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WORLD
HEALTH
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Food Safety Risk Analysis

PART I

An Overview and Framework Manual

Provisional Edition

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Acknowledgements

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Acronyms and abbreviations

ADI	Acceptable Daily Intake
ALOP	Appropriate Level of Protection
CAC	Codex Alimentarius Commission
EDI	Estimated Daily Intake
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
GEMS	Global Environment Monitoring System
GAP	Good Agricultural Practice
GMO	Genetically Modified Organism
HACCP	Hazard Analysis and Critical Control Point
IEDI	International Estimated Daily Intakes
ILSI	International Life Science Institute
IPPC	International Plant Protection Convention
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
MRL	Maximum Residue Limit
NEDI	National Estimated Daily Intakes
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effects Level
OIE	World Organisation for Animal Health
PRA	Pest Risk Assessment
RfD	Acute Reference Dose
SPS	Sanitary and Phytosanitary Agreement
TLR	Tolerable Level of Risk
TMDI	Theoretical Maximum Daily Intake
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction to this Manual

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. During the last several decades, risk assessment, risk management and risk communication have been formalized and incorporated into a process known as risk analysis. This new approach enables information on hazards in food to be linked directly to data on the risk to human health, a process which was not considered in the past. By providing a science-based approach to improve food safety decision-making processes, risk analysis contributes to a reduction in the incidence of food-borne disease and in continuous improvements in food safety.

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 Codex Alimentarius Commission, at its 1991 and 1993 sessions, endorsed the recommendation of the Conference to base its decision on risk assessment principles, particularly with regard to food contaminants, and encouraged the use of a uniform approach by the relevant Codex Committees. In 2003, the Codex Alimentarius Commission adopted Principles for Food Safety and Risk Analysis to be used in the Codex framework and initiated work on the development of food safety risk analysis principles for use by national authorities. During the last decade, considerable progress has been made in developing a framework and principles for risk analysis, which is currently being implemented in a number of different national and international settings, and further developments are ongoing.

This Manual has been developed to improve food safety regulators' understanding and use of risk analysis as the basic framework for a modern food safety system. It is intended to provide essential background information and practical guidance on the application of food safety risk analysis for regulators and other officials responsible for managing and/or supervising food control activities. It presents a framework, internationally agreed principles and examples to structure and guide the application of risk analysis, rather than a prescriptive formula to implement risk analysis.

Following an introductory chapter, which explains why risk analysis is an essential part of effective food safety management, the Manual presents a broad overview of risk analysis. The subsequent chapters introduce the three essential components of risk analysis in greater detail. They set out the principles and mechanisms to perform risk management, risk assessment and risk communication in practice, and clarify the linkages and relationships between them. Current information and knowledge, including materials developed by FAO and WHO, is incorporated throughout the Manual as applicable.

This Manual is the first part of a three-part set, all of which is available on CD-ROM, which includes:

Part I: Food Safety Risk Analysis – An Overview and Framework Manual
Introduces the rationale, concept, principles and mechanisms for risk analysis and its components (risk management, risk assessment and risk communication).

Part II: Food Safety Risk Analysis Case Studies
Introduces qualitative and quantitative risk assessment tools, and presents case studies of risk analysis for aspartame, *Vibrio parahaemolyticus* and fumonisins.

Part III: Resources for Building Capacity in Food Safety Risk Analysis (CD-ROM)
Provides a collection of up-to-date FAO and WHO tools and training materials related to risk analysis, as well as a slide presentation for use as a food safety risk analysis training module.

2. A Science-based Approach to Food Safety Management

2.1 Introduction to this chapter

Food safety is an essential public health issue for all countries. Microbiological and chemical contamination in food is a major cause of illnesses. 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 is affected by food-borne diseases each year, and the problem is likely to be even more widespread in developing countries. Food and water-borne diarrhoeal diseases are leading causes of illness and death in developing countries, killing some 2.2 million people each year, most of whom are children.

In theory, almost all food-borne diseases should be preventable. Knowledge about the hazards that cause food-borne disease, as well as the nature of the risks that these hazards pose to consumers, combined with the capacity to take appropriate interventions, should enable governments to significantly reduce food-borne disease. However, in the past, hazards associated with certain foods were not directly linked to food-borne disease epidemiological data, exacerbating the challenges facing traditional food safety systems.

New science-based approaches to food safety provide an effective way for governments to protect consumers against food-borne disease and plan appropriate response measures when necessary. Risk analysis, in particular, allows data on hazards in food to be systematically linked to food-borne disease epidemiological data, making it easier to determine the risk to human health.

Risk analysis has demonstrated its ability to improve food safety decision-making processes and produce improvements in public health. It offers governments a framework to effectively assess, manage and communicate food safety risks in cooperation with the diverse stakeholders involved. By providing a process to establish realistic, science-based targets to reduce the incidence of food-borne disease, plan and implement tailored interventions, and monitor the outcomes (both successful and unsuccessful) of these interventions, risk analysis contributes to continuous improvements in food safety.

In addition to improving public health, effective food safety systems are also vital to maintain consumer confidence in the food system and to provide a sound regulatory foundation for domestic and international trade in food, which supports economic development. New international trade agreements developed under the World Trade Organization (WTO) have emphasised the need for regulations governing international trade in foods to be based on scientific principles. The Sanitary and Phytosanitary Agreement (SPS) permits countries to take legitimate measures to protect the life and health of consumers, animals and plants 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. Article 9 of the SPS Agreement defines the obligation of developed countries to assist less developed countries to improve their food safety systems.

This chapter places risk analysis in the overall context of food safety. It illustrates how, at a time when both the incidence of food-borne disease and the number of disruptions to international trade in foodstuffs are increasing, it has never been more important for countries to implement an effective food safety system, guided by the modern concept of risk analysis, to respond to current challenges.

Box 1: Key points covered in this chapter

- Traditional food safety systems are inadequate to cope with the complex, persistent pervasive and evolving array of food safety issues existing today.
- Modern food safety systems need to be science-based to effectively cope with, and respond to, the wide range of food safety challenges presently confronting countries.
- Science-based approaches are an essential part of the risk analysis framework and crucial to creating a modern and effective food safety system.

2.2 Traditional food safety systems

Food safety is the responsibility of everyone involved with the food chain from regulators to producers to consumers. However, governments are responsible for providing an enabling institutional and regulatory environment for food control. Most developing countries already have some sort of food control system in place, usually based on hygiene and adulteration/fraud inspection. While these vary considerably, they usually incorporate food laws and regulations, food control management, inspection and laboratory services, and sometimes mechanisms for information, education and communication and monitoring of the food supply.

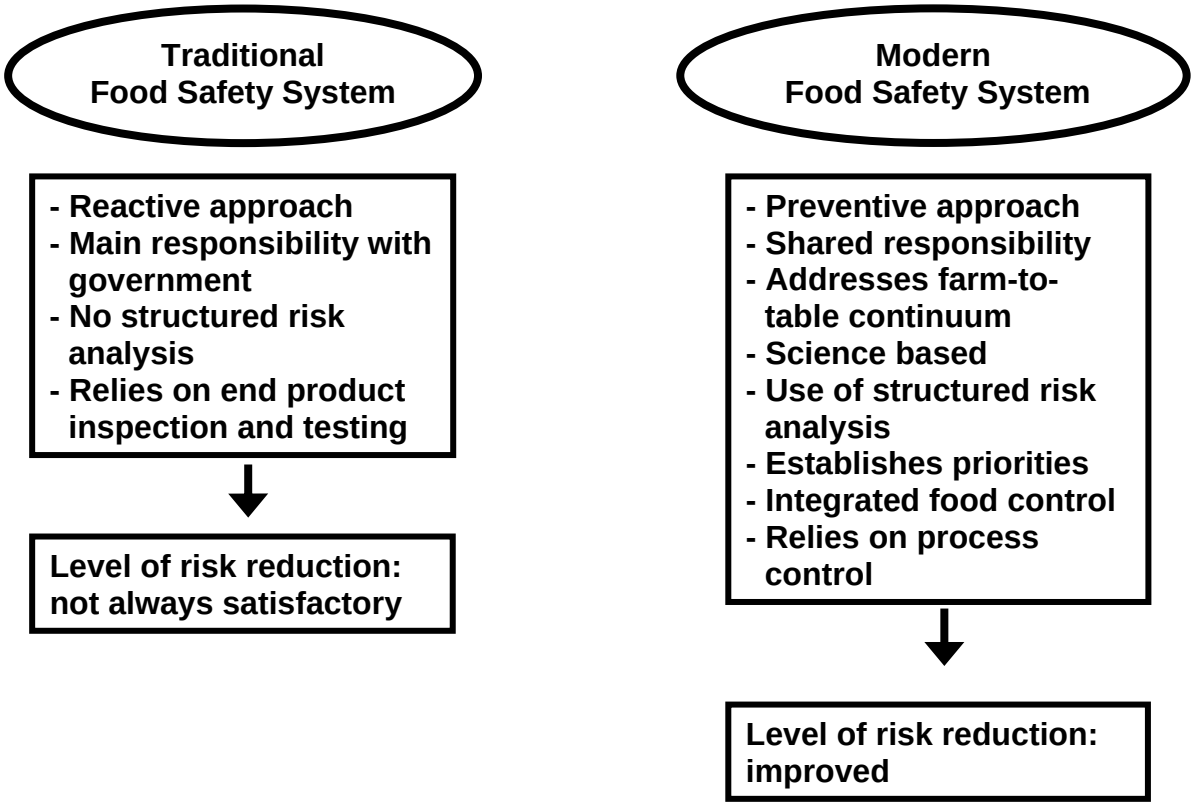
The increasing globalization of the food trade, urbanization, changing consumption patterns, the intensification of agriculture, increasing travel and tourism, and new types of production and manufacturing systems are just some of the trends that are having a serious impact on food safety in many countries. At the same time, a number of existing and new food safety hazards are of increasing concern (see Box 2). New pathogens are also frequently emerging, and existing ones evolving or re-appearing. For instance, the resistance of food-borne pathogens to anti-microbial agents is of increasing concern.

