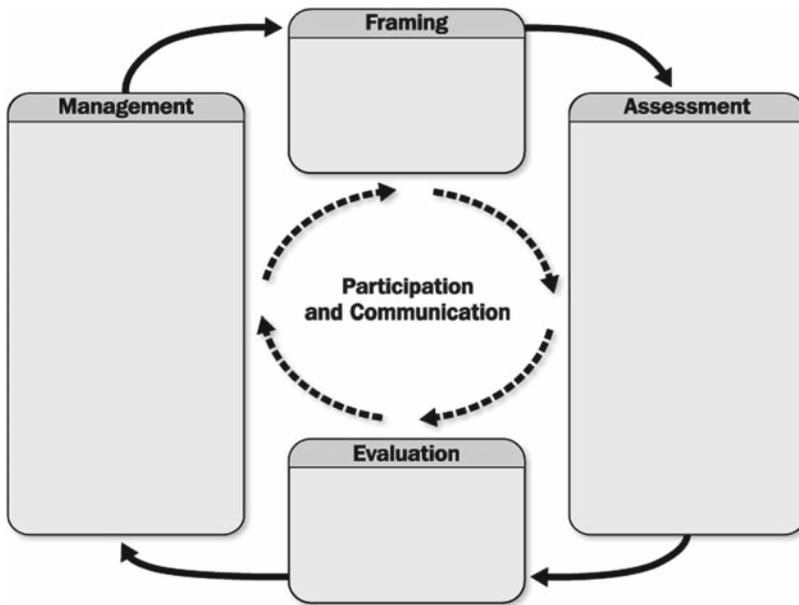
Fig. 2.4 A simplified representation of the General Framework for food safety governance

2.2 The General Framework: A Schematic Picture

In broad terms, the proposed framework includes the well-established stages of risk analysis described above, here referred to as *assessment* and *management*. Moreover, as the representation in Fig. 2.4 shows, the framework renders the established linear structure – in common with other contemporary conceptions of risk governance[3] – 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 (IRGC 2005). Furthermore, it includes two additional governance stages: firstly, *framing* which relates to risk assessment policy (in the terminology adopted by Codex Alimentarius 2005; Millstone et al. 2004), and, secondly, *evaluation* which relates to the process of assimilating and deliberating upon the outputs of the assessment phase and considering the tolerability or acceptability of a given threat more explicitly in the governance cycle. These two stages act to promote efficient and transparent mechanisms of interaction between risk assessment and risk management. All steps of the

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[3]Prime Minister's Strategy Unit/UK Cabinet Office (2002); NRC (1983); Royal Commission on Environmental Pollution (RCEP) (1998).

cycle are interlinked and involve multi-actor engagement processes that are specified in later parts of this document.

Several points are important to note at the outset, prior to the description of the advocated framework. The first is that this framework distinguishes between the *precautionary principle*, *precautionary assessment* and *prevention*. Section 1.1.2 focussed on the problem of the conditions under which the precautionary principle might be triggered by assessments of uncertainty. For the purpose of this book, and in line with the definitions given by the European Court of Justice and the General Food Law (Art. 7), we consider the precautionary principle to be a general governance principle employed in framing the overall process of framing, assessment, evaluation and management. In particular, as will be explained, precaution applies to the *screening* of food safety *threats*[4] for the properties of seriousness or uncertainty in order to determine their subsequent treatment in assessment and management. Precautionary assessment consists of a "more comprehensive" approach to assessment (as discussed in the previous chapter), adopted in cases where screening has identified a lack of scientific certainty of the kind referred to in the General Food Law. Prevention refers to the approach that is taken when a food safety threat is identified as being both serious and certain.

