

# Food safety risk analysis

A guide for national  
food safety authorities

FAO  
FOOD AND  
NUTRITION  
PAPER

87



World Health  
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Food and Agriculture  
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## Acronyms and abbreviations

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
ALOP	Appropriate Level of Protection
ALARA	As Low As Reasonably Achievable
BSE	Bovine Spongiform Encephalopathy
CAC	Codex Alimentarius Commission
CCFAC	Codex Committee on Food Additives and Contaminants
CCFH	Codex Committee on Food Hygiene
CCMH	Codex Committee on Meat Hygiene
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
GEMS	Global Environment Monitoring System
GAP	Good Agricultural Practice
GHP	Good Hygienic Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Point
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MC	Microbiological Criteria
ML	Maximum Level
MRL	Maximum Residue Level
NOAEL	No Observed Adverse Effect Level
OIE	<i>Office internationale des épizooties</i> (World Organisation for Animal Health)
PTWI	Provisional Tolerable Weekly Intake
RfD	Reference Dose
RMF	Risk Management Framework
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
TDI	Tolerable Daily Intake
WHO	World Health Organization
WTO	World Trade Organization

## Foreword

Ensuring food safety to protect public health and promote economic development remains a significant challenge in both developing and developed countries. Considerable progress to strengthen food safety systems has been achieved in many countries, highlighting the opportunities to reduce and prevent food-borne disease. However, unacceptable rates of food-borne illness still remain and new hazards continue to enter the food supply.

Food-borne risks to human health can arise from hazards that are biological, chemical or physical in nature. A key discipline for further reducing food-borne illness and strengthening food safety systems is risk analysis. During the last several decades, risk assessment, risk management and risk communication have been formalized and incorporated into the specific discipline known as food safety risk analysis. This approach has now gained wide acceptance as the preferred way to assess possible links between hazards in the food chain and actual risks to human health, and takes into account a wide range of inputs to decision-making on appropriate control measures. When used to establish food standards and other food control measures, risk analysis fosters comprehensive scientific evaluation, wide stakeholder participation, transparency of process, consistent treatment of different hazards and systematic decision-making by risk managers. Application of harmonized risk analysis principles and methodologies in different countries also facilitates trade in foods.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have played a leading role in the development of food safety risk analysis. In 1991, the Joint FAO/WHO Conference on Food Standards, Chemicals in Food, and Food Trade recommended that the Codex Alimentarius Commission (CAC) incorporate risk assessment principles into its decision-making process. The 19<sup>th</sup> and 20<sup>th</sup> sessions of the CAC, in 1991 and 1993, endorsed the recommendation of the Conference to base its food safety decisions and standards on risk assessment and encouraged the relevant Codex Committees to harmonize their standard-setting methodologies.

At the request of the CAC, FAO and WHO have convened a number of expert consultations to provide advice to Codex and member countries on practical approaches for the application of risk analysis to food standard issues. These have included expert meetings on risk assessment (1995), risk management (1997) and risk communication (1998). The initial consultations focused on the overall risk analysis paradigm, producing a number of definitions and broad principles for risk assessment, risk management and risk communication.<sup>1</sup> Subsequent consultations have addressed in greater detail some specific aspects of the risk analysis paradigm.<sup>2</sup>

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<sup>1</sup> For information, see: i) FAO/WHO. 1995. *Application of Risk Analysis to Food Standards Issues*. Report of the Joint FAO/WHO Expert Consultation. Geneva, 13-17 March 1995 (available at: [ftp://ftp.fao.org/es/esn/food/Risk\\_Analysis.pdf](ftp://ftp.fao.org/es/esn/food/Risk_Analysis.pdf)); ii) FAO/WHO. 1997. *Risk Management and Food Safety*. FAO Food and Nutrition Paper No. 65 (available at: <ftp://ftp.fao.org/docrep/fao/w4982e/w4982e00.pdf>); iii) FAO/WHO. 1998. *The application of risk communication to food standards and safety matters*. FAO Food and Nutrition Paper No. 70. (available at: <http://www.fao.org/docrep/005/x1271e/x1271e00.htm>).

<sup>2</sup> For information, see: i) FAO/WHO. 1999. *Risk Assessment of Microbiological Hazards in Foods*. Report of the Joint FAO/WHO Expert Consultation. Geneva, Switzerland, 15-19 March 1999 (available at: [http://www.who.int/foodsafety/publications/micro/en/march1999\\_en.pdf](http://www.who.int/foodsafety/publications/micro/en/march1999_en.pdf)); ii) FAO/WHO. 2000. *The interaction between assessors and managers of microbiological hazards in food*. Report of a WHO Expert Consultation in collaboration with the Federal Ministry of Health, Germany and FAO. Kiel, Germany, 21-23 March 2000 (available at: <ftp://ftp.fao.org/docrep/nonfao/ae586e/ae586e00.pdf>); iii) FAO/WHO. 2002. *Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards*,

The CAC adopted in 2003 the working principles for risk analysis for application in the framework of the Codex Alimentarius,<sup>3</sup> developed by the Codex Committee on General Principles (CCGP). The CAC asked relevant Codex committees to develop specific principles and guidelines on risk analysis in their specific areas. In this perspective, CCGP has initiated work to develop general risk analysis principles as guidance for national governments. Several subsidiary bodies of the Commission have developed specific guidance on risk analysis or are in the process of doing so, especially as regards food additives and (chemical) contaminants, food hygiene (microbial contaminants), pesticide residues, residues of veterinary drugs, and biotechnology.

As part of the body of work being carried out by FAO/WHO and the CAC, considerable progress has been made in developing a systematic framework for applying principles and guidelines for food safety risk analysis. Governments have moved quickly to incorporate much of this international work in national legislation and further developments in food safety risk analysis at the national level are ongoing.

FAO and WHO have developed this Guide to improve food safety regulators' understanding and use of risk analysis in national food safety frameworks. The primary audience is food safety officials at the national government level. The Guide provides essential background information, guidance and practical examples of ways to apply food safety risk analysis. It presents internationally agreed principles, a generic framework for application of the different components of risk analysis, and wide-ranging examples rather than prescriptive instructions on how to implement risk analysis. It complements and is aligned with other documents that have been, or are being, produced by FAO/WHO and the CAC, and can be revised and improved as new experiences and knowledge in the field of risk analysis become available.

Following an initial chapter that explains how risk analysis offers an essential framework for effective food safety management, the Guide introduces the three basic components of risk analysis in some detail. Principles and mechanisms for risk management, risk assessment and risk communication are explained in succeeding chapters. The emphasis throughout is on what food safety officials need to know in order to oversee and manage the risk analysis process. Current information and knowledge, including materials developed by FAO and WHO, are incorporated or referenced throughout the Guide as applicable. Case studies that provide practical examples of how risk analysis has been applied for methylmercury in fish and *Listeria monocytogenes* in ready-to-eat foods are attached as annexes.

The Guide is the first part of a two-part set, all of which is available on CD-ROM. The second part comprises a number of educational elements for capacity building, including a slide presentation for use in training, a collection of up-to-date FAO and WHO tools and training materials related to food safety risk analysis, and case studies of risk analysis for aspartame, *Vibrio parahaemolyticus* and fumonisins.

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*guidelines and related texts*. Report of a Joint FAO/WHO Consultation. Kiel, Germany, 18-22 March 2002 (available at: <ftp://ftp.fao.org/docrep/fao/006/y4302e/y4302e00.pdf>); and iv) FAO/WHO. 2006. *The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to improve food safety*. Report of a Joint FAO/WHO Expert Meeting in collaboration with the Federal Ministry of Food, Agriculture and Consumer Protection, Germany. Kiel, Germany, 3-7 April 2006 (available at: [http://www.fao.org/ag/agn/jemra/riskmanagement\\_en.stm](http://www.fao.org/ag/agn/jemra/riskmanagement_en.stm)).

<sup>3</sup> FAO/WHO. 2005. Working principles for risk analysis for application in the framework of the Codex Alimentarius. In *Codex Alimentarius Commission. Procedural Manual*. 15<sup>th</sup> Edition, pp 101-107 (available at: [ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual\\_15e.pdf](ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf)).

# 1. An Introduction to Risk Analysis

**Chapter summary:** Food safety is a fundamental public health concern, and achieving a safe food supply poses major challenges for national food safety officials. Changing global patterns of food production, international trade, technology, public expectations for health protection and many other factors have created an increasingly demanding environment in which food safety systems operate. An array of food-borne hazards, both familiar and new, pose risks to health and obstacles to international trade in foods. These risks must be assessed and managed to meet growing and increasingly complex sets of national objectives. Risk analysis, a systematic, disciplined approach for making food safety decisions developed primarily in the last two decades, includes three major components: risk management, risk assessment and risk communication. Risk analysis is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems. The use of risk analysis can promote ongoing improvements in public health and provide a basis for expanding international trade in foods.

## 1.1. Background

Food-borne disease remains a real and formidable problem in both developed and developing countries, causing great human suffering and significant economic losses. Up to one third of the population of developed countries may be affected by food-borne diseases each year, and the problem is likely to be even more widespread in developing countries, where food and water-borne diarrhoeal diseases kill an estimated 2.2 million people each year, most of them children. Chemical hazards in foods occasionally cause acute illnesses, and some food additives, residues of pesticides and veterinary drugs, and environmental contaminants may pose risks of long-term adverse effects on public health. New technologies such as genetic modification of agricultural crops have raised additional food safety concerns that require assessment and management, and proper risk communication.

### *1.1.1. The changing food safety environment*

Better scientific knowledge of the hazards that cause food-borne disease and the risks these hazards pose to consumers, combined with the capacity to take appropriate interventions, should enable governments and industry to significantly reduce food-related risks. However, the links between hazards in foods and illness in humans have sometimes been difficult to establish, let alone quantify and, where they have been identified, interventions have not always been technically, economically or administratively feasible. Serious challenges therefore continue to face food safety regulators in many countries.

In addition to improving public health, effective food safety systems maintain consumer confidence in the food supply and provide a sound regulatory foundation for domestic and international trade in food, which supports economic development. International trade agreements developed under the World Trade Organization (WTO) emphasize the need for regulations governing international trade in foods to be based on science and risk assessment. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) permits countries to take legitimate measures to protect the life and health of consumers provided such measures can be justified scientifically and do not unnecessarily impede trade.

Article 5 of the SPS Agreement directs countries to ensure that their sanitary and phytosanitary measures are based on an assessment of the risk to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organizations and bodies. Article 9 of the SPS Agreement defines the obligation of developed countries to provide technical assistance to less developed countries with the goal of improving their food safety systems.

### ***1.1.2. Evolving food safety systems***

Responsibility for food safety is shared by everyone involved with food from production to consumption, including growers, processors, regulators, distributors, retailers and consumers. However, governments have to provide an enabling institutional and regulatory environment for food control. Most countries have a food control system in place that incorporates a number of essential elements (see Box 1.1); these elements are in place to varying degrees in different countries. FAO and WHO have been working for several decades, in collaboration with national governments, scientific institutions, the food industry, consumers and others, to improve the safety and quality of food. More information about these activities, as well as recently convened FAO/WHO global fora of food safety regulators that have focused on mechanisms and strategies for building effective national food safety systems, including the use of risk analysis, is available on the Internet.<sup>4</sup>

#### **Box 1.1. Elements of food safety systems at the national level**

- Food laws, policies, regulations and standards.
- Institutions with clearly defined responsibilities for food control management and public health.
- Scientific capacity.
- Integrated management approach.
- Inspection and certification.
- Diagnostic and analytical laboratories.
- Standard-setting.
- Infrastructure and equipment.
- Monitoring structures and capabilities.
- Surveillance of human health problems related to food intake.
- Capacity for emergency response.
- Training.
- Public information, education and communication.

Regardless of the level of sophistication of national food control systems, a wide range of factors are placing generally increasing demands on national authorities responsible for food safety. Box 1.2 and Figure 1.1 describe rapidly changing dimensions of the global food system. Some of these changing factors contribute directly to increasing food-borne risks to human health, while others demand more rigorous evaluation and sometimes modification of existing food safety standards and approaches.

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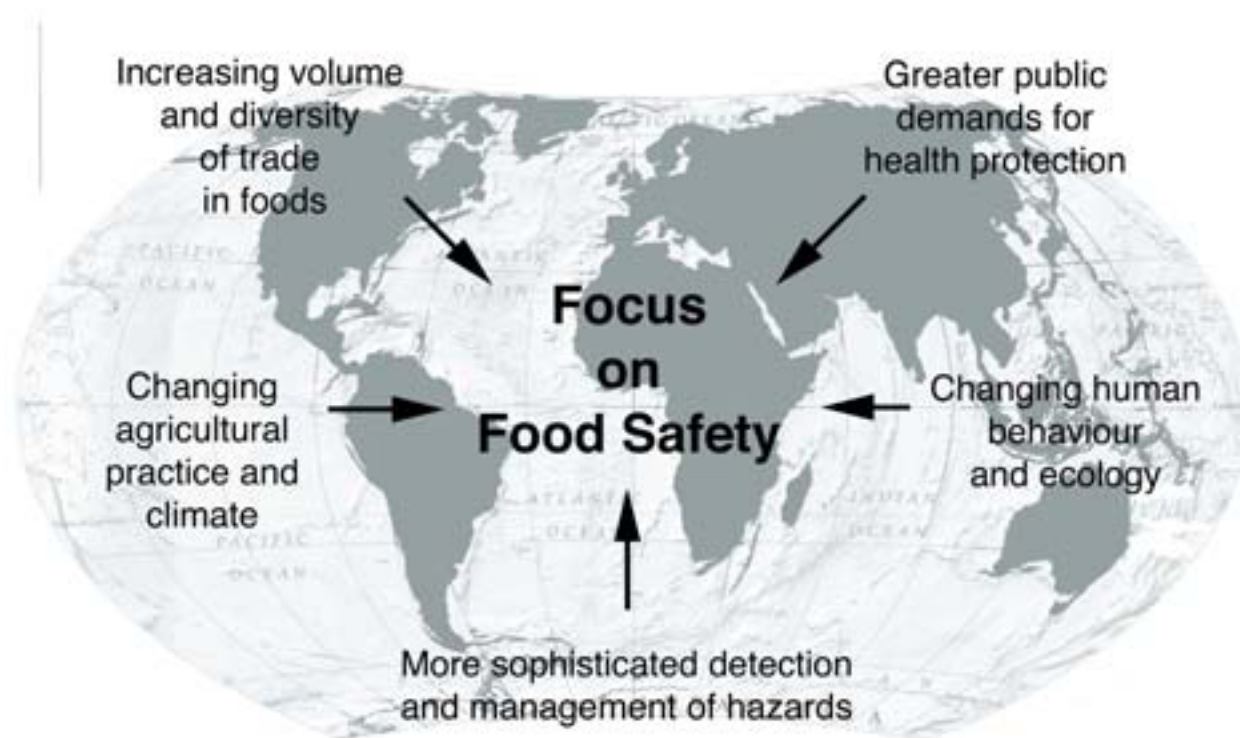
<sup>4</sup> Information on FAO/WHO food safety activities is available at [http://www.fao.org/ag/agn/index\\_en.stm#](http://www.fao.org/ag/agn/index_en.stm#) and <http://www.who.int/foodsafety/en/>. The first Global Forum of Food Safety Regulators was convened in Marrakesh, Morocco in January 2002. The second Global Forum took place in Bangkok, Thailand in 2004. The proceedings, conference room documents and other information related to these global fora are available at <http://www.foodsafetyforum.org/index.asp>.



### **Box 1.2. Changing global factors that affect national food safety systems**

- Increasing volume of international trade.
- Expanding international and regional bodies and resulting legal obligations.
- Increasing complexity of food types and geographical sources.
- Intensification and industrialization of agriculture and animal production.
- Increasing travel and tourism.
- Changing food handling patterns.
- Changing dietary patterns and food preparation preferences.
- New food processing methods.
- New food and agricultural technologies.
- Increasing resistance of bacteria to antibiotics.
- Changing human/animal interactions with potential for disease transmission.

**Figure 1.1. Factors driving changes in food safety systems**



### **1.1.3. An abundant array of hazards**

A food-borne hazard is defined by Codex as “a biological, chemical or physical agent in, or condition of, food, with the potential to cause an adverse health effect.” Box 1.3 lists a variety of food-borne hazards of current concern. Many of these hazards have long been recognized and addressed by food safety controls, however, some of the changing global conditions described in Box 1.2 may have exacerbated the problems they pose. A number of new and emerging hazards are also of growing concern. Some previously unidentified hazards have gained worldwide importance, such as the mutant protein (technically called a prion) that

causes “mad cow disease” or bovine spongiform encephalitis (BSE). Some familiar hazards are regaining prominence, for example acrylamide residues in baked and fried starchy foods, methylmercury in fish, and *Campylobacter* in poultry. Some new food hazards arise indirectly from other trends, such as the increasing presence in foods of bacteria that are resistant to antimicrobial agents, while certain food production methods, such as the use of antimicrobials as animal feed additives, may in turn contribute to those broader trends.

**Box 1.3. Examples of hazards that may occur in foods**

<b>Biological hazards</b>	<b>Chemical hazards</b>	<b>Physical hazards</b>
<ul style="list-style-type: none"> <li>• Infectious bacteria</li> <li>• Toxin-producing organisms</li> <li>• Moulds</li> <li>• Parasites</li> <li>• Viruses</li> <li>• Prions</li> </ul>	<ul style="list-style-type: none"> <li>• Naturally occurring toxins</li> <li>• Food additives</li> <li>• Pesticide residues</li> <li>• Veterinary drug residues</li> <li>• Environmental contaminants</li> <li>• Chemical contaminants from packaging</li> <li>• Allergens</li> </ul>	<ul style="list-style-type: none"> <li>• Metal, machine filings</li> <li>• Glass</li> <li>• Jewellery</li> <li>• Stones</li> <li>• Bone chips</li> </ul>

There are important differences among hazards of different classes, which require somewhat different approaches to risk analysis. Certain chemical hazards, especially those that can be tightly controlled in the food supply such as food additives, residues of crop pesticides and veterinary drugs, have historically been subject to a “notional zero-risk approach” (discussed in more detail in Chapters 2 and 3). In contrast, microbiological hazards are usually living organisms that can reproduce in foods and are ubiquitous in the environment; they require a different risk assessment approach and management strategies that seek to keep risks within tolerable limits, rather than to eliminate them entirely. These differences are discussed in greater depth in Chapter 2.

**1.1.4 Increasing demands on national food safety authorities**

Today, governments and other parties involved in food control are developing new methods and applying and enhancing a wide variety of existing administrative systems, infrastructures and approaches to ensuring food safety. While the main focus of these efforts remains improving food safety, national food control programmes must increasingly take other goals into account as well (see Box 1.4). For example, many national official bodies, sometimes called “Competent Authorities”, now have to review the cost-effectiveness of their structure and operations so that they do not impose unjustified compliance costs on industry. Also, such authorities must keep in mind the fair trading requirements of international agreements and establish mechanisms to ensure that domestic and import standards are consistent in intent and application.

#### **Box 1.4. Food control principles that increase demands on national authorities**

- Increasing reliance on science as the basic principle governing development of food safety standards.
- Shifting the primary responsibility for food safety to industry.
- Adopting a “production-to-consumption” approach to food control.
- Giving industry more flexibility in implementation of controls.
- Ensuring the cost-effectiveness and efficiency of government control functions.
- Increasing the role of consumers in decision making.
- Recognizing the need for expanded food monitoring.
- Epidemiologically-based food source attribution.
- Adopting a more “integrated” approach to working with related sectors (such as animal and plant health).
- Adopting risk analysis as an essential discipline to improve food safety.

## **1.2. Risk analysis**

Risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied. It can be used to support and improve the development of standards, as well as to address food safety issues that result from emerging hazards or breakdowns in food control systems. It provides food safety regulators with the information and evidence they need for effective decision-making, contributing to better food safety outcomes and improvements in public health. Regardless of the institutional context, the discipline of risk analysis offers a tool that all food safety authorities can use to make significant gains in food safety.

For instance, risk analysis can be used to obtain information and evidence on the level of risk of a certain contaminant in the food supply helping governments to decide which, if any, actions should be taken in response (e.g. setting or revising a maximum limit for that contaminant, increasing testing frequency, review of labelling requirements, provision of advice to a specific population subgroup, issuing a product recall and/or a ban on imports of the product in question). Furthermore, the process of conducting a risk analysis enables authorities to identify the various points of control along the food chain at which measures could be applied, to weigh up the costs and benefits of these different options, and to determine the most effective one(s). As such, it offers a framework to consider the likely impact of the possible measures (including on particular groups such as a food industry subsector) and contributes towards enhanced utilization of public resources by focusing on the highest food safety risks.

Risk analysis is comprised of three components: risk management, risk assessment and risk communication. Each of these components has been applied in essentially all countries for a long time, even before they came to be called by these names (see Box 1.5). During the past two decades or so, the three components have been formalized, refined and integrated into a unified discipline, developed at both the national and international levels, and now known as “risk analysis.” This section provides a broad introduction to food safety risk analysis, advantages of applying it, and conditions necessary for its successful implementation.

### Box 1.5. Welcome to the role of “risk managers”

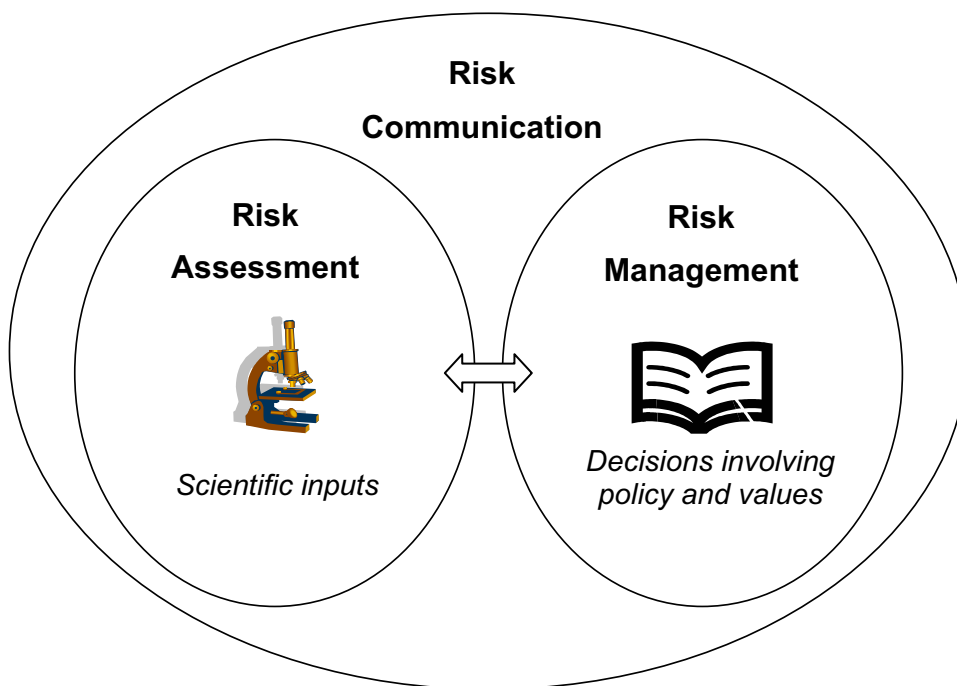
In risk analysis terminology, food safety officials working for national governments generally play the role of “risk managers.” They have overall responsibility for ensuring that a risk analysis is carried out, as well as the ultimate responsibility for choosing and implementing food safety control measures. National risk managers do not need to understand in detail how to carry out a risk assessment, but they do need to know how to commission one when that is required and see the task through to completion. They also need to understand the outcome of risk assessment in order to make appropriate risk management decisions. Similarly, national risk managers do not need to be experts at risk communication, but they need to know how risk communication supports successful risk analysis, and how to ensure that proper kinds and amounts of communication occur at all the appropriate steps in risk assessment and risk management.

The terminology used in risk analysis may seem daunting at first, but as readers come to understand the concepts it will become clear that risk analysis often applies recently developed, internationally agreed terms to familiar activities. By explaining these activities and providing practical examples, this Guide aims to help national food safety officials gain the advantages of applying risk analysis to their own food control activities.

#### 1.2.1. Components of risk analysis

Risk analysis represents a structured decision-making process with three distinct but closely connected components: risk management, risk assessment and risk communication (see Figure 1.2). The three components are essential, complementary parts of the overall discipline. Although the figure shows them as separate entities, in reality they are highly integrated. In the course of a typical food safety risk analysis, almost constant interactions occur between risk managers and risk assessors within an environment characterized by risk communication. Risk analysis is most effective when all three components are successfully integrated by the risk managers directing the process.

Figure 1.2. Generic components of risk analysis



The three main components of risk analysis have been defined by Codex as follows:

- **Risk assessment:** A scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.
- **Risk management:** The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
- **Risk communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk assessment is considered to be the “science-based” component of risk analysis, while risk management is the component in which scientific information and other factors, such as economic, social, cultural and ethical considerations, are integrated and weighed in choosing the preferred risk management options. In fact, risk assessment may also involve judgments and choices that are not entirely scientific, and risk managers need a sound understanding of scientific approaches used by risk assessors. The interactions and overlaps of science and non-scientific values at various stages in risk analysis will be explored in more detail in subsequent chapters concerned with risk management and risk assessment.

### ***1.2.2. Carrying out risk analysis***

The risk analysis process normally begins with a risk management step, to define the problem, articulate the goals of the risk analysis and identify questions to be answered by the risk assessment, if and when one is required (see Chapter 2, section on preliminary risk management activities). The science-based tasks of “measuring” and “describing” the nature of the risk being analysed are performed during the risk assessment phase (see Chapter 3). Risk management and risk assessment are performed within an open and transparent environment involving extensive communication and dialogue, in which a variety of interested parties may participate at appropriate points. The risk analysis process often culminates with the implementation of risk-reducing measures and continuous monitoring of their effectiveness by government, the private sector and other stakeholders.

### ***1.2.3. Risk analysis at the international and national levels***

Food safety risk analysis is carried out by national, regional and international food safety authorities. There are some important differences between these processes at the different levels. Internationally, Codex committees that recommend food safety standards (for example, the Committees on Food Hygiene, Meat Hygiene, Food Additives, Contaminants, Pesticide Residues, and Residues of Veterinary Drugs in Foods) act as risk managers. Risk assessments to support the development of Codex food safety standards are provided by the three Joint FAO/WHO Expert Bodies: the Joint Expert Committee on Food Additives (JECFA); the Joint Meeting on Pesticide Residues (JMPR); and the Joint Expert Meeting on Microbiological Risk Assessment (JEMRA). Additional risk assessments may be provided, on occasion, by *ad hoc* expert consultations, and by member governments that have conducted their own assessments.

Codex Committees act as risk managers in the sense that they organize and direct the decision-making process, weigh the results of the risk assessments and other legitimate factors such as the feasibility of risk management options and the interests of Codex members, and recommend standards to protect public health and ensure fair practices in the food trade. Their activities may include developing risk management tools referred to as related texts, such as guidelines, codes of practice and sampling plans, and standards for specific food-hazard combinations. Draft standards and related texts prepared by these committees are forwarded to the CAC for final adoption and publication in the Codex Alimentarius. Codex standards and related texts are voluntary in nature and have no direct binding effect to CAC members unless they are adopted in national legislation. Codex does not implement risk-mitigating measures. Implementation, enforcement and monitoring activities are within the responsibilities of Codex members, governments and institutions.

National food safety authorities, in contrast, generally are responsible for carrying out risk analysis in its entirety. Some governments have their own institutions and infrastructure for conducting risk assessments, choosing among risk management options, implementing and enforcing decisions, and monitoring and reviewing the impacts of decisions. Other countries may have fewer resources available to carry out risk analysis tasks. In such cases, and even where governments have their own capacities, components of risk analysis carried out at the international level can be very usefully applied in the national context.

International risk assessments done by JECFA, JMPR or JEMRA, for instance, can be partially or fully applied at the national level depending on particular circumstances (see Chapter 3). Similarly, international guidance on risk management for a particular hazard can identify an array of potential control options for national risk managers to consider in their own food control setting. Examples of both international and national risk analyses, and of some links between the two, are provided in subsequent chapters and in case studies presented in the Annexes to this Guide.

#### ***1.2.4. Essential characteristics of risk analysis***

Although figures depicting risk management (see Figure 2.1) and risk assessment (see Figure 3.1) may suggest a linear process that moves from one step to the next in a sequence, in reality risk analysis is highly iterative and ongoing, with many feedback loops and steps that are repeated as needed, or as better information is developed. A unifying overall characteristic is repeated interaction between and among risk managers, risk assessors and other participants. Risk analysis also does not end once a decision is reached and implemented. Members of the risk analysis team and others (e.g. industry) regularly monitor the success and impact of their decision, and may make modifications to control measures that have been implemented if that is indicated from new information being incorporated in the risk analysis.

In its Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, the CAC has stated that risk analysis should: i) follow a structured approach comprised of the three distinct components illustrated in Figure 1.2; ii) be based on the best available scientific evidence; iii) be applied consistently, for instance, to hazards of different types and from country to country; iv) be carried out in an open, transparent and well-documented process; v) be clear in its treatment of uncertainty and variability; and vi) be evaluated and reviewed as appropriate on the basis of new information.

Risk analysis is also a systematic discipline that fosters broad perspectives (such as “production to consumption” approaches), wide-ranging collection of data (for instance, on

risks and on risk management options), and comprehensive analysis of alternatives. It is based on a philosophy of transparent, fully documented decision-making and open processes in which participation by all parties affected by the risk or by measures to manage it is solicited.

The successful use of the risk analysis framework requires countries to have the essential foundations of a food safety system in place. As discussed in section 1.1.2 above, this includes enabling food laws, policies, regulations and standards, efficient food safety and public health institutions and mechanisms for coordination between them, operational food inspection and laboratory services, information, education, communication and training, infrastructure and equipment, and human resource capacity, among other elements. Other essential conditions necessary for a government to implement successful risk analysis include: having government officials and decision-makers at policy levels, as well as those at operational levels, who understand risk analysis and the value it adds to the public health perspective; having enough scientific capability to carry out needed risk assessments in the national context; and having the support and participation of key interested parties such as consumers, industry and academia (generally called “stakeholders” in this Guide). When these conditions are met, national food safety authorities have much to gain by adopting risk analysis as a discipline for their food control activities.

### **1.3. Benefits for national governments of using food safety risk analysis**

Applying risk analysis to food safety problems offers many advantages to all parties with a stake in these matters. Risk analysis supports taking decisions that are in proportion to the public health risks involved, and systematic evaluation of likely impacts of specific measures chosen to manage those risks. Risk analysis allows likely costs of compliance to be compared with expected benefits, and supports setting priorities among different food safety problems. By using risk analysis where practical and feasible, governments meet their obligations under the SPS Agreement and strengthen their basis for trading foods internationally. For instance, by helping to objectively demonstrate the absence of hazards or the effective control of hazards to produce safe food, risk analysis provides a solid basis to increase trade access to new markets. In addition, risk analysis identifies gaps and uncertainties in scientific knowledge on risks, which can help set research priorities and contribute in the long term toward improved understanding of food-related impacts on public health. For all of these reasons, risk analysis is the preferred approach for establishing food safety control measures.

### **1.4. Suggestions for further reading**

**FAO.** 2003. *Food Safety: Science and Ethics*. Report of an FAO Expert Consultation. Rome, 3-5 September 2002. FAO Readings in Ethics 1 (available at <ftp://ftp.fao.org/docrep/fao/006/j0776e/j0776e00.pdf>).

**FAO/WHO.** 1995. *Application of risk analysis to food standards issues*. Report of the Joint FAO/WHO Expert Consultation. Geneva, 13-17 March 1995 (available at: [ftp://ftp.fao.org/es/esn/food/Risk\\_Analysis.pdf](ftp://ftp.fao.org/es/esn/food/Risk_Analysis.pdf)).

**FAO/WHO.** 1997. *Risk Management and Food Safety*. FAO Food and Nutrition Paper No. 65 (available at: <ftp://ftp.fao.org/docrep/fao/w4982e/w4982e00.pdf>).

**FAO/WHO.** 1999. *The application of risk communication to food standards and safety matters*. Report of a Joint FAO/WHO Expert Consultation. Rome, 2-6 February 1998.

FAO Food and Nutrition Paper No. 70 (available at: <http://www.fao.org/DOCREP/005/X1271E/X1271E00.htm#TOC>).

**FAO/WHO.** 2000. *The interaction between assessors and managers of microbiological hazards in food*. Report of a WHO Expert Consultation in collaboration with the Institute for Hygiene and Food Safety of the Federal Dairy Research Centre, Germany and the Food and Agriculture Organization of the United Nations (FAO). Kiel, Germany, 21-23 March 2000 (available at: <ftp://ftp.fao.org/docrep/nonfao/ae586e/ae586e00.pdf>).

**FAO/WHO.** 2002. *Improving efficiency and transparency in food safety systems - sharing experiences*. Proceedings of the Global Forum of Food Safety Regulators. Marrakesh, Morocco, 28-30 January 2002 (available at: <ftp://ftp.fao.org/docrep/fao/meeting/004/Y3680E/Y3680E00.pdf>).