Box 2: Examples of concerns over potential food hazards

- Veterinary drug residues
- Fertilizer and growing aids
- Microbiological contamination
- Non permitted food additives
- Mycotoxins and other naturally occurring food toxicants
- Pesticide residues
- Pollutants
- Defective packaging and labelling
- Adulteration and tampering
- Extraneous matter (physical hazards)
- Animal feed additives

Although traditional food safety systems were somewhat effective in reducing food hazards in the past, they are unable to detect and resolve many current problems, and to effectively deal with the full range of complex, persistent pervasive and evolving challenges confronting different parts of the food chain. A modern food safety system, with the new Risk Analysis approach has the ability to much sharper diagnose the problems and also to suggest focused interventions to properly deal with them (see Figure 1).

Figure 1: Characterization of food safety systems



2.3 A science-based approach to food safety

A number of developing country governments are already taking steps to improve and strengthen their systems for food safety management. Several are moving away from the traditional approach focused on end-product control towards a process and science-based approach. Indeed, food safety regulators in many countries are already implementing different types of science-based actions and decision-making in their day-to-day work (see Box 3).

Box 3: Examples of science-based activities

- Implementation of Hazard Analysis and Critical Control Point (HACCP) systems
- Establishment of acceptable daily intakes for chemical additives and residues of pesticides and veterinary drugs in food
- Establishment of tolerable in takes for chemical contaminants, including natural toxins
- Use of science to develop labels to warn consumers about potential risks including food allergens
- Use of risk assessment to support food safety regulations
- Establishment of product safety standards, performance standards and specifications for use in international trade
- Resolution of trade disputes based on the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement)
- Establishment of dose-response relations for pathogenic micro-organisms
- Establishment of a Food Safety Objective to achieve an appropriate level of protection (ALOP)

A science-based approach strengthens the capacity of traditional food safety systems to meet current challenges and improve the availability of safe food for consumers. Scientific evidence can be used to minimize the occurrence of food-borne hazards, to reduce and manage risk, and to improve the outcomes of decision-making. A science-based approach enhances the ability of food safety regulators to:

i) identify hazards;

ii) characterize the nature and extent of those hazards;

iii) assess exposure to the identified hazards; and

iv) estimate the likelihood and magnitude of the resulting risks and impact on human health.

v) help set priorities between hazards

2.4 Risk analysis and modern food safety systems

Science-based approaches are an important and integral part of Risk Analysis to improve food safety systems. Risk analysis provides a means to strengthen the ability of traditional food safety systems to meet current challenges. It provides a framework to effectively manage, assess and communicate risks in cooperation with the diverse stakeholders involved. Risk analysis has been defined in the Codex Procedural Manual (13th Edition) as a process consisting of three components: risk assessment, risk management and risk communication[1].

[1] CAC. 2003. Procedural Manual. 13th Edition. Joint FAO/WHO Food Standards Programme (available at: www.codexalimentarius.net/procedural_manual.stm).

As a concept, a science-based approach to food safety is not completely new. It is related to processes such as good agricultural practices, good hygienic practices, good manufacturing practices and Hazard Analysis and Critical Control Point system (HACCP), which are already used in many countries. Scientific assessment of chemicals in general has also a rather long 'tradition'. What is new is the use of risk analysis as a framework to view and respond to food safety problems in a systematic, structured and scientific way in order to enhance the quality of decision-making throughout the food chain.

A science-based risk analysis framework requires modern food safety and public health institutions and infrastructure, as well as an overall environment that values and supports the risk analysis paradigm. Risk analysis is just one part of an effective food safety system. It will also be essential to develop and improve components of food safety systems including food safety policies, food legislation (encompassing food law, regulations and standards), food inspection, laboratory analysis, epidemiological surveillance of food-borne diseases, monitoring systems for chemical and microbiological contamination in foods, and information, education and communication.

In summary, the use of a science-based approach will enable governments to develop and implement a range of general improvements and interventions tailored to specific high-risk areas, which will ultimately improve food safety and reduce the burden of food-borne disease.

2.5 Suggestions for further reading

FAO/WHO. 1995. Application of risk analysis to food standards issues. Report of the Joint FAO/WHO Expert Consultation. Geneva, March 1995
(available at ftp://ftp.fao.org/es/esn/food/Risk_Analysis.pdf).

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

Institute of Medicine, National Research Council of the National Academies. 2003. Scientific criteria to ensure safe food. National Academies Press, Washington DC
(available at http://www.nap.edu/catalog/10690.html).

3. An Introduction to Risk Analysis

3.1 Introduction to this chapter

A risk analysis framework provides a process to systematically and transparently collect, analyse and evaluate relevant scientific and non-scientific information about a chemical, biological or physical hazard possibly associated with food in order to select the best option to manage that risk based on the various alternatives identified. This chapter provides a broad introduction to the food safety risk analysis process and the conditions necessary to ensure its successful implementation.

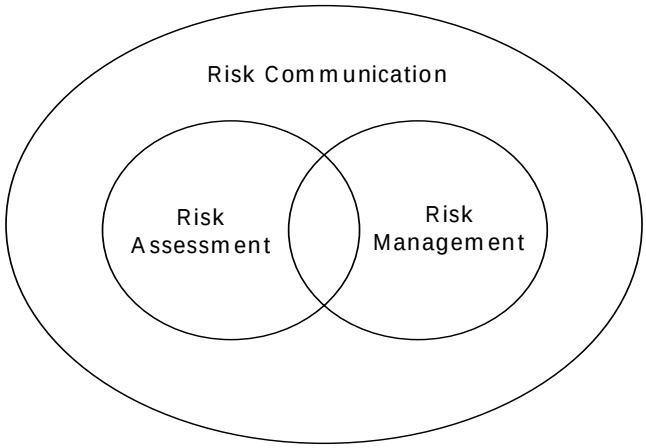
Box 4: Key points about risk analysis covered in this chapter

- Risk analysis comprises three components: risk assessment, risk management and risk communication (Codex).
- Risk analysis is an iterative, ongoing and highly interactive process that should be evaluated and reviewed as necessary on the basis of new data, information or changes in the context in which the food safety problem occurred.
- In order to perform successful risk analysis, countries need to have a well-functioning food safety system, the support and participation of key stakeholders (government, industry, academia, consumers), and basic knowledge about the three main components of risk analysis.
- Risk analysis should be based on all available scientific evidence, information on perceptions, costs, environmental, cultural factors, etc., which is gathered and analysed according to scientific principles to the extent possible.

3.2 Components of risk analysis

As a structured decision-making process, risk analysis includes three distinct but closely connected components: risk management, risk assessment and risk communication (see Figure 2). Each of these components plays an essential and complementary role in the risk analysis process. Although, risk management and risk communication tended to receive less attention than risk assessment in the past, it is important to stress that risk analysis will only be effective when all three components are successfully integrated.

Figure 2: Components of risk analysis



Unless otherwise indicated, all the definitions used in this Manual are taken from the Procedural Manual (13th Edition) of the Codex Alimentarius Commission.

Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
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.

3.3 The risk analysis process

Risk analysis provides food safety regulators with the information and evidence they need for effective decision-making. The process normally begins with risk management, which, as a first step, defines the problem, articulates the goals of the risk analysis and defines the questions to be answered by the risk assessment (see section 4.3.1 Preliminary risk management activities, Step 2: Develop a risk profile). The science-based tasks of 'measuring' and 'describing' the nature of the risk being analysed (i.e. risk characterization) are performed during the risk assessment. Risk management and assessment are performed within an open and transparent environment based on communication and dialogue. Risk communication encompasses an interactive exchange of information and opinions among risk managers, risk assessors, the risk analysis team, consumers and other stakeholders. The process often culminates with the implementation and continuous monitoring of a course of action by risk managers.

Box 5: Principles for risk analysis

Risk analysis should:

- follow a structured approach comprising the three distinct components: risk assessment, management and communication
- be based on all available scientific data
- be applied consistently
- be open, transparent and documented
- be evaluated and reviewed as appropriate on the basis of new scientific data
- be based on a clear consideration of uncertainty and variability

Source: CAC. 2003. Working principles for risk analysis for application in the framework of the Codex Alimentarius. alimentarius.net/reports.asp).