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

It is further important to note that the implementation of the procedural provisions envisaged by the General Framework does not necessarily require institutional changes but could be effected through the currently existing institutional arrangements. While the governance framework outlined here introduces certain innovative elements, especially at the interface between risk assessment and risk management, it generally fits into the existing legal and institutional framework of European food safety regulation as defined by the General Food Law and other, more case-specific pieces of framework legislation (such as the regulations and directives setting out the procedures for the authorisation of GMO products) as well as the current structures and practices of food safety regulation at the European level (cp. Vos & Wendler 2006b). Against this background, it is the intention of the proposed General Framework to make recommendations especially for the

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[4] For a definition of the term "*threat*" see Sect. 4.1.

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 limited institutional adaptations that will be suggested would, however, *facilitate* the working of the proposed procedural reforms. In the following chapters, we refer to two major adaptations: a *Screening Unit* and a *Panel on Concern Assessment* within EFSA as part of a proposal for the improvement of the capacities of EFSA to fulfil the functions foreseen in the General Framework, and two *food safety interface institutions* to improve the inclusiveness, transparency and coherence of the setting of terms of reference and evaluation. The latter comprise an *Internet Forum* (an online function, managed by the Commission that allows open and transparent communication between the Commission, EFSA, Member States and wider stakeholder groups) and an *Interface Committee* (which may take two different forms). These limited institutional changes are discussed in detail in Chap. 6.

2.3 An Overview of Framing: Review, Referral and Terms of Reference

Framing refers largely to what may be called the "meta-level" of food safety governance, involving the whole range of processes concerning the iterative design and development of the framework conditions of regulation in the face of new learning and feedback between the various processes, both through binding rules and non-binding conventions. By explicitly including this as an element in the General Framework, it is acknowledged that the implementation of food safety governance takes place at a number of organizational, legal and discursive levels that lie outside the detailed focus of this book (for example within Codex Alimentarius or the World Trade Organisation, WTO). Framing is made up of three activities – *review* of the technical and institutional conditions relating to food safety in its broadest sense, *referral* of specific threats to EFSA for the process of screening, and the setting of *terms of reference*, upon which EFSA will base their assessment. These are represented diagrammatically in Fig. 2.5.

2.3.1 Review

Review sets the structure of the legal and institutional design with respect to responsibilities, rights, obligations, division of labour, prescribed procedures, and oversight activities. It also includes the dynamic aspect of incorporating structural changes over time and is closely related to the underlying philosophy of food safety governance. Review thus involves activities such as the development and enactment of laws and regulations (e.g. the EU's General Food Law and its regulations on genetically modified food), the generation and use of legal principles (such as the
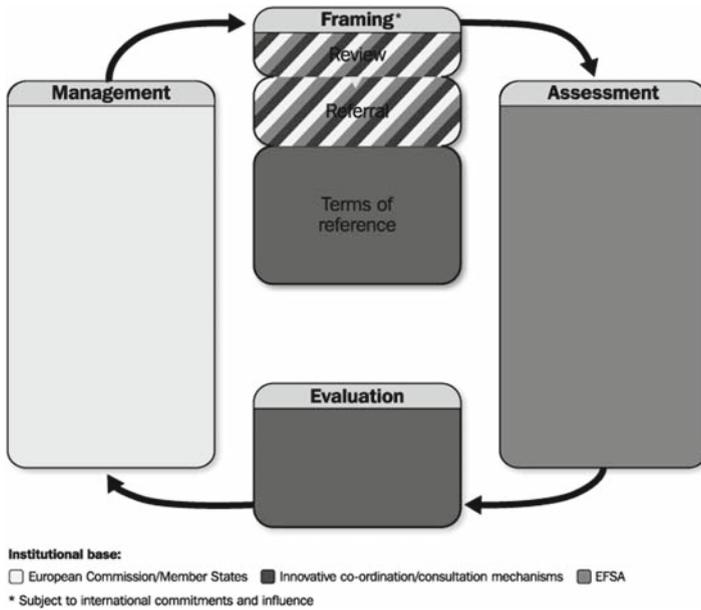
Fig. 2.5 The stages of *framing*, in relation to the rest of the governance cycle

Precautionary Principle), the determination of scientific conventions (such as statistical procedures), the establishment of predominant procedural perspectives (such as the three-step risk analysis process), and also the review of the conduct of the safety governance process as a whole. All of these activities have an impact on how the concrete design of the governance framework is spelled out and changes over time. The EU institutions are obviously highly influential in these framing activities, but also global organisations – the WTO and the Codex Alimentarius Commission, in particular – and the Member States exercise an influence.

