

Food safety risk analysis

A guide for national food safety authorities

FAO
FOOD AND
NUTRITION
PAPER

87



World Health
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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 international 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 19th and 20th 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.¹ Subsequent consultations have addressed in greater detail some specific aspects of the risk analysis paradigm.²

¹ 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); 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>).

² 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); 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,³ 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.

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).

³ FAO/WHO. 2005. Working principles for risk analysis for application in the framework of the Codex Alimentarius. In *Codex Alimentarius Commission. Procedural Manual*. 15th Edition, pp 101-107 (available at: 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.⁴

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.

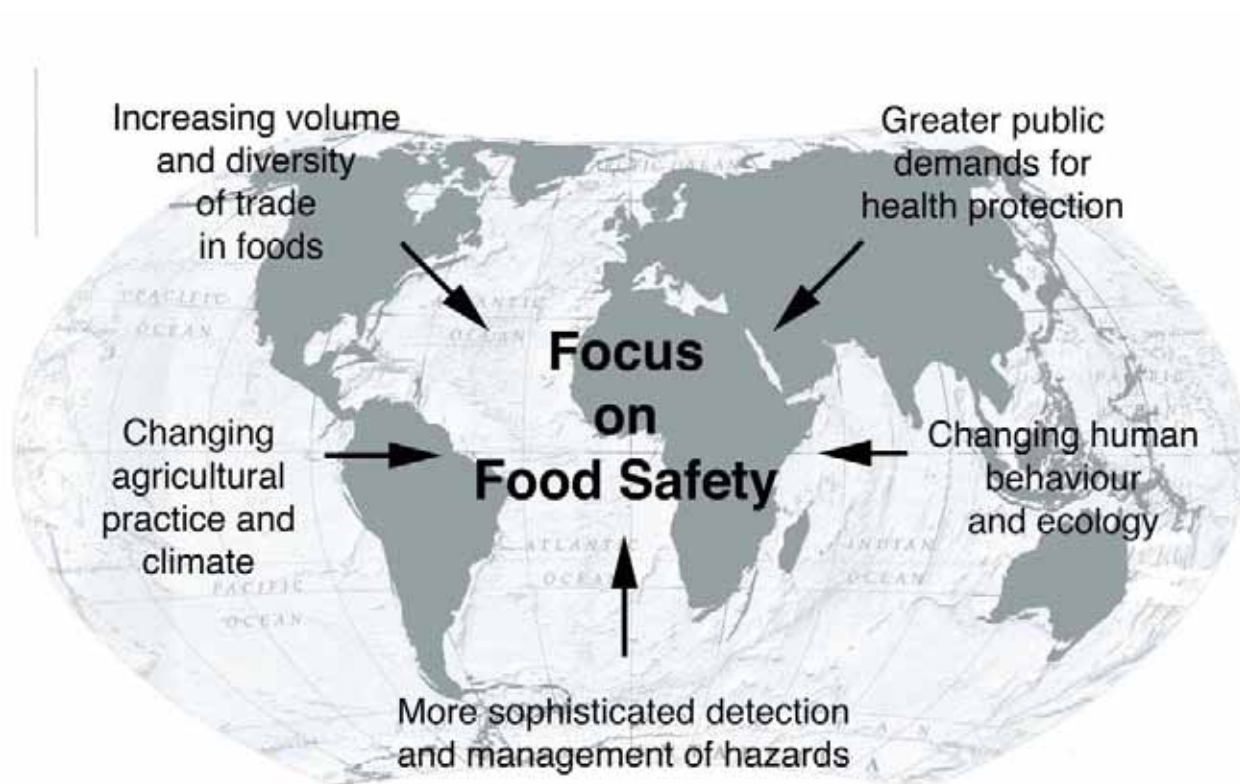
Regardless of the level of sophistication of national food control systems, a wide range of factors are placing generally increasing demands on national authorities responsible for food safety. Box 1.2 and Figure 1.1 describe rapidly changing dimensions of the global food system. Some of these changing 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.