Risk analysis provides a framework to collect and analyse the best available scientific information on a hazard that presents a risk to people, animals or plants in a certain country, region or even globally. Risk managers consider this scientific information in light of other important non-scientific information, identify a range of appropriate options to manage that risk, and select the best option from the various possibilities. This process is undertaken in an open and transparent manner and is facilitated by a continuous process of two-way communication among all the interested stakeholders about all aspects of the risk under consideration. Some guiding principles for risk analysis are presented in Box 5.

3.3.1 Essential characteristics of risk analysis

Risk analysis is an **iterative and ongoing** process in which steps are repeated when needed. The process does not end once a decision is reached. Members of the risk analysis team regularly monitor the success and impact of their decision. Modifications are made as required – on the basis of new data or information or changes in the context of the problem – to achieve further reductions in adverse human health effects.

Risk analysis is also a **highly interactive process**, which requires open and effective internal and external communication. Risk managers must interact and communicate frequently with risk assessors and other members of the risk analysis team (internal communication), as well as many different types of stakeholders (external communication) as often as needed.

3.3.2 Conditions necessary for risk analysis

Some essential conditions are necessary to implement successful risk analysis, notably:

- ***Operational food safety system***
  In order to perform risk analysis, countries should ideally have the essential foundations of a food safety system in place including adequate food laws and regulations, a national food control strategy, effective inspection and laboratory services, scientific and technical capacity, infrastructure, epidemiological data, and mechanisms for information, education and communication.

- ***Knowledge about risk analysis***

  Government officials and decision-makers at the highest level need to be aware of risk analysis and the value it adds to public health. Similarly, food safety regulators and scientists who become risk managers and risk assessors need to learn what risk analysis is, why it is carried out, and how to perform the three components of risk analysis. Although government has the main role in performing risk analysis, it is also important to ensure that the food industry and consumers understand the essence of risk analysis.

- ***Support and participation of key stakeholders***

  Risk analysis will only be effective if it takes place in an environment in which government, industry, academic institutions and consumers recognize value and participate in the process. Risk analysis must have the support of food safety regulators at the highest level of government. Industry must find value in the results of risk analysis. Academic institutions must produce information that meets the needs of risk analysis. Consumers and businesses must be able to recognize and derive clear benefits from the risk analysis process. Similarly, mechanisms must be in place to enable stakeholders to participate in the development of risk analysis policy, as well as in the various activities performed during risk analysis.

3.4 Suggestions for further reading

- CAC. Procedural Manual. 14th Edition. Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission, Rome
  (available at: www.codexalimentarius.net/procedural_manual.stm).

- 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/es/esn/food/Interaction%20report.pdf).

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

- Slovic, P. 2000. The perception of risk. Earthscan, London.

Risk Management

4.1 Introduction to this chapter

Together with risk assessment and risk communication, risk management is an essential component of risk analysis. This chapter introduces the risk management process and the factors needed for its successful implementation. It describes the steps to identify and evaluate a food safety risk, assess all the available options to manage that risk, implement a risk management decision, and ensure that the decision taken was the most appropriate one possible.

Box 6: Key points about risk management covered in this chapter

- Codex has developed a model specifically for food safety risk management.
- Risk management should take as comprehensive a view as possible toward managing human health risks.
- Risk management processes and decisions should be transparent and appropriately documented for different audiences.
- Risk management requires extensive communication, coordination and collaboration between risk managers and risk assessors, and with external stakeholders.
- Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment.
- Risk management should clearly determine and establish the organization's risk assessment policy before the risk assessment is initiated.
- Risk management should consider a full range of risk management options and arrive at a preferred option through a structured process that includes preliminary risk management activities, consideration of risk assessment outputs, evaluation of risk management options, implementation of the risk management decision, and monitoring and review. This process should engage interested stakeholders as well as other members of the risk analysis team.
- Risk management should be a continuing process that monitors the efficacy of measures and reviews new information, as it becomes available, in order to assess whether the existing risk analysis needs to be reviewed.
- Risk managers are responsible for ensuring that the food safety problem is carefully defined (see section 4.3.1, step 2 below), that the goals of the risk assessment are clearly articulated and the questions to be answered appropriate and understandable, and that sufficient resources are available.

4.2 Understanding risk management

Risk management has been defined as "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"(Codex). Risk management therefore plays a key role at the beginning of the risk analysis process in identifying food safety problems and considering the best ways to manage them.

The consideration of different policy alternatives (see section 4.3.2 Assessing risk management options) is a critical part of risk management. This requires a focus on the scientific aspects of the risk (i.e. the detail and the outcome of the risk assessment) as well as any associated economic, legal, ethical, environmental, social, and political factors that are important to people. The economic evaluation of possible risk management interventions (for instance using cost-benefit analysis) enables risk managers to evaluate the health impact and feasibility of an intervention relative to its cost, which is important for good management decisions. Risk management therefore must be carried out in consultation with interested stakeholders and in synergy with risk communication activities. The comprehensive assessment of all the available management options that results from this process will help to ensure that decision-makers are able to make an informed decision on the most appropriate prevention and control option.

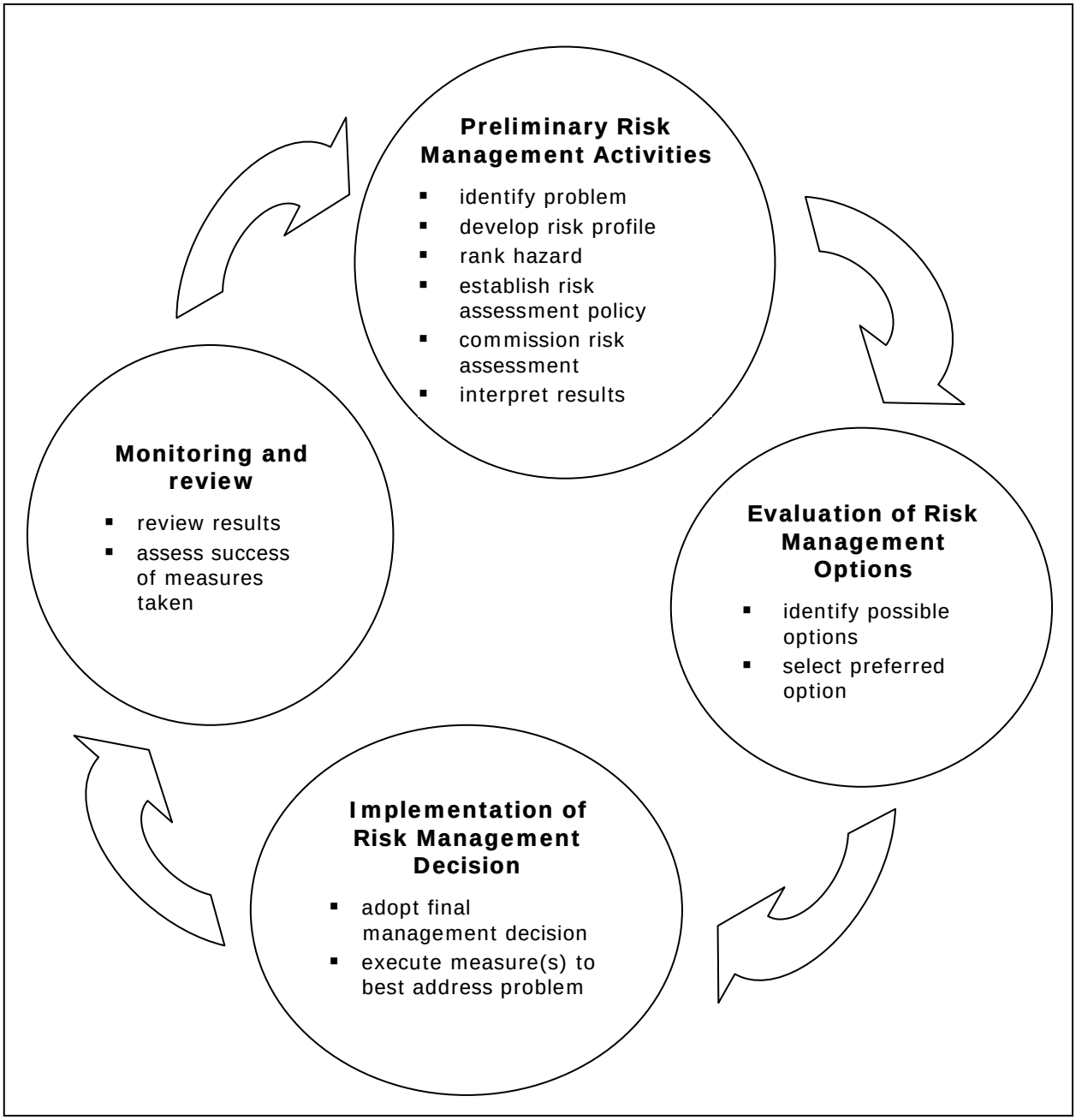
4.3 The risk management process

Risk management is not a linear process. Like the rest of risk analysis, risk management is an iterative process. Therefore, any model for risk management should be flexible enough to enable the various activities to be reviewed, repeated and adapted as necessary. The steps in the risk management process will not necessarily always occur in the same order. What is most important is that appropriate attention is paid to all the activities.