2.3.2 Referral

In contrast to the structural conditions under which regulation takes place, the step referred to as *referral* focuses on the concrete processes and procedures by which food safety problems are identified, formulated, and initially referred to EFSA for screening and assessment. Referral is based upon the legally prescribed regulatory framework of a product, a production method, an industrial process, or a commercial practice. Once such a substance, process or outcome is identified as possibly being subject to regulatory actions on the basis of the general legislative provisions (on the basis of Art. 29, GFL), and has to be submitted to specific licensing, certification,

or testing whether all standards are met, it is forwarded to EFSA for screening. Referral may hence be performed by applying existing laws or regulations or by initiating preliminary regulatory procedures resulting possibly in modifications of existing or even the drafting of news acts by the European institutions. The process of referral will often fall to the Commission or to Member States, however the establishment of the Internet Forum and Interface Committee will also allow the opening up of referral to a wider range of stakeholders. It is understood that in cases of self-tasking by EFSA, which are prescribed by Art. 29(1) (b) of the General Food Law, this step is omitted and the food safety governance cycle starts at the stage of screening.

2.3.3   Terms of Reference

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

2.4   An Overview of Assessment

A key element in the broader process of food safety governance lies in the assessment of risks and benefits from alternative products, processes, investments, standards, regulations, and strategies. In this document, we consistently use the broad term *assessment* (as opposed to "risk assessment" or "conventional risk assessment") to refer to the process of gathering, eliciting, synthesising and deliberating over information and perspectives that are pertinent to governance decisions. Assessment therefore

subsumes, with other methods which will be described in more detail below, the conventional procedures of "risk assessment" as variously defined. It is foremost assessment that informs, substantiates and justifies governance decisions, policies and wider institutional practices and commitments. As such, assessment helps ensure coherence, inform openness and provide accountability.

2.4.1 Screening

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

In order to address the challenges outlined in Sect. 1.1 (surrounding uncertainty, ambiguity and ignorance), assessment within our framework includes three novel approaches in addition to the conventional risk assessment procedure. These approaches address threats which are certainly and unambiguously serious calling for a *presumption of prevention*, threats subject to scientific uncertainty calling for a *precautionary assessment*, and threats subject to socio-political ambiguity calling for a *concern assessment* (in which systematic knowledge is collected about risk perceptions by individuals and groups, socio-economic impacts and other informa- tion related to the threat source). We propose that the process of screening threats to identify which of these (or conventional risk assessment) is most appropriate should be carried out within EFSA, by individuals who have expertise not only in technical risk assessment but also in issues relating to public concerns (usually associated with the social sciences).

Based on the screening process and drawing upon stakeholder perspectives sought through the Internet Forum and Interface Committee, the terms of reference will be drafted (as mentioned above). These will include a detailed description of

which approach to assessment should be followed by EFSA in order to address various aspects of the threat in question.

2.4.2 The Four Approaches to Assessment

The four different approaches to assessment are shown in Fig. 2.6 below. Each assessment approach is designed to gather the information necessary for making adequate and prudent governance decisions in different contexts. Where a given threat displays a number of different attributes, these different aspects may be allocated to parallel treatment by different types of assessment.