⁴ Information on FAO/WHO food safety activities is available at 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		
Biological hazards	Chemical hazards	Physical hazards
<ul style="list-style-type: none"> • Infectious bacteria • Toxin-producing organisms • Moulds • Parasites • Viruses • Prions 	<ul style="list-style-type: none"> • Naturally occurring toxins • Food additives • Pesticide residues • Veterinary drug residues • Environmental contaminants • Chemical contaminants from packaging • Allergens 	<ul style="list-style-type: none"> • Metal, machine filings • Glass • Jewellery • Stones • Bone chips

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”

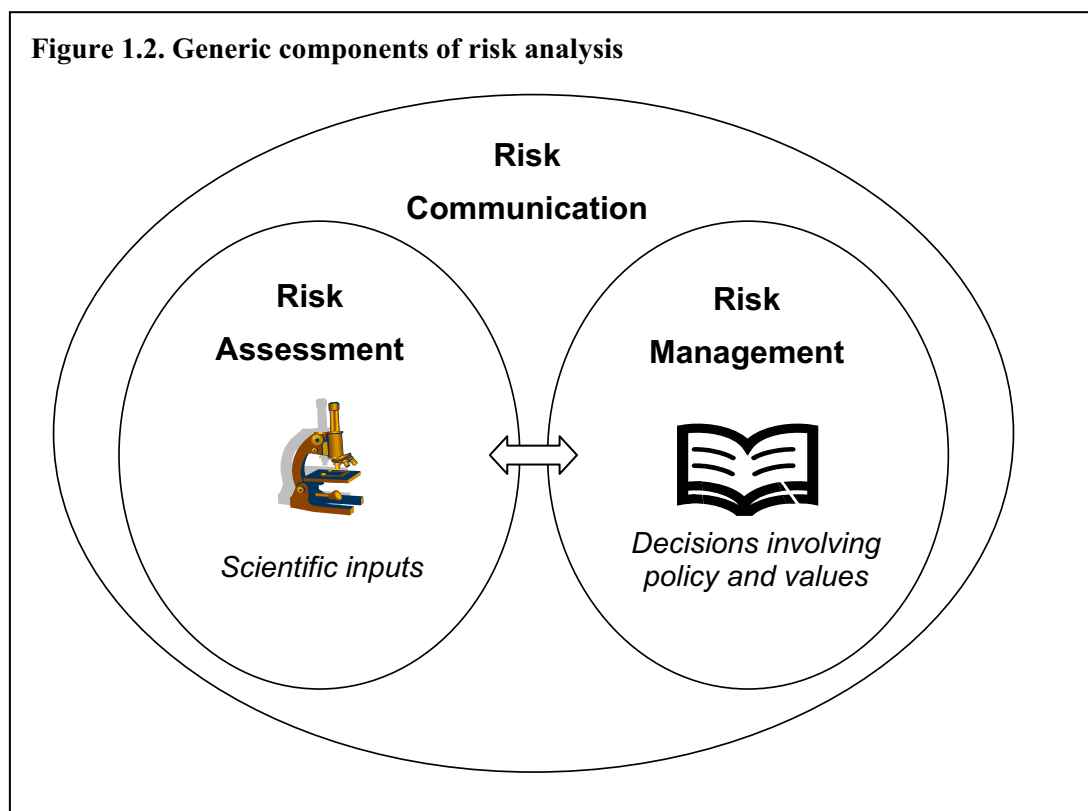
In risk analysis terminology, food safety officials working for national governments generally play the role of “risk managers.” They have overall responsibility for ensuring that a risk analysis is carried out, as well as the ultimate responsibility for choosing and implementing food safety control 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).

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*. 15th Edition. Joint FAO/WHO Food Standards Programme, Rome (available at: 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*. 15th Edition. Joint FAO/WHO Food Standards Programme, Rome. Pp 101-107 (available at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf).

FAO/WHO. 2005. *Building effective food safety systems*. Proceedings of the 2nd 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 managers⁵ 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.

⁵ 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.