**FAO/WHO.** 2002. *Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts*. Report of a Joint FAO/WHO Consultation in collaboration with the Federal Institute for Health Protection of Consumers and Veterinary Medicine, Germany and the Federal Ministry for Consumer Protection, Food and Agriculture, Germany. Kiel, Germany, 18-22 March 2002 (available at: <ftp://ftp.fao.org/docrep/fao/006/y4302e/y4302e00.pdf>).

**FAO/WHO.** 2003. *Assuring food safety and quality: Guidelines for strengthening national food control systems*. FAO Food and Nutrition Paper No. 76 (available at: <http://www.fao.org/DOCREP/006/Y8705E/Y8705E00.HTM>).

**FAO/WHO.** 2004. *The application of risk analysis in food control – challenges and benefits*. Paper prepared by Food Standards Australia New Zealand (FSANZ) for the FAO/WHO Regional Conference on Food Safety for Asia and the Pacific. Seremban, Malaysia, 24-27 May 2004 (available at: <ftp://ftp.fao.org/docrep/fao/meeting/006/j1985e/j1985e00.pdf>).

**FAO/WHO.** 2005. *Codex Alimentarius Commission. Procedural Manual*. 15<sup>th</sup> Edition. Joint FAO/WHO Food Standards Programme, Rome (available at: [ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual\\_15e.pdf](ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf)).

**FAO/WHO.** 2005. Working principles for risk analysis for application in the framework of the Codex Alimentarius. In *Codex Alimentarius Commission. Procedural Manual*. 15<sup>th</sup> Edition. Joint FAO/WHO Food Standards Programme, Rome. Pp 101-107 (available at: [ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual\\_15e.pdf](ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf)).

**FAO/WHO.** 2005. *Building effective food safety systems*. Proceedings of the 2<sup>nd</sup> FAO/WHO Global Forum of Food Safety Regulators. Bangkok, Thailand, 12-14 October 2004 (available at: <http://www.fao.org/docrep/meeting/008/y5871e/y5871e00.htm>).



## 2. Risk Management

**Chapter summary:** This chapter provides a comprehensive overview of the management of food-borne risks to consumers. A generic risk management framework (RMF) is described in some detail. The RMF consists of four steps: i) preliminary risk management activities; ii) identification and selection of risk management options; iii) implementation; and iv) monitoring and review. Where necessary and feasible, a risk assessment is commissioned within the RMF as a functionally separate exercise (Chapter 3). Most stages of risk management require extensive communication, coordination and collaboration, both between risk managers and risk assessors, and with external stakeholders (Chapter 4). Application of each step in the RMF is illustrated by examples of management for chemical and microbiological food-borne risks at the national and international levels.

### 2.1. Introduction

Risk analysis must occur in a context and, to be done effectively, requires a formal process. In a typical instance, a food safety problem or issue is identified and risk managers<sup>5</sup> initiate a risk management process, which they then see through to completion. This is best accomplished within a systematic, consistent and readily-understood framework in which scientific knowledge on risk and evaluations of other factors relevant to public health protection are used to select and implement appropriate control measures. The responsibilities of risk managers during this process also include commissioning a risk assessment when one is needed, and making sure that risk communication occurs wherever necessary.

The generic risk management framework (RMF) presented in this Guide provides a practical, structured process for food safety regulators to apply all the components of risk analysis. It is comprised of four major phases and numerous specific activities (see Figure 2.1). The complete process is cyclical and there may be many iterative loops between phases and steps. Parts of the RMF can be repeated as new information becomes available, or as work done at a later phase indicates a need to modify or re-examine work done at an earlier stage.

#### 2.1.1. Perspectives on risk

Food safety risks can be viewed in several ways (Box 2.1) and each of these perspectives may be applied by some participants in any given application of the food safety RMF. The “technical” view is the primary one for decision-making, but risk managers also apply psychological and sociological risk perspectives, as appropriate, in establishing food safety standards. As described in the next chapter, food safety risk assessment is anchored to the greatest extent possible in the technical perspective, and risk assessors are expected to base their work on scientific data and methods. The overriding consideration in the technical paradigm is that risk assessment is specific to the described scenario.

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<sup>5</sup> For the purposes of this Guide, risk managers are generally assumed to be officials of a national food safety authority (also called the “Competent Authority” in language of the SPS Agreement). In practice, managers in industry and many other officials can also serve as risk managers.

### **Box 2.1. Perspectives on risk**

<i>Technical paradigm:</i>	Focuses on and is limited to scientific evaluation of the likelihood and severity of harm. May include an economic subset in which harm can be described in terms of either health indices, such as Disability Adjusted Life Years (DALYs) or monetary values.
<i>Psychological paradigm:</i>	Evaluates risk as a function of individual perception, giving weight to such attributes as voluntariness of exposure, controllability of risk, catastrophic nature of risk, and so on. Risk perceived in these ways may differ in “magnitude” from technical risk estimates.
<i>Sociological paradigm:</i>	Views risk as a social and cultural construct, with the goal of distributing costs and benefits in socially acceptable and equitable ways.

## **2.2. A generic risk management framework**

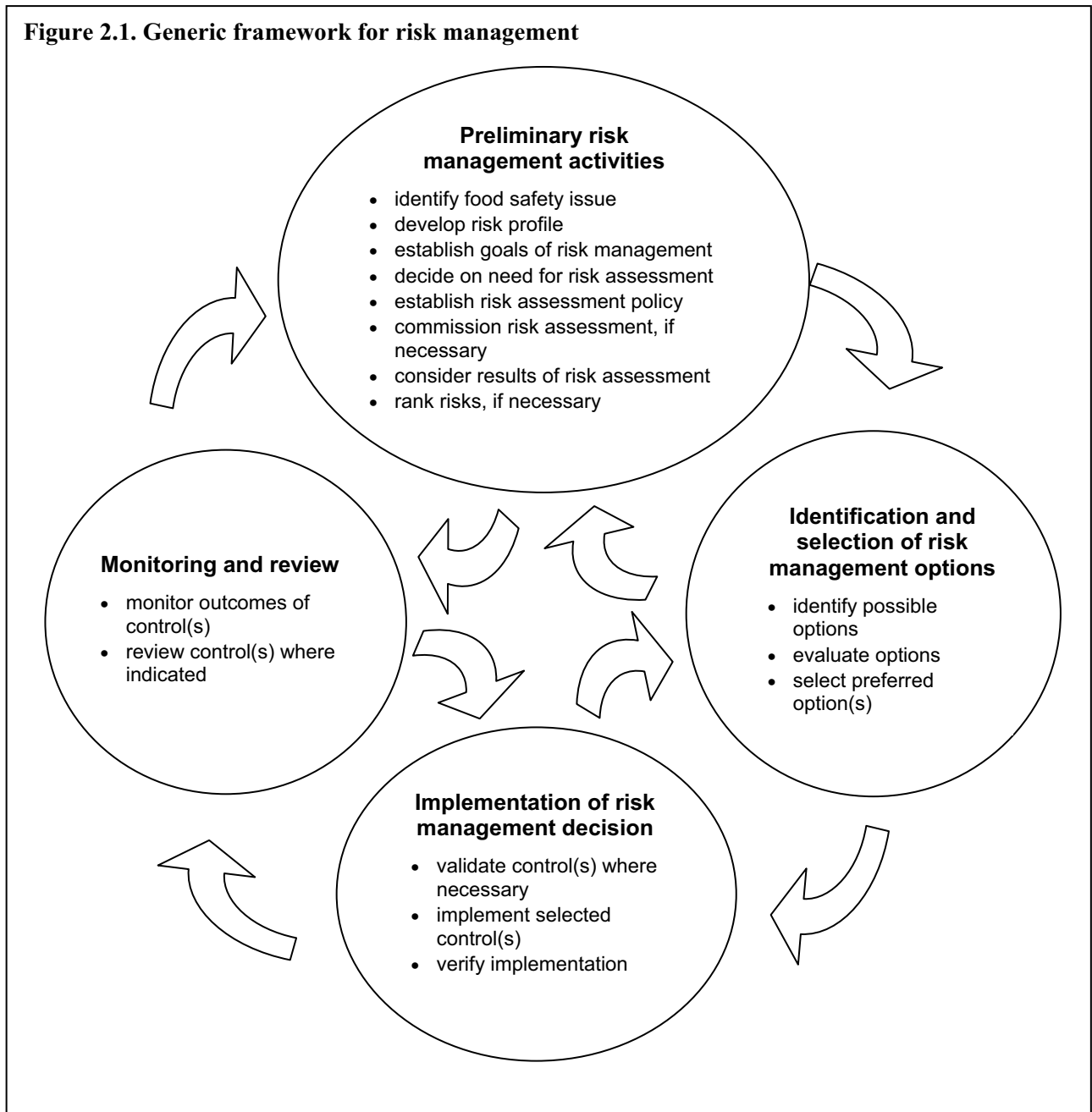
A generic process for carrying out risk management is presented in Figure 2.1. Such frameworks developed at the international level (e.g. the Codex Committee on Food Hygiene (CCFH) has developed principles and guidelines for the conduct of microbiological risk management<sup>6</sup>) provide useful templates for countries developing their own risk management systems.

A generic RMF for food safety risk management must be functional in both strategic, long-term situations (e.g. development of international and national standards when sufficient time is available) and in the shorter term work of national food safety authorities (e.g. responding rapidly to a disease outbreak). In all cases, it is necessary to strive to obtain the best scientific information available. In the former situation, risk managers will usually have access to extensive scientific information in the form of risk assessment reports. In the latter situation, risk managers are not likely to have access to a complete risk assessment and therefore will need to rely on whatever scientific information on risks is readily available (such as human health surveillance and food-borne disease outbreak data) as a basis for preliminary decisions on control measures.

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<sup>6</sup> FAO/WHO. 2005. Proposed draft principles and guidelines for the conduct of microbiological risk management. Appendix III In Report of the 37<sup>th</sup> Session of the Codex Committee on Food Hygiene. Buenos Aires, Argentina, 14-19 March 2005. ALINORM 05/28/13. Codex Committee on Food Hygiene (available at: [ftp://ftp.fao.org/codex/ccfh37/fh37\\_06e.pdf](ftp://ftp.fao.org/codex/ccfh37/fh37_06e.pdf) and <http://www.codexalimentarius.net/web/archives.jsp?year=05>).

**Figure 2.1. Generic framework for risk management**



### **2.3. Understanding risk management**

The first phase of the RMF shown in Figure 2.1 consists of “preliminary risk management activities”. After a food safety issue has been identified, available scientific information is aggregated into a risk profile that will guide further action. Risk managers may seek additional and more detailed scientific information on an assessment of risks from methodologies such as risk assessment, risk ranking or epidemiology-based approaches such as source attribution. Ranking using tools (see section 3.2.2) that rely on knowledge of risk factors to rank risks and prioritize regulatory controls may be carried out either within or without risk assessments. Epidemiology (see section 3.2.3) includes observational studies of human illness such as case-control, analysis of surveillance data and focused research, and is used to apportion risks and contribute to setting risk-based standards. These approaches are often used in combination.

If a risk assessment is needed, it can be commissioned from those responsible for that function, with iterative discussions between risk managers and risk assessors to determine the scope of the risk assessment and to decide on questions it is to answer. Near the end of this preliminary stage, the results of the risk assessment are delivered back to the risk managers and further discussions are generally held on the results and their interpretation.

During this “preliminary” phase, good risk communication is important. Communication with external interested parties often is needed to fully identify the food safety issue, obtain sufficient scientific information for risk profiling, and formulate questions to be answered by the risk assessment. Internal communication between risk managers and risk assessors is vital for many reasons, such as to ensure that the scope of the risk assessment is reasonable and achievable, and that the results are presented in a readily understandable form.

The second phase of the RMF consists of identifying and evaluating a variety of possible options for managing (e.g. controlling, preventing, reducing, eliminating or in some other manner mitigating) the risk. As before, effective communication is a prerequisite for success, as information from and opinions of affected stakeholders, particularly industry and consumers, are valuable inputs to the decision-making process.

Weighing the results of the risk assessment as well as any economic, legal, ethical, environmental, social and political factors associated with the risk-mitigating measures that might be implemented can be a complex task. Economic evaluation of possible risk management interventions enables risk managers to examine the health impacts and feasibility of a proposed intervention relative to its cost. An open and participatory process helps ensure that the final decision is understood and widely supported by those affected by it.

When preferred risk management options have been selected, they must be implemented by the relevant stakeholders. In many countries today, industry has the primary responsibility for implementing regulatory standards. However, some non-regulatory risk management options may be selected, such as quality assurance schemes at the farm level, or consumer education packages for food handling in the home. Generally, national food safety authorities must validate and verify implementation of regulatory standards.

Once control measures have been implemented, monitoring and review activities should be carried out. The goal is to determine whether the measures that were selected and implemented are in fact achieving the risk management goals they were meant to achieve, and whether they are having any other unintended effects. Both industry and government bodies are likely to be involved in monitoring and review activities. Both sectors usually monitor levels of hazard control, while government generally carries out health surveillance of the population to determine the level of food-borne illness. If monitoring information indicates a need to review the decision as to risk management options, the risk management process can begin a new cycle, with all interested parties participating as appropriate.

When dealing with a given specific food safety issue, a RMF can be entered at any phase and the cyclical process can be repeated as many times as is necessary. What is most important is that appropriate attention is paid to all the phases in the process. More than anything else, application of the RMF represents a systematic way of thinking about all food safety issues that require risk management. The level of intensity of each phase will be matched to the needs presented by each food safety issue and may range from simple, qualitative processes to complex scientific and social evaluations.

The succeeding sections of this chapter examine step-by-step application of the risk management framework, as described above.

## 2.4. Preliminary risk management activities<sup>7</sup>

### 2.4.1. Step 1: Identify and describe the food safety issue

Identifying and articulating the nature and characteristics of the food safety issue is an essential first task for risk managers. Sometimes the issue is already recognized and accepted as a food safety problem that needs formal risk assessment. At other times, the problem may be apparent but additional information is needed before further actions can be decided on and implemented.

A RMF can also be used to resolve food safety issues that do not necessarily require risk reduction (see Box 2.2). For example, as new processing technologies such as gas depelting of fresh meat carcasses become available, it is necessary to see whether these innovations produce any changes in bacterial contamination profiles that might affect the current level of consumer protection. In other situations, new technologies may require interventions to avoid increased risks. For instance, in the early stages of the BSE epidemic in the United Kingdom, the use of mechanical separation of muscle from bone in meat packing houses needed to be re-evaluated because this method commingles nervous tissue (a specific risk material) with meat fragments.

Food safety authorities learn about food safety issues that require resolution in a variety of ways. Safety problems may be identified by domestic and international (point of entry) inspection, food monitoring programmes, environmental monitoring, laboratory,

#### **Box 2.2. Some food safety issues that benefit from application of a RMF**

- A new or emerging potential hazard that constitutes an unknown level of risk; for example, Shiga toxin producing *E. coli* (STEC) from mammals.
- An indication of a high level of risk to consumers from a specific pathogen in a specific food; for example *Listeria monocytogenes* in delicatessen meats (see Annex 3).
- A need to rank and prioritize risks posed by a group of similar hazards; for example, enteric pathogens, for risk management.
- An indication of a high level of risk to consumers associated with a category of foods; for example, imported spices.
- Evaluation of new animal production methods, such as the use of a new veterinary drug for the treatment of animal diseases or changing intensity of animal husbandry.
- Introduction of a new pesticide chemical for use on food or animal feed crops.
- Evaluation of a new food processing technology, such as an alternative pasteurization regime for a heat-treated food product.
- Development of a basis for reaching a judgement on the equivalence of different production and processing systems or individual food safety measures in different countries.

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<sup>7</sup> Preliminary risk management activities were referred to as “risk evaluation” in the past. In the 13<sup>th</sup> Edition of the Codex Procedural Manual, “risk evaluation” was defined as a “preliminary risk management activity” to differentiate it from “risk assessment.”

epidemiological, clinical and toxicological studies, human disease surveillance, food-borne disease outbreak investigations, technological evaluation of novel foods and difficulties in achieving compliance with regulatory standards, among other ways. Sometimes academic or scientific experts, the food industry, consumers, special interest groups or the media expose food safety problems. At other times, food safety issues that are not necessarily driven by concerns about food-borne risks to consumers become apparent through legal action and disruptions to international trade. Box 2.3 presents examples, two of which are further developed in the annexes.

A brief initial description of the food safety issue provides the basis for developing a risk profile, which in turn generates a context and guide for further action. This first step also usually requires risk managers to determine their initial public health objectives. If the problem is urgent and solutions must be implemented rapidly, any risk analysis may be limited and the range of options considered may be fairly restricted. For less urgent problems, the scope of a risk analysis could potentially be very wide. But resource limitations, legal and political considerations, and other factors generally help risk managers make practical decisions about the depth and length of the risk analysis that is to be conducted in any given case.

**Box 2.3. Examples of Step 1: Identifying a food safety issue**

- ***Methylmercury in fish*** was first identified as a food-borne hazard in the 1950s when an outbreak of severe neurological disease occurred in babies whose mothers ate fish from Minamata Bay in Japan, which had been polluted by mercury from local industry. More recently, an epidemiological study in the Faeroe Islands, where the diet is rich in seafood, provided evidence that the amount of mercury in fish and whale meat in the absence of heavy pollution is still high enough in some circumstances to pose risks to the foetus (see Annex 2 for additional details).
- ***Listeria monocytogenes*** has long been recognized as an important food-borne pathogen. Several recent outbreaks of listeriosis in the United States, traced back to ready-to-eat meat products, have elevated public and regulatory concerns and made assessing and managing *L. monocytogenes* risks a high priority for both government and industry in the United States (see Annex 3 for additional details).
- ***The agent of BSE*** in meat from cattle was recognized as a food-borne risk to human health (as opposed to a disease of cattle only) in the United Kingdom in the 1990s. Since then, the World Organisation for Animal Health (OIE) has been developing relevant risk-based standards taking into account the BSE disease status of cattle in the exporting country.

**2.4.2. Step 2: Develop a risk profile**

A risk profile requires gathering relevant information on an issue and may take a number of forms. Its main purpose is to assist risk managers in taking further action. The extent of the information gathered can vary from case to case but should always be sufficient to guide the risk managers in determining the need for (and if needed, the extent of) a risk assessment. Risk managers are generally unlikely to carry out risk profiling themselves unless the food safety issue is urgent and there is a need for immediate action. Ordinarily, a risk profile is developed primarily by risk assessors and others with specific technical expertise on the issue(s) at hand.

A typical risk profile includes a brief description of: the situation, product or commodity involved; information on pathways by which consumers are exposed to the hazard; possible risks associated with that exposure; consumer perceptions of the risks; and the distribution of possible risks among different segments of the population. By gathering available information on risks, the risk profile should assist risk managers in setting work priorities, deciding how much further scientific information on the risks is needed, and developing a risk assessment policy. By describing current control measures, including those in place in other countries where relevant, the risk profile can also assist risk managers in identifying possible risk management options. In many situations, a risk profile can be thought of as a preliminary risk assessment that summarizes everything the risk managers know about the possible risks at that time. Examples of risk profiles are given Box 2.4.

#### **Box 2.4. Examples of Step 2: Developing a risk profile**

The New Zealand Food Safety Authority (NZFSA) has developed risk profiles for a large number of food-borne hazards, and they are posted on the authority's web site (<http://www.nzfsa.govt.nz/science/risk-profiles/index.htm>). Profiles for new hazard-food combinations are added to the library year-by-year. Profiles now posted address primarily microbiological contaminants of foods, including *Salmonella* and *Campylobacter* in poultry, *Listeria* in ice cream and ready-to-eat meats, and an array of other hazards. On the chemical side, NZFSA has developed risk profiles on aflatoxins in maize and glyphosate (an herbicide residue) in soy and soy products. For detailed illustrations of the kinds and amounts of information contained in a risk profile, readers are invited to examine the NZFSA examples.

The case studies on methylmercury in fish and *Listeria monocytogenes* in ready-to-eat foods, in Annexes 2 and 3 of this Guide, include brief descriptions of risk profiles.

A good risk profile provides the basis for commissioning a risk assessment where this is deemed necessary and assists in identifying the questions that need to be answered by the risk assessment. Formulating these questions usually requires significant interaction between risk assessors and risk managers, as well as dialogue with appropriate external parties (e.g. those with relevant information about the potential hazard).

Some types of information that may be included in a risk profile are listed in Box 2.5. The risk profile should be clearly and thoroughly documented, so that risk managers can use it to decide on further action in relation to a specific food safety issue. If links are made between risk profiles for other hazard-food combinations, risk profiles can provide the basis for qualitative ranking of food safety problems for subsequent risk management.

#### **2.4.3. Step 3: Establish broad risk management goals**

Following development of the risk profile, risk managers need to decide on the broader risk management goals. This is likely to occur in conjunction with a decision on whether or not a risk assessment is feasible or necessary. Delineating risk management goals must precede commissioning of a risk assessment and determines at least some of the questions to be asked of, and possibly answered by, the risk assessment. Some generic risk management goals that may require a risk assessment to resolve a food safety issue are shown in Box 2.6.

#### **2.4.4. Step 4: Decide whether a risk assessment is necessary**

Deciding whether a risk assessment is necessary is an iterative decision for risk managers and risk assessors and may be part of establishing broader risk management goals. Questions such as how a risk assessment might be approached, what questions it might try to answer, what

methods might yield useful answers, and where data gaps or uncertainties might likely preclude clear-cut answers, are significant issues. If the risk managers decide to progress to commissioning a risk assessment to support their risk management objectives, addressing such matters is essential. Identifying key data gaps at the outset also facilitates essential information being gathered to the extent possible before and during the risk assessment. These activities usually require the cooperation of scientific institutions, research-oriented bodies and the industry concerned.

A risk assessment is likely to be especially desirable when the nature and magnitude of the risk are not well characterized, when a risk brings multiple societal values into conflict or is a pressing public concern, or when risk management has major trade implications. A risk assessment also can guide research by facilitating the ranking of risks of most importance.

**Box 2.5. Examples of information that may be included in a risk profile**

- Initial statement of the food safety issue.
- Description of the hazard and food(s) involved.
- How and where the hazard enters the food supply.
- Which foods expose consumers to the hazard and how much of those foods are consumed by various populations.
- Frequency, distribution and levels of occurrence of the hazard in foods.
- Identification of possible risks from the available scientific literature.
- Nature of values at risk (human health, economic, cultural, etc.).
- Distribution of the risk (who produces, benefits from, and/or bears the risk).
- Characteristics of the commodity/hazard that might affect the availability and feasibility of risk management options.
- Current risk management practices relevant to the issue, including any regulatory standards in place.
- Public perceptions of the possible risks.
- Information about possible risk management (control) measures.
- Preliminary indication of questions that a risk assessment could (and could not) be expected to answer.
- Preliminary identification of important scientific data gaps that may prevent or limit a risk assessment.
- Implications of risk management in terms of international agreements (e.g. SPS Agreement).

Practical issues that impact on the decision as to whether a risk assessment is needed are: time and resources available; how urgently a risk management response is needed; consistency with responses to other similar issues; and availability of scientific information. If the risk profile indicates that food-borne risks are significant and immediate, the regulator may decide to impose interim regulatory control measures while a risk assessment is undertaken. On the other hand, some issues can be resolved simply and rapidly without need for a risk assessment. In some situations, a specific regulatory response will be deemed unnecessary because of the limited nature of possible risks. Box 2.7 offers some examples of cases in which a risk assessment is or is not likely to be needed.



**Box 2.6. Examples of generic risk management goals that may require a risk assessment to resolve a food safety issue**

- Developing specific regulatory standards or other risk management measures that can be expected to reduce risks associated with a specific food-hazard combination to an agreed acceptable level (e.g. for an emerging microbiological hazard).
- Developing specific regulatory standards or other risk management measures for a veterinary drug that leaves residues in foods to ensure that exposure to the residue is limited to levels that do not exceed the acceptable daily intake.
- Ranking risks associated with different hazard-food combinations to establish priorities for risk management (e.g. *Listeria monocytogenes* in different food categories, see Annex 3).
- Analysing the economic costs and benefits (risk reduction impacts) of different risk management options for a particular food safety issue, so as to choose the most suitable controls.
- Estimating “benchmark” levels of risk for certain priority hazards so that progress toward specific public-health goals can be measured (e.g. a 50 percent reduction in food-borne disease caused by enteric pathogens over a 10-year period).
- Demonstrating that no significant increase in risk to consumers is associated with the introduction of a new food production method or food processing technology.
- Demonstrating that no significant increase in risk to consumers is associated with the use by an exporting country of a control system or process to manage a risk, that is different from the control system or process used in an importing country (i.e. demonstrating equivalence); e.g. different pasteurization regimes.

**2.4.5 Step 5 Establish a risk assessment policy**

Many subjective judgements and choices arise in the course of a risk assessment, and some of those choices will affect the utility of the assessment’s results for decision making. Other choices may involve scientific values and preferences, such as how to deal with uncertainty and what assumptions to use when the available data are inconsistent, or how much caution to apply when recommending acceptable exposures.<sup>8</sup> See Chapter 3, section 3.3.4, for a more detailed discussion and examples of some of the “inferential bridges” that may be necessary for a risk assessment to proceed.

**Box 2.7. Examples of Step 4: Deciding whether a risk assessment is needed**

- Shards of metal are detected in canned peaches from a particular cannery. The source is identified as fragile blades on a newly installed slicer. The machine is repaired; a metal detector is installed. *Problem solved by Good Hygienic Practice (GHP); no risk assessment needed.*
- National food safety authorities are trying to decide whether to ban the use of certain antibiotics in animal feeds to help mitigate antimicrobial resistance. The economic stakes are high, with human health impacts quite uncertain. *Risk assessment is necessary to help determine the risk contribution of food-animal related uses of antimicrobials compared to that from use in human medicine.*
- *Listeria monocytogenes* produces a serious food-borne illness with a very high fatality rate. The pathogen can contaminate dozens of foods belonging to more than 20 different food categories. To set risk management priorities, the United States government carries out integrated risk assessments for *L. monocytogenes* in 23 food categories, yielding a clear priority ranking (see Annex 3). *Food safety issue managed based on a risk assessment.*

<sup>8</sup> FAO. 2003. *Food Safety: Science and Ethics*. Report of an Expert Consultation. Rome, Italy, 3-5 September 2002. FAO Readings in Ethics 1 (available at: [http://www.fao.org/documents/show\\_cdr.asp?url\\_file=/DOCREP/006/j0776e/j0776e08.htm](http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/j0776e/j0776e08.htm)).

A policy is often developed to provide an agreed framework for the conduct of risk assessment. Risk assessment policy is defined in the 15<sup>th</sup> Edition of the Codex Alimentarius Commission Procedural Manual as “documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained”. While establishing risk assessment policy is a responsibility of risk managers, it should be carried out in full collaboration with risk assessors, through an open and transparent process that allows appropriate inputs from relevant stakeholders. Risk assessment policy should be documented to ensure consistency, clarity and transparency.

A risk assessment policy underpins a clear understanding of the scope of the risk assessment and the manner in which it will be conducted. It often defines the parts of the food system, the populations, geographic areas and the time period to be covered. A risk assessment policy may include criteria for ranking risks (where, for example, the assessment covers different risks posed by the same contaminant, or risks posed by the contaminant in different foods) and procedures for applying uncertainty factors. Establishing a risk assessment policy provides guidance as to the appropriate level of protection and the scope of the risk assessment. An illustration is given in Box 2.8, and more details about risk assessment policy and examples from the perspective of the risk assessor are presented in Chapter 3 (section 3.3.4).

**Box 2.8. Example of Step 5: Establishing a risk assessment policy**

In the United States in 1996, Congress, acting as risk managers, established a new policy directing risk assessments by the United States Environmental Protection Agency (EPA) for pesticide residues in the diet. Legislation now requires the EPA to ensure that pesticide residue limits protect the most sensitive populations (infants and children); to apply an additional uncertainty factor when the evidence is insufficient to be reasonably certain that the standard uncertainty factors would ensure safety; and to consider the cumulative effects of multiple residues that share a common mechanism of toxic action, as well as exposures from water and home pesticide use, when defining tolerable exposure from food.

**2.4.6 Step 6 Commission the risk assessment**

Once a decision is made that a risk assessment is required, risk managers must arrange to get the risk assessment done. The nature of the risk assessment and the method by which it is commissioned may vary, depending on the nature of the risk, the institutional context and resources available and other factors. In general, risk managers must assemble an appropriate team of experts to carry out the task, and then interact with the risk assessors extensively enough to instruct them clearly on the work to be performed, while maintaining a “functional separation” between risk assessment and risk management activities.

Functional separation means separating out the tasks that are carried out as part of risk assessment or risk management at the time when they are being performed. While developed countries may have separate bodies and personnel to carry out risk assessment and risk management, in developing countries the same individuals may be responsible for both. What is important is that conditions are in place to ensure that the tasks are carried out separately of each other (even if they are performed by the same individuals) using existing structures and resources. Functional separation need not require the establishment of different bodies and personnel for risk management and risk assessment.

**Box 2.9. Responsibilities of risk managers in commissioning and supporting a risk assessment**

- Ensure that all aspects of the commissioning and conduct of the risk assessment are documented and transparent.
- Clearly communicate the purposes and scope of the risk assessment, the risk assessment policy, and the form of the desired outputs, to the risk assessors.
- Provide sufficient resources and set a realistic timetable.
- Maintain “functional separation” between risk assessment and risk management to the extent practicable.
- Ensure that the risk assessment team has an appropriate balance of expertise and is free from conflicts of interests and undue biases.
- Facilitate effective and iterative communication with the risk assessors during the entire process.

When ample time and resources are available, assembling an independent multidisciplinary team of scientists to conduct a risk assessment is often appropriate. In other cases, regulators may call on in-house expert resources or those available from dedicated external science providers, such as academic institutes. The most effective risk assessment teams are interdisciplinary; for instance, when dealing with a microbial hazard, the team may include food technologists, epidemiologists, microbiologists and biostatisticians.

Risk assessments carried out by the joint FAO/WHO expert bodies (JECFA, JMPR or JEMRA) are primarily intended to inform and assist the Codex Alimentarius Commission and governments in their choice of risk management measures for particular hazard-food combinations.<sup>9</sup> Historically, many governments have directly used international risk assessment work by adopting Codex standards for chemical hazards in foods. In other cases, international risk assessments have been used as a starting point for further, nationally-specific risk assessments and establishing national standards for chemical hazards. In the case of microbial hazards, few international risk assessments are available but those that are provide an important aid in the establishment of standards at the national level.

National risk managers must ensure that a risk assessment is appropriately commissioned and carried out. Whatever the scope and nature of a risk assessment and regardless of the identity of the risk assessors and risk managers, certain principles should govern this critical step (see Box 2.9). Box 2.10 provides examples of how specific risk assessments were commissioned.

In practice, “functional separation” means that risk managers and risk assessors have different jobs to do, and they each need to do their own jobs. Risk managers must avoid the temptation to “guide” the risk assessment so that it supports a preferred risk management decision, and risk assessors must assemble and assess the evidence objectively, without being influenced by risk management concerns such as economic benefits of an activity, costs of reducing exposure or consumer perceptions of risks.

In some situations, where resources and legal frameworks permit or require it, risk assessments may be carried out by an independent scientific institution, distinct from a food control authority. In other cases, particularly in smaller countries or countries with limited

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<sup>9</sup> Information about risk assessments carried out by JECFA, JEMRA and JMPR is available on the Internet. JECFA: [www.fao.org/ag/agn/jecfa/index\\_en.stm](http://www.fao.org/ag/agn/jecfa/index_en.stm) and [www.who.int/ipcs/publications/jecfa/en/index.html](http://www.who.int/ipcs/publications/jecfa/en/index.html); JEMRA: [www.fao.org/ag/agn/jemra/index\\_en.stm](http://www.fao.org/ag/agn/jemra/index_en.stm) and [www.who.int/foodsafety/micro/jemra/en/index.html](http://www.who.int/foodsafety/micro/jemra/en/index.html); and JMPR: [www.fao.org/ag/agp/agpp/pesticide/](http://www.fao.org/ag/agp/agpp/pesticide/) and <http://www.who.int/ipcs/publications/jmpr/en/>

resources, officials may of necessity serve in multiple roles with the same individuals carrying out both risk management and risk assessment tasks. Nevertheless, by striving to keep the two functions separate, and by following the principles outlined in Box 2.9, national risk managers can generally ensure that a risk assessment they commission is soundly conducted, objective and unbiased.

#### ***2.4.7. Step 7: Consider the results of the risk assessment***

The risk assessment should clearly and fully answer the questions asked by the risk managers as far as possible given the availability of data and, where appropriate, identify and quantify sources of uncertainties in risk estimates. In judging the risk assessment complete, risk managers need to:

- Be fully informed about the strengths and weaknesses of the risk assessment and its outputs.
- Be sufficiently familiar with the risk assessment techniques used, so that they can explain it adequately to external stakeholders.
- Understand the nature, sources and extent of uncertainties and variability in risk estimates.
- Be aware of and acknowledge all important assumptions made during the risk assessment and their impact on the results.

A collateral value of many risk assessments is identification of research needs to fill key gaps in scientific knowledge on a particular risk or risks associated with a given hazard-food combination.

At this point in the preliminary risk management phase, when the risk assessment is complete and can be reviewed and discussed with interested parties, effective communication among risk managers, risk assessors and others with a stake in the issue is essential (see Chapter 4).