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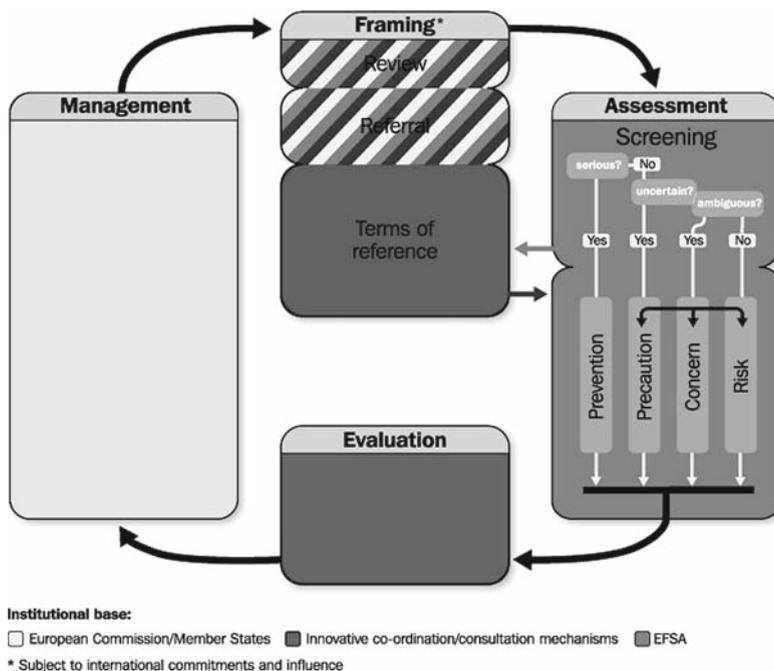

Fig. 2.6 The four approaches to *assessment*, and their relationship to *screening* and the other stages in the governance cycle

to evaluation and management considerations around the complexity and scale of the threat in question.

If screening is unable to allocate threats to straightforward preventive measures or to risk-based assessment, then more comprehensive assessment procedures are recommended. If a lack of scientific certainty has been identified in screening (illustrated by the question "uncertain?" in the same diagram), then the subsequent approach to assessment is *precautionary*. If socio-political ambiguity (illustrated by the question "ambiguous?") has been identified, then a process of *concern assessment* is adopted in subsequent assessment. Both conditions (uncertainty and ambiguity) can apply at the same time and for the same assessment candidate. In this case both approaches, i.e. the precautionary assessment approach and the concern assessment approach, need to be *combined*. Each of the four assessment approaches are discussed in more detail in Chap. 4.

2.5 An Overview of Evaluation

The step of *evaluation* which follows after the assessment stage is undertaken on the grounds of provisions of the General Food Law (Art. 3 (12)) requiring risk managers to consider "other legitimate factors" (i.e. wider societal and economic concerns) in addition to the results of the scientific risk assessment. Evaluation serves two main purposes:

– First, to reach a balanced, value-based judgment on the tolerability or acceptability of a given food safety threat, or to perform a trade-off analysis of a set of functional equivalents (of the product, process, or practice which is the threat source under consideration);
– Second, to initiate (if deemed necessary) a management process and make preliminary suggestions for the most suitable management approach.

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

The tolerability or acceptability judgement is informed by the results of the assessment process but it is not determined by it. Other important considerations on wider social and economic factors may be included transparently in the balancing process. The main elements of this process are:

– The summarizing of the results of the assessment process in terms of the likely consequences for food safety or other relevant endpoints (such as environmental quality, nutrition, etc.) if no management measures were taken;

– Deliberation over these results in consideration of wider social and economic factors (e.g. benefits, societal needs, quality of life factors, sustainability, distribution of risks and benefits, social mobilization and conflict potential), legal requirements and policy imperatives;
– Weighing pros and cons and trading-off different (sometimes competing or even conflicting) preferences, interests, and values.