A sample model for risk management is presented in Figure 3. Other models for risk management also exist. The Food Hygiene Committee of the Codex Alimentarius Commission is developing principles and guidelines for the conduct of microbiological risk management[2]. Such models provide a useful template for countries seeking to develop their own risk management models and procedures.

[2] CAC. January 2004. Draft principles and guidelines for the conduct of microbiological risk management (at step 3 of the procedure). Agenda Item 6 at the 36th Session, Washington DC, March 29 to April 3, 2004. Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene (available at: ftp://ftp.fao.org/codex/ccfh36/fh04_06e.pdf).

Figure 3: Model for risk management



4.3.1 Preliminary risk management activities[3]

Step 1: Identify the food safety problem

Identifying and articulating the nature and characteristics of the food safety problem is an essential first task for risk managers. Sometimes the problem may already be recognized and accepted as sufficient justification to conduct a risk assessment. At other times, the problem may be visible but additional information is needed. In general, even when the problem is apparent, additional or more detailed information about it is required to guide decision-making.

[3] 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".

Food safety regulators learn about food safety problems in a variety of ways including through inspection, environmental monitoring, laboratory, epidemiological, clinical and toxicological studies, disease surveillance, outbreak investigations and monitoring of contaminants in foods, permit applications, lack of compliance with standards, and. Sometimes local communities, academic or scientific experts, the food industry, special interest groups or the media expose problems. At other times, problems become apparent through legal action, disruptions to international trade or because of issues identified by other countries.

The outcome of the problem formulation is a clearly articulated, written description of a significant food safety problem(s) that justifies the need for risk analysis and provides a basis for the development of a risk profile.

Step 2: Develop a risk profile

A risk profile is a type of situation analysis that provides sufficient information on the food safety problem, the context in which it occurs and possible solutions in order to enable risk managers to make sound management decisions including the decision whether or not a risk assessment is needed. A typical risk profile might include a brief description of the situation, product or commodity involved; the values expected to be placed at risk (e.g. human health or economic concerns); potential consequences; consumer perception of the risks; and the distribution of risks and benefits. It will identify aspects of hazards relevant to prioritizing and setting the risk assessment policy, as well as aspects of the risk relevant to the choice of safety standards and management options. A risk profile can be thought of as a preliminary risk assessment, which presents everything known about the risk at that point in time.

While risk managers have the overall responsibility for developing the risk profile, risk assessors and other stakeholders should also actively participate. For instance, a good risk profile will ensure that the initial risk management goals and questions to be answered during the risk assessment are explicit in order to avoid misunderstanding. This will require extensive interaction between risk assessors and risk managers, as well as dialogue with relevant external stakeholders.

The types of information and degree of detail required in a risk profile will vary according to the potential significance of the risk and the intended use of the risk assessment (discussed in the next chapter). For instance, chemical, microbial and biotechnology risk assessments will require particular kinds of information. Similarly, risk profiles for foods consumed domestically may differ from risk profiles for foods traded internationally. Some of the types of information that may be included in a risk profile are illustrated in Box 7.

The risk profile should be documented in such a way that risk managers can use it to set priorities among food safety issues and to facilitate risk management decision-making. One of the main decisions emerging from the risk profile will be whether or not a risk assessment is needed (see Box 8). When a risk assessment is not considered necessary, other more appropriate actions may be taken; for instance, good hygiene or manufacturing practices may be immediately imposed. Some problems require little more than common sense. In some cases, the problem will be judged insignificant on the basis of the risk profile and no risk management measures will be taken. In other cases, the problems may require an immediate response and there will be no time to perform a risk assessment.

Box 7: Examples of types of information included in a risk profile

- Initial statement of the food safety problem (microbiological hazard, disease agent or toxin, outcome of exposure, etc.)
- Profile and characteristics of the food affected (processing, handling, consumption, distribution, market place, etc.)
- Institutional context (key agencies, roles and responsibilities, regulatory situation)
- Goals for the risk analysis
- Statement of the intended use of the risk assessment
- Required outcome of the risk assessment (risk estimation or an expression of relative risk levels between different product/pathogen combinations)
- Nature of risk (human health, economic, cultural, etc.)
- Distribution of risk (who produces, benefits from, and/or bears the risk)
- Characteristics of the commodity/agent that might affect risk management options
- Known risk management characteristics of the risk producer and of the risk bearer
- Current risk management practices relevant to the issue
- Public perceptions of the risk
- Conceptual risk assessment model
- Preliminary qualitative risk assessment to identify important data gaps
- Preliminary questions to be answered by the risk assessment
- International agreements, if any, that affect the risk issue
- Priorities for risk management
- A decision whether to pursue a full risk assessment or not, and, if so, whether it should be qualitative or quantitative

Recent experience, especially with microbial risk, suggests that a preliminary risk assessment or the development of a conceptual risk assessment model is an essential step in the risk profile. A clear understanding of what the risk assessment will and will not be able to achieve is necessary to support the decision-making process of risk managers. The identification of key data gaps at the outset of the risk analysis process is also important so that necessary data may be gathered before and during the risk assessment.

Box 8: Using the risk profile to decide whether a risk assessment is required

A risk assessment may not be needed if:

- an issue requires immediate action
- the risk is well described by definitive data
- a management decision can be made without one
- the problem is relatively simple
- the issue is not of regulatory concern
- a response based on common sense is sufficient

A risk assessment will most likely be needed if:

- there is little data and much uncertainty
- multiple values are in potential conflict
- the issue is of great concern to regulators or stakeholders
- continuous decision-making is required
- managers need information to guide research
- managers want to establish a baseline estimate of the risk
- the hazard is an emerging pathogen or agent, serious public health and/or trade concern
- a national standard is more demanding than an international one
- a country wants to export or import a new commodity
- there are several possible ways of addressing the risk in question

Step 3: Rank hazards for risk assessment and set priorities for risk management[4]

Food safety hazards are so numerous that no food safety system can address all the potential problems. A key part of risk management therefore involves ranking hazards for risk assessment and setting priorities for risk management to enable informed decision-making and resource allocation.

In order to rank hazards and establish priorities, appropriate goals and criteria for risk management must exist. These goals can be formulated on the basis of the food safety problem identified and the risk profile. They will primarily focus on public health, as well as economic or social considerations. In some cases, goals may be directed or mandated by statute, policy or regulatory considerations. The goals should be set so that when they are achieved, the food safety problem has been solved or progress has been made toward its resolution. For instance, possible goals might include:

- a specific reduction in the lifetime risk associated with exposure to a particular chemical contaminant;
- a specific reduction in the pathogen load on a commodity at the point of sale;

[4] In cases where risk management is focused on one hazard only, this step will not apply.

- a specific reduction in illnesses caused by a particular pathogen;
- protection of jobs in the food industry associated with the risk; or
- maintenance of a country's market share in international food trade.

Once the goals are established, they should be shared with the members of the risk analysis team and other stakeholders. Hazards can then be ranked in order to establish priorities for risk management.

Step 4: Establish a risk assessment policy

Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors. Risk assessment policy has been defined 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" (Codex Procedural Manual). The risk assessment policy provides a clear understanding of the purpose and scope of the risk assessment and the manner in which it will be conducted. It clearly defines the parts of the food chain, the population, the geographic area and the time period to be covered. It also establishes the institutional, procedural and logistical basis for the risk assessment. For instance, it may include criteria for ranking hazards and procedures for the application of safety factors. Establishing a risk assessment policy protects the scientific integrity of the risk assessment and offers guidance to balance value judgements (judgements that are not unequivocally based on factual evidence[5]), policy choices and the management of uncertainties during the course of the assessment. The risk assessment policy should be documented to ensure consistency, clarity and transparency.

Step 5: Commission the risk assessment

Once a decision is made that a risk assessment is required, risk managers must establish a risk assessment team. While the exact composition of the risk assessment team will vary according to the nature of the risk, it should include experts with knowledge and skills in all the relevant areas. To be most effective, the team should be interdisciplinary so that members with complementary knowledge and skills work together in synergy and achieve much more together than would be possibly individually.

Once the team is established, it is important to clearly define and agree on, in consultation with risk assessors, the goals, resources and schedule for the risk assessment, the format of the expected output, and the established risk assessment policy. This should be communicated to the risk analysis team and external stakeholders. It will be important to ensure that the resources are sufficient to meet the goals set, and that the schedule is realistic based on any significant data gaps identified in the risk profile as well as the iterative nature of risk analysis. Internal communications will be crucial to ensure that the members of the risk assessment team and the risk managers have a common understanding of the purpose and scope of the risk assessment, the context of the food safety problem, the risk profile and the specific questions to be answered by the risk assessment. The process to perform a risk assessment is described in detail in the following chapter.