#### ***2.4.8. Step 8: Rank food safety issues and set priorities for risk management<sup>10</sup>***

National food safety authorities must deal with numerous food safety issues, often simultaneously. Resources inevitably are insufficient to manage all issues at any given time and ranking of issues in priority for risk management, as well as ranking risks for assessment, are important activities for food safety regulators.

The primary criterion for ranking is generally the perceived relative level of risk each issue presents to consumers, so that risk management resources can be optimally applied to reduce overall food-borne public health risks. Issues may also be prioritized based on other factors, including serious restrictions in international trade resulting from different food safety control measures; the relative ease or difficulty of resolving the issues; and, sometimes, pressing public or political demand that attention be paid to a particular problem or issue. Application of risk ranking tools is described in more detail in Chapter 3. The risk ranking exercise with *Listeria* in food in the United States (see Box 2.3) illustrates a case in which the relative risk per food category was totally different from the absolute risk.

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<sup>10</sup> In cases where risk management is focused on a single hazard, this step will not apply.

## **Box 2.10. Examples of Step 6: Commissioning a risk assessment**

### **Case study 1: Total aflatoxins in peanuts**

When aflatoxins were evaluated for the first time by the 31<sup>st</sup> session of JECFA in 1987, sufficient information was unavailable to establish a figure for a tolerable level of intake. At its 46<sup>th</sup> session, JECFA considered potency evaluations and population estimates and recommended that these analyses be completed and presented in an updated toxicological review.

Concurrently, the Codex Committee on Food Additives and Contaminants had been considering the establishment of a maximum level for aflatoxins in peanuts for further processing for several sessions but could not reach consensus on a proposed maximum level of 15µg/kg. The 29<sup>th</sup> session of CCFAC (1997) asked JECFA, in the framework of its re-evaluation of aflatoxins, to consider the public health implications of a level of 15µg/kg, as compared to 10µg/kg, as these were the two levels under discussion.

The 49<sup>th</sup> JECFA session (1997) completed the toxicological evaluation of aflatoxins and concluded that the potency of aflatoxins in individuals who carry the hepatitis B virus (HBsAg<sup>+</sup>) was substantially higher than in individuals who do not carry the virus. Reduction of the intake of aflatoxins in populations with a high prevalence of HBsAg<sup>+</sup> individuals would therefore have greater impact on reducing liver cancer rates. The analysis of the application of hypothetical levels (10 µg/kg and 20 µg/kg aflatoxin in food) to model populations indicated that: i) populations with a low prevalence of HBsAg<sup>+</sup> individuals and/or with a low mean intake are unlikely to exhibit demonstrable differences in population risks for levels in the range of the hypothetical cases; and ii) populations with a high prevalence of HBsAg<sup>+</sup> individuals and high mean intake of aflatoxins would benefit from reductions in aflatoxin intake.

As regards the two aflatoxin levels proposed, JECFA concluded that the higher level would yield almost identical liver cancer risks as the lower level. It indicated that “when a substantial fraction of the food supply is heavily contaminated, reducing the aflatoxin contamination levels may detectably lower cancer rates. Conversely, when only a small fraction of the food supply is heavily contaminated, reducing the level by an apparently substantial amount may have little appreciable effect on public health.” Taking into account the results of the JECFA evaluation, the CCFAC agreed on a maximum level of 15 µg/kg for total aflatoxins in peanuts for further processing, that was adopted, with the corresponding sampling plan, by the Codex Alimentarius Commission in 1999.

### **Case study 2: Residues of nitrofurans\* in prawns in Australia**

In 1993 JECFA withdrew the acceptable daily intake for four nitrofurans\* chemicals (furazolidone, furaldalone, nitrofurantoin and nitrofurazone) due to the incomplete nature of the toxicological database and concerns about carcinogenicity in animal studies. As a result, several countries, including Australia, restricted, or prohibited, the use of nitrofurans in food-producing animals and subsequently, detectable residues in food products were not permitted. In October 2003, data became available indicating that very low levels of a furazolidone metabolite, 3-amino-oxazolidinone, had been found in certain imported prawns. Where residues had been detected, they were at a few parts per billion (µg/kg). However, in the absence of a specific maximum residue level in the Australian Food Standards Code, these residues were not permitted.

As a result of these test findings, Food Standards Australia New Zealand (FSANZ) undertook a risk assessment to establish the level of food safety risk to consumers from the levels of residue being detected in prawns. The risk assessment was undertaken to help inform enforcement agencies as to whether any risk management actions should be taken to protect consumer health, such as testing of prawns and/or recalls of batches of prawns containing detectable residues. The dietary exposure assessment component of the risk assessment utilized the residue concentrations found in an industry survey, and the hazard identification and characterization was based on a re-evaluation of the data summarized in the JECFA monographs.

\* Nitrofurans are synthetic broad-spectrum antimicrobial agents used in some countries in human and veterinary medicine. This example has been reproduced from a case study prepared by FSANZ (available at: <http://www.fao.org/docrep/meeting/006/j1985e/j1985e00.htm>).

## 2.5. Selection of risk management options

The second major phase of the generic RMF (presented above in Figure 2.1) involves the identification, evaluation and selection of risk management options. Although this step ordinarily cannot be fully undertaken until a risk assessment has been completed, as a practical matter, it begins very early in a risk analysis, and is reiterated as information about the risk grows more complete and quantitative. A risk profile may contain some information about possible risk management measures (see Box 2.5 above), and when risk managers commission a risk assessment, they may ask specific questions, the answers to which may guide the choice among risk management options. Also, as discussed at Step 3 in section 2.4 above, in urgent food safety situations, it may be necessary to choose and implement at least some preliminary risk management measures before a risk assessment can be carried out.

As was true for the first phase of risk management, this phase also consists of several distinct substeps. The exact order in which these activities are carried out is less important than the fact that they each take place.

### 2.5.1. Step 1: Identify available management options

Bearing in mind the risk management goals already established (see Step 3, section 2.4) and the outcome of the risk assessment, risk managers will generally identify a range of risk management options with the capacity to resolve the food safety issue at hand. The risk managers are responsible for the process that identifies appropriate measures, but need not always perform all the work themselves. Often risk assessors, scientists from food industry, economists and other stakeholders also play important roles in identifying options based on their expertise and knowledge. Examples of generic options for managing food-related risks (whether the hazards involved are chemical or microbiological) are illustrated in Box 2.11.

#### **Box 2.11. Examples of generic approaches to identifying risk management options**

- Eliminate potential for risks (e.g. ban sales of an imported food with a history of high levels of microbial contamination, prohibit use of a carcinogenic food additive).
- Identify those points between production and consumption where food safety measures could be implemented to:
  - ~ prevent or limit initial levels of hazards in raw materials (e.g. select ingredients that have been pasteurized, ensure good veterinary practice (GVP) in use of veterinary drugs in food animals);
  - ~ reduce potential for environmental contamination, cross-contamination and/or growth (e.g. mandate environmental hygiene controls, food processing controls, storage temperature controls);
  - ~ reduce hazard levels in foods (e.g. physical inspection regimes, pasteurization standards, decontamination processes, use of preservatives).
- Apply standardised pre-market toxicological evaluation and regulatory approval processes for chemical hazards (e.g. food additives, pesticide residues and veterinary drug residues) and set monitoring standards (MRLs) based on GAP, GMP, GVP.
- Require labelling to inform consumer groups who may be especially susceptible, e.g. people allergic to nuts, or pregnant women exposed to methylmercury in fish.
- Identify non-regulatory measures when risk is generated largely outside of regulatory jurisdictions, e.g. industry-led quality assurance programmes at the producer level, consumer education for handling foods in the home.

The process of identifying options is conceptually simple but is often restricted by limits on food safety risk managers' ability to implement selected options. While risk managers should try to take into account the entire continuum from production to consumption when identifying possible control measures (see Box 2.12), in many cases a particular regulatory agency has jurisdiction over only a segment of that continuum. In other situations, a risk assessment may be restricted to a small part of the food production chain and only measures within the scope of the risk assessment may be identified for possible implementation.

**Box 2.12. The production-to-consumption approach to risk management**

Food safety regulators in many countries are adopting a “production-to-consumption” approach to food safety. This approach strives to apply risk-based regulatory and non-regulatory control measures at appropriate points in the food production chain to achieve risk management goals in the most efficient and cost-effective manner. The approach assumes that basic good hygienic practices and good manufacturing practices are in place all along the food production chain and that opportunities exist to identify and implement targeted risk-reducing measures at relevant points along the continuum. Ideally, benefit-cost analysis and risk assessment are both conducted to inform risk management choices.

The complexity of food production systems and the ever-changing nature of international trade in foods make it impractical to realize this approach fully in many situations. Certain inputs to food production, such as hazard profiles of animal feeds in different countries may change rapidly. Further, the administrative framework for national food control systems may not be integrated throughout the entire food production continuum. When risks are generated in one country, as during primary production of a food, but managed in another country, such as when specific characteristics of a high-susceptibility population subgroup in the importing country must be managed, basing risk-management decisions on benefit-cost analysis is often impractical.

In some cases, a single measure may have the potential to successfully manage the risks associated with a particular food safety issue. In other cases, a combination of measures may be necessary. In some cases, a very limited range of risk management options may be available, over and above what is in place as good hygienic practice. In general, to the extent practicable, it is valuable to consider initially a relatively broad range of possible options, then to select the most promising alternatives for more detailed evaluation. It is also important at this stage to seek input from a variety of interested parties with knowledge of the food safety issue in question.

In some situations, effective control of a hazard in a particular part of a food production chain will require a systems approach, for example, control of faecal contamination of the carcass during the many steps in slaughter and dressing of red meat and poultry carcasses where this type of contamination can occur. Where a risk assessment process has identified the level of control required at the end of such a process, the risk management options may be integrated into a complete “food safety plan” based on a generic system such as HACCP, rather than described as distinct, narrower control measures.

**2.5.2. Step 2: Evaluate the identified management options**

The evaluation of identified risk management options is sometimes straightforward, for instance if the solution is obvious and relatively easy to implement, or if only a single option is under consideration. On the other hand, many food safety problems involve complex processes, and many potential risk management measures vary in feasibility, practicality and the degree of food safety they can achieve, and may require cost-benefit analysis and evaluating trade-offs among competing societal values.

One of the most critical elements in evaluating and selecting food safety measures is to recognize that a clear link must be established between the risk management option being evaluated and the level of risk reduction and/or consumer protection that is provided (see Box 2.13).

**Box 2.13. “Risk-based” food safety measures**

Food safety measures based on risk assessments are generally designed to reduce risks to a target level, and risk managers must determine the degree of health protection they are aiming to achieve. Through good communication with risk managers, risk assessors will likely have examined the relative impacts of different controls on reducing risks, providing the risk managers with objective data that supports decisions on the most appropriate controls. The overriding objective of risk management is to maximize risk reduction while ensuring that the measures employed are efficient and effective and not overly restrictive.

In this context, “risk-based” controls are formulated according to current knowledge about the human health risks associated with a food-borne hazard, whether expressed quantitatively or qualitatively. Control measures are aimed at achieving an established level of human health protection (which also may be expressed quantitatively or qualitatively) and should be explained and validated on those terms. For foods in international trade, the established level of consumer protection in the importing country is called the “appropriate level of protection” (ALOP).

There are no strict rules about how to select the best options; rather, there are a variety of possibilities based on the food safety issue at hand and the risk management goals that apply. In the ideal situation, the following information should be available for evaluating individual or groups of possible risk management options:

- A “menu” of estimates of risk that would result from application of potential risk management measures (either singly or in combination), expressed either qualitatively or quantitatively.
- Estimates of the relative impact of different potential risk management measures (either singly or in combination) on risk estimates.
- Technical information on the feasibility and practicality of implementing different options.
- Benefit-cost analysis of different potential measures, including both magnitude and distribution (i.e. who benefits, who pays the costs).
- WTO SPS implications of different options in international trade situations.

Any stakeholder group, including risk managers and risk assessors, may participate in this process by providing some of the needed information, commenting on the relative weight to be given to the different considerations, or offering other appropriate inputs.

Benefit-cost analysis is often difficult, even though it is a mandatory element of food safety policy decisions in some countries. Estimating the magnitude and distribution of benefits and costs of particular risk management options may require addressing such concerns as: changes in the availability or nutritional quality of foods; impacts on access to international food markets; impacts on consumer confidence in the safety of the food supply or in the food regulatory system; and other societal costs and consequences of both food safety risks and choices made in managing them. Many of these variables may be difficult to predict or quantify.

Economic estimates often have considerable uncertainty associated with them; for instance, it is difficult to predict how market participants will react to a risk-based regulation and how



future markets may change. Rapid advances in science and technology add to the uncertainty in predicting benefits and costs. Thus benefit-cost analysis by itself cannot determine the best risk management choices, but as a systematic discipline for collecting and evaluating data and data gaps, it informs the decision-making process. Preferences and perceptions of those most affected by the decisions, typically, industry and consumers also need to be considered. Risk managers need to assess critically the quality of information they receive at this stage, and often must make subjective judgments as to how much weight particular considerations, and the data on which they are based, should be given.

Risk management options also often have important ethical dimensions, although they are most typically implied, rather than explicit. For example, ethical principles that underlie specific options might include the view that industry has the responsibility to provide safe food; that consumers have a right to be informed about risks associated with the foods they eat; or that government needs to act to protect those who cannot protect themselves. It may seem easier for risk managers to explain and defend food safety decisions based on scientific and economic analysis, which provide a more objective basis than ethics. But the ethical choices embedded in risk management decisions need to be openly examined to facilitate transparency and good communication.<sup>11</sup>

For examples and discussion of evaluating risk management options in two specific cases, see Annexes 2 and 3.

The process used for evaluating risk management options may vary from one risk to the next within any given country, as well as from country to country and between the national and the international levels. A desirable characteristic at all levels is an open process that provides opportunities for industry, consumers and other interested parties to provide information, to comment on proposals, and to suggest criteria for choosing preferred options. Balancing the advantages and disadvantages of multiple risk management options is already a challenging task; expanding communication with stakeholders can make this stage of the process more difficult to manage, and may lengthen the time required to complete it. Nevertheless, risk managers will find that an extensive and inclusive consultation process generally improves both the quality and the public acceptability of the ultimate decision as to the preferred risk management options.

When evaluating risk management options for microbial hazards in food, regulators should provide as much flexibility as possible in regulatory standards for the industry that is implementing them, as long as the outcome in terms of consumer protection is achieved. The HACCP system fits nicely into this flexible and outcome-driven approach. In recent years, this principle has led to the concept of risk-based targets for control of hazards at particular steps in the food production chain. Development of specific quantitative microbiological metrics – such as food safety objectives (FSOs), performance objectives (POs) and performance criteria (PCs) – that can be incorporated in regulation is discussed in Boxes 2.14 and 2.15.

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<sup>11</sup> FAO. 2003. *Food Safety: Science and Ethics*. Report of an Expert Consultation. Rome, Italy, 3-5 September 2002. FAO Readings in Ethics I (available at: [http://www.fao.org/documents/show\\_cdr.asp?url\\_file=/DOCREP/006/j0776e/j0776e08.htm](http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/j0776e/j0776e08.htm)).

#### **Box 2.14. Codex definitions of quantitative microbiological food safety metrics\***

- **Food safety objective (FSO):** The maximum frequency and/or concentration of a hazard in a food at the point of consumption that provides, or contributes to, achievement of the ALOP.
- **Performance objective (PO):** The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain that provides, or contributes to, achievement of the ALOP.
- **Performance criterion (PC):** The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective.

\* *Metrics* are described as: “quantitative expressions that indicate a level of control at a specific step in a food safety risk management system. For the purpose of this report the term ‘metric’ is used as a collective for the new risk management terms of food safety objective, performance objective and performance criteria, but it also refers to existing microbiological criteria”. FAO/WHO. 2006. *The Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to improve food safety*. Report of a Joint FAO/WHO meeting in collaboration with the German Federal Ministry of Food, Agriculture and Consumer Protection. Kiel, Germany, 3-7 April 2006.

Risk management options for chemical hazards in foods are often generic, such as ensuring that use of a pesticide or veterinary drug according to GAP will not result in harmful residues in food (and establishing an MRL for monitoring purposes – see next section). Where chemicals are not *intentionally* used in food production settings (e.g. environmental contaminants such as dioxins or methylmercury), more specific risk management options often are evaluated (e.g. imposing conditions on harvesting, providing information to consumers so that they can voluntarily limit exposure). Exposure guidelines such as Provisional Tolerable Weekly Intakes (PTWIs) (see Annex 2) can then provide a reference point for maximum safe intake, and risk management measures can be put in place that aim to prevent consumers from exceeding that safe upper limit of exposure (see next section).

Risk management options for many chemical hazards rely on approaches that estimate an acceptable exposure level for avoiding chronic adverse health effects, such as an NOAEL or RfD methodology (see Chapter 3). When other risk modelling approaches are used, such as linear modelling for carcinogenic effects, different risk management options may be identified and evaluated, such as banning or severely restricting the use of the chemical.

#### **2.5.3. Step 3: Select a risk management option(s)**

Various approaches and decision-making frameworks can be used to select risk management options (see Box 2.16). There is no one preferred approach, and different ways of reaching decisions may be appropriate for different risks and in different contexts. In essence, the risk management decision on appropriate options is arrived at by considering and integrating all of the evaluation information described above.

Although there are some cases where risk reduction is not the primary objective, for example when judging the equivalence of different measures in their ability to protect human health, the foremost objective in most risk management decision-making is to reduce food-borne risks to human health. Risk managers should focus on selecting those measures that have the greatest risk-reducing impact and weigh those impacts against other factors that influence decision-making, including the feasibility and practicality of potential measures, cost-benefit considerations, stakeholder equity, ethical considerations, and creation of countervailing risks such as decreases in the availability or nutritional quality of foods.

This weighting process is essentially qualitative because of the obviously different nature of the values involved. Risk managers must decide how much weight to give each value

considered. Thus the selection of the “best” risk management option is fundamentally a political and social process. Given that, the options chosen should always be in proportion to the actual public health risks involved.

#### **Box 2.15. Using quantitative microbiological metrics as risk management options**

Quantitative microbiological metrics (as defined in Box 2.14) based on risk assessments can be useful in risk management. At the international level, Codex recognizes the desirability of using POs and/or PCs as a basis for establishing practical standards, such as risk-based microbiological criteria (MC), process criteria or product criteria, but methods for doing so are still being developed.

An FSO established at the point of consumption of the food provides a reference for developing microbiological targets at other points in the food production chain.

One or more POs or PCs may be necessary at different stages along the chain to specify the required level of microbiological control at a particular step in food production; setting a standard on this basis (e.g. requiring a process that reduces *Salmonella* levels by one-million-fold when cooking ground beef) may be a risk-based regulatory option.

A process criterion is a physical control measure (e.g. time, temperature) at a step, or combination of steps, that can be applied to achieve a PO. Process criteria should be validated to determine that they are achieving the required level of microbiological control on a consistent basis before being set as standards. A product criterion (pH, water activity/ $a_w$ ) similarly serves as a physical control measure.

Process and product criteria should be risk-based to the extent possible and criteria should not be set that represent unnecessary levels of pathogen control; for instance, current processing standards for pasteurization of milk may be more severe than necessary to deliver an acceptable level of consumer protection.

Methods for translating POs and PCs into risk-based MCs are still being developed. While the former specify the maximum levels of particular micro-organisms allowable in food, a risk-based MC must incorporate sampling plans of sufficient stringency that they can assure risk managers that the probability of exceeding maximum allowable limits is very low.

Decisions as to where along the food production chain to apply standards based on POs (see below) may be influenced by overarching risk management goals. For example, the primary source of contamination of the food may be at the farm level (such as *Campylobacter* in poultry) and risk managers may be able to most effectively reduce consumer risk by setting a PO at an early point in the production chain. Alternatively, when the primary source of contamination is inadequate control at a late stage of processing (such as *Listeria* in cold-smoked salmon), the risk manager can exert the greatest influence on poor hygienic practice by setting a PO for a later point in the food production chain.

#### 2.5.3.1. Identifying a desired level of consumer health protection

The level of consumer health protection provided by a decision on risk management measures is often called the “Appropriate Level of Protection” (ALOP).<sup>12</sup> ALOP is defined in the WTO SPS Agreement as “the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”<sup>13</sup> The ALOP concept is sometimes also referred to as “acceptable level of risk.” It is

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<sup>12</sup> See Annex 5 (Introducing the WTO SPS and TBT Agreements) In FAO. 2003. *Assuring food safety and quality. Guidelines for strengthening national food control systems*. FAO Food and Nutrition Paper No. 76 (available at: <ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf>).

<sup>13</sup> FAO/WHO. 2000. *The Interaction between assessors and managers of microbiological hazards in food*. Report of a WHO Expert Consultation in collaboration with the Institute for Hygiene and Food Safety of the

important to note that the ALOP is an expression of the level of protection achieved in relation to food safety at the current time. However, because the currently achieved level of consumer health protection may change (for example, new technologies may change the level of a contaminant in a food), an ALOP may be revised over time. Future objectives or goals in terms of consumer health protection may also be established. Once achieved these objectives or public health goals/targets will lead to a revision of the ALOP.

ALOPs may range from general to specific, depending upon the level of information available with regard to the source of hazards and risks. An example of a general ALOP could be the current level of *Salmonella* infections in a country (an example of an ALOP was the incidence of *Salmonella* in Finland and Sweden when they joined the European Union). An example of a specific ALOP was the background level of cryptosporidiosis in the United States as a basis for establishing levels of treatment for drinking water.

Expression of public health goals may range from the general to the specific, depending upon the level of source attribution. For example, a general public health goal would be to reduce the incidence of human *Salmonella* Enteritidis infections. A specific public health goal would be to reduce the incidence of human cases of *Salmonella* Enteritidis associated with consumption of eggs. Goals may be set either in absolute terms (e.g. number of cases per 100,000 population) or in terms of relative improvement (e.g. a percentage reduction in the number of cases).

Expression of the ALOP or a future goal with regard to the level of consumer health protection for a specific food-borne public health risk is obviously a core risk management function and, in most cases, is tied to the feasibility and practicality of available risk management options. In considering and integrating all of the evaluation information described above, a measure or measures linked to a specific level of consumer protection will be selected.

The concept of ALOP or similar future targets is essential in establishing the linkage between risk management actions and the level of consumer health protection achieved. A range of tools or approaches are available to the risk manager in bridging between practical control measures and level of consumer health protection. Some examples of these approaches are provided in Box 2.16.

For chemical contaminants, the output of the risk assessment generally includes an estimate of a tolerable intake, such as a tolerable daily intake (TDI) or PTWI (see the methylmercury case study in Annex 2 for a detailed example). For food additives, pesticide residues and residues of veterinary drugs, the risk assessors normally determine an acceptable daily intake (ADI). A TDI, PTWI or ADI is generally based on an estimate made by the risk assessors of a dose level that is reasonably certain to have no adverse health effects. It thus provides an ALOP that is pre-determined by public policy to be “notional zero risk.” A range of risk management measures that should achieve the required ALOP can be then selected for implementation; for example, enforcing GAP at farm level to minimize pesticide residues, setting MRLs for residues in specific foods, and using the MRLs to monitor the food supply.

**Box 2.16. Examples of approaches to setting an Appropriate Level of Protection that are used in selecting risk management options**

- **Notional zero risk approach** Hazards are kept at levels that equate to a pre-determined “negligible” or “notional zero” risk, based on a risk assessment indicating that such low exposure levels are reasonably certain not to cause harm. Used in setting ADIs for chemical hazards in food. For example, the insecticide chlorpyrifos can potentially disrupt brain development in young children. To protect against this risk, the JMPR has established an ADI for chlorpyrifos and based on this the Codex Committee on Pesticide Residues (CCPR) has set MRLs for its residue on a variety of foods on which it may be used.
- **As low as reasonably achievable approach** Hazard levels are limited by risk management measures to the lowest level technically possible and/or economically feasible under the circumstances. Some residual risk to consumer typically remains; for example for enteric pathogens of animal origin in fresh or undercooked meat products, or for levels of unavoidable environmental contaminants in otherwise wholesome foods.
- **Threshold approach** Risks must be kept below a specific numerical level as pre-determined by public policy; this approach may be used for chemical hazards, particularly carcinogens. For example, in the United States, certain food colourings that pose estimated risks greater than one additional expected cancer case above background incidence per 100,000 consumers exposed for a lifetime have been banned.
- **Benefit-cost approach** Both a risk assessment and a benefit-cost analysis are carried out and risk managers then weigh risk reduction units against monetary costs of achieving reductions when choosing measures. An example is selecting risk-based measures to control *Campylobacter* in chickens in the Netherlands (see section 3.6). According to a qualitative benefit-cost approach, sodium nitrite, a preservative that may pose a cancer risk but also prevents botulism, is restricted in many countries to a maximum level of 100 parts per million in specified foods.
- **Comparative risk approach** Benefits of reducing a particular risk are compared with countervailing risks that may be generated as a consequence of the decision; e.g. possible loss of nutritional benefits if people eat less fish in order to avoid methylmercury, possible increase in cancer risks where chlorinated water is used to minimize pathogens in food during processing.
- **Precautionary approach** Where information exists to suggest that a hazard in food may pose significant risks to human health, but the scientific data are not sufficient to estimate actual risks, interim measures may be put in place to limit the risk while steps are taken to make possible and carry out a more definitive risk assessment; e.g. bans on feed additives of animal origin and on trade in beef during the early stages of the BSE epidemic in Europe.

In some countries, quantitative probabilistic approaches to risk assessment of chemical hazards are changing the way decisions are made on selecting risk management options. These methods estimate changes in risks associated with changes in chemical exposure levels. A level of risk that is judged acceptable can be defined by public policy, and risk management measures can then be chosen to keep risk below that “threshold,” sometimes referred to as a “virtually safe dose.” Box 2.16 includes examples of approaches to determining an ALOP for a chemical hazard in food.

2.5.3.2. Reaching a decision on the preferred risk management option(s).

Risk managers must consider both the desired level of consumer protection and the availability and efficacy of risk management options when making this decision. Some examples have been presented in the discussion above. In general, most decision frameworks for selection of risk management options have as their primary purpose “optimization” of outcomes. That is, the decision-makers aim to achieve the “best” level of consumer protection in a manner that is as cost-effective, technically feasible, and sensitive to the rights of consumers and other stakeholders, as possible. Cost-risk-benefit analysis generally requires large amounts of information on both risks and the consequences of different risk

management options. As noted, no single approach to decision-making is best for all cases, and more than one approach can be appropriate for any given food safety decision.

**Box 2.17. Examples of voluntary / non-regulatory risk management measures**

- Reduction of lead levels in canned foods through the phase-out of lead-soldered cans by food processing industries.
- Reliance on good veterinary practices and Codex guidelines to minimize and contain antimicrobial resistance associated with antibiotic use in food animals.
- Selection of consumer education approaches for reducing exposure to methylmercury from certain fish and seafood (see Annex 2).

A systematic, rigorous evaluation of options, in an open process where affected parties can participate and communicate with decision-makers, is most likely to produce a sound, widely accepted decision. Given the importance of non-scientific values in the resolution of food safety problems, participation by external stakeholders is appropriate and can be critical to the successful completion of this stage. Where possible, risk management should consider the entire continuum from production to consumption, regardless of the number of authorities involved and their respective responsibilities, in order to develop the best management solutions. Any regulatory measures must be able to be enforced on the basis of the national framework of legal and regulatory authorities. However, in some countries, good results have been achieved by adopting measures that are voluntary rather than legally binding (Box 2.17). Finally, in today's global food marketplace, regulatory measures must take into account international trade agreements and the additional obligations they impose on national authorities (see Box 2.18).

**Box 2.18. Risk management and the WTO SPS Agreement**

The WTO SPS Agreement sets out the basic rules for establishing safety measures for foods that are traded internationally. An SPS measure by its nature can restrict trade, for example by limiting imports of foods that do not comply with national regulations. The SPS Agreement stipulates that food safety control measures can be applied only to the extent necessary to protect human health, and should not be applied in a manner which would constitute a disguised restriction on international trade. However, some governments may, for various reasons, adopt standards that are stricter than what is required to protect health, which could be perceived as barriers to trade. Challenges to such barriers must be based on risk assessment but because of the uncertainties inherent in risk assessment and the possibility that different assessments of the same risk may yield different outcomes, and given the frequent complexity of import standards, "protectionist devices" can be difficult to identify and remove.

Harmonized and transparent application of a RMF to identify and select risk management options in different countries should significantly advance the goal of preventing unjustified and unfair restrictions in the international trading of food.

2.5.3.3. Dealing with uncertainty

Uncertainty is an inescapable element in risk assessments and in efforts to project the impacts of risk management measures. When making risk management decisions, national food safety authorities need to take into account uncertainty, as transparently as they can. In predicting the outcome of a risk-based measure, the risk assessor should preferably use probability to express the uncertainty related to the estimate (for more discussion, see Chapter 3). From the risk manager's perspective, uncertainty must be well enough characterized that the decision-

maker “knows when he knows enough to act”. In this context, risk managers can test their interim decisions by requesting:

- A sensitivity analysis to determine how perturbations in model inputs affect the results.
- An uncertainty analysis to determine the consequences of all the uncertainty.

In most situations, despite the acknowledged uncertainties, a preferred risk management option or options will emerge from the decision-making process. Occasionally, when uncertainties are judged to be large enough to impede a definitive choice, interim measures may be adopted while additional data are gathered to support a better-informed decision, after an additional cycle of application of the RMF.

## **2.6. Implementation of the risk management decision**

Risk management decisions are implemented by a variety of parties, including government officials, the food industry and consumers. The type of implementation varies according to the food safety issue, the specific circumstances and the parties involved.

To effectively execute control measures, food producers and processors generally implement complete food control systems using comprehensive approaches such as GMP, GHP and HACCP systems. These approaches provide a platform for specific food safety risk management options as identified and selected by risk managers.

Industry has the primary responsibility to implement food safety controls (both regulatory and voluntary); many different national legislative arrangements provide for this allocation of food safety responsibility. Government agencies can use a variety of verification activities to ensure compliance with standards by industry. Some governments or regulatory bodies implement control measures such as physical inspection and product testing themselves, which places the primary cost of verifying compliance with standards by industry on the regulatory authority.

For some hazards, it may not be practical or cost-effective for industry to implement food control measures at each individual location at which they operate, for example testing for chemical residues of one sort or another. National chemical residue programmes can provide the data necessary to assure that appropriate control of hazards is being achieved in such circumstances. Programmes of this sort may be implemented by government, industry or both acting jointly.

In recent years, new approaches to the organization of national food safety authorities have emerged in different countries. Integrating all nationally-mandated food inspection systems under a single authority may have several advantages, such as reducing duplication of efforts and overlap of responsibilities, and improving the implementation of governmental food controls. A consolidation of multiple legislative and functional activities previously spread over several legislative jurisdictions gives practical meaning to multidisciplinary approaches to food safety and implementation of a risk-based “production-to-consumption” approach.

In parallel, food safety systems today depend increasingly on an integrated systems approach that shares responsibility for implementing food safety decisions. Innovative partnerships across the production-to-consumption continuum provide flexibility, which may be lacking in less integrated regulatory systems. For example, quality assurance systems can be extended in the case of ante- and post-mortem inspection of slaughtered animals to co-regulatory systems

that include industry and veterinary service activities. For instance, in Australia, the official veterinary service is now responsible for the broad design of the inspection system and its audits and sanctions, while industry is responsible for further developing, implementing and maintaining the system. The veterinarian responsible for a specific slaughterhouse ensures that the quality assurance programme implemented by industry meets regulatory requirements on an ongoing basis.

## 2.7. Monitoring and review

Risk management does not end when a decision has been taken and implemented. Risk managers are responsible for verifying that the risk mitigation measures are achieving the intended results, that there are no unintended consequences associated with the measures, and that risk management goals can be sustained in the longer term. Risk management decisions should be reviewed periodically when new scientific data or insights become available, as well as when experience, such as data gathered during inspection and monitoring, warrants a review. This phase of risk management includes gathering and analysing data on human health, and on food-borne hazards that pose risks of interest, to provide an overview of food safety and consumer health.

Surveillance of public health (which is a component of monitoring in a broad sense) is usually carried out by national public health authorities. It offers evidence of changes in food-borne illness rates that may follow implementation of risk management measures, as well as the potential for identifying new food safety problems as they emerge. When surveillance yields evidence that required food safety goals are not being achieved, redesign of food safety controls by government and industry is needed.

Box 2.19 illustrates some kinds of information that are useful for monitoring the effects of risk management measures.

### **Box 2.19. Examples of information that can be used for monitoring the effects of risk management measures**

- National surveillance databases for notifiable diseases.
- Disease registries, death certificate databases, and time-series data derived from these.
- Targeted human surveys (active surveillance) and analytical epidemiological studies where specific risks and risk factors are being investigated.
- Outbreak investigation data for food-borne illness events, blended with sporadic food-borne illness statistics, for food source attribution purposes.
- Frequency and levels of occurrence of chemical or microbiological contaminants in foods at various points from production to consumption.
- Frequency of persistent organic pollutants (POPs) in human breast milk.
- Frequency of occurrence and levels of contaminants in blood, urine or other tissues gathered from representative samples of the population(s) at risk, such as mercury levels in hair and blood (see Annex 2).
- Food consumption survey data, updated periodically, and to the extent possible, for specific subpopulations that may be at risk because of dietary preferences.
- Microbiological “fingerprinting” methods to trace specific genotypic strains of pathogens causing illness in humans through the food chain (e.g. multilocus gene sequence typing).