While assessment deals with knowledge claims (around what are the causes, and what are the effects), evaluation deals with *value claims* (around what is good, acceptable, and tolerable). Defined as a tolerability or 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" (Art. 3(12)). While the General Food Law determines this task as an element of risk management alongside "if need be, selecting appropriate prevention and control options" (Art. 3(12)), the General Framework, as it is presented here, refers to it as a *separate step* in the overall safety governance process *mediating* between the two stages of assessment and management.[5] Ideally, this step should, like the setting of terms of reference, involve both assessment actors and managers in conjunction with representatives of key stakeholder groups. This is best accomplished through the application of the Internet Forum in order to open up evaluation to the widest possible values base, and the Interface Committee to enable direct co-ordination between managers, assessors, and stakeholders.

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

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[5] 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 (Ravetz 1999: 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 vs. values involves different routes of legitimisation and validation. This is one of the main reasons for making an analytical distinction between assessment, evaluation and management.

given in the General Food Law (Art. 3(12)) and is, therefore, conducted by both the Commission and the Member States. Based on the output of the evaluation exercise, it is at this point that *decisions* on management measures are taken. This requires the consideration of policy choices among contending possible management measures. Such measures may include numerical limits for concentrations of substances in food items, standards for production and consumption, performance control, food preparation guidelines, monetary incentives, labels, and others. In some ways, this is analogous to the process already undertaken in assessment and evaluation. Here, however, the information is based on the positive and negative implications of a series of different regulatory interventions and not of particular threats. Depending on the context, the relevant information might best be gathered through assessment, by reference to the most relevant measures. In other cases, it will be necessary to undertake this information-gathering process at the management stage in addition – and as a complement – to the evidence gathered during assessment.

Either way, the series of steps involved in the decision-making process around management measures is as follows (cp. IRGC 2005: 40–48):

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

As in the assessment stage, there are various approaches to management which may be more or less appropriate in dealing with decision-making around specific measures. These broadly follow similar themes to the assessment approaches outlined in Sect. 2.4 above, but the assessment approach for a specific threat that was identified in screening does not automatically determine the most appropriate management approach. The process of evaluation, especially through eliciting value preferences around tolerability and acceptability from stakeholders, will play a large part in determining the appropriate management approach. The finer details of this process are discussed in Chap. 5 on evaluation and management.

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

– Implementation of measures, and
– The monitoring of how these measures perform in practice.

Note that monitoring the outputs and effectiveness of management may lead to problems to be reframed, thus completing the food safety governance cycle. The stage of management, along with its institutional base (primarily the European Commission and Member States) and the relationship to other stages in the governance process, is illustrated in Fig. 2.7 below.
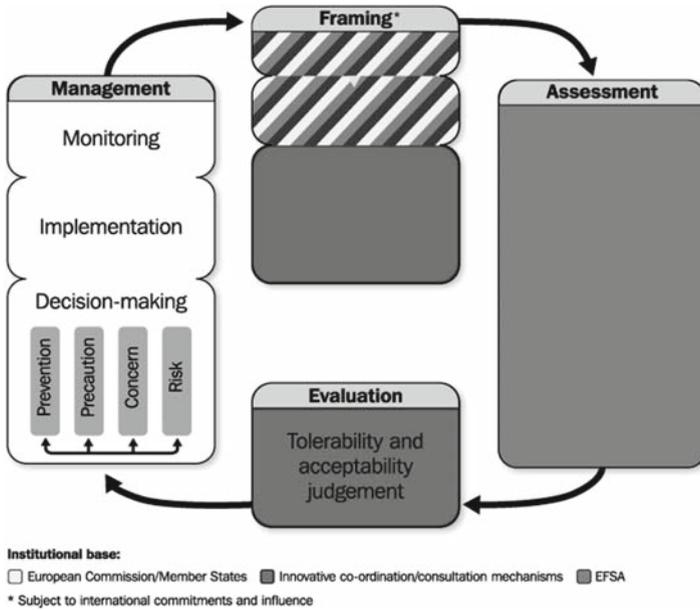
Fig. 2.7 The primary features of *management*, and their relationship with the other stages in the governance cycle

2.7 An Overview of Communication and Participation

Effective *communication* and *public involvement* are at the core of any successful activity to assess and manage food safety threats. Both tasks are placed in the middle of the food safety governance cycle (see Fig. 2.4). They constitute *integral parts* of all four stages: framing, assessment, evaluation, and management. In particular, the General Framework advocates to replace the traditional paradigm of collecting data, decision making and defending what has been decided by a new concept of an open and transparent governance process, enriched by multiple opportunities for stakeholders to feed back their knowledge and values, and a constant activity to communicate information on process as well as results to a wider public (IRGC 2005: 54).