[5] FAO. 2004. Expert Consultation on Food Safety: Science and Ethics. Rome, Italy, 3-5 September 2002 (available at: http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/j0776e/j0776e08.htm).

Step 6: Interpret the results of the risk assessment

Once the risk assessment has been completed, risk managers need to determine that the assessment has generated satisfactory answers to the questions posed, and to interpret the results. The risk assessment should provide risk managers with sufficient science-based information to understand the nature and extent of the food safety risk and of the uncertainties in the assessment. This scientific information is then analysed together with other information on economic, cultural, environmental and other aspects of the risk. This is an essential moment for interaction with internal and external stakeholders (see section 3.3.1).

Risk managers are responsible for considering whether the level of risk identified in a risk assessment is tolerable or not. If the risk is too high, managers should determine a level of risk that is acceptable. The level of a risk can be expressed in different ways. The Appropriate Level of Protection (ALOP) offers a good way of expressing the level of risk to be achieved through risk management[6]. It is noted that so far the ALOP approach is mainly applied in relation to microbiological risks. ALOP is defined in the 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[7]. This ALOP concept is sometimes referred to as "acceptable level of risk". The actual level of risk in a country can be identical to or lower than the ALOP; if the actual level of risk is higher that the ALOP, then action should be considered to lower the risk to the selected ALOP level (see Box 9).

For chemical contaminants, the risk assessment estimates a tolerable intake, such as a tolerable daily intake (TDI). On the basis of the risk assessment and other factors, the risk manager can set a maximum level, which is a regulatory limit.
For food additives and residues of pesticides and veterinary drugs, the risk assessors determine an acceptable daily intake (ADI). On the basis of the ADI and Good Manufacturing Practices for additives, Good Agricultural Practices for pesticides and Good Practices in the use of veterinary drugs, risk managers can set maximum levels for food additives and maximum residue levels (MRL) for pesticides and veterinary drugs.

To interpret the assessment results effectively, risk managers need to:

- be fully informed about the strengths and weaknesses of the risk assessment including any limitations;
- be sufficiently familiar with the risk assessment protocol used to explain it in accurate but general terms to external stakeholders;
- understand the meaning and limitations of the absolute or relative risk estimates (sometimes expressed as probabilistic values that are not always clear to decision-makers and stakeholders) provided by the risk assessors;
- understand the nature, source and extent of uncertainty and variability in the risk characterization; and

[6] See Annex 5 "Introducing the WTO SPS and TBT Agreements" in FAO Food and Nutrition Paper No. 76: Assuring food safety and quality. 2003.
[7] 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.

- be aware of and acknowledge all important assumptions made during the risk assessment and their impact on the risk characterization and risk assessment findings.

Box 9: Determining an acceptable level of risk for microbiological hazards

A hypothetical risk assessment might estimate that the risk of falling ill due to *Salmonella Enteritidis* as a result of eating shell eggs is one in ten people per year or find that there are 1 000 illnesses per year due to *Salmonella Enteritidis* in shell eggs. If this number of illnesses is trivial compared to the other food safety problems that exist then this risk may be considered tolerable. If there are no opportunities (technical, logistical, or otherwise) to reduce the level of illness further, the impact on society may be considered bearable. In either case, the existing level of protection may by default be considered as an appropriate level.

However, if options to reduce the number of illnesses exist or the number of illnesses is not trivial, an Appropriate Level of Protection (ALOP) may be established on the basis of what is technically possible to achieve or on a more acceptable number of illnesses in light of national public health priorities. An ALOP may specify that it is acceptable that there are no more than 500 illnesses per year in the nation due to *Salmonella Enteritidis* in shell eggs. In this event, the ALOP would then be used to define appropriate control measures (i.e. risk management options) targeted at industry or consumers.

4.3.2 Evaluation of risk management options

Once the risk assessment has been completed, the various options to manage the risk must be identified, reviewed and evaluated. In similarity to other risk analysis tasks, there is no best time to identify and evaluate risk management options. In some cases, options may be identified at the start of a risk analysis and the risk analysis process may do little more than scientifically affirm the desirability of a particular option. In other cases, a risk management option may only become apparent at the last minute. Therefore, the exact order in which the following activities are carried out is less important than the fact that they take place. The draft principles and guidelines for the conduct of microbiological risk management, which are under development by the Codex Committee on Food Hygiene, allow for such flexibility[8].

Step 1: Identify available management options

Risk managers are responsible for identifying a range of risk management options with the capacity to resolve food safety problems. They are accountable for the process that identifies these appropriate measures, but need not always perform all the work themselves. Often risk assessors also play an important role in identifying options based on their scientific expertise and knowledge. Examples of possible options to manage risk are illustrated in Boxes 10 and 11.

[8] CAC. January 2004. Draft principles and guidelines for the conduct of microbiological risk management (at step 3 of the procedure). Agenda Item 6 at the 36th Session, Washington DC, March 29 to April 3, 2004. Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene (available at: ftp://ftp.fao.org/codex/ccfh36/fh04_06e.pdf).

The process to identify options is conceptually simple. The first step is to identify all the measures (i.e. a change that occurs somewhere along the farm-to-table food chain) that could possibly achieve or contribute to the identified risk management goal. This process is repeated for each risk management goal.

The second step focuses on the creation of options based on the measures identified. The various measures are developed, in complimentary and non-exclusive ways, into coherent risk management options with the potential to achieve risk management goals and resolve the particular food safety and public health problem(s).

Box 10: Examples of microbiological risk management options

- Avoid risks, e.g. ban or limit sales of food with history of contamination or toxicity under certain conditions
- Reduce exposure, e.g. inform susceptible consumer groups not to eat specific foods
- Educate consumers, e.g. label products to warn and inform susceptible consumer groups
- Control initial levels of hazards, e.g. select ingredients that have been pasteurised
- Prevent an increase in the levels of hazards, e.g. ensure appropriate food controls at different points in the food chain and prevent growth of pathogens by temperature control, pH, water activity (aw), preservatives, etc.
- Reduce levels of hazards, e.g. destroy pathogens/parasites by freezing, disinfection, pasteurization, irradiation
- Remove pathogens, e.g. washing, ultra-filtration, centrifuging
- Do nothing as appropriate to the food safety issue under consideration and the output of the risk assessment

Source: FAO/WHO. 2002. Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. Also known as the "Kiel 2 Report"
(available at: www.who.int/foodsafety/publications/micro/en/march2002.pdf).

Preserving the status quo is always one of the possible risk management responses if the risk estimate is judged to be tolerable. More often, risk management might include setting a range of protective goals in terms of risk reduction and risk protection. The primary objective of evaluating risk management options is optimization of the interventions necessary to prevent and control food safety risks. Optimization aims to select the option(s) that achieve the appropriate level of public health protection for the particular hazard/commodity in a way that is: a) most cost-effective, b) technically feasible for industry, and c) best for consumers.

In some cases (for instance, when a risk assessment is initiated to examine the cost effectiveness of current controls or to evaluate a new technology for control) a list of possible options for consideration may have been included in the scope of the risk assessment. At the other end of the spectrum, risk assessments undertaken to estimate baseline risks (such as the situation with an emerging pathogen) may pay little attention to the evaluation of risk management options.

A frequently occurring shortcoming at this stage is a failure to identify all the viable management options. Food safety regulators cannot be confident they have identified the best option for their purpose unless they have considered all the possible options. Formulating a comprehensive set of management options is therefore an essential step in good risk management.

Box 11: Commissioning a targeted risk assessment – aflatoxins example

The naturally occurring mycotoxins, aflatoxins, are considered to be carcinogenic to humans, and the initial risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) resulted in the recommendation to take management actions to reduce aflatoxin intake to the lowest practicable levels. After additional scientific data became available, and several risk management options were considered, the Codex Committee on Food Additives and Contaminants (CCFAC) commissioned a targeted risk assessment to JECFA*: to evaluate the potency of these contaminants, to link these potency estimates to intake estimates and to estimate the impact of different standards, i.e. maximum limits, on the overall cancer risk. The outcome of the potency estimates and the evaluation of the impact of different standards assist the risk manager in the decision making process to set regulatory limits for these contaminants in the food supply.

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* WHO Food Additive Series 40, WHO 1998

Step 2: Select the preferred management option

There are no hard and fast rules about how to select the best risk management options. Rather, there are a number of possibilities based on the food safety issue at hand and the risk management approach used. Available options may be identified at the national, regional or international level depending on the context of the provisions of international agreements, differences in the prevailing levels of risk and variations in technical capabilities.

The selection of a preferred risk management option, or a combination of preferred risk management options, involves a systematic analysis, comparison and evaluation of the likely impact of the various options to reduce or prevent risk (see Box 12). The possible options are evaluated, against a minimum set of criteria, to determine whether they are worthy of further consideration or not. Options that fail to qualify will either be dropped from further consideration or reformulated so that the inherent weaknesses are overcome.