Most food safety authorities apply regulatory programmes at various points in the food production chain to monitor the presence of specific hazards; for example, national residue surveys, national monitoring programmes for microbial pathogens in fresh meat. Even though these programmes may not be integrated into an overall food control system, they provide valuable information on the changing prevalence of hazards over time and the level of regulatory compliance.

Human health surveillance to complete the RMF process is ordinarily outside of the jurisdiction of many food safety authorities but may be a responsibility of an overarching government authority. Monitoring and review activities should be specifically designed to support management of food-borne risks and provide the opportunity for multidisciplinary inputs in a risk-based food safety system. Food-borne disease investigations, analytical epidemiological studies such as food source attribution, case-control investigations and strain typing of bacterial hazards to genotype level can provide a valuable adjunct to human health surveillance.

In some cases, monitoring might result in a request for a new risk assessment, perhaps reducing previous uncertainties, or updating the analysis with new or additional research findings. Revised risk assessment results could lead to reiteration of the risk management process, with possible changes in risk management goals and the risk management option chosen. Changes in broad-based public health goals, changing societal values and technological innovations all can provide reasons to revisit risk management decisions previously taken.

## **2.8. Suggestions for further reading**

**FAO/WHO.** 1997. *Risk management and food safety*. Report of a Joint FAO/WHO Consultation. Rome, Italy, 27-31 January 1997. FAO Food and Nutrition Paper No. 65 (available at: <http://www.fao.org/docrep/W4982E/w4982e00.htm>).

**FAO/WHO.** 1999. *The application of risk communication to food standards and safety matters*. Report of a Joint FAO/WHO Expert Consultation. Rome, 2-6 February 1998. FAO Food and Nutrition Paper No. 70 (available at: <http://www.fao.org/docrep/005/x1271e/x1271e00.htm>).

**FAO/WHO.** 2002. *Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts*. Report of a Joint FAO/WHO Consultation. Kiel, Germany, 18-22 March 2002 (available at: <ftp://ftp.fao.org/docrep/fao/006/y4302e/y4302e00.pdf>).

**FAO.** 2004. *Food Safety: Science and Ethics*. Report of an Expert Consultation. Rome, Italy, 3-5 September 2002. FAO Readings in Ethics (available at <ftp://ftp.fao.org/docrep/fao/006/j0776e/j0776e00.pdf>).

**FAO/WHO.** 2005. *Report of the 37th Session of the Codex Committee on Food Hygiene*. Buenos Aires, Argentina, 14-19 March 2005. ALINORM 05/28/13 (available at: <http://www.codexalimentarius.net/web/archives.jsp?year=05>).

**FAO/WHO.** 2006. *The Use of Microbiological Risk Assessment Outputs to develop Practical Risk management Strategies: Metrics to improve food safety*. Report of a Joint FAO/WHO Meeting in collaboration with the German Federal Ministry of Food,

Agriculture and Consumer Protection. Kiel, Germany, 3-7 April 2006 (available at: [http://www.fao.org/ag/agn/jemra/index\\_en.stm](http://www.fao.org/ag/agn/jemra/index_en.stm)).

**Morgan, G. and Henrion, M., eds.** 1992. *Uncertainty: A guide to dealing with uncertainty in quantitative risk and policy analysis*. Cambridge University Press, New York.

## 3. Risk Assessment

**Chapter summary:** Risk assessment is the scientific foundation of risk analysis. This chapter takes a broad view of risk assessment methodologies and their essential characteristics. The four steps in the Codex risk assessment system are fully explored, together with risk ranking and epidemiological approaches. The responsibilities of risk managers in commissioning and administering a risk assessment are described and differences between risk assessment approaches for chemical compared with microbiological hazards are illustrated. The relative merits of qualitative and quantitative approaches are examined, as are recent approaches using probabilistic models of risks.

### 3.1. Introduction

Risk assessment is the central scientific component of risk analysis and has evolved primarily because of the need to make decisions to protect health in the face of scientific uncertainty. Risk assessment can be generally described as characterizing the potential adverse effects to life and health resulting from exposure to hazards over a specified time period.

Risk management and risk assessment are separate but closely linked activities, and ongoing, effective communication between those carrying out the separate functions is essential. As described in Chapter 2, risk managers applying the RMF must decide whether a risk assessment is possible and necessary. If this decision is affirmative, risk managers commission and manage the risk assessment, carrying out tasks such as describing the purpose of risk assessment and the food safety questions to be answered, establishing risk assessment policy, setting time schedules and providing the resources necessary to carry out the work.

This chapter describes the substantive content of the food safety risk assessment process and explains how risk assessment fits into application of the RMF. While the main focus is on application of risk assessment methodology as defined by Codex (i.e. systematic application of the four steps listed in section 1.2.1), a broader view of risk assessment is also taken. All methods for assessing risks described here use the best scientific knowledge available to support risk-based standards or other risk management options.

Individual risk assessments should be “fit-for-purpose” and can generate estimates of risks in various forms. Where they are feasible, quantitative risk assessments have the additional advantage of being able to model the effects of different interventions and this probably is their greatest strength. Scientific approaches that combine risk assessment, epidemiology<sup>14</sup> and economics are likely to be most useful to risk managers trying to integrate and balance risks and benefits.

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<sup>14</sup> Epidemiology data are important for risk assessment. Epidemiology, as a tool, can also be used independently of risk assessment, for example in food source attribution (see section 3.2).

### ***3.1.1. Risk assessment and the WTO SPS Agreement***

WTO members are bound by the provisions of the SPS Agreement, which places risk assessment within a coherent SPS system for developing and applying standards for food in international trade. The scope of the SPS Agreement in the context of this Guide covers risks to human life and health, and requires that WTO members:

- Shall ensure that any measure is applied only to the extent necessary to protect human life and health.
- Shall base their measures on risk assessment, taking into account the techniques developed by the relevant international organizations.
- May implement a measure that differs from international norms where a higher “appropriate level of health protection” is a legitimate goal.
- Shall apply the principles of equivalency where a different measure in an exporting country achieves their appropriate level of protection.

These provisions reflect the notion that the scientific conclusions of a risk assessment must reasonably support the SPS measure in question, and this in turn underpins the explanation of a “risk-based standard” presented in Chapter 2. However, case law resulting from disputes between countries is still limited and certain aspects of the WTO SPS provisions and obligations in regard to risk assessment methodology remain open to interpretation, for example, when evaluating the proportionality between the level of risk and the SPS measure<sup>15</sup>, when deciding how rigorous a risk assessment should be in low-risk situations, and when judging the sufficiency of scientific evidence. Nevertheless, the scientific robustness and quality of the risk assessment in question primarily drive decisions of this type.

### ***3.1.2. Relative positions of risk assessment and risk management***

The place occupied by risk assessment during an application of the RMF by risk managers is described in Chapter 2. Although risk managers commission and guide the production of a risk assessment and evaluate its outputs, the risk assessment itself is generally an external product, independently produced by scientists.

## **3.2. Scientific approaches for assessing risks**

When addressing a particular food safety issue, an early risk management decision concerns the scientific approach that will be taken (see section 2.4.1, Step 3). While this chapter is focused on risk assessment as an input to the RMF, there are many situations at the national level where no risk assessment of any form is available or feasible. In other situations, an active decision may be taken to use a scientific approach that does not include risk assessment. Obviously the advantages that flow from using risk assessment to set food safety control measures (see Chapter 2) cannot be realized in such scenarios; nevertheless, choices to apply other scientific approaches are likely to be reasonable and appropriate in their own right.

This Guide takes the broad view that several approaches to risk assessment can be used to establish an association of sufficient strength between food-borne hazards, control measures

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<sup>15</sup> “Proportionality” means that control measures should be in proportion to the risk; e.g. if the risk assessment identifies negligible risks it is unreasonable to introduce an SPS measure that requires a stringent and costly regulatory regime.

and risks to consumers, such that controls can be genuinely described as “risk-based” (see Chapter 2). Often, a combination of approaches may contribute to the risk assessment as a whole. This perspective shifts the focus from prescription of risk assessment methodology (as in Codex) to the outcome, and encourages food regulators to use methods best suited to the task. Where resources are limited, this Guide also may provide regulators with simpler methods that still lead to standards that can reasonably be described as risk-based, i.e. based on a scientific assessment of risk. Recognition that a range of approaches can lead to a risk-based standard also brings flexibility to the issue of the level of risk assessment rigor needed in low-risk situations.

In promulgating a flexible approach to use of risk assessment methodology, this Guide advocates that the RMF process should always include a risk profile of some sort. In applying the RMF, risk managers may *directly* use the information in the risk profile to identify and select food standards. Box 3.1 and Box 3.2 present examples illustrating the direct use of a risk profile as a basis for risk management decisions in cases where it was either unnecessary or not feasible to carry out a risk assessment. While basing risk management decisions on a risk profile may be fully justifiable in particular circumstances, the resulting standards are not ordinarily considered to be risk-based.

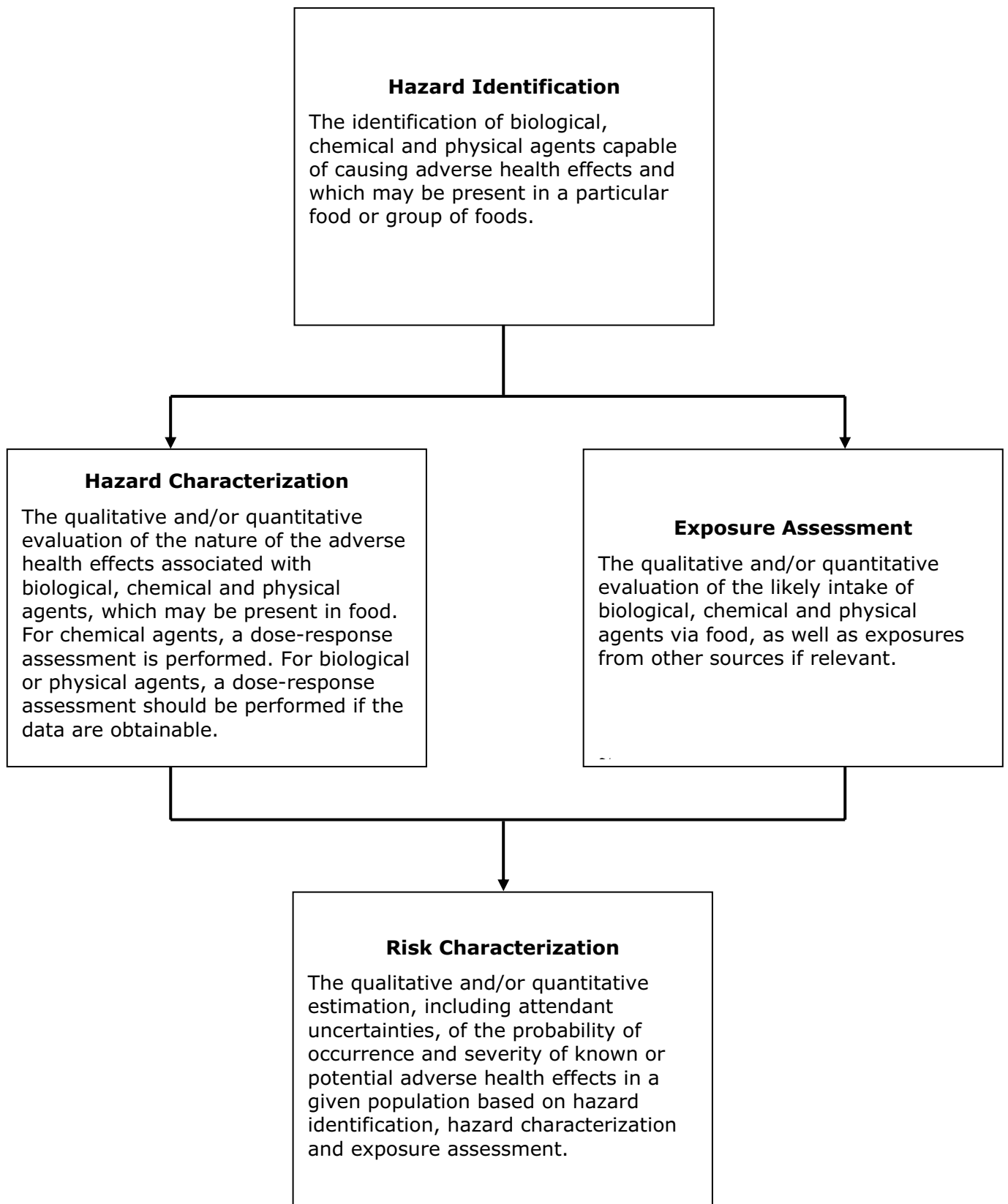
**Box 3.1. Examples of direct use of a risk profile to establish food safety standards**

- In the 1990s, microbial resistance to a range of antibiotics used in both animal health and human medicine was found to be widespread. Risk profiles indicated the proportion of resistant pathogens in surveys of food animal and human populations, and identified the unique value of certain individual antibiotics in treating human infections as well as the availability of substitute antibiotics. As a result, some countries took steps to deregister certain antibiotics for animal health uses, even though as yet no measurable change in the incidence of human disease has convincingly been linked to those uses.
- The recent discovery in Sweden that acrylamide, a substance known to cause cancer in laboratory animals, is formed through normal heat-treatment of baked and fried starchy foods, led to widespread recognition of significant exposure of consumers via a range of food types. Scientific studies showed that reducing cooking temperatures and/or times can lower consumer exposure levels. Modification of commercial food processes was instituted on this basis, even though the actual risk and the impact of process changes on risk reduction are still not fully known.

**3.2.1. Risk assessment**

Risk assessment incorporating, in one way or another, the four analytical steps described by Codex (see Figure 3.1) is the main focus of this chapter. The way those steps are applied differs somewhat for microbiological and chemical hazards.

**Figure 3.1. Generic Codex description of the components of risk assessment**



For microbiological hazards, the occurrence and transmission of the hazard at various stages from food production to consumption is evaluated, thus moving “forward” through the various stages of the food chain to arrive at an estimate of risk. While the accuracy of estimated risks is often limited by uncertain dose-response information, the greatest strength of such risk assessments arguably lies in their ability to model the relative impacts of different food control measures on risk estimates.

**Box 3.2. The Canadian approach to regulating *Listeria monocytogenes* in ready-to-eat foods**

When the Canadian government did a risk profile of this problem they recognized that contamination by *L. monocytogenes* could be reduced, but not eliminated from the final product or the environment. Risk management policy focuses inspection, testing and compliance action on ready-to-eat foods that are capable of supporting growth of *L. monocytogenes*. Specific attention is paid to those foods that have been linked to food-borne illness, and those with more than a ten day shelf life. In this approach, ready-to-eat foods are placed in one of three categories:

- Category 1 foods have been causally linked to human illness and are most intensively regulated. The presence of any *Listeria* in Category 1 foods results in a Class I recall that may include a public alert.
- Category 2 foods are capable of supporting *Listeria* growth and have a shelf life of more than 10 days; presence of *Listeria* in Category 2 foods requires a Class II recall with possible consideration of a public alert. Category 2 foods also have second highest priority in inspection and compliance activity.
- Category 3 contains two types of ready-to-eat products: those supporting growth with less than a ten day shelf life, and those not supporting growth. These products receive the lowest priority in terms of inspection and compliance, and the action level for presence of the hazard in food is 100 organisms per gram.

**Note:** The Canadian Food Inspection Agency assigns numerical designations to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. **Class I** is “a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death”. **Class II** is “a situation in which the use of, or exposure to, a violative product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote”. See [http://www.hc-sc.gc.ca/fn-an/securit/eval/reports-rapports/fers-siua\\_08\\_e.html](http://www.hc-sc.gc.ca/fn-an/securit/eval/reports-rapports/fers-siua_08_e.html) for further information.

In contrast, for chemical hazards, “safety evaluation” is a standard risk assessment methodology.<sup>16</sup> In that approach, maximum exposure levels are identified to fit a “notional zero risk” outcome (a dose level that is reasonably certain to pose no appreciable risk to the consumer). This approach does not produce precise estimates of risk versus dose and cannot model the impact of various interventions in terms of risk reduction. These differences are explored further in section 3.5.

### 3.2.2. Use of ranking tools

Risk ranking, using tools that rely on knowledge of risk factors to rank risks and prioritize regulatory controls, is often commissioned by risk managers (Box 3.3). Such rankings may or may not be based on risk assessments. Some tools categorize a food business against specified risk factors, e.g. by type of food, type of food preparation, type of business, compliance

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<sup>16</sup> The term “safety evaluation” is often used in regard to chemical hazards because the chief output is a definition of a presumptive “safe” exposure level, without detailed assessment of how risk varies with exposure to differing doses.

### **Box 3.3. Examples of risk ranking tools**

- The Business Food Safety Classification Tool developed by the Australian Government Department of Health and Aging is a software programme that incorporates a decision tree to assess the potential public health risk from different types of food businesses and food producers. This tool identifies those food industry sectors/businesses that are candidates for priority regulatory control and verification.
- The Risk Categorizing Model for Food Retail/Food Service Establishments developed by the Canadian Federal Provincial Territorial Food Safety Policy Committee categorizes food establishments so that the competent authority can give greater attention to those where a failure of regulatory controls would cause the greatest potential risks to consumers.
- The Food Safety Research Consortium in the United States is developing a model to produce rankings by pathogens, by food, and by pathogen/food combination, using five criteria for ranking impact on public health: number of cases of illness, number of hospitalizations, number of deaths, monetary valuations of health outcomes, and loss of Quality Adjusted Life Years.
- The National Institute for Public Health and the Environment in the Netherlands applied a quantitative methodology (developed by WHO) to calculate disease burden using Disability Adjusted Life Years and cost-of-illness in monetary terms in order to assist risk managers in prioritizing regulatory activities according to pathogen.
- Risk Ranger, a software programme developed at the University of Hobart, Australia, extends the above risk ranking tools to allow risk ranking of hazard-food combinations in national settings. Categories used in the tool include rankings for hazard severity and susceptibility of the consumer, probability of exposure to the food and probability of the food containing an infectious dose. Comparative risk in the population of interest is expressed as a relative ranking between zero and 100.

record, food user subpopulation. Other tools are used to rank hazard-food combinations in a national context by deriving a “comparative risk” scoring system. While risk ranking methods not based on risk assessments assist risk-based food regulation, their use of scoring systems (which inevitably have subjective, arbitrary elements) to derive regulatory standards has inherent shortcomings. Thus they are not a good substitute for ranking methodologies that do incorporate risk assessment.

### **3.2.3. Epidemiology**

Epidemiology is increasingly being used in food safety to study the links between the frequency and distribution of adverse health effects in specific populations and specific food-borne hazards. This includes observational studies of human illness such as case-control, analysis of surveillance data, and focused research. The usefulness of epidemiology depends on the availability of data.

Epidemiology is probably the most reliable approach to assess the current burden of illness, follow trends over time and attribute risks to sources. It is an important source of information for risk assessment, particularly the hazard identification and hazard characterization steps. As a stand-alone tool, epidemiology uses human illness data and works “backwards” to attribute risks and risk factors to foods; therefore it cannot generally be used to investigate the effects of different food safety control measures in reducing risk. However, risk assessment incorporating epidemiological data can be used to evaluate the impact of various changes or interventions in the food chain in terms of reducing risks. In other words, the risk assessment approach works forward from the relevant points in the food chain to estimate the risk to human health normally associated with a particular hazard-food combination.



### **Box 3.4. Examples of food source attribution supporting the development of risk-based standards for microbiological hazards in foods**

- Many shellfish toxins have been identified and regulatory interventions initiated only after epidemiological studies linked shellfish with outbreaks of human illness; e.g. domoic acid in shellfish in Canada, azaspiracids in shellfish in Ireland.
- Case-control studies carried out by the United States Centers for Disease Control and Prevention (CDC) have implicated ground beef as an important risk factor in *E. coli* O157:H7 infection in humans, and outbreak reports continue to be associated with this pathogen. Control efforts have focused on both slaughterhouse/processing plant hygiene and educating consumers as to proper preventive food handling and cooking methods.
- New Zealand does not have the recognized antibiotic multi-resistant *Salmonella* serotypes in food animals that can cause severe disease in humans. However, there are similar levels of antibiotic susceptible serotypes to those in other countries. Faced with applications for importation of foods from countries with multi-resistant serotypes, a source attribution model was used to apportion any potential increase in risks from imported foods against risks introduced via other transmission pathways (e.g. domestically-produced food, travellers, imported live animals, migratory birds, pet food). This model allows decisions to be made on import health standards that are proportional to risks and non-discriminatory to trade.
- Denmark has an integrated system in which data from public health surveillance and pathogen monitoring of foods of animal origin and animals at primary production and processing are routinely collected, collated and analysed by a single coordinating body. Cultures collected from infected persons, animals and retail food sources are subtyped, allowing the direct comparison of surveillance and monitoring data and the identification of public health outcomes by food source. The basic premise for this model is the predominance of at least one “distinctive” *Salmonella* subtype in each main animal reservoir; human infections of distinctive subtypes are assumed to have originated from that reservoir. The model has proven valuable for identifying pathogen reservoirs in animal populations, tracking trends of human salmonellosis and guiding interventions.

Food source attribution is particularly valuable in food safety risk management (see Box 3.4). Risk assessments often address only a single hazard or, in the microbiological field, a single hazard-food combination, whereas at some stage risk managers need to have good scientific information on all transmission pathways and their relative contributions to the aggregate risk from the hazard. Risk assessments can be designed to answer this question (see example in Annex 3), but other food source attribution approaches are more commonly used, such as analysis of outbreak data, or genotyping of human microbial isolates from multiple outbreak situations where it is known that some genotypes occur predominantly in a single animal reservoir or food type. However, food source attribution often proves difficult as sporadic cases of illness are rarely represented in the available surveillance data and these may collectively cause many more cases than the outbreaks that are primarily recorded.

The use of analytical epidemiology to support development of risk-based standards depends on the availability of sufficient surveillance data on food-borne illness. Many governments are currently strengthening surveillance systems so they can better apply analytical epidemiological techniques, as well as validate microbiological risk assessment models. A detailed description of the application of epidemiological techniques is beyond the scope of this chapter.

#### **3.2.4. Combinations of approaches**

Distinctions are drawn in this chapter between risk assessment approaches based on the four analytical steps described by Codex, the use of ranking tools and the use of analytical

epidemiological techniques. However, as a practical matter these various approaches are often used in combination or feed into each other (e.g. epidemiological data feed into hazard identification and hazard characterization steps of any risk assessment). Ways in which they can be integrated vary widely on a case-by-case basis, but all are subject to the general principles and guidelines described in the sections that follow.

The remainder of this chapter is focused on risk assessment conducted according to the Codex methodology.

### **3.3. Responsibilities of risk managers in commissioning & administering a risk assessment**

The decision to proceed with a risk assessment depends on factors such as the health risk priority ranking, urgency, regulatory needs and availability of resources and data.

It is likely that a risk assessment will *not* be commissioned when:

- The risk is well described by definitive data.
- The food safety issue is relatively simple.
- The food safety issue is not of regulatory concern or not subject to regulatory mandate.
- An urgent regulatory response is required.

It is likely that a risk assessment *will* be commissioned when:

- The hazard exposure pathway is complex.
- Data on the hazard(s) and/or health impacts are incomplete.
- The issue is of significant regulatory and/or stakeholder concern.
- There is a mandatory regulatory requirement for a risk assessment.
- There is a need to verify that an interim (or precautionary) regulatory response to an urgent food safety problem is scientifically justified.

#### **Box 3.5. General responsibilities of risk managers in commissioning and administering a risk assessment**

- Risk managers should request the relevant scientific bodies to assemble the risk assessment team or, where this is not possible, establish the risk assessment team.
- Risk managers, in consultation with risk assessors, should establish and document the:
  - ~ purpose and scope of the risk assessment;
  - ~ questions that need to be addressed by the risk assessment;
  - ~ risk assessment policy; and
  - ~ form of the outputs of the risk assessment.
- Risk managers should ensure that sufficient time and resources are available to complete the risk assessment according to specifications.

Risk managers, in consultation with risk assessors, should fulfil several tasks when commissioning a risk assessment and seeing it through to completion (Box 3.5). While risk managers do not need to know all the details of how a risk assessment is carried out, they do need a general understanding of risk assessment methodologies and what the outcomes mean.

This understanding is both acquired through, and contributes to, successful risk communication (see Chapter 4).

### **3.3.1. Forming the risk assessment team**

A risk assessment team should be appropriate to the circumstances. When strategic and large-scale risk assessments are undertaken, the general criteria described below relating to risk assessment teams apply. However, small-scale and straightforward risk assessments may be undertaken by very small teams or even by individuals, especially where a primary risk assessment is already available and the scientific work involves mostly adaptation using local data.

A large-scale risk assessment generally requires a multidisciplinary team that may include experts with biological, chemical, food technology, epidemiological, medical, statistical and modelling skills, among others. Finding scientists with the required knowledge and expertise can be a challenging task for risk managers. Where government food safety agencies do not have a large scientific staff of their own upon which to draw, risk assessors are generally recruited from the national scientific community. In some countries, national science academies may organize expert committees to carry out risk assessments for the government, and private companies that conduct risk assessments on a contract basis are also becoming more widespread.

Risk managers need to take care to ensure that the assembled team is objective, balanced in terms of scientific perspectives, and free from undue biases and conflicts of interest. It is also crucial to elicit information about potential financial or personal conflicts of interest that could bias an individual's scientific judgement. Typically, this information is solicited by a questionnaire before appointments are made to a risk assessment team. Exceptions are sometimes made if an individual has essential, unique expertise; transparency is essential when any such decisions on inclusion are made. The FAO/WHO framework for the provision of scientific advice on food safety and nutrition may provide guidance in this area.<sup>17</sup>

### **3.3.2. Specification of purpose and scope**

Risk managers should prepare a "purpose statement" for a risk assessment, which should identify the specific risk or risks to be estimated and the broad risk management goal(s). For example, a risk assessment might be designed to provide quantitative estimates of food-borne risks due to *Campylobacter* in broiler chickens on an annual basis for the national population, and the risk assessment might be primarily used to evaluate risk management options at various points from production to consumption of broiler chickens, to maximize reduction in risk. The purpose statement generally flows directly from the risk management goal(s) agreed on when the risk assessment is commissioned (see Chapter 2, section 2.4.3).

In some situations, an initial exercise may be to set up a risk assessment framework model, to identify data gaps and establish the research programme required to generate the scientific inputs needed to complete a risk assessment at a later date. Where a risk assessment can be completed using currently available scientific knowledge, the model can still identify further research that will allow later refinement of the outputs.

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<sup>17</sup> FAO/WHO. 2006. *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries)*. Final draft for public comments (available at: [ftp://ftp.fao.org/ag/agn/proscad/framework\\_en.pdf](ftp://ftp.fao.org/ag/agn/proscad/framework_en.pdf)).

The “scope” portion of the risk assessment description should identify the parts of the food production chain that are to be evaluated and should establish boundaries for risk assessors with regard to the nature and extent of scientific information to be considered. Risk managers addressing specific food safety issues at the national level should also be aware of international risk assessments and other pre-existing scientific efforts on relevant subjects before they commission new work (see Chapter 1, section 1.2.3, and Chapter 2, section 2.4.6). By considering existing risk assessments in consultation with their risk assessors, risk managers may be able to substantially narrow the scope of the work and the data needed.

### **3.3.3. Questions to be addressed by risk assessors**

Risk managers, in consultation with risk assessors, should formulate the specific questions that need to be answered by the risk assessment. Depending on the scope of the risk assessment needed and the resources available, considerable discussion may be required to arrive at clear and realizable questions which will yield answers to guide risk management decisions. As with the statement on purpose and scope, questions to be addressed by the risk assessment often flow from the broad risk management goal(s) agreed on when the risk assessment is commissioned. Examples of questions that risk managers might ask risk assessors to answer are illustrated in Box 3.6. The questions asked by the risk managers can have an important influence on the choice of risk assessment methodologies used to answer them.

#### **Box 3.6. Examples of questions to be addressed by risk assessors**

*In the example of Campylobacter in broiler chickens used in section 3.3.2, risk assessors could be asked to address any of the following questions:*

- Quantify relative impacts of specified food safety controls for *Campylobacter* in broiler chickens, either alone or in combination, on levels of consumer risk.
- Quantify influence of different levels of hazard control at specified steps in the food production chain (including prevalence at the farm level) on risk estimates (e.g. what is the impact on risk to consumers if flock prevalence is reduced by 50 percent?).
- Estimate the likely proportions of human campylobacteriosis transmitted by broiler chickens compared to other food transmission pathways.

*In the case of aflatoxin contamination of a particular crop, risk assessors could be asked to address any of the following questions:*

- Quantify the comparative lifetime cancer risk from consumption of the crop where the mean concentration of aflatoxin was reduced from 10 ppb to 1 ppb.
- Quantify the comparative lifetime cancer risk from consumption of the crop in the same scenario but for an exposed population with a significant level of liver damage from hepatitis A.
- Assess the proportionate lifetime cancer risk from current aflatoxin levels in the crop compared with other significant sources of aflatoxin in the diet (e.g. other types of crops and nuts).

### **3.3.4. Establishing risk assessment policy**

While risk assessment is fundamentally an objective, scientific activity, it inevitably contains some elements of policy and subjective scientific judgement. For example, when scientific uncertainty is encountered in the risk assessment, inferential bridges are needed to allow the process to continue. The judgements made by the scientists or risk assessors often entail a choice among several scientifically plausible options, and policy considerations inevitably affect, and perhaps determine, some of the choices. Thus gaps in scientific knowledge are

### **Box 3.7. Examples of choices that might be part of a risk assessment policy**

#### *Policies governing values-based choices:*

- Where a chemical hazard may be deliberately introduced into the food supply (e.g. as a food additive or technological aid) use should be limited to levels where there is “notionally zero-risk” to consumers, i.e. the amount permitted should be without any appreciable human health risk.
- Hazard characterization in microbiological risk assessment should include description of the type and severity of adverse health effects and categorize these in risk estimates.
- When calculating an acceptable daily intake for a chemical hazard, it is appropriate to start with the dose at which no adverse effect is observed in appropriate animal tests for the most sensitive relevant end-point (toxic effect), and to apply a 100-fold safety factor: a ten-fold factor to account for possible differences between humans and test animals in sensitivity to toxic effects, and a second ten-fold factor to account for variability in susceptibility of individuals or subgroups of the population to the toxic effect.

#### *Policies governing science-based choices:*

- When animal test data are available from relatively high-dose exposures to carcinogenic chemicals but these are considered insufficient to define the shape of the dose-response curve in the low-dose region and extrapolation is needed, a linear model may be deemed appropriate for public health protection purposes.
- Microbiological risk assessments should be constructed in modular form so that food chain parameters can be changed, or new modules added, to estimate the impact on risk.
- Toxicological reference values for carcinogenic chemicals should be based on a combination of epidemiological and animal data where available.

bridged through a set of inferences and “default assumptions.” At other points in a risk assessment, assumptions may be required that are driven by values-based, social consensus, often developed through long experience with how such issues should be handled. Box 3.7 presents some examples of each of these types of choices that might arise in a food safety risk assessment.

Documentation of all such default assumptions contributes to the consistency and transparency of risk assessments. These policy decisions are spelled out in a risk assessment policy, which should be developed by risk managers and risk assessors in active collaboration in advance of the risk assessment. Policies governing values-based choices and judgements should be decided primarily by risk managers (see Chapter 2), whereas policies governing science-based choices and judgements should be decided primarily by risk assessors, with active communication between the two functional groups in each case.

Pre-determining risk assessment policy for scientific aspects of a risk assessment is especially difficult when it concerns sufficiency of scientific evidence. Often, only limited data sets are available at a particular step and scientific judgements are required if risk assessment is to proceed. While risk assessment policy in a broad sense may be able to guide these judgements, they are more likely to be made on a “case-by-case” basis. Different national legal contexts also influence the way sufficiency of evidence and scientific uncertainty are addressed.

#### **3.3.5. Specification of form of the outputs**

Outputs of a risk assessment may be sought in non-numerical (qualitative) or numerical (quantitative) form. Non-numerical risk estimates provide a less definitive basis for decisions but are adequate for several purposes, such as establishing relative risks or evaluating relative

impacts on risk reduction of different control measures. Numeric estimates of risk can take one of two formats:

- Point estimate, which is a single numerical value representing for example the risk in a worst case scenario.
- Probabilistic risk estimates, which include variability and uncertainty and are presented as a distribution reflecting more real-life situations (see section 3.4.5).

To date, point estimates have been more common outputs of chemical risk assessments while probabilistic outputs are the usual product of microbiological risk assessments.

### ***3.3.6. Time and resources***

While it is desirable to maximize scientific inputs and commission specific research to fill data gaps when conducting a risk assessment, all risk assessments are inevitably constrained in some ways. In commissioning a risk assessment, risk managers must ensure that sufficient resources (e.g. time, money, personnel and expertise) are available relative to the purpose and scope, and establish a realistic timetable for completion of the work.