The field of risk communication initially developed as a means of investigating how expert assessments could be communicated to the public best, so that the tension between public perceptions and expert judgement could be bridged. In the course of time, this original objective of educating the public about risks has been modified and even reversed. The professional risk community has realised that most members of the public refused to become "educated" by the experts, but rather insisted on alternative positions and risk management practices being selected by the professional community in their attempt to reduce and manage food safety threats (Leiss 1996: 85ff; Plough & Krimsky 1987).

The General Framework provides for communication about food safety threats throughout the governance cycle, from the framing of the issue to the monitoring

of the management impacts. The precise form of communication needs to reflect the nature of the threats under consideration, their context and whether they arouse, or could arouse, societal concern. Communication, as advocated by the General Framework, is a means of ensuring that:

- Those who are central to framing, assessment, evaluation, or management understand what is happening, how they are to be involved, and, where appropriate, what their responsibilities are (internal communication).
- Others outside the immediate processes of framing, assessment, evaluation, or management are informed and engaged (external communication).

Although food safety communication implies a stronger role for the risk professionals to provide information to the public rather than vice versa, the governance framework, as it is proposed here, regards it as a *mutual learning process* in line with the requirements of good governance including transparency, accountability, and legitimacy. Concerns, perceptions and experiential knowledge of the targeted audience(s) should thus guide assessors and managers in their selection of topics and subjects: it is not the task of the communicators to decide what people *need* to know, but to respond to questions of what people *want* to know.[6] Communication on food safety threats requires professional performance both by food safety and communication experts. Scientists, communication specialists, and regulators are encouraged to take a much more prominent role in food safety communication, because effective communication can make a strong contribution to the success of comprehensive and responsible food safety governance.

In addition to the need for food safety communication at all stages, the General Framework provides input on all governance levels from a diversity of social groups. It promotes the idea of *inclusive governance* understood as the obligation to ensure the early and meaningful involvement of all stakeholders and, in particular, civil society (Jasanoff 1993: 123–129). Inclusive governance is based on the assumption that affected and interested parties have something to contribute to the governance process and that mutual communication and exchange of ideas, assessments and evaluations improve the final decisions, rather than impede the decision-making process or compromise the quality of scientific input and the legitimacy of legal requirements.[7] As the term governance implies, analysing and managing food safety threats cannot be confined to private companies and regulatory agencies. It rather involves a wider array of actors: political decision makers, scientists, economic players, and civil society actors.

There are two major provisions envisioned in the proposed governance framework to further improve the interaction of these actors. The first of these are the *food safety interface institutions*, the Internet Forum and the Interface Committee. They present permanent deliberation and consultation platforms to facilitate the coordination between assessment and management and to address the concerns of corporate and civil society actors throughout the governance process. The Internet Forum, our basic

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[6] For an explanation of the "right-to-know" concept, see Baram (1984).

[7] Similar arguments in Webler (1999) and Renn (2004).