Box 12: Microbiological food safety objective

A Food Safety Objective (FSO) is a nationally, regionally or internationally developed statement that expresses the level of a hazard in a food that is tolerable in relation to the level of risk possibly associated with that food. The definition adopted by the 27th Session of the Codex Alimentarius Commission for an FSO is "the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)" (Codex ALINORM 04/27/41*).

A FSO contains the food of concern, the hazard of concern and an expression of the appropriate level of protection of the population from the hazard, and has a fully traceable relationship with the risk assessment. A FSO cannot be related to a public health goal independently of a TLR or ALOP. The best FSOs are quantitative and may be set considering that a particular margin of safety is required to deal with unforeseen or uncertain risk contributing factors.

A FSO might be something like "an x log concentration of pathogen Y (e.g. *Salmonella* Enteritidis) in commodity Z (e.g. shell eggs) at the time the food is consumed" and when this level is met, it means that the TLR/ALOP it is derived from (e.g. 1 in 10^6 or less chance in a population of falling ill from salmonellosis as a result of consuming shell eggs) is attained.

* Codex ALINORM 04/27/41 is available at:

www.codexalimentarius.net/download/report/621/al04_41e.pdf

Risk managers and risk assessors both participate in the process of selecting risk management options. Risk assessors are often called upon to evaluate the effects of various risk management options, in order clarify the expected effects of interventions that have been evaluated in the Risk Assessment External stakeholders also play a critical role at this stage given the importance of non-scientific values in the resolution of food safety problems. Values, beliefs and biases can also enter the evaluation process at this point in the risk analysis.

Risk managers can apply various approaches to facilitate their decision-making process (Box 13). The effects of the different management options on the human health risk and other values of importance to people are compared, taking into account the differences among options, the potential costs and benefits of each, and the uncertainty in the output of the risk assessment. However, the selection of the 'best' risk management option is fundamentally a political process that balances scientific and other values, and weighs policy alternatives, usually on the basis of subjective value judgements.

Box 13: Examples of approaches to facilitate decision-making

- Zero risk
- Weight-of-evidence
- Sound science
- Precautionary principle
- ALARA principle
- Reasonable relationship
- Balancing standards Risk-benefit
- Comparative risk
- Cost-benefit analysis

Sometimes, a variety of risk management measures are implemented simultaneously as part of the best overall risk management option. Implementing a variety of risk management options at the same time is increasingly part of a more flexible approach to meet public health goals, which is supported by governments that are moving away from strict mandatory measures to manage food safety.

The general goals of risk management are to determine whether a hazard represents an acceptable health risk, develop and consider the available risk reduction actions, and select an effective and feasible course of action to reduce or eliminate risk. A risk management plan that gives stakeholders some choice in how to best achieve these goals is desirable whenever feasible.

4.3.3 Implementation of risk management decision

Step 1: Make a final management decision

The final decision on the risk management option should be based on all the available scientific, technical, economic and other relevant information. Priority should be given to preventing risks whenever possible, rather than simply controlling them. Risk management should consider the entire farm-to-table continuum, regardless of the number of authorities involved and their respective responsibilities. Whenever possible, measures taken to manage the risk should offer groups affected by the risk a range of choices to achieve the desired level of public health protection.

Risk managers make their final decisions on measures for the reduction of risk in consultation with stakeholders, following discussions on the technical feasibility and practicality of the various management options. The option or mix of options decided upon must be feasible to implement, and the benefits should exceed the costs or be in reasonable proportion to them. Any elements within the purview of public authority must be able to be enforced on the basis of the national legal and regulatory structure. However, in some countries, good results are achieved by adopting interventions that are voluntary rather than legally binding, for instance in regulations that do not have a legal status.

Step 2: Execute measure(s) to control the risk

Risk management decisions can be implemented by a variety of stakeholders including government officials, representatives of the food industry and consumers. The exact type of implementation will vary according to the situation and the types of stakeholders involved. Some governments or regulatory bodies will use traditional regulatory approaches based on periodic inspection or end-product testing, which places the burden of compliance with the regulatory authority. Food manufacturers may take specific measures via good manufacturing practices, good hygiene practices and Hazard Analysis and Critical Control Point (HACCP) systems. Education and information campaigns and product labelling targeted at consumers can encourage them to pay greater attention to safe preparation or cooking practices, for instance to avoid cross-contamination.

Efficient, modern food safety systems depend increasingly on an integrated systems approach that shares responsibility for the implementation of food safety decisions. Innovative partnerships across the farm-to-table continuum provide flexibility, which is lacking in more

rigid traditional systems. The HACCP system is an example of a new approach to implementing food safety risk management in the private sector.

4.3.4 Monitoring and review

Step 1: Review results

Risk managers are responsible for verifying that the risk mitigation measures are achieving the intended results and that performance is robust and can be sustained in the longer-term. Risk management decisions should be reviewed periodically on the basis of new scientific information or insights, as well as data gathered during monitoring. This will enable risk management decisions, as well as the public health goals of risk management, to be revised as needed.

Step 2: Assess success of measures taken

During monitoring, risk managers may measure the performance of certain processes or the prevalence or concentration of the pathogen concerned in specific parts of the food chain. Data from relevant points in the food chain should be gathered and analysed on an ongoing basis to ensure that food safety goals are being achieved. Various types of data will be required according to the nature of the risk. For instance, the following data would be important to monitor microbiological risk management measures: i) prevalence of a pathogen in animals or birds; ii) pathogen prevalence at the start and end of processing; and iii) pathogen prevalence in a food commodity at the retail level.

The capacity of the risk management option to reduce the risk to the desired levels among the affected population should also be monitored and verified. Epidemiological data and incident investigation data are necessary for this purpose. Where there is no existing infrastructure for this kind of monitoring and review, it should be established so the effectiveness of the measures can be verified.

In some cases, monitoring might result in a revision of the risk assessment to reduce previous uncertainties or update the analysis with new or additional information. The revised risk assessment results could lead to another iteration of the risk management process with a possible impact on the goals of the risk analysis and the risk management option chosen. Changes in public health goals, changing values, or technological innovations are all reasons to revisit the risk management option and possibly update the risk analysis.

4.4 Suggestions for further reading

CAC. 2004. Report of the thirty-sixth session of the Codex Committee on Food Hygiene, Washington DC, 29 March to 3 April 2004. ALINORM 04/27/13 (available at: http://www.codexalimentarius.net/download/report/615/al04_13e.pdf).

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

5. Risk Assessment

5.1 Introduction to this chapter

As explained in the previous chapter, the decision whether or not to initiate a risk assessment is made during risk management. This chapter describes the food safety risk assessment process. It introduces a range of techniques that can be used to support risk assessment in practice, and outlines the essential characteristics of a good risk assessment. The discussion provides a general introduction to the different types of food safety risk assessment that are undertaken in response to chemical and microbial hazards. Expanded descriptions of some of these risk assessment techniques can be found in Annexes 2 through 7.

Box 14: Key points about risk assessment covered in this chapter

- The four components of a risk assessment are hazard identification, hazard characterization, exposure assessment and risk characterization. In one form or another, they occur in every risk assessment approach followed.
- The risk profile is an essential precondition for a risk assessment. It frames the problem in a food safety context, provides information to guide the assessment and determines whether the assessment is needed.
- Risk assessment can be used to direct research, provide baseline estimates of risks, attribute risk to its source(s), assist the development of new food safety regulations and/or support comprehensive risk management.
- There is no one right way to do risk assessment. The types of process will depend on the nature of the risk (chemical or microbial or physical) and the particular context in which it occurs.
- The risk assessors' toolbox is filled with many tools, models and techniques that can be used to craft a risk assessment.
- Good risk assessment uses scientific evidence and techniques to answer specific risk management questions.
- Risk assessment is a structured scientific process

5.2 Understanding risk assessment

Codex defines risk assessment as a scientifically based process consisting of four steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization. The definition includes quantitative risk assessment, which emphasises reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

Several aspects of this definition are important to highlight. Firstly, risk assessment is a systematic and science-based process, which involves four major steps. Secondly, risk assessment explicitly addresses uncertainty (i.e. what is not known about the risk) in a logical, transparent and well-documented manner that is clearly indicated to everyone involved in the risk analysis process. Finally, risk assessment can be descriptive or narrative, qualitative,

semi-quantitative or quantitative. Both qualitative and quantitative risk assessments are important in different circumstances and there is nothing inherently superior or inferior about either.

Qualitative risk assessment is the process of compiling, combining and presenting evidence to support a statement about risk. While numerical data and analysis may be part of the input into a qualitative risk characterization, the final risk estimate does not necessarily result from attempts to produce a mathematical or computational representation of the risk producing system. Examples of qualitative food safety risk assessments include rating systems used by retail or foodservice establishments.