## **3.4. General characteristics of risk assessment**

Irrespective of the context, risk assessments generally share a number of basic characteristics (Box 3.8). While these attributes are described comprehensively in the sections that follow, in some situations a specific risk assessment is a relatively simple and straightforward exercise. In such cases, the general characteristics can be substantially modified; for instance, it may sometimes be possible for experts within a government food safety agency to conduct an adequate risk assessment quickly and efficiently, without the need to assemble a multidisciplinary risk assessment team.

### **Box 3.8. General characteristics of food safety risk assessments**

- A risk assessment should be objective, transparent, fully documented and available for independent scrutiny.
- The functions of risk assessment and risk management should be carried out separately to the extent practicable.
- Risk assessors and risk managers should engage in an iterative and on-going dialogue throughout risk assessment.
- Risk assessment should follow a structured and systematic process.
- Risk assessment should be based on scientific data and should take into account the whole “production-to-consumption” food pathway.
- Uncertainties in risk estimates and their origins and impacts should be clearly documented, and explained to risk managers.
- A risk assessment should be subject to peer review if considered appropriate.
- A risk assessment should be reviewed and updated as new information permits or requires.

### ***3.4.1. Objectivity and transparency***

A risk assessment should be objective and unbiased. Opinions or value judgements on issues other than science (for instance on economic, political, legal or environmental aspects of the risk) should not be allowed to influence the outcome and risk assessors should explicitly identify and discuss any judgements on the sufficiency of the science that was relied on.

A participatory process should be used in initiating, performing and finalising a risk assessment and reporting should be in a style that allows risk managers and other stakeholders to properly understand the process. Above all, a risk assessment must be transparent and in documenting the process the risk managers should:

- Describe the scientific rationale.
- Reveal any biases that may affect the conduct or results of the risk assessment.
- Identify clearly and concisely all scientific inputs.
- Clearly state all assumptions.
- Provide an interpretive summary for lay readers.
- Where possible, make assessments available to the public for comment.

#### ***3.4.2. Functional separation of risk assessment and risk management***

In general, the functions of risk assessment and risk management should be carried out separately to the extent practicable, so that the science remains independent from regulatory policy and values. However, delineating the functional boundaries between risk assessors, risk managers and risk communicators in all situations is a significant challenge. Functional separation may be more obvious when different bodies or officials are responsible for risk assessment and risk management tasks. However, functional separation can also be achieved in countries with limited resources and personnel where risk assessments are undertaken by people who act as both risk assessors and risk managers. What is important in these cases is to have conditions in place which ensure that risk assessment tasks are carried out separately from risk management tasks (see section 2.4.6). In such cases, particular attention should be devoted to ensuring that the risk assessment meets the criteria laid out in Box 3.8. Whatever the functional separation arrangements, a highly interactive, iterative process is essential for risk analysis as a whole to be effective. Communication between risk assessors and risk managers is also a critical element in the process, as described in more detail in Chapter 4.

#### ***3.4.3. Structured process***

Risk assessments should follow a structured and systematic process; see section 3.5 on risk assessment methodology.

#### ***3.4.4. Basis in science***

It is a primary tenet that risk assessment be soundly based on scientific data. Data of sufficient quality, detail and representativeness must be located from appropriate sources and assembled in a systematic manner. Descriptive and computational elements should be supported with scientific references and accepted scientific methodologies, as appropriate.

When a risk assessment is commissioned, there often are insufficient data available to complete the assignment. Scientific information to support many food safety risk assessments is available from a variety of sources, both national and international (Box 3.9). Risk assessments carried out at the national level are rapidly increasing in number and many of them can be accessed through web-based portals. For instance, microbiological risk assessments carried out by the United States Food Safety and Inspection Service are available at [www.fsis.usda.gov/Science/Risk\\_Assessments/index.asp](http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp).

FAO and WHO administer international panels of experts on chemical (JECFA and JMPR) and microbiological hazards (JEMRA) to provide risk assessments as the basis for Codex standards. These assessments are also used by risk assessors and risk managers at the national level.

#### **Box 3.9. Sources of scientific information for risk assessments**

- Published scientific studies.
- Specific research studies carried out (by the government agency or external contractors) in order to fill data gaps.
- Unpublished studies and surveys carried out by industry, such as data on the identity and purity of a chemical under consideration as well as toxicity and residue studies carried out by the chemical's manufacturer\*.
- National food monitoring data.
- National human health surveillance and laboratory diagnostic data.
- Disease outbreak investigations.
- National food consumption surveys, and regional diets e.g. those constructed by FAO/WHO.
- Use of panels to elicit expert opinion where specific data sets are not available.
- Risk assessments carried out by other governments.
- International food safety databases.
- International risk assessments carried out by JECFA, JMPR and JEMRA.

\* Manufacturers often may agree to supply data only if it remains confidential. Risk managers must judge the need to trade off transparency so as to obtain relevant and sufficient data.

While risk assessors conducting a given risk assessment may try to fill data gaps and to obtain adequate input data, inevitably default assumptions will need to be made at some steps during risk assessment. These assumptions must remain as objective, biologically realistic and consistent as possible. Risk assessment policy provides broad guidelines but default assumptions specific to a particular problem may have to be made on a case-by-case basis. It is essential that any such assumptions are transparently documented.

Sometimes when data are lacking, expert opinions can be used to address important questions and uncertainties. A variety of knowledge elicitation techniques have been developed for this purpose. Experts may be unaccustomed to describing what they know or how they know it; knowledge elicitation techniques reveal expert knowledge and help to make expert opinions as evidence-based as possible. Approaches that can be used include interviews, the Delphi method,<sup>18</sup> surveys and questionnaires, among others.

#### **3.4.5. Dealing with uncertainty and variability**

Definitive data needed to derive quantitative risk estimates are often lacking, and sometimes there are significant uncertainties inherent in biological or other models used to represent the processes that contribute to risk. Uncertainty about the available scientific information is often addressed in a risk assessment by using a range of possible data values.

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<sup>18</sup> The Delphi method is a technique for eliciting and refining group judgements. The objective is generally the reliable and creative exploration of ideas or the production of suitable information for decision making (further information on this method is available at: <http://www.iit.edu/~it/delphi.html>).



### **Box 3.10. Examples of uncertainty and variability in risk assessments**

- ***Methylmercury in fish (Annex 2).*** The two best-designed large epidemiological studies have yielded results interpreted by some scientists as inconsistent. In the United States, risk assessors relied on only the study yielding stronger evidence to assess the risk, and risk managers adopted a TDI with a 10-fold default uncertainty margin. At the international level, JECFA integrated exposure data from both studies and applied a 6.4-fold data-derived uncertainty factor in recommending a somewhat higher PTWI. The uncertainty factors applied in each case were in response to the known variability of individuals in susceptibility to harm from methylmercury.
- ***Listeria in ready-to-eat foods (Annex 3).*** A preliminary risk assessment in the United States revealed substantial uncertainties regarding the relative risks posed by *Listeria monocytogenes* in different foods. Risk managers chose to collect more data and carry out a much more detailed risk assessment, which suggested substantially clearer regulatory priorities. Variability in hazard levels, food consumption and human susceptibility to harm were included and accounted for in the detailed assessment.

Two distinct characteristics of scientific information are relevant in this context. *Variability* is a characteristic of phenomena that differ from one observation to the next; for example, people eat different amounts of a food, and the level of a particular hazard present in a food also can vary widely from one serving of food to another. *Uncertainty* is the quality of being unknown, for example because inadequate data exist, or because the biological phenomena involved are not well understood. For instance, in assessing a chemical hazard scientists may need to rely on data from toxicity tests in rodents because insufficient human epidemiological data exist. For examples of each kind of uncertainty, see Box 3.10.

Risk assessors must ensure that risk managers understand the impacts of limitations of available data on the results of the risk assessment. Risk assessors should provide an explicit description of uncertainties in the risk estimate and their origins. The risk assessment should also describe how default assumptions may have influenced the degree of uncertainty in the outputs. As necessary or appropriate, the degree of uncertainty in the results of a risk assessment should be described separately from the effects of variability inherent in any biological system.

Deterministic chemical risk assessments (see section 3.5.2.1) for chronic adverse health effects use point estimates to represent data and typically do not explicitly quantify uncertainty or variability in outcomes (see section 3.5).

#### **3.4.6. Peer review**

Peer review reinforces transparency and allows wider scientific opinion to be canvassed in relation to a specific food safety issue. External review is especially important where new scientific approaches are being applied. Open comparison of the outcomes of similar risk assessments where different scientific defaults and other judgements have been used can yield useful insights.

### **3.5. Risk assessment methodology**

Different risk assessment methods are used in different countries and within countries, and different methods may be used to assess different kinds of food safety problems. Methods vary according to the class of hazard (i.e. chemical, biological or physical hazard), the food safety scenario (e.g. concerning known hazards, emerging hazards, new technologies such as biotechnology, complex hazard pathways such as for antimicrobial resistance) and the time and resources available. This section provides only a brief overview of methods; readers who wish to gain deeper understanding can consult the references listed at the end of the chapter.

Differences in risk assessment methodology are most apparent for chemical compared with microbiological hazards. This is partly due to intrinsic differences between the two classes of hazards (Box 3.11). The differences also reflect the fact that for many chemical hazards, a choice can be made as to how much of the chemical may enter the food supply, e.g. for food additives, residues of veterinary drugs and pesticides used on crops. Use of these chemicals can be regulated or restricted so that residues at the point of consumption do not result in risks to human health. Microbial hazards, in contrast, are ubiquitous in the food chain, they grow and die, and despite control efforts, they often can exist at the point of consumption at levels that do present obvious risks to human health.

**Box 3.11. Some characteristics of microbial and chemical hazards that influence the choice of risk assessment methodology**

<b>Microbial Hazard</b>	<b>Chemical Hazard</b>
<ul style="list-style-type: none"> <li>• Hazards can enter foods at many points from production to consumption.</li> <li>• The prevalence and concentration of hazard changes markedly at different points along the food production chain.</li> <li>• Health risks are usually acute and result from a single edible portion of food.</li> <li>• Individuals show a wide variability in health response to different levels of hazard.</li> </ul>	<ul style="list-style-type: none"> <li>• Hazards usually enter foods in the raw food or ingredients, or through certain processing steps (e.g. acrylamide or packaging migrants).</li> <li>• The level of hazard present in a food after the point of introduction often does not significantly change.</li> <li>• Health risks may be acute but are generally chronic.</li> <li>• Types of toxic effects are generally similar from person to person, but individual sensitivity may differ.</li> </ul>

**3.5.1. Basic components of a risk assessment**

The risk assessment process is generally represented as consisting of four steps, described by Codex (see Figure 3.1 in section 3.2.1 above). Following identification of the hazard(s), the order in which these tasks can be carried out is not fixed; the process is normally highly iterative, with steps repeated as data and assumptions are refined.

3.5.1.1. Hazard identification

Specific identification of the hazard(s) of concern is a key step in risk assessment and begins a process of estimation of risks specifically due to that hazard(s). Hazard identification may have already been carried out to a sufficient level during risk profiling (see Chapter 2); this generally is the case for risks due to chemical hazards. For microbial hazards, the risk profile may have identified specific risk factors associated with different strains of pathogens, and subsequent risk assessment may focus on particular subtypes. Risk managers are the primary arbiters of such decisions.

3.5.1.2. Hazard characterization

During hazard characterization, risk assessors describe the nature and extent of the adverse health effects known to be associated with the specific hazard. If possible, a dose-response relationship is established between different levels of exposure to the hazard in food at the point of consumption and the likelihood of different adverse health effects. Types of data that

can be used to establish dose-response relationships include animal toxicity studies, clinical human exposure studies and epidemiological data from investigations of illness.

Response parameters may be categorized according to the risk management questions that are asked of risk assessors; for example, for chemical hazards, type of adverse health effects induced by different doses of chemical hazards in animal tests; for microbial hazards, infection, morbidity, hospitalization and death rates associated with different doses. Where economic analyses are undertaken, hazard characterization should include the large impact of food-borne illness that is due to complications following the acute phase, e.g. with haemolytic uraemic syndrome with *E. coli* O157:H7, and with Guillain-Barré syndrome with *Campylobacter*.

#### 3.5.1.3. Exposure assessment

Exposure assessment characterizes the amount of hazard that is consumed by various members of the exposed population(s). The analysis makes use of the levels of hazard in raw materials, in food ingredients added to the primary food and in the general food environment to track changes in levels throughout the food production chain. These data are combined with the food consumption patterns of the target consumer population to assess exposure to the hazard over a particular period of time in foods as actually consumed.

Characterization of exposure may vary according to whether the focus is on acute or chronic adverse health effects. Risks from chemical hazards are typically assessed against long-term or lifetime chronic exposure to the hazard, often from multiple sources. Acute exposures are also frequently considered for certain contaminants and pesticide and veterinary drug residues. Risks from microbial hazards are typically evaluated in terms of single exposures to a contaminated food.

The level of a hazard in a food at the time of consumption is often very different from that when the food is being produced. Where necessary, exposure assessment can scientifically evaluate changes in levels of hazard throughout the production process to estimate the likely level at the time of consumption. In the case of chemical hazards in foods, there may be relatively little change from levels in raw materials. In the case of microbiological hazards in foods, marked changes in levels can occur due to pathogen growth, and cross-contamination at the time of final preparation for consumption may add to the complexity of the evaluation.

#### 3.5.1.4. Risk characterization

During risk characterization, outputs from the previous three steps are integrated to generate an estimate of risk. Estimates can take a number of forms and uncertainty and variability must also be described if possible (see section 3.4.5). A risk characterization often includes narrative on other aspects of the risk assessment, such as comparative rankings with risks from other foods, impacts on risk of various “what if” scenarios, and further scientific work needed to reduce gaps.

Risk characterization for chronic exposure to chemical hazards does not typically include estimates of the likelihood and severity of adverse health effects associated with different levels of exposure. A “notional zero risk” approach is generally taken and where possible the goal is to limit exposure to levels judged unlikely to have any adverse effects at all (see section 3.5.3 below).

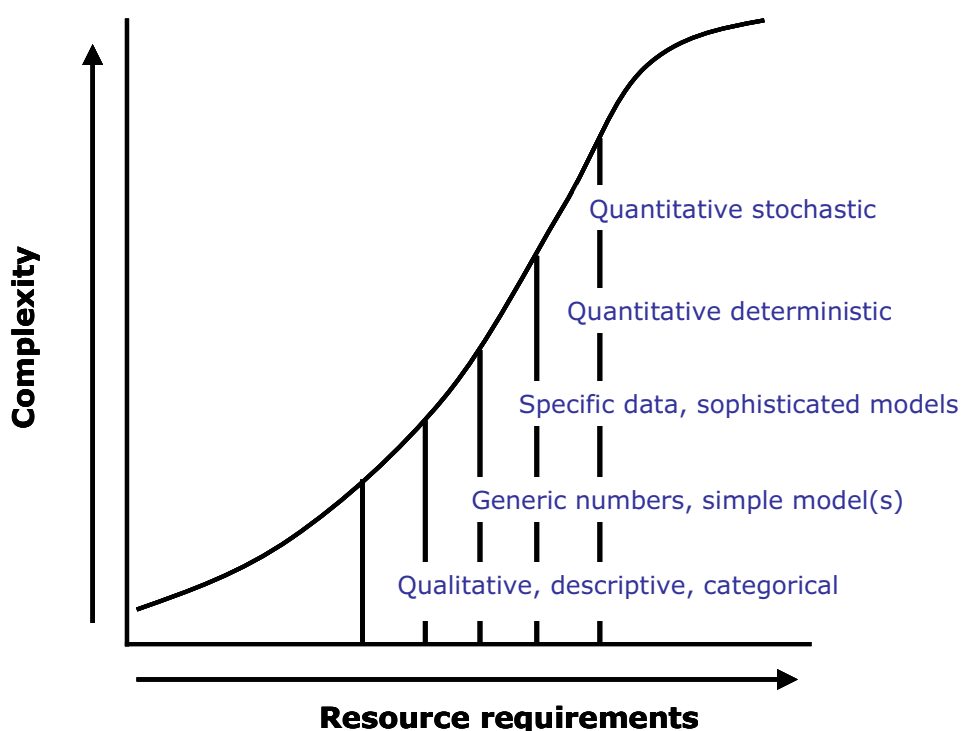
### 3.5.2. Qualitative or quantitative?

Risk assessment outputs can range from qualitative to quantitative with various intermediate formats (see Figure 3.2). The characteristics of risk assessments presented above apply to all types. In qualitative risk assessments, outputs are expressed in descriptive terms such as high, medium or low. In quantitative risk assessments, the outputs are expressed numerically and may include a numerical description of uncertainty. In some cases, intermediate formats are referred to as semi-quantitative risk assessments. For instance, one semi-quantitative approach may be to assign scores at each step in the pathway and express outputs as risk rankings.

#### 3.5.2.1. Deterministic (point estimate) approaches

The term “deterministic” describes an approach in which numerical point values are used at each step in the risk assessment; for example, the mean or the 95<sup>th</sup> percentile value of measured data (such as food intake or residue levels) may be used to generate a single risk estimate. Deterministic approaches are the norm in chemical risk assessment, for instance to determine whether any risk may arise from consumption of a single food containing a chemical residue arising from a use governed by an MRL.

**Figure 3.2. Continuum of risk assessment types**



#### 3.5.2.2. Stochastic (probabilistic) approaches

In stochastic approaches to risk assessment, scientific evidence is used to generate statements of probabilities of individual events, which are combined to determine the probability of an adverse health outcome. This requires mathematical modelling of the variability of the phenomena involved, and the final risk estimate is a probability distribution. Stochastic (probabilistic) models are then used to create and analyse different scenarios of risk. This approach is generally viewed as being most reflective of the real world, but stochastic models are often complex and difficult to generate.

Stochastic models are only now beginning to be used to complement the “safety evaluation” approaches traditionally used in managing chemical food-borne hazards, in particular for contaminants. On the other hand, probabilistic approaches are the norm in the newer discipline of microbial risk assessment and provide a mathematical description of the dynamics of hazard transmission from production to consumption. Exposure data are combined with dose-response information to generate probabilistic estimates of risk. Even one colony-forming unit of the pathogen in an edible portion of food is assumed to have some probability of causing infection; in this respect, such risk models resemble risk assessment methodology for chemical carcinogens.

### ***3.5.3. Risk assessment for chemical hazards***

Chemical hazards in foods include food additives, environmental contaminants such as mercury and dioxins, natural toxicants in food, such as glycoalkaloids in potatoes and aflatoxins in peanuts, acrylamide, and residues of pesticides and veterinary drugs. The scientific rationale for risk assessment of chemical hazards is somewhat different from that for biological hazards. Adverse health effects are usually predicted for long-term exposure to chemicals, whereas biological hazards are generally assessed in terms of a single exposure and an acute health risk.<sup>19</sup> For certain chemicals, such as some mycotoxins, marine toxins, pesticides and veterinary drugs, both acute and chronic health effects need to be considered.

Considerable amounts of data of the types needed to establish standards have been provided by long-standing global data-gathering systems and other information sources specific to the class of chemical hazard under consideration, such as industry registration packages for pesticides and veterinary drugs or for food additives.

On the risk management side, many quantitative standards for chemical hazards in foods have been established by Codex and some national governments over several decades based on the mostly predictive risk assessment processes for chemicals. These generally employ a “worst case” standard-setting scenario based on a “notional zero risk” ALOP (see Box 2.16 in Chapter 2 for examples).

#### **3.5.3.1. Hazard identification**

Hazard identification describes the adverse effects of the substance, the possibility of causing an adverse effect as an inherent property of the chemical, and the type (age group, gender, etc.) and extent of the population that may be at risk. Because sufficient human data from epidemiological studies are often not available, risk assessors frequently rely on results from toxicological studies in experimental animals and in vitro studies.

#### **3.5.3.2. Hazard characterization**

Hazard characterization describes and evaluates dose-response relationships for the most sensitive adverse effects reported in the available studies. This includes consideration of mechanistic aspects (e.g. whether the mechanism of action of the chemical observed in often high-dose experimental studies is also relevant to human exposure at lower levels).

In cases where the toxic effect results from a mechanism that has a threshold, hazard characterization usually results in the establishment of a safe level of intake, an acceptable

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<sup>19</sup> Note that many natural toxins such as mycotoxins and marine toxins need insight into biology as well as chemistry for their risk assessment.

daily intake (ADI), or tolerable daily intake (TDI) for contaminants. For some substances used as food additives the ADI may not need to be specified, i.e. no numerical ADI is considered necessary. This may be the case when a substance is assessed to be of very low toxicity, based on the biological and toxicological data, and the total dietary intake of the substance, arising from the levels permitted in foods to achieve the desired function does not represent a hazard.

#### Estimation of safe level of intake<sup>20</sup>

Estimation of the ADI or TDI (PTWI) includes the application of default “uncertainty factors” to a no-effect-level or low-effect level observed in experimental or epidemiological studies, to account for uncertainties inherent in extrapolating from an animal model to humans and to account for inter-individual variability (see Box 3.7). An ADI or TDI therefore represents a crude but conservative approximation of an actual chronic safe daily intake; both the estimate of risk and the inherent uncertainties remain unquantified. If sufficient data are available, the default uncertainty factors can be replaced by data-derived chemical-specific extrapolation factors. The term tolerable daily intake (TDI) or provisional tolerable weekly intake (PTWI), as opposed to an ADI, is used for contaminants and established by applying the same methods and principles.

The conservatism considered to be inherent in such a safety evaluation is generally thought to ensure sufficient protection of human health.

Methods have also been developed for calculating reference doses for acute exposures to toxic chemicals when such potential adverse health effects are plausible, even if rare. For example, an acute reference dose (ARfD) may be calculated for a pesticide to take into account the possibility of occasional intake of residues that far exceed the MRL.

Toxicological reference values used by different authorities for (genotoxic) carcinogenic chemicals vary. Some are based on a combination of epidemiological and animal data, some may be based on animal data alone, and different mathematical models may be used to extrapolate risk estimates to low doses. These differences can lead to significant variability in cancer risk estimates for the same chemical.

#### 3.5.3.3. Exposure assessment

Exposure assessment describes the exposure pathway or pathways for a chemical hazard and estimates total intake. For some chemicals, intake may be associated with a single food, while for others the residue may be present in multiple foods, as well as in drinking water, and sometimes in household products, such that food accounts for only a portion of total exposure. For chemicals, exposure assessment often uses values at certain points on the continuum of exposure, such as the mean or the 97.5<sup>th</sup> percentile. Such point estimates are referred to as deterministic models. Some exposure models are emerging, such as for intake of pesticide residues, that take into account the distribution of food consumption by a population. These models, generally called probabilistic, provide more details on the distribution of exposed consumers, but are not inherently more accurate than deterministic models.

The outcome of the exposure assessment is compared to the ADI or TDI in order to determine whether estimated exposures to the chemical in foods are within safe limits.

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<sup>20</sup> These are toxicological reference values, or also called health-based guidance values.

#### 3.5.3.4. Risk characterization

Risk characterization in chemical risk assessment primarily takes the form of defining a level of exposure presumed to pose a “notional zero risk.” That is, the ALOP is set below a dose associated with any significant likelihood of harm to health. Standards are then typically based on “worst case” exposure scenarios in order to keep risk below this ALOP.

Quantitative risk assessment methodologies have only rarely been applied for chemical hazards thought to pose no appreciable risk below certain very low levels of exposure (i.e. those with mechanisms of toxic action believed to exhibit a threshold), probably because the approach described above has generally been considered to provide an adequate margin of safety without a need to further characterize the risk. In contrast, quantitative risk assessment models have been applied by some governments as well as by international expert bodies (JECFA) for effects that are judged to have no threshold, i.e. for genotoxic carcinogens. These models employ biologically-appropriate mathematical extrapolations from observed animal cancer incidence data (usually derived from tests using high doses) to estimate the expected cancer incidence at the low levels typical of ordinary human exposure. If epidemiological cancer data are available, they also can be used in quantitative risk assessment models.

Annex 2 provides an example of chemical risk assessment methods applied to characterize the risk of a non-carcinogen, methylmercury, as a contaminant in fish.

#### 3.5.3.5. Application of toxicological guidance values

For veterinary drug and pesticide residues, maximum residue levels (MRLs) are derived from controlled studies and are generally established so that the theoretical maximum daily intake of residues (calculated by any of several accepted methods) does not exceed the ADI.

For environmental contaminants and other chemicals that appear in food, regulatory standards often define “permissible levels” (or maximum levels (MLs) established by risk managers). In assessing the risks of these hazards it is recognized that as a practical matter it is often neither economically nor technically feasible to apply the same “notional zero risk” model to unavoidable contaminants as to other chemicals in the food supply. MLs are generally set so that the estimated intake does not exceed the TDI or PTWI. Risk managers may ask the risk assessors to compare the health protection impact of different proposed MLs. In such cases, the risk assessors focus on the exposure assessment to provide a more in-depth scientific basis for the risk management choices.

### **3.5.4. Risk assessment for biological hazards**

Biological risk assessments typically use a quantitative model to describe the baseline food safety situation and estimate the level of consumer protection currently afforded. Then, some of the inputs into the model are changed, such as the level of the hazard in the raw food at the time of primary production, the conditions of processing, the temperature at which packaged material is held during retail and in the home. Changing inputs in a series of simulations enables the risk assessors to predict the impacts of the various control measures on the level of risk compared to that estimated in the baseline model.

#### 3.5.4.1. Hazard identification

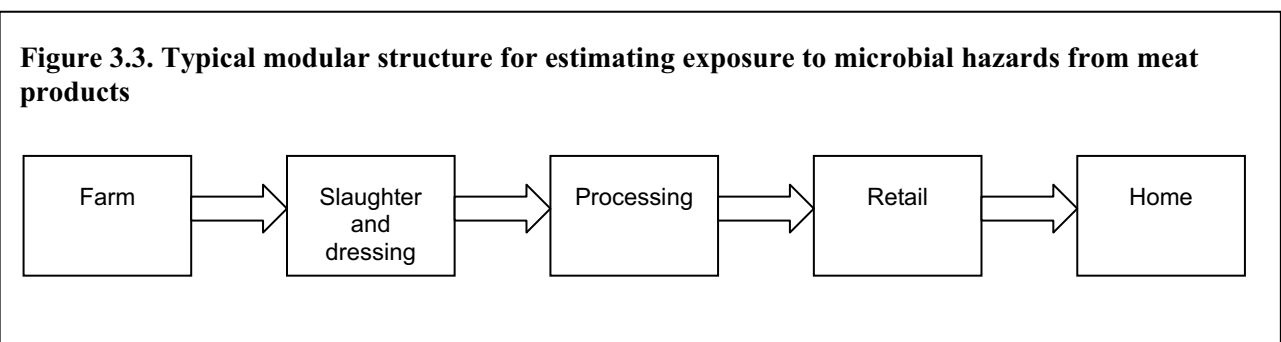
A wide range of biological hazards can cause food-borne illness. Long-familiar hazards include microbes, viruses, parasites and toxins of biological origin, but new hazards are continually being identified, such as *E. coli* O157:H7, the prion agent of BSE, and multi-

antibiotic resistant strains of *Salmonella*. In a given case, a risk profile may have identified specific strains or genotypes of pathogens that pose risks in a particular situation, and assessment may focus on these.

#### 3.5.4.2. Hazard characterization

A wide range of hazard factors (e.g. infectivity, virulence, antibiotic resistance) and host factors (e.g. physiological susceptibility, immune status, previous exposure history, concurrent illness) affect hazard characterization and its associated variability. Epidemiological information is essential for full hazard characterization.

While dose-response data are essential for quantitative biological risk assessment, such data are often difficult to obtain for specific hazards. Relatively little human data is available to model dose-response curves for specific populations of interest, and assumptions often have to be made in this area, e.g. by using surrogate dose-response data from a different pathogen.



However, data from outbreak investigations can be a useful source in establishing the dose-response relationship.

Dose-response relationships can be developed for a range of human responses, e.g. infection, morbidity, hospitalization, and death rates associated with different doses.

#### 3.5.4.3. Exposure assessment

A food-chain exposure pathway model up to the point of consumption is developed for the hazard so that a human dose-response curve can be used to generate estimates of risk (Figure 3.3). Consideration of the whole food chain, while not always necessary, should be encouraged to the extent required to answer the risk managers' questions. The level of human exposure depends on many factors including: the extent of initial contamination of the raw food, characteristics of the food and the food processes in terms of the hazard organism's survival, multiplication or death, and storage and preparation conditions before eating. Some transmission pathways, for instance those for *Campylobacter* in poultry, may involve cross-contamination at retail or in the home.

#### 3.5.4.4. Risk characterization

Risk estimates can be qualitative, e.g. high, medium or low rankings for a pathogen, or presented in quantitative terms, e.g. cumulative frequency distributions of risk per serving(s), annual risks for targeted populations, or relative risks for different foods or different pathogens.

Considerable challenges lie ahead in carrying out national quantitative microbial risk assessments for hazard-food combinations that pose significant risks to human health. Codex



has stated in its guidelines for microbiological risk assessment that “a microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread”.<sup>21</sup> However, biological characteristics of the pathogen/host relationship are often uncertain and modelling the exposure pathway from production to consumption often suffers from substantial data gaps.

Bearing these challenges in mind, risk characterization for microbial hazards may be somewhat inaccurate, but the greater strength of microbial risk assessment lies in its ability to model different food control measures and their impact on estimates of relative risks. Modelling “what-if” scenarios, such as changing the assumed prevalence of infection in the live animal population from which the food is derived, is also an essential part of economic analysis (see section 3.6).

Annex 3 provides an example of the use of microbial risk assessment in managing *Listeria monocytogenes* in ready-to-eat foods.

### **3.5.5. Biotechnology risk assessment**

Risk analysis principles and food safety assessment guidelines have recently been elaborated by Codex for foods derived from “modern biotechnology”, i.e. those containing, derived from or produced using genetically modified organisms. Potential adverse health effects that require assessment include transfer of, or creation of new, toxins or allergens into foods with introduced genetic traits.

Safety assessment is carried out to identify whether a hazard, nutritional or other safety concern is present, in which case information on its nature and severity should be collected and analysed. The safety assessment should include a comparison between the whole food derived from modern biotechnology (or component thereof) and its conventional counterpart, taking into account both intended and unintended effects.

If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health, using those testing and risk assessment methods appropriate to the nature of the identified concern. In this context, animal feeding studies may not be suitable as a test system to characterize risks arising from modern biotechnology, and a relatively broad range of other tests may need to be applied to fully assess the potential for risks to human health.

Pre-market safety assessments should be undertaken on a case-by-case basis using a structured and integrated approach.

### **3.5.6. Sensitivity analysis**

Sensitivity analysis is a tool that can help risk managers select those controls that best achieve risk management goals. Sensitivity analysis, as a scientific process, shows the effects of changes in various inputs (data or assumptions) on the outcomes of a risk assessment. One of the most useful insights gained from a sensitivity analysis is estimating how much the

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<sup>21</sup> FAO/WHO. 1999. *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*. Codex Alimentarius Commission. CAC/GL 30-1999 (available at: [http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en))

uncertainty or variability associated with each input factor contributes to the overall uncertainty and variability in the risk estimate. Input distributions where uncertainty has the greatest impact on the outcome can be identified, and this process also can help set priorities for research to reduce uncertainty.

### ***3.5.7. Validation***

Model validation is the process of evaluating a simulation model used in a risk assessment for its accuracy in representing a food safety system, e.g. by comparing model predictions of food-borne disease with human surveillance data, or by comparing model predictions on hazard levels at intermediate steps in the food production chain with actual monitoring data.

While validation of the outputs of a risk assessment is desirable, this activity is not always practical. This is especially true for chemical risk assessments, where chronic adverse health effects in humans may be predicted from animal tests but can rarely be validated with human data.

### ***3.5.8. Establishment of “targets” in the food chain as regulatory standards***

The concept of setting food safety “targets” at various points in the food production chain as flexible implementation tools was described in Chapter 2. Developing and evaluating specific, quantitative microbiological metrics, such as performance objectives and performance criteria that can be incorporated in regulations, was described in Boxes 2.14 and 2.15.

Risk assessors are involved in developing risk-based microbiological targets by simulating their impacts in risk models. In most cases, the goal of such simulations is to develop practical risk-based metrics than can be directly incorporated (and monitored) in HACCP plans, such as process criteria, product criteria and microbiological criteria. However, considerable methodological challenges remain in this area.

The concept of regulatory targets is equally applicable to chemical hazards. Currently, standards for chemical hazards in foods are often generic, such as requiring use of a pesticide or veterinary drug according to good agricultural practice (GAP) and good veterinary practice (GVP). MRLs developed from this process are not directly related to health outcomes. An appropriate performance target developed from a quantitative risk assessment could be the level of chemical hazard that is permissible at a specified step in the food chain, weighted relative to the ADI.