recommendation for creating a food safety interface structure, should act as a site for the dissemination of information associated with every stage in the governance process in order to promote the governance principles of openness and accountability. It should be designed in such a way as to facilitate proportionate deliberation between the core institutions of food safety governance with stakeholders and citizens. The modalities for ensuring effective, but proportionate, deliberation through this route are outlined in Chap. 6. It should provide an outlet for framing (e.g. referring to the appropriate European and international frameworks at issue). It can act as a dissemination and deliberation mode for the outputs of EFSA's engagement activities, particularly the Stakeholder Consultative Platform (formalized membership), annual colloquia (by invite/expressions of interest), technical meetings (by invite/expressions of interest), and science conferences and scientific colloquia (by invite). In addition, many of EFSA's current practices for public consultations and requests for data should be made more easily available to risk managers and stakeholders through hosting on the Internet Forum. These include various activities linked to assessment, such as EFSA's Pesticide Risk Assessment Peer Review (PRAPeR, 40-day consultation for new pesticide draft assessment reports), public consultations on genetically modified organisms (GMOs), additives, products and substances in animal feed, biological hazards, science committee consultations, requests for data on scientific issues, corporate events, and "Porte Aperte" (engagement with the public in the Parma region).[8] The forum would also act as a site where the Commission's consultations and decisions could be relayed transparently to the European public, allowing accountable demonstration of effectiveness and coherence in decision making. We propose to combine the Internet Forum with an Interface Committee (which is discussed in two variants with different degrees of formalisation and scope of mandate in Chap. 6). This Committee would bear responsibilities for the two interface activities of setting the terms of reference and evaluation, and composed of representatives of the Commission, EFSA and key stakeholder groups.

Specific food safety cases may require that participation through the Internet Forum and the Interface Committee is complemented by additional participatory instruments. As a second major provision to improve further the involvement of corporate and civil society groups into the governance process, the General Framework offers a *default assumption* that under the conditions of high levels of scientific uncertainty and/or socio-political ambiguity, the use of further participatory processes is required. Chapter 7 provides an outline of the implications for participation of such challenging cases in relation to each of the four governance stages.

2.8   Summary

As has been stressed throughout the present part of this book, it is important that food safety governance can adapt to the identification of new uncertainties or ambiguities within an open, iterative governance cycle. In certain cases, this may require

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[8] http://www.efsa.europa.eu/en/stakeholders_efsa/participating.html. Accessed 10 April 2007.
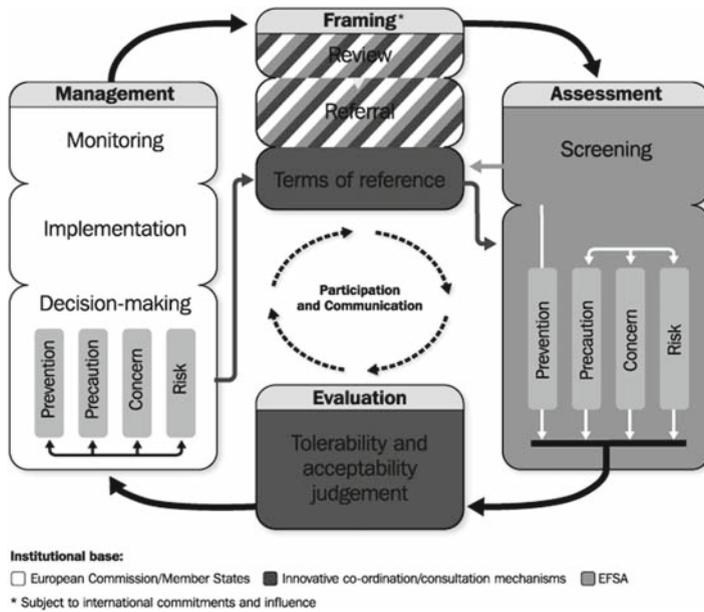
Fig. 2.8 A detailed representation of the General Framework, including the institutional allocation of tasks

feedback from later stages of the governance cycle to earlier stages, so that improvements can be made and problems averted. Specific examples of where this may be appropriate include:

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

Figure 2.8 illustrates the entire General Framework for food safety governance that has been presented above, including the various components of framing, assessment, evaluation and management, the cross-cutting activities of food safety communication and public involvement, the full set of possible interactions and feedback between all of these stages and the institutional bases to which the various tasks are allocated. The following chapters will discuss each of these stages, the cross-cutting activities, and the institutional implications in more detail.

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