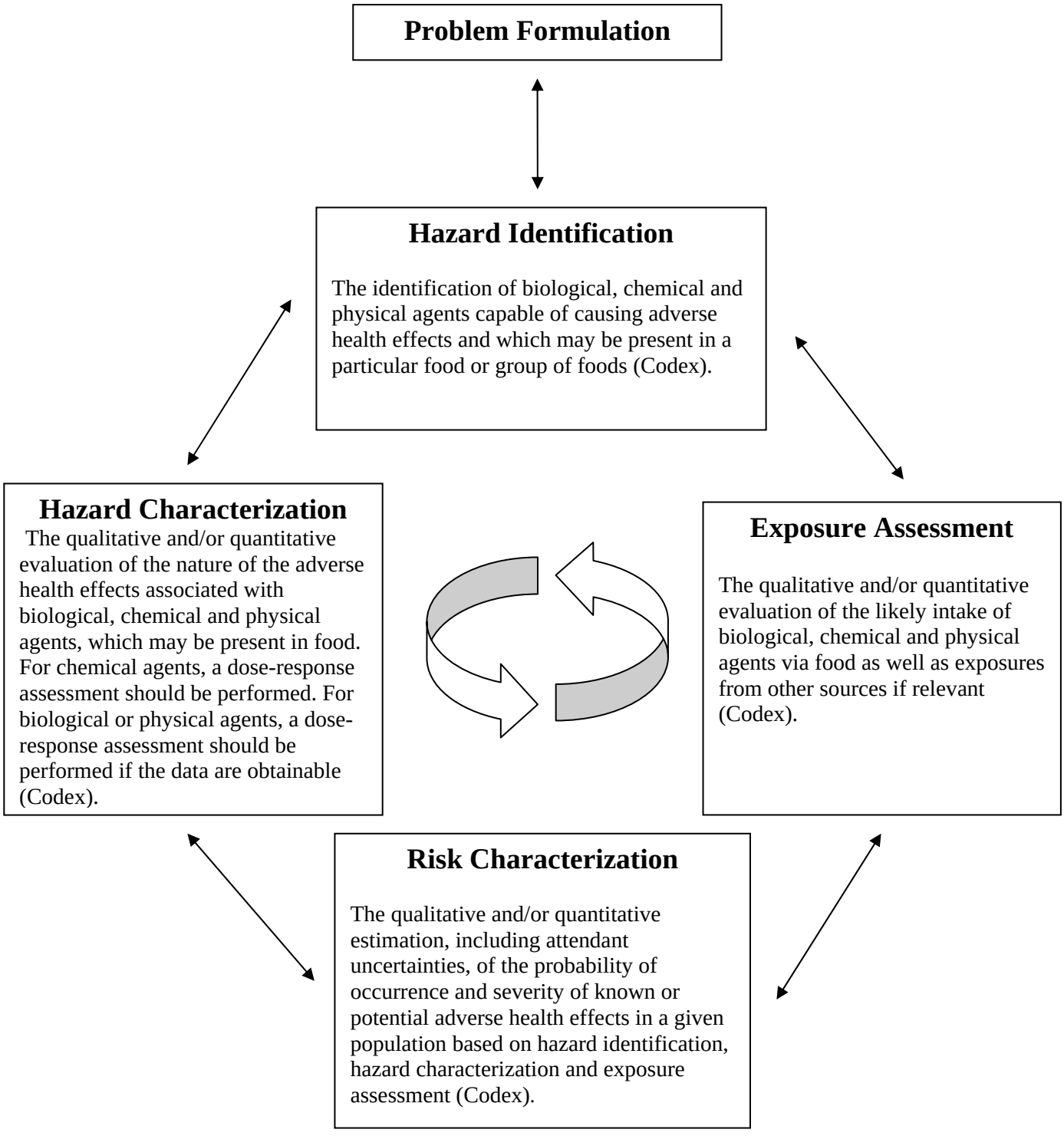
Quantitative risk assessment is based on numerical data and analysis. It can be deterministic (e.g. food additive safety assessment) or probabilistic (e.g. microbial risk assessment). Quantitative risk assessments should describe uncertainty in numerical terms with uncertainty distributions determined by various statistical methods. A quantitative risk assessment can address risk management questions at a finer level of detail than a qualitative risk assessment.

5.3 The food safety risk assessment process

There is no one way to perform a food safety risk assessment. Different models for food safety risk assessment exist and the process will vary according to the type of risk, the model used and the questions to be answered. Indeed, in some cases (e.g. when the risk management response is obvious and acceptable to all the parties concerned or when there is insufficient data), it may either be unnecessary or impossible to perform a full risk assessment according to Codex guidelines. As is the case with risk analysis, the risk assessment should be an interactive and often iterative process.

There are four major components in any food safety risk assessment as illustrated in Figure 4. Recent insights do not require a linear order of consecutive elements of the assessment, but allow for different orders depending on specific requirements and availability of data.

Figure 4: Steps in the risk assessment process



Hazard identification

Various biological, chemical and physical hazards are at the source of food safety risks (see Box 15). Although the task of identifying a hazard is often considered part of risk management, risk assessors usually also play an important role in hazard identification. In particular, when possible hazards need to be analysed and prioritized on the basis of scientific evidence, risk assessors provide scientific expertise to help risk managers select the hazard of greatest concern. In other cases, where risk managers have already identified the hazard, risk assessors provide supplementary information on the scientific nature of the hazard.

Hazard characterization

During hazard characterization, risk assessors develop a complete profile of the nature and extent of the adverse health effects associated with the identified hazard. The impact of varying amounts of the hazardous material on human health can be considered quantitatively (in a dose-response relationship) and/or qualitatively in a narrative fashion.

Box 15: Examples of Hazards

Biological hazards	**Chemical hazards**	**Physical hazards**
• bacteria • toxin-producing micro-organisms • moulds • parasites • viruses • other biological hazard	• naturally occurring toxins • direct and indirect food additives • pesticide residues • residues of veterinary drugs • chemical contaminants)	• metal, machine filings • tools • glass • insect parts • jewellery • stones

Exposure assessment

The exposure assessment provides scientific insight on the presence of the hazard in the product(s) consumed. It combines information on the prevalence and concentration of the hazardous material in the consumer's food supply and environment, and the likelihood that the consumer will be exposed to various quantities of this material in their food. Information on the prevalence and concentration of the hazard could include estimates of the number of pathogens in a serving of food or the amount of a food additive consumed daily by a representative consumer. Depending on the nature of the problem, exposure assessment takes into account the relevant production, storage and handling practices along the food chain.

Risk characterization

During risk characterization, all the evidence from the previous three steps is combined in order to obtain a risk estimate (i.e. an estimate of the likelihood and severity of the adverse health effects that would occur in a given population with associated uncertainties) and respond to the questions posed by the risk managers. In general, the risk characterization includes a summary description of the consequences of exposure to the hazard, as well as an estimate of the likelihood of the adverse consequences of interest in a risk estimate.

The outputs of a risk characterization should clearly identify important data gaps, assumptions and uncertainties in order to help risk managers judge how close the characterization might come to describing reality. Risk characterization rarely gives more than a reasonable estimate or an informed view of the risk in reality.

5.4 Chemical and microbial risk

Food safety risk assessments are undertaken in response to identified chemical or microbial risks to human health. Chemical risk assessments focus on the presence of chemicals such as food additives, food contaminants or residues of veterinary drugs. Some chemicals, such as food additives and colourings, are deliberately added to food in small amounts to make food look or taste better, to maintain or improve nutritive value, to help processing or preparation, to maintain freshness or to help preserve food (direct additives). In addition, indirect additives or 'contaminants' can enter food accidentally during handling, processing (through equipment) or packaging (through migration), or can be generated through chemical processes in the food itself ('chemical reaction'). Technical aids used in primary production (such as pesticides or veterinary drugs) can also remain as residues in food products. As the number of direct and indirect additives to food has increased, so too has public concern about the type and amount of these additives and their potential to cause cancer or other illnesses in people.

A microbial risk assessment evaluates the likelihood of adverse human health effects occurring after exposure to a pathogenic microorganism or to the medium in which the organism occurs. The hazard in microbial risk assessment is fundamentally different from the hazard in a chemical risk assessment (see Box 16). In particular, the hazard in a microbial risk assessment is alive, which reorients the focus of the risk assessment significantly. One of the most unique aspects of a living hazard is that the levels of pathogen in a food can change radically over time. Most microbial hazards can grow, decline or die many times before a food is consumed.

Box 16: Characteristics of microbial and chemical hazards

Microbial Hazard	Chemical Hazard
• Usually acute and the result of a single exposure	• Can be lifetime risk or acute
• High degree of variability in both the host and the pathogen	• Toxicology does not usually vary greatly from person to person and the toxicity of the chemical itself is invariant
• Continuously changing in quantity and characteristics	• Tend to be fixed in quantity and hazardous characteristics
• Non-homogenous presence in foods (they tend to clump and be distributed non-uniformly throughout a food)	• Can be a homogenous presence (e.g. direct food additives), or heterogeneous (chemical contaminants)
• Can enter the food chain at many points	• Usually enters the food at specific points (e.g. cleaning agent residues during manufacturing, veterinary drugs on the farm)

Given the characteristics of the hazard in microbial risk, there is much more complexity involved in performing a microbial risk assessment than a chemical risk assessment. In addition, because of the potential for a pathogen to enter the food chain at many points, microbial risk assessment often requires a farm-to-table perspective. By comparison most chemical risk assessments focus on a particular part of the food chain. Microbial risk assessments also tend to encounter many more data gaps and greater uncertainties than chemical risk assessments.