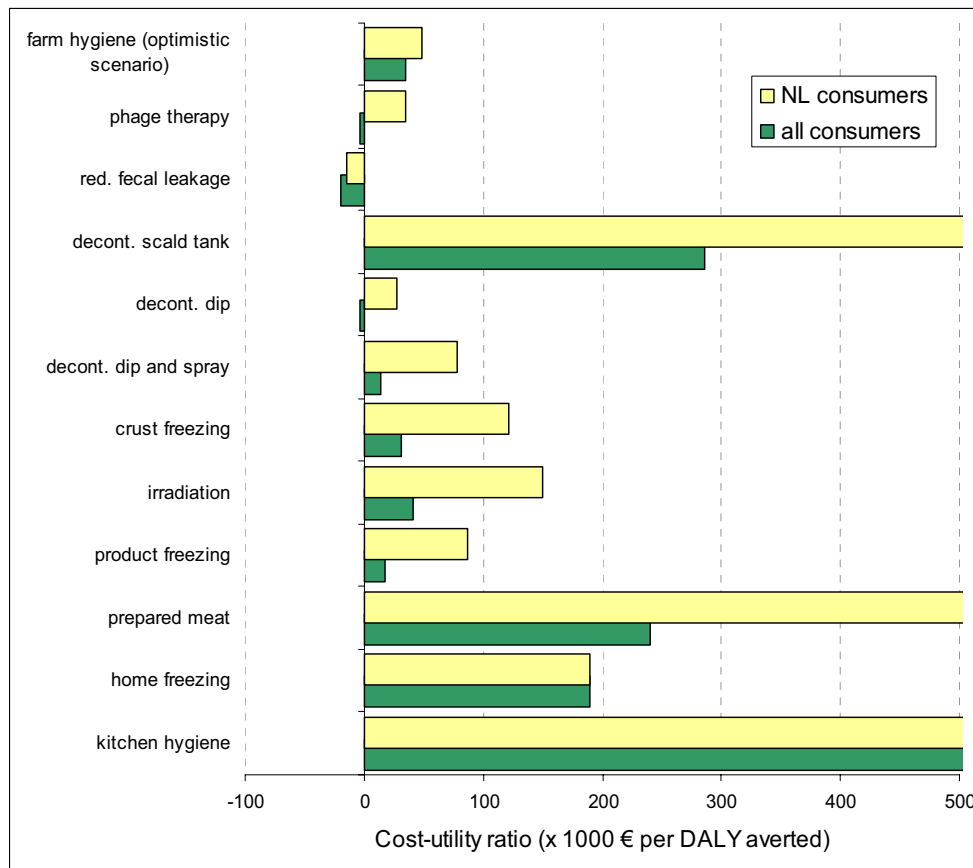
## **3.6. Integrating risk assessment and economic assessment**

As both risk assessment and economic assessment suffer from uncertainty, there are real benefits in integrating the two disciplines to gain more realistic descriptions of the consequences of decisions that may be made by risk managers. The common element is being able to create a single matrix for decision-making. Typically, such matrices convert all outcomes, health impacts, economic costs and other costs, into units (such as dollars, “disability-adjusted life years”, DALYs, or “quality-adjusted life years”, QALYs) that permit ready comparison. While noting the increasing interest in using such tools, it is beyond the scope of this Guide to examine economic methodologies for estimating costs and benefits of different risk management options.

Nevertheless, one good recent example of integrated risk assessment and economic assessment is the work of Havelaar and others in the Netherlands, who estimated cost-utility ratios for different interventions to reduce contamination of broiler chickens with

*Campylobacter*. Figure 3.4, from their analysis, makes the cost per unit of health risk averted (DALY) very transparent to risk managers making decisions on control measures. It shows that decontamination in the scald tank, cooking (prepared meat) and good kitchen hygiene have by far the greatest cost-utility.

**Figure 3.4. Cost-utility ratios for different interventions to reduce contamination of broiler chickens with *Campylobacter* \***



\* Data are presented for effect on Dutch consumers (NL) and for effect on all consumers (including those who consume exports from the Netherlands), from Havelaar and others, 2005.

### 3.7. Suggestions for further reading

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- FAO/WHO.** Risk assessments and publications of JECFA, JEMRA and JMPR are available on the FAO and WHO web sites:
- JECFA: [http://www.fao.org/ag/agn/jecfa/index\\_en.stm](http://www.fao.org/ag/agn/jecfa/index_en.stm)  
<http://www.who.int/ipcs/publications/jecfa/en/index.html>
- JEMRA: [http://www.fao.org/ag/agn/jemra/riskassessment\\_en.stm](http://www.fao.org/ag/agn/jemra/riskassessment_en.stm)  
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## 4. Risk Communication

**Chapter summary:** Risk communication is a powerful but often underutilized element of risk analysis. This chapter examines the role played by good risk communication in the application of the generic food safety RMF. Critical steps within the RMF at which effective communication is essential are identified, and the specific communication processes required at each stage are described. Practical aspects of communication, such as choosing appropriate goals for risk communication and how to identify and engage external stakeholders, are briefly reviewed. While ensuring good risk communication requires thoughtful planning and some commitment of resources, risk managers may find that establishing an infrastructure for communication and a climate in which communication is encouraged, expected and flows naturally, are among the most important steps they can take to achieve a successful outcome for a risk management process. This chapter does not explain “how to talk about risk”, a separate topic beyond the scope of this Guide, but readers are referred to the reference materials at the end of the chapter for advice on that subject.

### 4.1. Introduction

Risk communication is an integral part of risk analysis and an inseparable element of the RMF. Risk communication helps to provide timely, relevant and accurate information to, and to obtain information from, members of the risk analysis team and external stakeholders, in order to improve knowledge about the nature and effects of a specific food safety risk. Successful risk communication is a prerequisite for effective risk management and risk assessment. It contributes to transparency of the risk analysis process and promotes broader understanding and acceptance of risk management decisions.

Numerous reports in the international literature have described how to communicate about risks. Communicating effectively with different audiences requires considerable knowledge, skill and thoughtful planning, whether one is a scientist (a risk assessor), a government food safety official (a risk manager), a communication specialist, or a spokesperson for one of the many interested parties involved in food safety risk analysis.

This chapter examines the role of risk communication in risk analysis, and describes practical approaches for ensuring that sufficient, appropriate communication takes place at necessary points in application of the RMF. It illustrates some effective methods for fostering essential communication within the risk analysis team and for engaging stakeholders in dialogue about food-related risks and the selection of preferred risk management options. This chapter does not attempt to explain how to communicate about risks, but readers are encouraged to consult the sources listed in the references for this chapter for material on that topic.

The emphasis in this Guide is on situations where risk communication is a planned and orderly part of application of the RMF and the effective resolution of a food safety issue. However, there may be other situations, such as food safety emergencies, or technical contexts such as developing “equivalent” food standards, in which government risk managers have less opportunity and/or less need, to engage in risk communication in such a comprehensive manner. The guidance offered here should therefore be tailored as appropriate to suit specific needs on a case-by-case basis.

## 4.2. Understanding risk communication

Risk communication is defined as “an interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.”<sup>22</sup>

Risk communication is a powerful yet often neglected element of risk analysis. In a food safety emergency situation, effective communication between scientific experts and risk managers, as well as between these groups, other interested parties and the general public, is absolutely critical for helping people understand the risks and make informed choices. When the food safety issue is less urgent, strong, interactive communication among the participants in a risk analysis almost always improves the quality of the ultimate risk management decisions, particularly by eliciting scientific data, opinions and perspectives from a cross section of affected stakeholders. Multi-stakeholder communication throughout the process also promotes better understanding of risks and greater consensus on risk management approaches.

Given its value, why is risk communication frequently underutilized? Sometimes food safety officials are simply too overwhelmed with collecting information and trying to make decisions to engage in effective risk communication. Risk communication also can be difficult to do well. It requires specialized skills and training, to which not all food safety officials have had access. It also requires extensive planning, strategic thinking and dedication of resources to carry out. Since risk communication is the newest of the three components of risk analysis to have been conceptualized as a distinct discipline, it often is the least familiar element for risk analysis practitioners. Nevertheless, the great value that communication adds to any risk analysis justifies expanded efforts to ensure that it is an effective part of the process.

Risk communication is fundamentally a two-way process. It involves sharing information, whether between risk managers and risk assessors, or between members of the risk analysis team and external stakeholders. Risk managers sometimes see risk communication as an “outgoing” process, providing the public with clear and timely information about a food safety risk and measures to manage it; and indeed, that is one of its critical functions. But “incoming” communication is equally important. Through risk communication, decision-makers can obtain vital information, data and opinions, and solicit feedback from affected stakeholders. Such inputs can make important contributions to the basis for decisions, and by obtaining them risk managers greatly increase the likelihood that risk assessments and risk management decisions effectively and adequately address stakeholder concerns.

Everyone involved in a risk analysis is a “risk communicator” at some point in the process. Risk assessors, risk managers, and “external” participants all need risk communication skills and awareness. In this context, some food safety authorities have communication specialists on their staffs. When such a resource is available, integrating the communication function into all phases of a risk analysis at the earliest opportunity is beneficial. For example, when a risk communication specialist can be assigned to the risk assessment team, their presence

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<sup>22</sup> Definition from the Codex Alimentarius Commission. Procedural Manual, 15<sup>th</sup> Edition.

heightens sensitivity to communication issues and can greatly facilitate communication about the risk assessment that occurs later in the process.

### **4.3. Key communication elements of food safety risk analysis**

While good communication is essential throughout application of the RMF in addressing a food safety issue, effective communication is particularly critical at several key points in the process (underlined in Figure 4.1). Risk managers therefore need to establish procedures to ensure that communication of the required nature(s) occurs at the required times, and that the appropriate participants are involved in each case.

#### ***4.3.1. Identifying a food safety issue***

During this initial step in preliminary risk management activities, open communication among all parties with information to contribute can be invaluable for accurately defining the issue. As explained in Chapter 2, information about a particular food safety issue may be brought to risk managers' attention by a wide range of potential sources. Risk managers then need to pursue information from other sources that might have knowledge of the specific issue, such as the industry that produces or processes the foods involved, academic experts and other affected parties as circumstances may dictate. As the definition of the issue evolves, an open process with frequent back-and-forth communication among all the participants helps to promote both an accurate definition and common perception of the issue that needs to be addressed.

#### ***4.3.2. Developing a risk profile***

At this step, the critical communication is primarily between risk managers, who are directing the process, and risk assessors or other scientists who are developing the risk profile. The quality of the result is likely to be enhanced if the same open and broadly representative communications network described in the previous step is maintained, and used to obtain input and feedback as the profile is developed. During this activity, the experts developing the risk profile need to establish their own communication networks with the external scientific community and industry to build up a sufficient body of scientific information.

#### ***4.3.3. Establishing risk management goals***

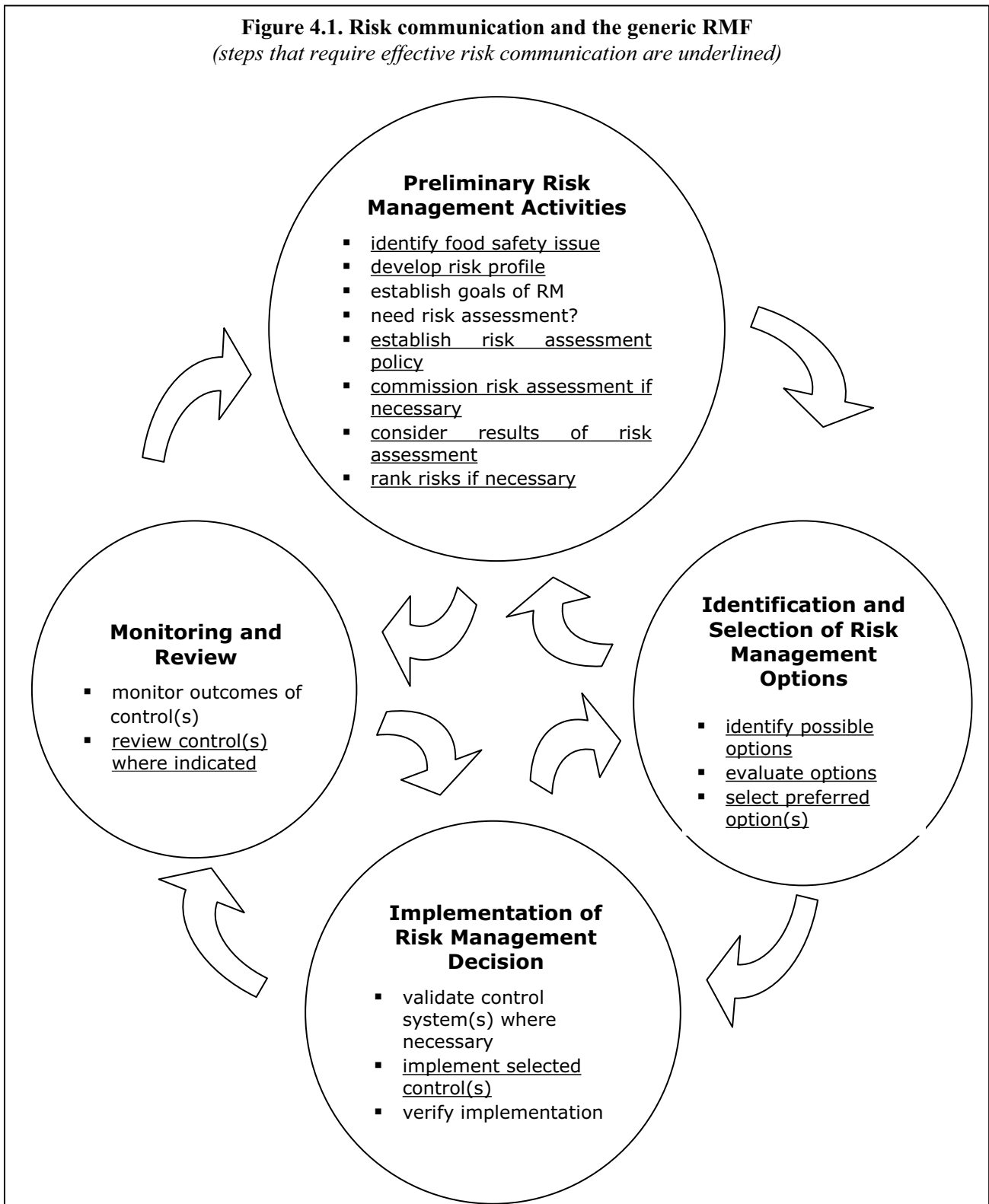
When risk managers establish risk management goals (and decide whether or not a risk assessment is feasible or necessary), communication with risk assessors and external stakeholders is essential; the risk management goals should not be established by risk managers in isolation. The government policy aspects included in the goals will vary on a case-by-case basis. The risk managers have to be comfortable that the risk management questions asked can be reasonably addressed by a risk assessment, and this assurance can come only from risk assessors. Once risk management goals for resolving a particular food safety issue have been established, they should be communicated to all interested parties.

#### ***4.3.4. Developing a risk assessment policy***

As described in section 3.2.4, a risk assessment policy provides essential guidelines for subjective and often value-laden scientific choices and judgements that risk assessors must make in the course of a risk assessment. The central communication process at this step involves risk assessors and risk managers. Often, face-to-face meetings are the most effective mechanism, and a considerable amount of time and effort may be required to complete the process. Usually, a number of complex issues must be considered and resolved, and even when the risk assessors and risk managers have worked with each other for some time, the



**Figure 4.1. Risk communication and the generic RMF**  
*(steps that require effective risk communication are underlined)*



different terminologies and different “cultures” of these two groups can require time and patience to agree on a risk assessment policy.

Input from external interested parties with knowledge and points of view on these policy choices is also both appropriate and valuable, at this step. Stakeholders may be invited to comment on a draft or invited to participate in a public meeting where the risk assessment policy is being considered, for example. Risk assessment policies also should be documented and accessible for review by parties who may not have taken part in developing them.

#### ***4.3.5. Commissioning a risk assessment***

When risk managers form a risk assessment team and ask the risk assessors to carry out a formal risk assessment, the quality of communication at the outset often contributes significantly to the quality of the resulting risk assessment product. Here too, the communication that matters most is that between risk assessors and risk managers. The subjects to be covered include, most centrally, the questions that the assessment should try to answer, the guidance provided by the risk assessment policy, and the form of the outputs. Other practical aspects at this stage are clear and unambiguous communication of the purpose and scope of the risk assessment, and the time and resources available (including availability of scientific resources to fill data gaps that emerge).

As in the step above, face-to-face meetings between the two groups is generally the most effective communication mechanism, and the discussions should be iterated until clarity is achieved by all participants. There is no single approach for ensuring effective communication between risk managers and risk assessors. At the national level, mechanisms may depend on agency structure, legislative mandates and historical practices.

Because of the need to protect the risk assessment process from the influence of “political” considerations, the role of external stakeholders in discussions between risk assessors and risk managers is generally limited; however, it is possible to obtain useful inputs in a structured manner (see next section).

#### ***4.3.6. During the conduct of a risk assessment***

Traditionally, risk assessment has been a comparatively “closed” phase of risk analysis, in which risk assessors do their work largely out of the public eye. Ongoing communication with risk managers is essential here, of course, and questions the risk assessment seeks to answer may be refined or revised as information is developed. As explained in Chapter 2, interested parties who have essential data, such as manufacturers of chemicals and food industries whose activities contribute to exposure may also be invited to share scientific information with the risk assessment team. However, in recent years, the general trend towards greater openness and transparency in risk analysis has had an impact on risk communication, encouraging more participation by external stakeholders in processes surrounding successive iterations of a risk assessment. Some national governments and international agencies have recently taken steps to open up the risk assessment process to earlier and wider participation by interested parties (Box 4.1).

#### ***4.3.7. When the risk assessment is completed***

Once the risk assessment has been done and the report is delivered to risk managers, another period of intense communication generally occurs (see Chapter 2). Risk managers need to make sure they understand the results of the risk assessment, the implications for risk management, and the associated uncertainties. The results also need to be shared with interested parties and the public, and their comments and reactions may be obtained. Since the results of a risk assessment often are complex and technical in nature, the success of communication at this stage may rest to a large extent on a history of effective communication by and among the relevant participants at appropriate earlier points in the risk analysis process.

Because of its central importance as a basis for risk management decisions, the output of a risk assessment is usually published as a written report. Some examples of published risk assessments are cited in the case studies in Annexes 2 and 3. In the interests of transparency,

**Box 4.1. External stakeholder participation in processes related to the conduct of food safety risk assessments at international (FAO/WHO) and national levels**

- The Internet has created opportunities for wider participation in the work of the FAO/WHO joint expert bodies. JECFA and JMPR each have web sites (on the FAO and WHO web sites), on which calls for experts, rosters of experts and requests for data are posted. Any interested experts may submit an application to be included on a roster. Interested parties may submit scientific data for consideration by the expert committees in response to specific calls for data. Increasingly, e.g. when risk assessment methodologies are updated, public input is sought via posting of draft documents on the dedicated web sites.
- When the United States conducted its risk assessment for *Listeria monocytogenes* in ready-to-eat foods (see Annex 3), it solicited extensive inputs from industry, consumer groups and others with an interest in and knowledge of the problem. The government held public meetings with stakeholders to discuss questions to be addressed, to ask for data and to hear suggestions about analytical approaches. A draft of the risk assessment was published and comments were solicited from the public. Extensive additional scientific data and other inputs were received, especially from industry, and the process led to several improvements between the first draft and the final risk assessment.

such reports need to be complete, explicit about assumptions, data quality, uncertainties and other important attributes of the assessment, and thoroughly documented. In the interests of effective communication, they need to be written in clear, straightforward language, readily accessible to the non-specialist. Assigning a communication expert to the risk assessment team, from the outset if possible, is often helpful for meeting this latter objective.

**4.3.8. Ranking risks and setting priorities**

When this step is necessary (see Chapter 2), risk managers should ensure a broadly participatory process that encourages dialogue with relevant stakeholder groups. Priority judgements are inherently value-laden, and ranking risks in priority for risk assessments and risk management attention is fundamentally a political and social process, in which those stakeholder groups affected by the decisions should participate.

Box 4.2 presents some examples of national processes that involved such multiparty consultation with external stakeholders. Food safety officials in various contexts have established new communication forums that bring industry, consumer representatives and government officials together to discuss problems, priorities and strategies in collegial, non-adversarial settings. Such contacts can build bridges and common understandings of issues, such as the value of risk analysis or emerging problems; they are less useful for resolving current specific disputes, although they do improve understanding of each other's general perspectives.

**4.3.9. Identifying and selecting risk management options**

Decisions on issues such as risk distribution and equity, economics, cost-effectiveness and arriving at an ALOP are often the crux of risk management. Effective risk communication during this stage of the RMF is therefore fundamental to the success of the risk analysis.

**Box 4.2. Examples of national and regional experiences with multiparty processes for communication about broad food safety issues**

- ***New Zealand Consumers Forum.*** In 2003, the New Zealand Food Safety Authority (NZFSA) initiated an on-going biannual forum with representatives of more than two dozen consumer, environmental health and other civil-society groups with an interest in food safety, and invites them to discuss how NZFSA makes decisions, and how civic organizations could productively be involved in that process. Stakeholders also identify their own food safety priorities on an annual basis, and a portion of NZFSA operational research funds is dedicated to investigating the scientific basis of those concerns.
- ***Lebanese National Food Safety Committee.*** In 2005, Lebanon's Minister of Agriculture set up an independent national committee for food safety. The committee is advisory and includes representation from a cross section of interested stakeholders, including food producers, processors, retailers, and consumer organizations. The committee began its work by focusing on issues related to pesticides and animal health as each relates to food safety.
- ***UK stakeholder forum on BSE.*** The Food Standards Agency (FSA) in the UK set up a forum for consultation with stakeholders, to communicate about risks of BSE and measures for managing the risks. The forum was chaired by the chair of the FSA Board and included participants representing all segments of the food production chain, from cattle and feed producers to consumer organizations. For details about the forum and its activities see: <http://www.food.gov.uk/news/newsarchive/2002/jul/otmstakeholdersjuly>.
- ***Uruguayan Food Safety Agency.*** In Uruguay, Parliament is considering a new food safety law that would establish a national food safety agency. The proposed agency will have an advisory board of stakeholders, which will include industry, consumers and other designated participants. Also under discussion is the possibility of including experts from various stakeholder sectors on the Scientific Board of the new agency.
- ***Latin America: COPAIA.*** In 2001, Latin American governments and the Pan American Health Organization established COPAIA, a commission on food safety in the region with 20 appointed members, 10 from government and five each from industry and consumer organizations. The group serves in an advisory role to the regional council of agricultural and health ministers and has made a variety of consensus policy recommendations, focused mainly on the use of risk analysis and on strategies for involving interested sectors of the public in national food safety decision making.
- ***United States National Academy of Sciences Food Forum.*** In the early 1990s, United States federal food safety agencies and the National Academy of Sciences (NAS) set up this forum which brings together experts on food safety and nutrition from government, industry, consumer organizations, academia and professional societies. The group meets several times a year to study issues; it also has organized large public science-and-policy meetings on numerous topics it identified as important and likely to benefit from in-depth discussion. The Food Forum does not make policy recommendations to the government but provides a mechanism to identify priorities and emerging issues, and suggests possibly effective problem-solving strategies. It has also fostered a team approach among differing sectors whose experts have rarely worked together outside this setting.

While government food safety risk managers, based on their experience managing other food-related risks, may have a clear idea of potential risk management options, and perhaps some preliminary preferences for managing a new food safety issue, consultation at this stage may well alter these views, for instance where there is a range of possible risk management options for controlling a hazard at different points in the food production chain. The extent of this consultation will depend on the individual food safety issue. Some mechanisms for consultation with stakeholders at the national level are illustrated in Box 4.3.

**Box 4.3. Some examples of processes for communication with national stakeholders on evaluation and selection of risk management options**

- The United States Food and Drug Administration (FDA) regularly convenes public meetings to solicit feedback from stakeholders on particular food safety issues including the assessment of particular food safety risks and ways to manage them. For instance, in 2004, FDA announced a series of public meetings to discuss the proposed rule for prevention of *Salmonella* enteritidis (SE) in shell eggs during production in follow-up to the publication in the Federal Register of a proposed rule for egg safety national standards. The purpose of the public meetings was to solicit public comments on the proposed rule and provide the public an opportunity to ask questions. An announcement about the planned public meetings was placed on the Internet along with information on how to register. Interested parties were encouraged to attend to present their comments, concerns and recommendations regarding the proposed rule. In addition to seeking oral presentations from specific individuals and organizations at the public meeting, the FDA also encouraged the submission of written comments on issues of concern. Further information on these public meetings is available at: <http://www.cfsan.fda.gov/~dms/egg1004.html>.
- In September 2003, the Advisory Committee on the Microbiological Safety of Food (ACMSF) in the UK Food Standards Agency set up an ad hoc group to develop advice on the potential risk to human health associated with the consumption of chilled or frozen baby foods, particularly in relation to *Clostridium botulinum*. In June 2005, this Group presented a final draft report of its work to the Committee. At this meeting, the ACMSF agreed to publish the report for public consultation. The consultation took place between September and December 2005. Comments received in response to the consultation were considered by the ad hoc Group and several minor amendments were made to the report. For further information, see <http://www.food.gov.uk/multimedia/pdfs/acm780.pdf>.
- Annexes 2 and 3 provide additional examples, both from the United States, of participation by stakeholders at this stage of risk analyses for methylmercury in fish and for *Listeria* in ready-to-eat foods.

Industry experts often have critical information and perspectives on possible food safety control measures, their effectiveness and their technical and economic feasibility. Consumers, who generally bear the risks from food-borne hazards, typically represented by consumer organizations and other NGOs with an interest in food safety, can also provide important insights on risk management options. This is especially likely when the options considered include information-based measures, such as consumer education campaigns or warning labels. Consulting with consumers about such measures is essential to learn what information the public wants and needs, and in what forms and media such information is most likely to be noticed and heeded.

When risk management options are being evaluated, the risk analysis process sometimes becomes an overtly political one, with different interests within a society each seeking to persuade the government to choose the risk management options they prefer. This can be a useful phase; if managed effectively, it can illuminate the competing values and trade-offs that must be weighed in choosing risk management options, and support transparent decision making. WTO members are required to implement the SPS Agreement based on transparency as a means to achieve a greater degree of clarity, predictability and information about trade rules and regulations (see Box 4.4).

In such public debates about food safety controls, industry and consumers often seem to be trying to push the government in opposite directions. While there can be genuine differences and unavoidable conflicts between what consumers want and what industry wants, the differences are sometimes less than they might seem. Food safety officials may find it useful

#### **Box 4.4. Transparency provisions in the WTO SPS Agreement**

Governments are required to notify other countries of any new or changed sanitary requirements which affect trade, and to set up offices (called “Enquiry Points”) to respond to requests for more information on new or existing measures. They also must open to scrutiny how they apply their food safety regulations. The systematic communication of information and exchange of experiences among the WTO’s member governments provides a better basis for national standards. Such increased transparency also protects the interests of consumers, as well as of trading partners, from hidden protectionism through unnecessary technical requirements.

A special Committee has been established within the WTO as a forum for the exchange of information among member governments on all aspects related to the implementation of the SPS Agreement. The SPS Committee reviews compliance with the agreement, discusses matters with potential trade impacts, and maintains close co-operation with the appropriate technical organizations. In a trade dispute regarding a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

to seek common ground by fostering direct communication between industry and consumer representatives, in addition to the ongoing communication that each sector maintains with the government agencies themselves (see Box 4.2).

#### **4.3.10. Implementation**

To ensure that a chosen risk management option is implemented effectively, government risk managers often need to work closely, in an ongoing process, with those upon whom the burden of implementation falls. When implementation is carried out primarily by industry, government generally works with the industry to develop an agreed plan for putting food safety controls into effect, then monitors progress and compliance through the inspection, verification and audit process. When risk management options include consumer information, outreach programmes are often required, for example to enlist health care providers in disseminating the information.

Surveys, focus groups and other mechanisms also can be pursued to measure how effectively consumers are receiving and following the government’s advice. While the emphasis at this stage is on “outgoing” communication, the government needs to explain to those involved what is expected of them, mechanisms should be built into the process to collect feedback and information about successes or failures of implementation efforts.

#### **4.3.11. Monitoring and review**

At this stage, risk managers need to arrange for the collection of relevant data needed to evaluate whether the implemented control measures are having the intended effects. While risk managers take the lead in developing formal criteria and systems for monitoring, other inputs may enhance this determination. Parties other than those designated as responsible for monitoring and review activities may be consulted or may bring information to the attention of the authorities at this stage as well. Risk managers sometimes use a formal risk communication process to decide whether new initiatives are needed to further control risks.

Communication with public health authorities that are not integrated in food safety authorities is especially important during this step. The importance of integrating scientific information from all aspects of monitoring hazards throughout the food chain, risk assessments, and human health surveillance data (including epidemiological studies) is emphasized throughout this Guide.

## 4.4. Some practical aspects of risk communication

While the advantages of effective risk communication are obvious, communication does not occur automatically and it has not always been easy to achieve. Communication elements of a risk analysis need to be well organized and planned, just as risk assessment and risk management elements are. When resources permit, governments may include specialists in conducting or managing communication aspects of food safety risk analysis among their staff. Whether managing risk communication falls to a specialist or to someone with more general responsibilities, a number of practical questions are inevitably encountered. This section examines some of those questions and suggests some workable approaches for answering them in the national context.

### 4.4.1. Goals of communication

When planning for communication, an essential first step is to determine what the goal is. For instance, at each of the steps examined in section 4.3 above, communication has a somewhat different focus. Those planning communication programmes need to establish: i) what the subject of the communication is (for example, risk assessment policy, understanding outputs of a risk assessment, identifying risk management options); ii) who needs to participate, both *generically* (i.e. risk assessors, affected industry) and *specifically* (i.e. which individuals); and iii) when during the risk analysis process each kind of communication should take place. The answer to this last question can be “often”; that is, some communication processes do not occur once, but may be reiterated, or ongoing, during large portions of or throughout application of the entire RMF.

#### Box 4.5. Some pitfalls to avoid: What risk communication is *not* good for

- ***Risk communication is not public education.*** Public education on food safety requires risk communication skills, but the two endeavours are separate and distinct activities. “Education” implies a “teacher/student” relationship, in which the expert authorities have knowledge to pass on to the (largely uninformed) public. The public may in fact already have a great deal of information; effective communication is a two-way exchange of information, not a one-way transfer. In a risk analysis context, gathering information is often as important as conveying it.
- ***Risk communication is not public relations.*** Much of the literature on communicating with consumers about risks and control measures conveys the strong message that risk communication is a useful tool for making the public see the issues the way the experts or risk managers see them. But in fact, ordinary citizens often have an equally rational but fundamentally different perspective on risks (see Box 2.1). The essence of good communication is for each group to understand and appreciate the other’s perspective, not for the group with greater communication resources to convince the others that their perspective is the correct one.
- ***Telling people a food is safe will not necessarily reassure them.*** One common, difficult risk communication situation arises when government and industry food safety officials perceive that consumers are unduly frightened about a risk. In that situation, simply asserting that the available scientific information shows the risk is insignificant generally does not make people worry less. In fact, if consumers perceive that their concerns are being dismissed too lightly, they may trust those in authority less and worry more. The most effective response to perceived public fears is to engage in dialogue with consumers, to listen and respond to their concerns. Honest discussion of what scientific data about the risk show (including uncertainties) will help put risk in perspective.

It is also important to avoid choosing inappropriate risk communication goals (see Box 4.5). Communication efforts undertaken without sufficient care as to what they are intended to accomplish often turn out to be counterproductive.

#### **4.4.2. Communication strategies**

A great many specific strategies for effective risk communication have been developed for use in various contexts, including food safety, and in different cultures. Some basic components of a risk communication strategy in the context of food safety risk analysis are summarized in Box 4.6. An in-depth review of such strategies and principles is beyond the scope of this Guide; readers are encouraged to consult the references at the end of this chapter for more detail.

##### **Box 4.6. Strategies for effective communication with external stakeholders during a food safety risk analysis**

- Collect, analyse and exchange background information about the food safety risk.
- Determine risk assessors', risk managers' and other stakeholders' perceptions of and knowledge of the food safety risk or risks involved, and their resulting attitudes and risk-related behaviour.
- Learn from external stakeholders what their risk-related concerns are and what their expectations are for the risk analysis process.
- Identify and be sensitive to related issues that may be more important to some stakeholders than the identified risk itself.
- Identify the types of risk information stakeholders consider important and want to receive, and the types of information they possess and wish to convey.
- Identify types of information needed from external stakeholders, and determine who is likely to have information to contribute.
- Identify the most appropriate methods and media through which to disseminate information to, and obtain information from, different types of stakeholders.
- Explain the process used to assess risk, including how uncertainty is accounted for.
- Ensure openness, transparency and flexibility in all communication activities.
- Identify and use a range of tactics and methods to engage in an interactive dialogue involving risk analysis team members and stakeholders.
- Evaluate the quality of information received from stakeholders and assess its usefulness for the risk analysis.

#### **4.4.3. Identifying “stakeholders”**

While risk managers may agree with the general goal of inviting affected stakeholders to participate at appropriate points in application of a RMF, it is not always a simple matter to know specifically who those parties are, or to get them engaged in a particular risk analysis process. Often, affected stakeholder groups are known to risk managers from the outset, or identify themselves and seek to participate early in the process. Sometimes, however, some affected stakeholders may be unaware of the need for or the opportunity to participate, and authorities may need to reach out to them. Most countries have laws and policies about how and when stakeholders can participate in public decision-making processes. Risk managers can work within such frameworks to optimize participation. Box 4.7 lists some sectors of society who may have a stake in a given food safety risk analysis. When risk managers seek to identify appropriate stakeholders, the criteria in Box 4.8 may be useful.