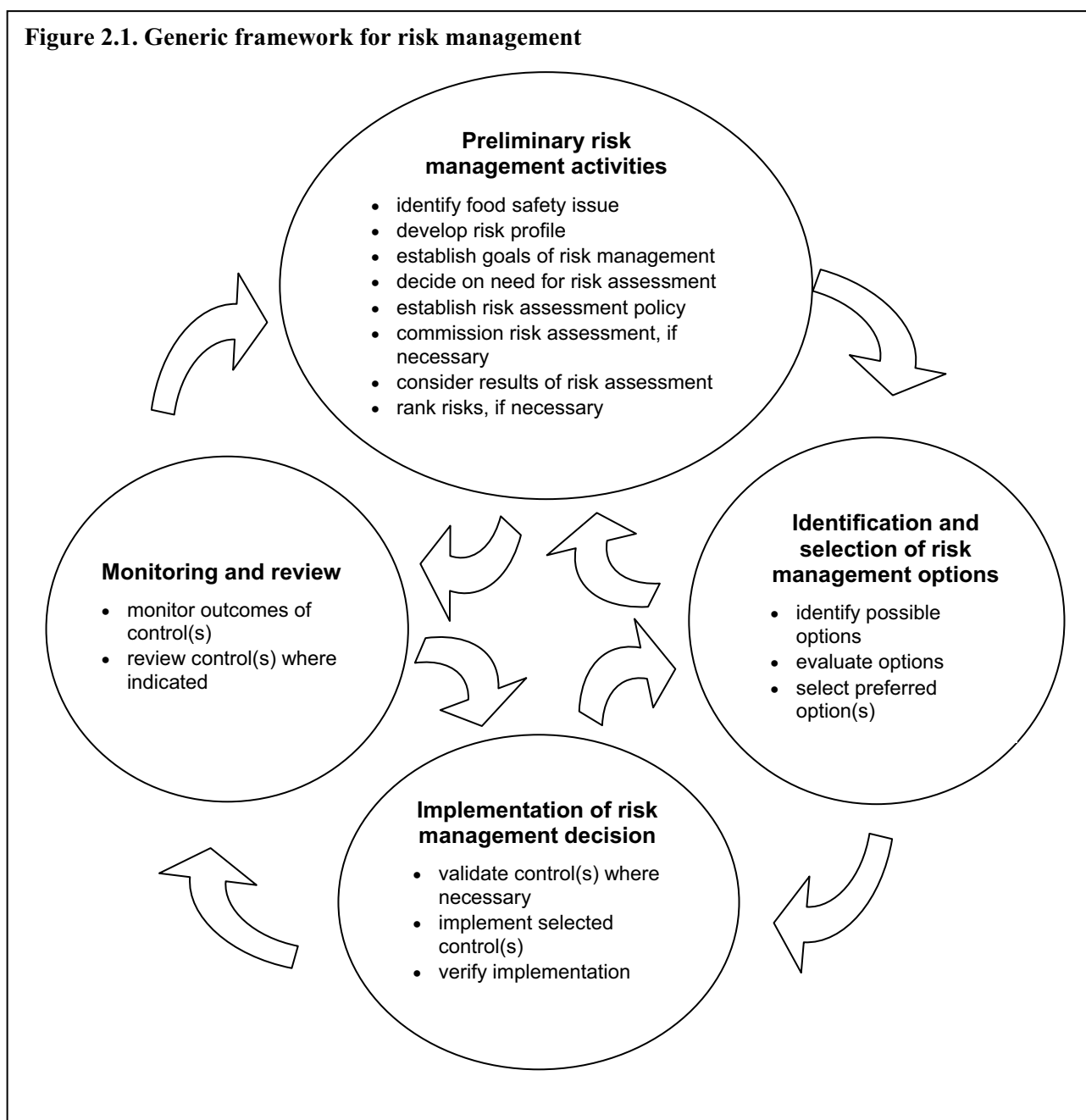
2.2. A generic risk management framework

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 management⁶) 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.

⁶ FAO/WHO. 2005. Proposed draft principles and guidelines for the conduct of microbiological risk management. Appendix III In Report of the 37th 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 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 activities⁷

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.

⁷ Preliminary risk management activities were referred to as “risk evaluation” in the past. In the 13th 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.⁸ 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.*

⁸ 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).

A policy is often developed to provide an agreed framework for the conduct of risk assessment. Risk assessment policy is defined in the 15th 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.⁹ 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

⁹ 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 and www.who.int/ipcs/publications/jecfa/en/index.html; JEMRA: www.fao.org/ag/agn/jemra/index_en.stm and www.who.int/foodsafety/micro/jemra/en/index.html; and JMPR: www.fao.org/ag/agp/agpp/pesticid/ 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 management¹⁰

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.

¹⁰ 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 31st session of JECFA in 1987, sufficient information was unavailable to establish a figure for a tolerable level of intake. At its 46th 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 15 µg/kg. The 29th 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 15 µg/kg, as compared to 10 µg/kg, as these were the two levels under discussion.

The 49th 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⁺) 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⁺ 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⁺ 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⁺ 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, furaltadone, 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.¹¹

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.

¹¹ 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).

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).¹² 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.”¹³ The ALOP concept is sometimes also referred to as “acceptable level of risk.” It is

¹² 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>).

¹³ 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.
- **ALARA (“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).

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.