**Box 4.7. Examples of potential stakeholders in a particular food safety risk analysis**

- Farmers, ranchers, fishermen and other food producers
- Food processors, manufacturers, distributors and their vendors
- Food wholesalers and retailers
- Consumers and consumer organizations
- Other citizen advocacy groups (environmental, religious, etc.)
- Community groups (neighbourhood associations, co-operatives, etc.)
- Public health community and health care providers
- Universities and research institutions
- Government (local government, state and federal regulatory agencies, elected officials, importing countries etc.)
- Representatives of different geographic regions, cultural, economic or ethnic groups
- Private sector associations
- Businesses
- Labour unions
- Trade associations
- Media

Mechanisms have been established in many countries for engaging stakeholders in food safety decision making at the national level in a general, ongoing way. Participation by interested parties in such broader activities may increase their awareness of new food safety issues, and builds the government's familiarity with interested sectors of the society. For example, some countries have set up a national food safety advisory committee, a national Codex committee, a network of industry and civil-society contacts who wish to take part in Codex-related activities, and similar organizations. To the extent that such networks exist, they can be used to ensure appropriate risk communication with relevant stakeholder groups. Where such mechanisms have not yet been established, the benefits they offer in terms of supporting participation of affected interested parties in risk analysis is only one of many advantages national food authorities may gain by creating them.

**Box 4.8. Criteria for identifying potential stakeholders to participate in a given food safety risk analysis**

- Who might be affected by the risk management decision (including groups that already know or believe they are affected, as well as groups that may be affected but as yet do not know it)?
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?
- Who has expressed interest in being involved in similar decisions before?
- Who should rightfully be involved, even if they have not asked to be?

Once stakeholders are identified, their role in a given risk analysis needs to be defined. While potentially valuable inputs from stakeholders in different sectors can occur at most stages of the generic risk management process, constraints may exist in specific cases. For example, in a situation that demands urgent action, time for consultation may be very limited. In some cases stakeholder participation may not have much genuine influence on the decision; if the decision is not really negotiable, stakeholders should be informed so that they do not feel that they are wasting their time.

#### 4.4.4. Methods and media for communication

Depending on the nature of the food safety issue, the number and nature of the stakeholder groups involved, and the social context, a great many alternatives may be appropriate for conveying and receiving information at various points in application of the RMF. Box 4.9 lists some of the more widely applicable options.

#### **Box 4.9. Some tactics for engaging stakeholders in a food safety risk analysis**

<b>Meeting techniques</b>	<b>Non-meeting techniques</b>
<ul style="list-style-type: none"><li>• Public hearings</li><li>• Public meetings</li><li>• Briefings</li><li>• Question and answer sessions</li><li>• Town hall meetings</li><li>• Panel discussions</li><li>• Focus groups</li><li>• Workshops</li></ul>	<ul style="list-style-type: none"><li>• Interviews</li><li>• Hotlines and toll-free numbers</li><li>• Web sites</li><li>• Advertising and flyers</li><li>• Television and radio</li><li>• Reports, brochures and newsletters</li><li>• Booths, exhibits and displays</li><li>• Contests and events</li></ul>

While there will probably always be a need for detailed written documents, scientific reports and official government analyses of food safety issues and decisions, effective communication often requires additional approaches. Some of the familiar mechanisms, such as meetings, briefings and workshops, can be tailored so as to attract participation by different stakeholders whose involvement is desired. For instance, a workshop on scientific and economic aspects of the food safety controls relevant to the issue under consideration would be likely to attract robust food industry participation, while a panel discussion on the latest advances in risk analysis methodologies should appeal to many academic experts, as well as to other stakeholders.

Some of the “non-meeting” approaches can be quite creative. For example, a number of years ago government officials and consumer organizations in Trinidad and Tobago organized a calypso contest to engage community members in promoting awareness of food safety and a variety of other consumer issues. Especially when the goal is to inform and engage the public, messages intended for specific audiences need to be presented in media the audiences pay attention to, and efforts to gather information need to be carried out in a place and in a manner that will encourage those with the desired information to take part in the process.

Which of these approaches, or perhaps others, may be most appropriate will depend on the issue, the type and nature of stakeholder groups, and the context. In general, large public meetings are not especially effective for eliciting the transparent dialogue that risk communication seeks to achieve. When involving members of the general public is one of the objectives, internet discussion boards and chat rooms and call-in television and radio programmes enable members of the general public to share views and concerns and to obtain information from experts and decision-makers.

#### 4.5. Suggestions for further reading

**FAO/WHO.** 1999. *The application of risk communication to food standards and safety matters.* Report of a Joint FAO/WHO Expert Consultation. Rome, Italy. 2–6 February

1998. FAO Food and Nutrition Paper No. 70 (available at: <http://www.fao.org/DOCREP/005/X1271E/X1271E00.htm#TOC>).
- Fischhoff, B.** 1995. Risk perception and communication unplugged: Twenty years of process. *Risk Analysis*, 15: 137-145.
- Joint Institute for Food Safety and Applied Nutrition.** Web site of the Food Safety Risk Analysis Clearinghouse. A joint project between the University of Maryland and the United States Food and Drug Administration. Collection of resources related to food safety risk communication (available at: [http://www.foodrisk.org/risk\\_communication.cfm](http://www.foodrisk.org/risk_communication.cfm)).
- National Research Council.** 1989. *Improving Risk Communication*. Washington, DC: National Academy Press.
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- Slovic, P.** 2000. *The perception of risk*. Earthscan, London.
- University of Maryland.** Food safety risk communication primer. Available on the web site of the Joint Institute for Food Safety and Applied Nutrition (see above).
- WTO.** 2002. Operating the SPS Enquiry Point. Chapter 4 in *How to Apply the Transparency Provisions of the SPS Agreement. A handbook*. WTO Secretariat (available at: [http://www.wto.org/english/tratop\\_e/sps\\_e/spshand\\_e.pdf](http://www.wto.org/english/tratop_e/sps_e/spshand_e.pdf)).

## Annex 1: Glossary

### **Acceptable daily intake (ADI) <sup>A</sup>**

An estimate of the amount of a substance in food or drinking water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg). The ADI is listed in units of mg per kg of body weight.

### **Appropriate level of protection (ALOP) <sup>B</sup>**

The level of protection deemed appropriate by the Member (member country of WTO) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. This concept is also referred to as the acceptable level of risk.

### **Dose-response assessment <sup>C</sup>**

The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

### **Food Contaminant <sup>C</sup>**

Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

### **Food hygiene <sup>C</sup>**

Food hygiene comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.

### **Good agricultural practices (GAP)**

The application of knowledge that addresses environmental, economic and social sustainability for on-farm production and post-production processes resulting in safe and healthy food and non-food agricultural products.

### **Good hygiene practices (GHP)**

All practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of food chain.

### **Good manufacturing practices (GMP) <sup>D</sup>**

Conformance with codes of practice, industry standards, regulations and laws concerning production, processing, handling, labelling and sale of foods decreed by industry, local, state, national and international bodies with the intention of protecting the consumer from food-borne disease, product adulteration and fraud.

## **HACCP**

An acronym for Hazard Analysis Critical Control Points, refers to a systematic approach that identifies, evaluates and controls hazards which are significant for food safety.

## **Hazard<sup>C</sup>**

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

## **Maximum level (ML)<sup>E</sup>**

The Codex maximum level (ML) for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the CAC to be legally permitted in that commodity.

## **Maximum residue level (MRL)**

The maximum concentration of residue in a food or animal feed resulting from use of a veterinary drug or a pesticide, (expressed in mg/kg or µg/kg on a fresh weight basis).

## **Tolerable daily intake (TDI)<sup>F</sup>**

Analogous to Acceptable Daily Intake. The term Tolerable is used for agents which are not deliberately added such as contaminants in food.

## **Tolerable intake<sup>F</sup>**

Estimated maximum amount of an agent, expressed on a body mass basis, to which each individual in a (sub) population may be exposed over a specified period without appreciable risk.

## **Uncertainty factor<sup>F</sup>**

Reductive factor by which an observed or estimated no-observed-adverse effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk.

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## **Sources**

<sup>A</sup> Joint Expert Committee on Food Additives (JECFA). Glossary of terms (<http://www.who.int/ipcs/food/jecfa/glossary.pdf>).

<sup>B</sup> WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (available at: [http://www.wto.org/English/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm)).

<sup>C</sup> FAO/WHO. 2005. *Codex Alimentarius Commission. Procedural Manual*. 15th Edition (available at: [http://www.codexalimentarius.net/web/procedural\\_manual.jsp](http://www.codexalimentarius.net/web/procedural_manual.jsp)).

<sup>D</sup> FAO/WHO. 2003. *Assuring food quality and safety. Guidelines for strengthening national food control systems*. FAO Food and Nutrition Paper 76 (available at: <ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf>).

<sup>E</sup> Codex General Standard for Contaminants and Toxins in Foods. CODEX STAN 193-1995.

<sup>F</sup> International Programme on Chemical Safety (IPCS). Harmonization Project. IPCS Risk Assessment Terminology  
(<http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf>).

## Annex 2: Case Study of Methylmercury in Fish

### Background

Mercury is released into the environment as inorganic mercury compounds from a variety of natural and human-made sources. Inorganic mercury can be converted to an organic form, methylmercury, by microbial action in soils and sediments. Methylmercury is taken up by aquatic organisms and is bio-magnified in the food web; long-lived, predatory species high in the aquatic food chain can accumulate high levels. The toxic effects of methylmercury in people were first documented among individuals who consumed heavily contaminated fish from Minamata Bay, Japan, which was polluted by industrial mercury sources, in the 1950s.<sup>23</sup> Children born to women who had consumed contaminated fish were most severely affected, exhibiting devastating damage to the central nervous system, which is especially vulnerable during prenatal development.

In the decades since Minamata, several epidemiological studies of populations with a diet either high in fish or in fish and marine mammals have provided evidence that typical levels of methylmercury in some types of fish, not unusually high levels associated with pollution, pose some health hazards, again with a focus on the developing brain.<sup>24</sup> There is some evidence that methylmercury exposure from a diet rich in fish and seafood may adversely affect cognitive function in adults.<sup>25</sup> Nevertheless, damage associated with prenatal exposure is considered the most sensitive effect and is the central concern of risk management. Evidence that these potential health risks may be associated with “normal” levels of fish consumption has led to both national and international efforts to assess the risks from methylmercury in fish, and to establish guidelines for safe maximum exposure.

Methylmercury risks may be a concern for any national or subnational population that consumes large amounts of fish. Different fish species tend to accumulate methylmercury to different degrees, and the degree of exposure to methylmercury will vary depending on which fish species are important in a population’s diet, and how much methylmercury is present in the specific fish species consumed locally. Risk assessments, in particular the exposure assessment part, must therefore be population-specific. If excessive methylmercury exposure is found, risk management can be challenging. Fish consumption has many nutritional benefits, and fish is the main source of dietary protein for some populations. Reducing fish consumption to avoid methylmercury exposure might therefore damage public health in the broader sense. Risk communication, in particular educating consumers so that they can choose low-mercury fish species, is an important risk management tool for managing methylmercury risks.

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<sup>23</sup> Huddle, N., M. Reich and N. Stisman. 1987. *Island of Dreams: Environmental Crisis in Japan*. Rochester, VT: Schenkman Books, Inc.; 2<sup>nd</sup> Edition.

<sup>24</sup> Grandjean, P., et al. 1997. Cognitive deficit in 7-year-old children with prenatal exposure to methyl mercury. *Neurotoxicol Teratol* **19**:417-428; National Research Council. 2000. *Toxicological Effects of Methylmercury*. Washington, DC: National Academy Press.

<sup>25</sup> For example, Yokoo, E.M., et al. 2003. Low level methylmercury exposure affects neuropsychological function in adults. *Environmental Health: A Global Access Science Source* **2**:8. Also, Newland, C.M. and E.B. Rasmussen. 2003. Behavior in Adulthood and During Aging Is Affected by Contaminant Exposure in Utero. *Current Directions in Psychological Science* **12**(6):212-217.

This case study briefly reviews two examples of risk analyses for methylmercury in fish.

- The United States Environmental Protection Agency (EPA) has established a Reference Dose (RfD), which is a safe upper intake limit, similar to a Tolerable Daily Intake. The United States has also established an Action Level, which is a guideline for a maximum acceptable mercury level in fish, and has issued fish consumption advice.
- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established a safe upper intake limit, called a Provisional Tolerable Weekly Intake (PTWI), based on a scientific review and risk assessment, and the Codex Alimentarius Commission (CAC) has established Guideline Levels for Methylmercury in Fish (CAC/GL 7-1991).

## **Risk Management of Methylmercury in Fish**

The cases described in this Annex illustrate how previously completed risk analyses were reviewed and updated in the United States and at the international level. Methylmercury in fish has been a recognized hazard for several decades, and these cases illustrate the ongoing, iterative nature of risk analysis in which scientific understanding of, and risk management responses to, a problem are updated as necessary and as new scientific data become available. Despite this inherently cyclic process, steps in the risk analyses for methylmercury are described here in the sequence laid out in the generic RMF presented in Chapter 2 of this Guide.

### **Risk Management, Phase 1: Preliminary Risk Management Activities**

#### ***Step 1: Identify the problem***

This risk arises when a population consumes fish that have absorbed potentially harmful levels of methylmercury from the environment. The focus of this case study is on methylmercury in commercially caught fish consumed by the general population. Problems also exist with methylmercury in fish caught by sport fishermen from locally polluted waters, but that narrower situation is outside the scope of this analysis.

#### ***Step 2: Develop a risk profile***

The extent of the problem varies depending on several factors: i) the quantity of fish consumed by the population; ii) the kinds of fish eaten; iii) the amount of methylmercury contained in those particular fish species; iv) the amounts of particular methylmercury-accumulating species consumed by the population; v) the characteristics of the population (such as being female and of childbearing age); and, sometimes, vi) particular genetic or cultural attributes of the population that may enhance or reduce risk.

The population group most often considered at risk from methylmercury exposure are women of childbearing age because damage to the developing foetal brain is currently considered to be the health risk of greatest concern, i.e. the most sensitive endpoint. However, methylmercury has other toxic effects (e.g. it affects the nervous system in adults).<sup>26</sup>

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<sup>26</sup> For a review of the relevant literature, see National Research Council. 2000 (footnote 24 above). Also see JECFA's 2003 assessment, WHO Food Additives Series, **52**, Safety evaluation of certain food additives and contaminants, Prepared by the 61<sup>st</sup> meeting of the Joint FAO/WHO Expert Committee on Food Additives. International Programme on Chemical Safety, World Health Organization, Geneva, 2004. Pages 565-623, Methylmercury.



Therefore, concern is not strictly limited to potential effects on the foetal brain; people who eat a great deal of fish may also be at some risk for as yet sparsely documented effects. In some countries, only a small subset of the total population consumes enough fish to warrant any health concerns, while in other countries, where fish is the primary source of dietary protein, “high-end” consumers may include much of the general population.

The risk profile developed by the EPA focuses on women who are or may become pregnant, and on a handful of particular fish species that accumulate fairly high levels of methylmercury. The JECFA/Codex approach recognizes that methylmercury in fish may be a public health concern for many member countries, and also that a specific risk profile needs to be developed for each individual country contemplating action, since fish consumption patterns and thus the associated risk vary from country to country. These risk profiles were developed primarily by risk assessors (JECFA for FAO/WHO and Codex; government scientists in the USA), who were working and communicating with the risk managers in each case.

### ***Step 3: Establish risk management goals***

At both the national and the international levels, the general goal of risk management was to reduce consumer exposure to methylmercury from fish consumption in order to prevent adverse effects on public health. Risk managers at both levels had in mind a number of alternative risk management options that might be applied (see discussion in later sections of this Annex), and in each case a collateral goal was to try to reduce risk without losing the nutritional benefits of fish consumption. The risk managers in these cases (United States government agencies, FAO/WHO and Codex) did not require a risk assessment to help them choose among risk management options so much as they needed an updated and more precise definition of a “safe” level of exposure to methylmercury to support their determinations of the appropriate level(s) of protection for exposed populations.

### ***Step 4: Decide whether a risk assessment is needed***

At both the national and international levels, risk assessments for methylmercury in fish have been carried out many times in the past. However, as new scientific evidence continues to become available, risk assessments require updating. In the United States, the EPA determined that a new risk assessment for methylmercury was needed in the late 1990s. The EPA sought to establish an RfD, a term the EPA uses for a safe upper exposure limit, for methylmercury, and needed a safety/risk assessment to support that policy decision. The EPA conducted its own internal risk assessment and asked the United States National Academy of Sciences/National Research Council (NAS/NRC) to serve as a peer-review and advisory expert group.

At the international level, JECFA has reviewed methylmercury on several occasions during the period from 1972 to 2006. At its 2000 session, and at the request of the CAC, JECFA noted that evidence was accruing from two major ongoing epidemiological studies, and agreed that an additional review be conducted, specifically to advise on whether the existing PTWI should be revised in light of recent evidence, when additional data became available. That review occurred at the 61<sup>st</sup> JECFA meeting, in 2003. Thus, in the United States, the need for a risk assessment was driven primarily by risk managers planning a policy action, while internationally, risk assessors, monitoring emerging scientific evidence, determined that the time had come to update the risk assessment, knowing that risk managers were prepared to review the related risk management decisions.

### ***Step 5: Establish a risk assessment policy***

In neither case examined here was establishing risk assessment policy a formal, clearly defined step. This step has not yet become a routine part of risk analysis as practiced either within Codex or by most member governments. Most risk assessors and risk managers have at least a general sense of principles that would be part of a formal risk assessment policy if one were developed, but as a rule those principles have been neither transparently documented nor formally applied.

### ***Step 6: Commission a risk assessment***

Good communication between risk assessors and risk managers is essential when a risk assessment is commissioned. In the case of the NAS/NRC review, the EPA provided a detailed set of questions it needed answered by the committee (and which it presumably also sought to answer in carrying out its own internal risk assessment). Communication between risk managers in the government and risk assessors within federal agencies and at the NAS/NRC was also extensive and ongoing after the NAS/NRC risk assessment was completed.

At the international level, JECFA communicates closely with CCFAC, the risk managers who apply the PTWI in managing risks of methylmercury in fish. Since CCFAC and JECFA each meet once a year at different times and in different countries, communication between them mostly occurs through the JECFA Secretariat. Subsequent to the 2003 JECFA review, CCFAC posed some specific questions to JECFA, which were taken up at the JECFA session in 2006. The discussion at CCFAC is continuing and further interaction with JECFA may occur as the process moves forward.

A key step in commissioning a risk assessment is to assemble the risk assessment team. Finding qualified experts who are knowledgeable about the specific problem but are not committed to a predetermined point of view can be a challenging task for risk managers. The EPA put together a group of scientists drawn from its health effects research staff. The NAS/NRC assembled a group of experts from the national scientific community, following procedures (described on the NAS web site)<sup>27</sup> to ensure appropriate expertise, to balance viewpoints and to exclude those with possible biases or conflicts of interest. Internationally, the JECFA Secretariat assembled an expert group from FAO and WHO rosters of experts, drawn from the worldwide scientific community, in accordance with FAO/WHO procedures to balance expertise and screen out potential conflicts of interest.<sup>28</sup>

### ***Step 7: Consider the results of the risk assessment***

To avoid repetition this step will be discussed below after the description of the risk assessments that were conducted.

### ***Step 8: Rank risks***

This step is useful when risk managers are confronted with multiple food safety problems that all need to be managed, and have limited resources. However, enough knowledge already

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<sup>27</sup> See <http://www.nationalacademies.org/onpi/brochures/studyprocess.pdf>

<sup>28</sup> Further information about FAO/WHO rosters of experts is available in the *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition (to Codex and member countries)* (at: [www.fao.org/ag/agn/proscad/index\\_en.stm](http://www.fao.org/ag/agn/proscad/index_en.stm)) as well as on the JECFA web site (at [www.fao.org/ag/agn/jecfa/experts\\_en.stm](http://www.fao.org/ag/agn/jecfa/experts_en.stm) and [www.who.int/ipcs/food/jecfa/experts/en/index.html](http://www.who.int/ipcs/food/jecfa/experts/en/index.html)).

exists to establish that methylmercury is a serious public health concern, and it has been a priority for risk management for many years. The risk ranking step therefore was not necessary either in the United States or internationally in this case.

## **Risk Assessment**

The initial step (not given a step number in Chapter 3) reiterates two preliminary risk management activities, *identify the problem* and *develop a risk profile*, described above. The primary focus of the risk assessments in both examples here was on updating previous assessments to take into account results of recent research.

### ***Step 1: Hazard identification***

The hazard in this case was clearly identified as the organic mercury compound, methylmercury, which is more toxic than inorganic mercury, and also accounts for the vast majority of the total mercury in fish.

### ***Step 2: Hazard characterization***

This step requires qualitative and, to the extent practical, quantitative evaluation of the adverse effects of exposure to methylmercury, ideally with the development of dose-response relationships that permit defining a safe level of exposure. The main focus of the risk assessments examined here (also called “safety assessments” by many practitioners, see discussion in Chapter 3) remained on the potential damage to the developing brain. The risk assessors agreed that methylmercury may also have other adverse health effects, but found the data on those other effects insufficient to establish a cause-effect relationship and to characterize dose-response relationships.<sup>29</sup>

Unlike the examples presented in Chapters 2 and 3, which describe how changes in risk associated with given increases or decreases in exposure are quantified and used to determine an Appropriate Level of Protection, the risk assessors in these methylmercury cases used a somewhat different approach. In each case, the (limited) available dose response data were used to calculate a Benchmark Dose Lower Confidence Limit (BMDL) or to estimate a No-Observed Effect Level (NOEL). Uncertainty factors were then applied to estimate the nominally “safe” dose (RfD by the EPA, PTWI by JECFA).

The EPA and NAS/NRC each concluded, after reviewing the new epidemiological evidence, that a long-term study in the Faeroe Islands, testing for methylmercury effects in children born to women with a diet rich in fish and whale meat,<sup>30</sup> provided the best available evidence on potential adverse health effects. The Faeroe Islands study has associated prenatal methylmercury exposure with observed effects on brain nerve signal transmission and on several indices of cognitive development. Neither of the risk assessments in the United States

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<sup>29</sup> For a description of the EPA risk assessment, see Rice, D.C., R. Schoeny and K. Mahaffey. 2003. Methods and rationale for derivation of a reference dose for methylmercury by the US EPA. *Risk Analysis* **23**(1):107-115. For a description of the NAS/NRC risk assessment, see National Research Council. 2000 (footnote 24 above). For a description of the JECFA risk assessment, see WHO Food Additives Series, **52**, Safety evaluation of certain food additives and contaminants, Prepared by the 61<sup>st</sup> session of the Joint FAO/WHO Expert Committee on Food Additives. International Programme on Chemical Safety, World Health Organization, Geneva, 2004. Pages 565-623, Methylmercury.

<sup>30</sup> Grandjean, P., et al. 1997. Cognitive deficit in 7-year-old children with prenatal exposure to methyl mercury. *Neurotoxicol Teratol* **19**:417-428; Murata, K., et al. 2004. Delayed Brainstem Auditory Evoked Potential Latencies in 14-year-old Children Exposed to methylmercury. *J. Pediatr.* **144**:177-183.

relied on a similar study of a population with a high-fish diet in the Seychelles Islands,<sup>31</sup> which has examined children for effects comparable to those studied in the Faeroe Islands, but has to date not identified statistically significant adverse effects, and thus was not deemed suitable for the risk assessment EPA wished to perform. JECFA, on the other hand, relied on both studies to derive an average dose from a BMDL (Faeroe Islands) and the NOEL (Seychelles).

The EPA next estimated a variety of BMDLs using several models and associations between methylmercury doses and neurological developmental outcomes from the Faeroe Islands study. One BMDL was then selected and a ten-fold default uncertainty factor was applied to account for the variability in individual sensitivity, and a RfD of 0.1 µg/kg of body weight (µg/kg-bw) per day, or 0.7 µg/kg-bw per week was established which corresponds to a blood mercury level of 5.8 µg/litre.<sup>32</sup> JECFA, relying on the same evidence, used a slightly different approach. The committee calculated a steady-state intake of methylmercury of 1.5 µg/kg-bw per day from a maternal hair mercury level of 14 mg/kg, which is the average dose from the two studies. It was the lower confidence limit of the benchmark dose from the Faeroe Islands study, and the calculated NOEL from the Seychelles study. JECFA then applied a data-derived, 6.4-fold uncertainty factor to calculate a PTWI for exposure of pregnant women of 1.6 µg/kg-bw per week.<sup>33</sup> This value is slightly lower than the previous JECFA PTWI of 3.3 µg/kg-bw per week, which was derived based on the lowest effect levels noted in earlier studies of populations exposed to methylmercury contamination via food.

The recommendations reached by experts in the USA and JECFA cases described here differed by approximately a factor of two. However, in view of the uncertainties in the scientific evidence and the different approaches taken by the two groups of risk assessors who made those determinations, these recommendations are actually quite close.

### ***Step 3: Exposure assessment***

The EPA and the United States Food and Drug Administration (FDA) assembled detailed information from which exposures could be characterized. Food consumption surveys indicate that a few percent of Americans consume more than 12 ounces (340 grams) of fish per week, considered “high consumption” in the USA.<sup>34</sup> Extensive data on mercury in fish, collected by the FDA and other agencies, show that several species consumed in the USA contain relatively high methylmercury levels.<sup>35</sup> A national survey that examines a representative sample of the United States population for a variety of health and nutritional indices each year was expanded to include tests for blood mercury levels, beginning in 1999; data collected over a four-year period indicate that about 6 percent of women of childbearing age have blood Hg values above the EPA reference level of 5.8 µg/l.<sup>36</sup> Several independent studies of

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<sup>31</sup> Myers, G.J., et al. 2003. Prenatal methylmercury exposure from ocean fish consumption in the Seychelles child development study. *Lancet* 361:1686-1692.

<sup>32</sup> See Rice et al., footnote 29 above.

<sup>33</sup> JECFA report, cited in footnote 29 above, page 615.

<sup>34</sup> Carrington, C.D. and P.M. Bolger 2002. An exposure assessment for methylmercury from seafood for consumers in the United States. *Risk Anal.* 22:689-699.

<sup>35</sup> For FDA data on mercury levels in fish; see <http://www.cfsan.fda.gov/~frf/sea-mehg.html>.

<sup>36</sup> Mahaffey, K.R., R.P. Clickner, and C.C. Bodurow. 2004. Blood Organic Mercury and Dietary Mercury Intake: National Health and Nutrition Examination Survey (NHANES), 1999 and 2000. *Environ Health Perspect* 112: 562-570; Schober, S.E., et al. 2003. Blood Mercury Levels in US Children and Women of Childbearing Age, 1999-2000. *JAMA* 289(13):1667-1674; see Jones, R.L., et al. 2004. Blood Mercury Levels in Young

subgroups of the United States population who consume unusually high amounts of fish have also reported evidence of exposure well above the EPA RfD in at least some members of these subgroups.<sup>37</sup>

JECFA assembled data from five national exposure studies, and calculated possible methylmercury intake associated with the five WHO GEMS/Food-regional diets, using estimated average fish intake and data on the average mercury content of fish submitted by various member governments. JECFA estimated that high-end fish consumers in most of the countries for which it had data were exposed to methylmercury doses greater than the PTWI. The highest estimate for the average methylmercury dose from the five GEMS/Food-regional diets (JECFA did not say which regional diet was highest) was 1.5 µg/kg-bw per week, just below the new PTWI of 1.6 µg/kg-bw per week, indicating that almost half the people with that diet would exceed the tolerable level of methylmercury intake.<sup>38</sup>

#### ***Step 4: Risk characterization***

As indicated above in the United States, according to the National Health and Nutrition Examination Survey (NHANES) reports, about 6 percent of the study population had body burdens of mercury that slightly exceeded the blood level which is equivalent to the RfD.

JECFA did not characterize the risk for particular regions or countries, but clearly suggested that exposure to methylmercury doses above the PTWI is relatively commonplace in countries where fish is important in the diet, and that national governments may now need to carry out population-specific exposure assessments.

Risk characterizations of the type developed for methylmercury are relatively imprecise; risk is not quantitatively characterized in terms of the probability and severity of adverse health effects relative to defined levels of exposure, but rather, presumptively “safe” exposure levels are estimated (see Chapter 3 for discussion). Such “safety assessments” can nonetheless provide a basis for risk management decisions.

### **Risk communication aspects**

The EPA, the NAS/NRC and JECFA have each published detailed reports on their methylmercury risk assessments, which explain the scientific evidence considered, the interpretations and judgments made by the risk assessors, conclusions and recommendations of the expert groups, uncertainties and data gaps that remain, and steps taken to address uncertainties in the risk assessments.<sup>39</sup> Publication of a risk assessment offers an important opportunity for risk communication and in the USA, extensive communication took place among the interested government agencies, the scientific community, and a variety of stakeholders, ranging from fishing industry interests to NGOs concerned about methylmercury hazards in foods.

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Children and Childbearing-Aged Women – United States, 1999-2002. *Morbidity and Mortality Weekly Reports* 53(43):1018-1020, November 5, 2004. United States Centers for Disease Control and Prevention.

<sup>37</sup> For a review of this evidence, see Mahaffey, K.R. 2005. “Update on Mercury,” presentation at the 2005 Fish Forum, September 19, 2005 (available at [http://epa.gov/waterscience/fish/forum/2005/presentations/Monday%20Slides%200919/afternoon/Mahaffey\\_Fish%20Forum%202005%20-%20Mahaffey%20Final.ppt](http://epa.gov/waterscience/fish/forum/2005/presentations/Monday%20Slides%200919/afternoon/Mahaffey_Fish%20Forum%202005%20-%20Mahaffey%20Final.ppt)).

<sup>38</sup> See JECFA report (cited in footnote 29 above) pp. 607-609.

<sup>39</sup> These reports are cited in footnote 29 above.

As attention returned to risk management aspects, the process in the United States was open to participation by stakeholders.<sup>40</sup> Some of those stakeholders have communicated aggressively, both with the government and with the public at large. For example, fishing interests, especially the United States tuna industry, have criticised the EPA risk assessment and RfD as excessively precautionary, denied that methylmercury in fish poses risks to public health, and spent millions of dollars on public relations and advertising campaigns to persuade people to ignore methylmercury risks and eat more fish.<sup>41</sup> Public health, environmental and consumer organizations have concluded, in contrast, that methylmercury risks are a significant public health concern, and sought in their own ways to inform the public and persuade policy-makers of their view.<sup>42</sup> There has been so much risk communication on the methylmercury problem in the United States that an intense public controversy exists.

Communication about the JECFA risk assessment has been somewhat less intense. When CCFAC received the JECFA recommendation for a lowered PTWI, the committee initiated a review of the Codex guidelines for methylmercury in fish. Some CCFAC members had questions, seeking clarification of JECFA's reasoning on certain points.<sup>43</sup> In particular, some members were uncertain whether JECFA intended that the new, lower PTWI should be applied to everyone in the general population, or whether it applied only to women who were or might become pregnant. JECFA considered this request in 2006 and clarified that the previous PTWI of 3.3 µg/kg-bw had, in fact, been withdrawn in 2003. JECFA confirmed the existing PTWI of 1.6 µg/kg-bw, set in 2003, based on the most sensitive toxicological endpoint (developmental neurotoxicity) in the most susceptible species (humans). However, the Committee noted that life-stages other than the embryo and foetus may be less sensitive to the adverse effects of methylmercury. In the case of adults (with the exception of women of childbearing age for protection of the developing foetus), JECFA considered that intakes of up to about two times higher than the existing PTWI of 1.6 µg/kg-bw would not pose any risk of neurotoxicity. For infants and children JECFA could not identify a level of intake higher than the existing PTWI that would not pose a risk of developmental neurotoxicity for infants and children, hence for this age group the new PTWI applies.

## **Risk Management, Phase 2: Identification and selection of risk management options**

Once the findings of the risk assessment are available, risk managers can proceed to manage the risk. At the international level, WHO and CCFAC each have distinct roles as risk managers with respect to methylmercury in fish. Since neither WHO nor Codex committees implement risk management measures, the international bodies' actions serve primarily as guidance for national risk managers.

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<sup>40</sup> Mercury in fish was discussed extensively at a December 10, 2003 meeting of the FDA's Food Advisory Committee (transcript available at <http://www.fda.gov/ohrms/dockets/ac/cfsan03.html>). It was addressed in written comments submitted by industry groups and by Consumers Union among others.

<sup>41</sup> Many examples of denial of the evidence of mercury risks and promotion of increased fish (and specifically, tuna) consumption are accessible on the United States Tuna Foundation web site. For example, see [http://www.tunafacts.com/news/eat\\_more\\_fish\\_081505.cfm](http://www.tunafacts.com/news/eat_more_fish_081505.cfm). Also see, <http://www.fishscam.com>, an industry-funded web site created by a public relations firm in an effort to discredit mercury risk concerns.

<sup>42</sup> For example, see Groth, E. 2005. *Risks and Benefits of Fish Consumption: Yes, Mercury is a Problem*. Report prepared for Oceana and the Mercury Policy Project, December, 2005 (available at [http://www.oceana.org/fileadmin/oceana/uploads/mercury/Final\\_Report\\_12-5.pdf](http://www.oceana.org/fileadmin/oceana/uploads/mercury/Final_Report_12-5.pdf)).

<sup>43</sup> See the report of the 2005 CCFAC meeting, ALINORM 05/28/12, paragraphs 201-205.

The CCFAC, based on the new JECFA PTWI, is now considering further appropriate actions it might pursue. At its 2004 meeting, CCFAC asked a drafting group to prepare a discussion paper, outlining possible risk management options that national governments might consider. The paper,<sup>44</sup> prepared with the leadership of the European Commission, focused on both the Codex Guideline Levels for Methylmercury in Fish, and on providing information to stakeholders, especially consumers, as a risk management option. It was discussed at the 2005 CCFAC session,<sup>45</sup> which agreed to organize a workshop on risk communication as a risk management tool. This workshop was held in conjunction with the CCFAC session in April 2006.

WHO is also currently drafting a document to provide advice to member governments on how to conduct risk analysis for methylmercury in fish. International advice on this subject will be drawn from national experiences. The rest of this section, therefore, examines the national aspect of this case study, the experience in the United States.

### ***Step 1: Identify risk management options***

Several risk management options can be identified which might help reduce methylmercury risks at the national level. A general option, important for addressing local pollution problems that may put specific fish-eating populations at risk, is to control industrial mercury emission sources; however, this approach will have negligible short-term impact on the methylmercury levels in migratory oceanic fish species. Furthermore, pollution control is generally outside the authority of food safety agencies, which have the primary risk management responsibility for food-borne contaminants such as methylmercury.

Among actions that can be taken by national food safety authorities, the following are some risk management options that could be considered:

- The sale of certain fish species that are very high in methylmercury could be banned.
- A maximum contaminant level could be set for mercury or methylmercury in fish, and used to restrict sale and consumption of fish that exceed the established limit.
- The fishing industry and fish processors and retailers could be required to implement a code of Good Hygienic Practice or a HACCP system designed to prevent fish with potentially harmful levels of methylmercury from reaching consumers.
- Consumers can be educated and informed about methylmercury levels in fish and the associated risks, so that they can manage their own methylmercury exposure.

### ***Step 2: Evaluate the options***

The pros and cons of these options have been examined in several cycles of risk analysis on methylmercury in the United States. The United States government has not been willing to ban the sale or consumption of any fish species, even those with very high methylmercury levels, such as swordfish or marlin. High-mercury fish still has nutritional benefits, and most high-mercury species are eaten only infrequently by the vast majority of consumers, so bans have been viewed as unjustified, as well as impractical to enforce. Social and economic concerns, such as the possibility of putting fishermen out of work, have also been considerations weighed in evaluating this option.

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<sup>44</sup> Available at [ftp://ftp.fao.org/codex/ccfac37/fa37\\_35e.pdf](ftp://ftp.fao.org/codex/ccfac37/fa37_35e.pdf)

<sup>45</sup> See Report of 2005 CCFAC session (cited in footnote 43 above).

The United States adopted an “Action Level,” a guideline value for the acceptable upper limit of methylmercury concentrations in fish, in 1969. Originally set at 0.5 parts per million (ppm), the Action Level was raised to 1.0 ppm in 1979, after the fishing industry successfully sued the FDA. The court ruled that FDA’s exposure assessment and resulting safety assessment which it used as the justification for the 0.5 ppm level were unnecessarily conservative and inappropriate. Many other national governments, and CCFAC, have issued similar guidelines, generally set either at 0.5 or 1.0 ppm.<sup>46</sup>

In the United States, the Action Level is rarely if ever enforced; FDA concedes, for instance, that a significant portion of swordfish sold in national markets contains more than 1.0 ppm of mercury. While such a limit can, in theory, be used to prevent sale of fish that exceed it, in practice the United States Action Level has proved difficult and costly to enforce, and if strictly enforced, it could have negative socioeconomic effects similar to those discussed for a ban, above. Also, since the level of mercury in fish is just one of several factors that determine risk, efforts to keep high-mercury fish off the market cannot, by themselves, effectively reduce exposure and the associated risk. Someone who ate a great deal of fish with, for example, 0.25 ppm mercury could exceed the safe intake limit by a wide margin, while someone else who ate swordfish once or twice a year, for instance, might not be particularly at risk. Since the Action Level cannot be adjusted to take into account other factors that determine risk, enforcing it has not been a high priority. In sum, while it is seen as a useful guideline, the United States Action Level for mercury in fish has not significantly reduced exposure.

GHP or HACCP approaches that could help fish and seafood industries reduce the amount of methylmercury in products they sell appear to have significant potential for mitigating the problem, but this approach has not been pursued to date in the USA.

A few other private-sector initiatives have had modest effects. Some retail grocery chains are working with state governments and NGOs in the United States to provide information on the mercury content of different fish at the point of sale (e.g. at supermarket fish counters). Other sellers of fish, including chefs at famous restaurants, have promised to stop offering certain high-mercury species.

Information-based options have been the recent focus of risk management for methylmercury in the USA. Because the risk depends on multiple factors (including who is consuming the fish, which fish they choose to consume, how much of each fish species they eat, and how much methylmercury the fish in question contain) education and risk communication have attracted great interest as risk management options. These approaches can address the complexity of the problem, do not require costly and impractical enforcement efforts, can be implemented relatively quickly and at relatively minimal cost, and hold at least the potential for reducing methylmercury exposure substantially, without adverse nutritional or economic consequences.

### ***Step 3: Select the preferred option(s)***

As should be clear from the discussion above, the currently preferred risk management option and main focus of risk managers in the United States is providing information to consumers.

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<sup>46</sup> CCFAC has adopted a two-tiered system, with a list of species that should not exceed 1 ppm, i.e. large predatory fish that tend to accumulate relatively high mercury levels, and a second list that should not exceed 0.5 ppm, i.e. fish that tend to accumulate moderate but still relatively significant amounts of mercury



### **Risk Management, Phase 3: Implementation**

Once the preferred risk management option has been selected, governments and other stakeholders need to implement the chosen option. In the United States, the FDA issued a national “advisory” on methylmercury and fish consumption in 2001, targeting women of childbearing age, telling them to avoid four species with high mercury levels, i.e. swordfish, tilefish, shark and king mackerel. In 2004, the FDA and EPA issued a joint, updated, expanded “advisory”, which emphasized the nutritional benefits of fish consumption, urged women to consume a variety of low-mercury fish, listed several widely available low-mercury fish and seafood choices, listed the same four species that should be avoided, advised limiting consumption of canned albacore tuna, and said that children’s fish consumption should follow similar guidelines. The “advisory” has been published on the government’s web sites<sup>47</sup> and was publicized heavily when it was initially issued. FDA has taken steps within its modest resources to promote awareness of the advisory and to work with industry, professional (medical and nutritional) societies, and other interested parties to educate consumers on how to manage their own methylmercury exposure.

Several State Health Departments within the United States have also issued consumer advice on methylmercury in fish, as have some professional organizations and numerous NGOs. American consumers have no shortage of advice and “educational” information on this topic; in fact, one concern has been that differences in the advice from different sources may be confusing consumers. The 2004 joint FDA/EPA “advisory” was in part undertaken as an effort to get the federal government, at least, to speak with a single voice on this subject.

Since implementation is a responsibility of national authorities, there is no section on this phase of risk management in the JECFA/Codex risk analysis for methylmercury.

### **Risk Management, Phase 4: Monitoring and Review**

The “final” stage of risk analysis occurs when risk managers assess how well the risk management options implemented are working and weigh the need to examine new evidence and update risk assessments and management strategies. Since each of the risk analysis cases described in this Annex were to a large extent reviews and updates, or reiterations, of previous efforts, they essentially began at this point. In the case of the United States risk analysis documented here, relevant government agencies continue to monitor of the effects of risk management actions.

The “advisory” option being pursued now in the USA was implemented in 2004, and there has not been enough time to determine most of its expected effects. For example, a key indicator of effectiveness of the EPA/FDA “advisory” will be whether national surveys show that a decreasing percentage of women have blood mercury levels above the EPA reference level, but such data are not expected to be available for several years.

Nevertheless, some efforts to assess the effects of the informational approach in the USA are now under way. Before it issued the 2004 advisory, the government conducted sessions with consumers (“focus groups”) to assess how they would understand and respond to both the

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<sup>47</sup> “What You Need to Know About Mercury in Fish and Shellfish,” the current (2004) EPA/FDA advisory (available at <http://www.epa.gov/waterscience/fishadvice/advice.html>). For an Australian example, see the Food Safety Authority of New South Wales’s advice on mercury in fish for women who may become pregnant (available at <http://www.foodauthority.nsw.gov.au/pregnancy.htm?lk=consinfo>).

information and the advice provided. Since the advisory was issued, a concern has arisen that warnings about contaminants like methylmercury in fish may make consumers afraid to eat fish, and cause them to lose important nutritional benefits associated with fish in the diet. Whether this is true or not is far from clear at this point,<sup>48</sup> but the question has attracted a great deal of attention from academic researchers, state and federal governments, and interested stakeholders. Investigations now under way may lead to fine-tuning the advice offered to consumers, so that they can continue to consume low-mercury fish for their nutritional benefits, while minimizing their mercury exposure.

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<sup>48</sup> See Groth. 2005 (footnote 42 above) for discussion.

## Annex 3: Case Study of *Listeria Monocytogenes* in Ready-to-Eat Foods

### Background

*Listeria monocytogenes* is a food-borne bacterial pathogen that can cause listeriosis, a severe disease that can result in septicemia, meningitis and spontaneous abortion. Given the importance of this disease, the “USA Healthy People 2010” goals for national health promotion and disease prevention called on federal food safety agencies to reduce food-borne listeriosis by 50 percent by the end of the year 2005. While increased government and industry attention to general aspects of *L. monocytogenes* control would result in some decrease in incidence, specific risk management actions were needed.

This case study illustrates application of the generic RMF presented in this Guide.

### Risk Management, Phase 1: Preliminary Risk Management Activities

#### *Step 1: Identify the problem*

Listeriosis typically occurs in susceptible individuals including the elderly, pregnant women and immunocompromized people (e.g. patients undergoing cancer therapy, transplant recipients and people with AIDS). Although the total number of cases in any population is relatively low (about 2,500 cases per year in the United States), listeriosis has an estimated case fatality rate of 20 to 40 percent.

*L. monocytogenes* is widespread in the environment but the predominant food-borne disease pathway is via ready-to-eat<sup>49</sup> foods. In addressing the *L. monocytogenes* problem in the United States, risk managers made an early decision to only evaluate risks associated with ready-to-eat foods because the organism is destroyed in other types of foods that are cooked or further processed before consumption.

In addition to good hygienic practice (GHP), a “zero tolerance” regulatory standard of no *L. monocytogenes* cells being detected in the food sample tested is maintained in the United States. A typical food test for *L. monocytogenes* is two samples at 25 grams each, which equates to a standard of less than 0.04 cfu/g. The existing regulatory standards are not achieving the level of public health protection required and better “risk-based” control measures are needed.

#### *Step 2: Develop the risk profile*

The concerned government agencies gathered all relevant information on *L. monocytogenes* in foods to inform further action. Different types of ready-to-eat foods were considered including meat products, seafood, dairy products, fruits, vegetables and delicatessen salads.

Preliminary data collection activities identified many gaps in the scientific information available on *L. monocytogenes* in ready-to-eat foods. In particular, exposure data was deficient for a number of ready-to-eat food types and a specific survey was commissioned to fill this data gap. While most samples were found to be negative for *L. monocytogenes*, those

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<sup>49</sup> Products that may be consumed without any further cooking or reheating

that were positive typically contained less than 1.0 cfu/g, with almost all foods containing less than 100 cfu/g.

### ***Step 3: Establish risk management goals***

The primary risk management goal was to estimate relative risks associated with different types of ready-to-eat foods and develop targeted food control measures that would significantly reduce the overall incidence of food-borne listeriosis in line with “USA Healthy People 2010”. The relative risk ranking would identify priority food categories for risk management.

A subsidiary goal was to estimate the relative risks of serious illness and death for three age-based subpopulations: i) prenatal/perinatal (16 weeks after conception to 30 days after birth); ii) the elderly (60 years of age or more); and iii) an intermediate age population.

Interventions in the ready-to-eat food chains that presented the greatest relative risks would be evaluated for their individual ability to reduce risks.

### ***Step 4: Decide whether a risk assessment is needed***

In the United States, government agencies are required to do risk assessments when making major food safety policy decisions. In this case, the risk managers decided that the most value would be gained from estimating relative risks from a wide range of ready-to-eat food categories. The decision to base control measures on estimates of relative risk was predicated by limitations in data availability.

### ***Step 5: Establish risk assessment policy***

While this is a formal step in the generic RMF developed in this Guide, establishment of risk assessment policy was not conducted as a discrete exercise in this case study. However, there were a number of situations where a standardised approach to dealing with scientific data was agreed. A policy decision was made that data sets that were more recent and/or came from peer-reviewed publications would be given a higher weighting than others, and data collected outside the United States could be used if the product was imported. Exposure data would be represented as presence/absence data rather than actual numbers of *L. monocytogenes* in foods and this allowed all the available exposure data to be utilized in some form.

For the dose-response assessment, a policy decision was made to use a non-threshold model rather than a threshold model. A non-threshold model assumes that there is a small but finite probability of illness even if only a single organism is consumed.

### ***Step 6: Commission the risk assessment***

Before commissioning, a public meeting was held to invite comment on the planned assessment and a request was made for scientific data and information to be submitted for use in the assessment. The advice and recommendations of the National Advisory Committee on Microbiological Criteria for Foods were sought on the assumptions therein and the model structure to be used.

The risk assessment was carried out by the Food Safety and Inspection Service (FSIS) in the United States Department of Agriculture (USDA), the United States Department of Health and Human Services (HHS), the United States Food and Drug Administration (FDA) and the United States Centres for Disease Control and Prevention (CDC) over a period from 1999 to

2003. The risk assessment team was a multidisciplinary group of government scientists including food microbiologists, epidemiologists and mathematicians.

A total of 23 separate assessments were undertaken, which allowed an analysis of the relative risks of serious illness and death associated with a wide range of ready-to-eat food categories (<http://www.foodsafety.gov/~dms/lmr2-toc.html>). Primary considerations were: consumption by susceptible persons; types of contaminated foods; foods that support growth; storage time; and storage temperature.

Risk communication included presentations at scientific meetings and public meetings, the latter being held for the purpose of soliciting feedback and peer review. An initial draft risk assessment was released in 2001 to allow public comment and input from the scientific community before the assessment was finalised. This generated additional data for risk assessment and was an effective method for communicating with all stakeholders before the assessment was finalised.

### ***Step 7: Consider the results of the risk assessment***

Elements of the risk assessment are summarized in Box A3-1.

The primary output of the risk assessment is shown in Figure A3-1 as estimated cases of listeriosis associated with different ready-to-eat food categories for the total United States population on a per serving basis. In the United States, delicatessen meats, frankfurters (not reheated), pâté and meat spreads pose a much greater risk (about 1 case of listeriosis per 10<sup>7</sup> servings is predicted) than hard cheeses, cultured milk products and processed cheeses, where the predicted level of illness is approximately 1 case of listeriosis per 10<sup>14</sup> servings. The main reason for this is that the former group of foods supports the growth of *L. monocytogenes* to high numbers even during refrigerated storage, while the latter group does not.

The risk assessment generated risks per serving to an individual consumer and risks per annum to various populations; the latter representing total disease burden. Ready-to-eat foods ranked as **very high risk**, both risk per serving and per annum, included delicatessen meats and frankfurters (not reheated). This is due to high consumption, high rates of contamination and rapid growth to high numbers in stored products. Ready-to-eat foods ranked as **high risk** included pâté and meat spreads, smoked seafood, pasteurized and unpasteurized fluid milk, and soft unripened cheeses. Here, high relative risks are generated either from high contamination but low consumption rates or low contamination but high consumption rates e.g. pasteurized fluid milk. Ready-to-eat foods ranked as **moderate risk** (e.g. dry/semi-dry fermented sausages and frankfurters (reheated)) include a bactericidal step or inhibitors, so that growth to high numbers is prevented or retarded. Ready-to-eat foods ranked as **low risk** (e.g. preserved fish and raw seafood) have both low contamination rates and low consumption rates, and may have natural barriers to growth. Ready-to-eat foods ranked as **very low risk** (e.g. hard cheese) do not support growth.

The dose-response curves show that elderly and perinatal populations are more likely to contract listeriosis than the general population. The dose-response curves also suggest that the relative risk of contracting listeriosis from low dose exposures is less than previously estimated, even for susceptible populations.

**Box A3-1. Summary of elements of the risk assessment of *L. monocytogenes* in ready-to-eat foods**

**Hazard characterization:** Severe illness or death in three age-based populations were considered: prenatal/perinatal; the elderly; and an intermediate age population. Dose-response relationships were estimated by using contamination and growth data to predict levels of *L. monocytogenes* at the time of consumption for all ready-to-eat foods. These data were combined with epidemiology data to derive a dose-response model for each population group. The shape of the dose-response curve was based on mouse lethality data for *L. monocytogenes* but the position of the dose-response curve was fixed by “anchoring” the curve to annual disease statistics for the United States. Mild non-invasive listerial gastroenteritis was not considered in the risk assessment.

**Exposure assessment:** Exposure assessments were based on estimates of the frequency of contamination of foods, the numbers of cells on ready-to-eat foods, the amount of growth before consumption, the amount of each food type consumed at a typical serving and the number of servings consumed per year.

Servings per year of each ready-to-eat food category varied considerably, as did the amount of food eaten at each serving. As examples for the whole United States population, there were  $8.7 \times 10^{10}$  servings of pasteurized milk per year at 244 g,  $2.1 \times 10^{10}$  servings of delicatessen meats at 56 g, and  $2 \times 10^8$  servings of smoked seafood at 57 g. Initially “expert opinion” was used to fill a significant data gap on the length of time for which foods were stored by consumers and its effect on *L. monocytogenes* numbers. Later, a survey of consumer practices was commissioned by the meat industry to obtain data to allow better estimates to be made for hot dogs and delicatessen meats.

Most (1,300) contaminated servings of food per person per year contained fewer than one organism per serving; 19 servings contained between 1.0 and 1,000 cfu/g; and 2.4 servings contained between 1,000 and 1,000,000. Less than one serving per person per year contained more than one million *L. monocytogenes*.

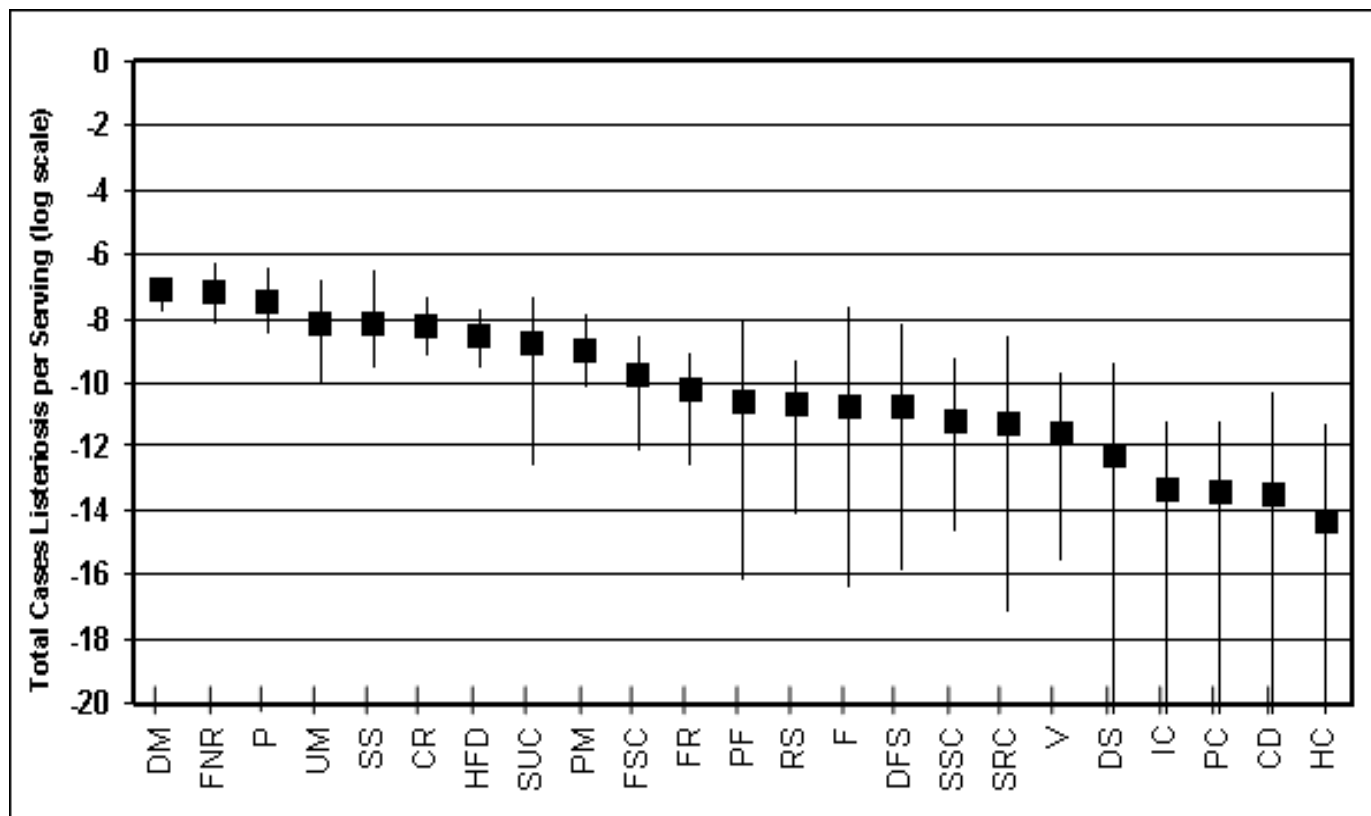
**Risk characterization:** Individual food category data and the dose-response model were used to estimate the number of cases of illness per serving and per year for each food category and each population group. This allowed foods to be ranked according to two different measures of relative risk. An uncertainty analysis was performed and results were compared with existing epidemiological knowledge to validate the outputs of the risk assessment. The ability of a food to support growth of *L. monocytogenes* to high numbers and the opportunity for growth is a key risk factor in food-borne listeriosis. The model indicates that it is the few servings with very high levels of contamination that are responsible for most of the illnesses and deaths.

**Step 8: Rank risks**

Ranking of risks associated with the 23 ready-to-eat food types was a key design element of this case study and provided the platform for the risk management options subsequently chosen. Relative risk rankings are shown in Figure A3-1.

Once the risk assessment was finalised, a series of reports were released. The first report was a short executive summary of the findings. The second report was an interpretive summary, with a more detailed review of the findings. The third report was the risk assessment. A fact sheet with questions and answers was also released. By providing the information in many formats, different audiences were properly addressed.

**Figure A3-1: Estimated cases of listeriosis associated with different food categories for the total United States population on a per serving basis**



The box indicates the median predicted number of cases of listeriosis (log scale) and the bar indicates the lower and upper bounds (i.e. the 5<sup>th</sup> and 95<sup>th</sup> percentiles). The y-axis values are presented on a log scale. For example a log of -6 is equivalent to 1 case of listeriosis in a million servings.

DM = Delicatessen meats; FNR = Frankfurters (not reheated); P= Pâté and Meat Spreads; UM= Unpasteurized Fluid Milk; SS= Smoked Seafood; CR = Cooked Ready-To-Eat Crustaceans; HFD = High Fat and Other Dairy Products; SUC = Soft Unripened Cheese; PM = Pasteurized Fluid Milk; FSC = Fresh Soft Cheese; FR = Frankfurters (reheated); PF = Preserved Fish; RS = Raw Seafood; F = Fruits; DFS= Dry/Semi-dry Fermented Sausages; SSC = Semi-soft Cheese; SRC = Soft Ripened Cheese; V = Vegetables; DS = Delicatessen-type Salads; IC= Ice Cream and Frozen Dairy Products; PC = Processed Cheese; CD = Cultured Milk Products; HC = Hard Cheese.

## **Risk Management, Phase 2: Identification and selection of risk management options**

The results of the risk assessment were used in different ways by the different government agencies. HHS used the risk assessment to develop a risk management action plan for *L. monocytogenes* (<http://www.cfsan.fda.gov/~dms/lmr2plan.html>) whereas USDA FSIS used the risk assessment primarily as a basis for new regulatory measures.

### ***United States Department of Health and Human Services (HHS)***

FDA and CDC developed a risk management action plan to target the products and practices that generate the greatest risks of food-borne listeriosis. The action plan included the following objectives:

- Develop and revise guidance for processors, retail outlets, food service and institutional establishments that manufacture or prepare ready-to-eat foods.

- Develop and deliver training for industry and food safety regulatory employees.
- Enhance consumer and health care provider information and education efforts.
- Review, redirect and revise enforcement and regulatory strategies including microbial product sampling.

In evaluating different risk management options, risk managers worked with risk assessors to change one or more input parameters in the risk model and measure the change in relative risk outputs. These “what if” scenarios included:

- *Refrigerator temperature scenario*, where the impact of ensuring home refrigerators do not operate above 45 °F was evaluated. Here, the predicted number of cases of listeriosis would be reduced by approximately 69 percent. At 41 °F or less, the predicted number of cases would be reduced by approximately 98 percent.
- *Storage time scenario*, where maximum storage time scenarios were evaluated. Limiting the storage time for delicatessen meat, for example, from a maximum 28 days to 14 days, reduces the median number of estimated cases in the elderly population by 13.6 percent. Shortening storage time to ten days results in a 32.5 percent reduction.

Other scenarios included modelling of different contamination level scenarios in retail foods and specifically modelling fresh soft cheese made from unpasteurized milk. Risk assessment outputs and modelling of “what if” scenarios resulted in development of new published guidance for processors on prevention of post-processing contamination with *L. monocytogenes*, including improved sanitation practices and environmental sampling for ready-to-eat foods, and improved distribution practices. This includes updated guidance on enhancing the safety of milk and milk products and fresh-cut produce. Existing training programmes and long-distance teaching instruments were also updated.

Additional messages to consumers and health care providers on the prevention of listeriosis were developed. These include advice on safely selecting, storing, and handling foods with special emphasis on short storage times in combination with minimising storage temperatures to as cold as necessary (and not exceeding 40 °F). Educational programmes aimed at pregnant women, older adults, and people with weakened immune systems were also updated. As examples, these population groups are advised not to eat hot dogs and luncheon meats unless they are reheated until steaming hot, soft cheese unless it is labelled as made with pasteurized milk, refrigerated smoked seafood unless it is contained in a cooked dish, and raw (unpasteurized) milk.

Regulatory risk management options include increased inspection of regulated food processing facilities that produce ready-to-eat foods ranked moderate to high risk in the risk assessment. This focuses inspection efforts on post-process contamination potential, sanitation practices, and environmental testing programmes.

***Food Safety and Inspection Service, United States Department of Agriculture (FSIS, USDA)***

During the development of the HHS/USDA risk assessment, FSIS initiated several regulatory actions based on current scientific knowledge with the aim of reducing food-borne listeriosis associated with meat products. When the first draft of the risk model was released in 2001, it showed that delicatessen meats (such as cooked ready-to-eat turkey or ham) presented a relatively high risk for listeriosis. As a consequence FSIS decided to focus risk management activities on delicatessen meats and initiated a further risk assessment specific to the product



group. “What if” scenarios showed that combinations of interventions (e.g. sanitation/testing of food contact surfaces, pre- and post-packaging lethality interventions, and growth inhibitors) were much more effective than any single intervention in reducing estimated risks from deli meats ([http://www.fsis.usda.gov/PDF/Lm\\_Deli\\_Risk\\_Assess\\_Final\\_2003.pdf](http://www.fsis.usda.gov/PDF/Lm_Deli_Risk_Assess_Final_2003.pdf)).

As a consequence, FSIS amended its regulations to require that official establishments that produce certain ready-to-eat meat and poultry products put in place specific controls to prevent contamination with *L. monocytogenes* if those products are exposed to the environment after lethality treatments. So as to provide flexibility to industry, the regulatory rule allows establishments to incorporate one of three strategies: i) employ both a post-lethality treatment and a growth inhibitor for *L. monocytogenes* on ready-to-eat products; ii) employ either a post-lethality treatment or a growth inhibitor; or iii) employ sanitation measures only. These in-plant requirements are underpinned by new compliance guidelines and FSIS inspection procedures (see below).

Regulatory change was accompanied by education and outreach programmes. These risk communication activities were harmonized with those of FDA to ensure that consumer messages on listeriosis remained consistent.

### **Risk Management, Phase 3: Implementation**

#### ***United States Department of Health and Human Services (HHS)***

FDA and CDC continue to work on implementation activities, including disseminating guidance for processors. Technical assistance is provided to small and very small establishments (e.g. dairy facilities) on an ongoing basis.

Consumer information and education efforts continue, including specific education packages for highly susceptible population groups and medical guidance for health care professionals. An example of a targeted education programme is that to Hispanic women of child-bearing age to only eat fresh soft cheeses made with pasteurized milk.

Regulatory risk management options that focus on increased inspection of establishments that produce “high risk” ready-to-eat foods have also been implemented. FDA is also working with states to eliminate the unlawful production and sale of raw milk soft cheeses.

#### ***Food Safety and Inspection Service, United States Department of Agriculture (FSIS, USDA)***

A specific aspect of implementation of the new FSIS regulations is the matching of FSIS verification activities to the specific control strategy chosen by the processor. Establishments that chose sanitary measures alone have the highest frequency of inspection whereas establishments that chose both a post-lethality treatment and a growth inhibitor for *L. monocytogenes* on ready-to-eat products are subject to FSIS activity that only focuses on verification of post-lethality treatment effectiveness. This way, establishments are encouraged to select the most effective strategies to control for *L. monocytogenes*. FSIS also places increased scrutiny on operations that produce hotdogs and delicatessen meats. Compliance guidelines to control *L. monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products were published in the United States Federal Register in May 2006 ([http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM\\_Rule\\_Compliance\\_Guidelines\\_May\\_2006.pdf](http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf)).

FSIS is currently working on a risk-based *L. monocytogenes* verification algorithm that rewards highly-performing establishments by reducing inspection frequency.

## **Risk Management, Phase 4: Monitoring and review**

### ***United States Department of Health and Human Services (HHS)***

The risk management action plan developed by FDA and CDC also includes the objectives of:

- Enhance disease surveillance and outbreak response.
- Coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

Monitoring of both domestically-produced and imported food is focused on “high-risk” ready-to-eat foods.

To detect illness outbreaks more quickly and accurately, CDC is continuing to increase the number of laboratories capable of *L. monocytogenes* analysis through CDC’s “PulseNet” laboratory network and will evaluate additional methods for rapid subtyping of pathogenic strains. A CDC comprehensive case-control study to gather additional information about food-borne listeriosis is also being undertaken.

Risk managers identified a number of future research needs to refine the existing risk assessment so as to facilitate review the risk management options chosen. These include scientific evaluation of: the effectiveness of post-packaging pasteurization; use of bacteriocins, irradiation, high pressure processing, and inhibitory compounds to eliminate or prevent the growth of *L. monocytogenes*; and development of improved epidemiological methods for food source attribution.

### ***Food Safety and Inspection Service, United States Department of Agriculture (FSIS, USDA)***

Establishments must share data and information relevant to their controls for *L. monocytogenes* with FSIS. Additionally, FSIS carries out its own random testing of ready-to-eat meat and poultry products and this is used to rank establishments for verification purposes. These data are subject to ongoing evaluation, with review of regulation if necessary. It should be noted that human health surveillance as a specific “monitoring and review” activity is not within the jurisdiction of USDA.

## **Risk communication**

Risk communication was incorporated at various points throughout the risk analysis as indicated in the above discussion. Different approaches were used to communicate with external stakeholders about the nature and effects of the specific food safety risks faced. These included public meetings and calls for scientific data and information before the risk assessment was commissioned, public meetings to seek feedback from interested groups (including the scientific community) and peer review an initial draft risk assessment, and complementary activities to enhance knowledge among consumers and health care providers about the prevention of listeriosis.

In the case of proposed risk management options for ready-to-eat meat and poultry products, FSIS published proposals for interim regulatory requirements in the Federal Register and are continuing to engage with industry on practical aspects of their implementation.

Risk analysis offers a tool that national food safety authorities can use to make significant gains in food safety. Encompassing three major components (risk management, risk assessment and risk communication), risk analysis provides a systematic, disciplined approach for making food safety decisions. It is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied. Risk analysis can support and improve the development of standards, as well as address food safety issues that result from emerging hazards or breakdowns in food control systems. It provides food safety regulators with the information and evidence they need for effective decision-making, contributing to better food safety outcomes and improvements in public health.

FAO and WHO have developed this Guide to assist food safety regulators' understanding and use of risk analysis in national food safety frameworks. The primary audience is food safety officials at the national government level. The Guide provides essential background information, guidance and practical examples of ways to apply food safety risk analysis. It presents internationally agreed principles, a generic framework for application of the different components of risk analysis, and wide-ranging examples rather than prescriptive instructions on how to implement risk analysis. It complements and is aligned with other documents that have been produced or are being developed by FAO, WHO and the Codex Alimentarius Commission.

This Guide is the first part of a two-part set, all of which is available on CD-ROM. The second part comprises a number of educational elements for capacity building, which include a slide presentation for use in training, a collection of up-to-date FAO and WHO tools and training materials related to food safety risk analysis, and specific examples and case studies of risk analysis carried out at the national and international level.

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