Examples of risk assessments for food additives, microbial risk, mycotoxins, as well as plant and animal health risk assessment models are presented in Part II and in the annexes to this Manual.

5.5 Techniques used in food safety risk assessment

Food safety risk assessment must be based on sound scientific evidence. Food safety regulators must have access to appropriate scientific data, information and expertise in order to assign a risk assessment. Depending on the nature of the hazard and circumstances in which it occurs, various scientific experts (including biologists, chemists, medical experts, geneticists, epidemiologists, toxicologists, microbiologists, agronomists, botanists, entomologists, zoologists, and others) may be involved.

The exact combination of analytical tools and techniques used in qualitative and quantitative risk assessment will vary according to the specific context and type of the risk assessment. In order to apply these techniques and perform risk assessment, certain basic infrastructure (including laboratories, scientific equipment, technology and research facilities) will be essential.

5.5.1 Statistical techniques

Although risk assessment does not usually require expertise in the most advanced and contemporary statistical techniques, a solid understanding of basic statistical techniques is essential for quantitative risk assessment, especially probabilistic risk assessment. Knowledge of the following basic techniques is required for successful risk assessment:

- descriptive statistical techniques to extract useful information from scientific data and evidence;
- inferential statistical techniques to obtain information about populations from samples; and
- different statistical tests to establish the most likely explanation of the observed phenomena.

Box 17: Statistics and probability

Statistics

- facts or data assembled and classified so as to present significant information
- collection, calculation, description, manipulation, and interpretation of the mathematical attributes of large sets or populations
- a branch of mathematics dealing with collection, analysis and interpretation of data

Probability

- being probable
- something that is probable
- a ratio expressing the chances that a certain event will occur
- a branch of mathematics studying chances of random events

More sophisticated statistical techniques (such as curve fitting, regression analysis, meta-analysis, experimental design, bootstrapping, and the like) can also be used to support risk

assessment. When these skills are unavailable to food safety regulators, opportunities to develop, acquire, trade or share them could be explored with other national agencies, industry or countries.

5.5.2 Probability

Probability encompasses variability and uncertainty, both of which are always present in the context of food safety risk assessment. Probability is different from statistics (see Box 17 and Box 18). A basic knowledge of probability is essential to understand, assess, manage and communicate risk as even the simplest definitions of risk (such as "chance of a bad thing" or "probability of harm") underline the role of chance.

Risk assessors need a good command of basic probability concepts and techniques, including the ability to make basic probability calculations, in order to perform most kinds of quantitative risk assessment. Probabilistic risk assessment also requires a solid understanding of probability distributions and their characteristics since variability and uncertainty are both frequently described using probability distributions. Knowing how to choose a proper distribution for use in a risk assessment is one of the most commonly identified difficulties encountered in probabilistic risk assessment. In general, it will be sufficient for one member of the risk analysis team to be an expert in probability.

Box 18: Theories of probability

A theory of probability connects the mathematics of probability, which is the set of consequences of the axioms of probability, with the real world of observation and experiment. There are several common theories of probability. According to the frequency theory of probability, the probability of an event is the limit of the percentage of times that the event occurs in repeated, independent trials under essentially the same circumstances. According to the subjective theory of probability, probability is a number that measures how strongly we believe an event will occur. The number is on a scale of 0-100 percent (or 0 to 1), with 0 percent indicating that we are completely sure it won't occur, and 100 percent indicating that we are completely sure that it will occur.

Source: http://www.shodor.org/interactivate/dictionary/t.html#theories

5.5.3 Monte Carlo process

The Monte Carlo process has been applied to a large range of complex problems that involve random behaviour. It is a procedure that generates values of a random variable based on one or more probability distributions. It has been used extensively in microbial risk assessment and is increasingly being applied in other types of quantitative risk assessments, e.g. for intake assessment of chemicals in food. The Monte Carlo process encompasses two steps:

i. a random number is generated over the [0,1] interval
ii. that number is transformed into a useful value using a probability distribution specified by the individual responsible for the model

5.5.4 Probabilistic scenario analysis

Creating and analysing different scenarios of risk is a useful tool for risk assessment. A scenario can be defined as an outline for any proposed series of events, real or imagined. In other words, a scenario is a series of events that could happen. In risk assessment, a scenario is defined by a set of assumptions about model input values and how those input variables are related.

Probabilistic scenario analysis is used to generate different scenarios and undertake a probabilistic analysis of the most likely scenarios and their outcomes. The worst-case scenario is often used in deterministic risk assessment. Scenarios can and have been considered deterministically. However, because of the extent of variability and uncertainty in the world, it is often difficult to identify the full range of possible outcomes of any risk management decision with just a few carefully circumscribed scenarios.

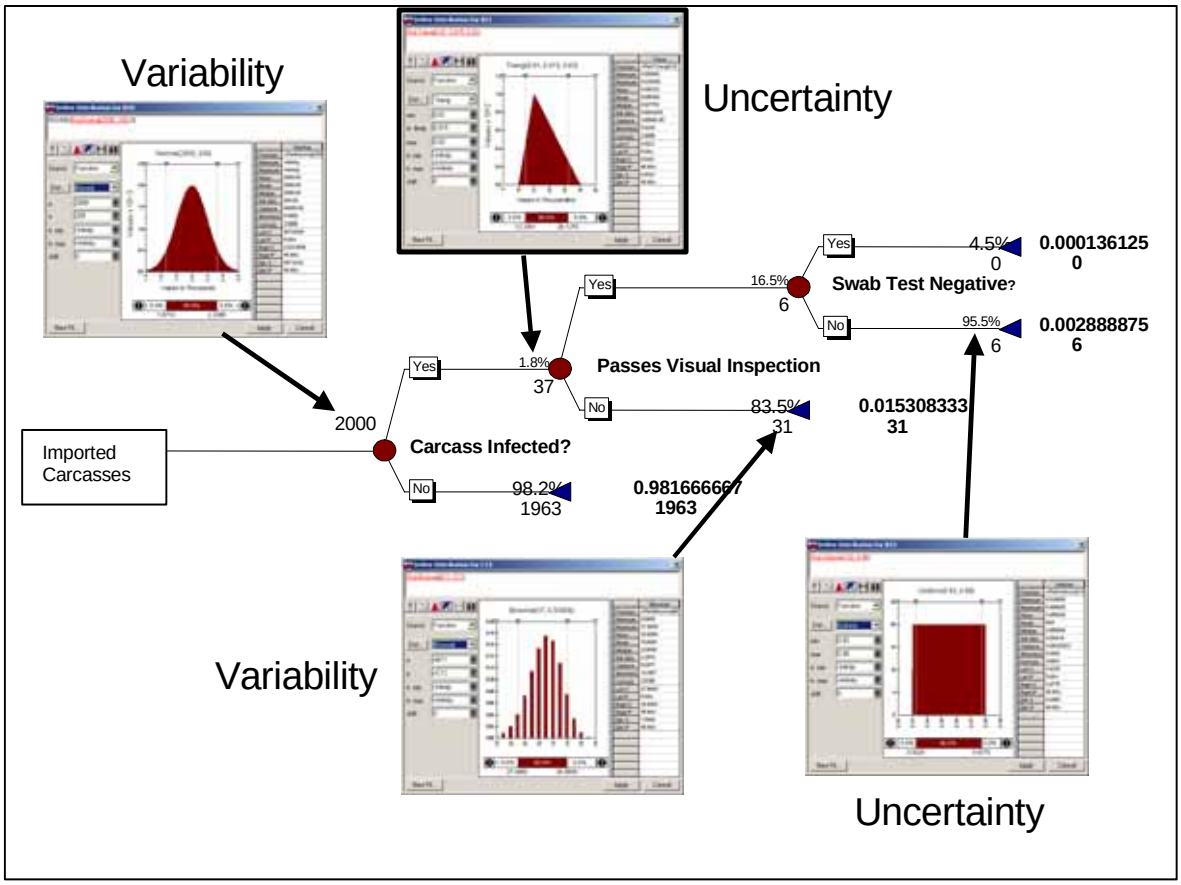
Risk assessors find it useful to describe the outcome of an uncertain situation (such as a baseline risk estimate) as completely as possible. Given the variability in the natural universe and the uncertainty inherent in risk assessment, this sometimes involves the generation of a very large number of scenarios (sometimes thousands). The Monte Carlo process described above is a probabilistic numerical method used to generate a large number of possible scenarios. The generation of distributions of outcomes in risk assessment models has made it possible to characterize risks and the effects of risk management measures in probabilistic ways.

Risk assessors can use a wide variety of tools to identify and study scenarios. Some examples of these include:

- Event tree based on forward logic (see Figure 5)
- Fault trees based on backward logic
- Decision trees comprising decisions that can be controlled and chance events that cannot be controlled
- Probability trees where each of the branch values are probabilities
- Other models such as flow diagrams, process charts and models, farm-to-table models, and so on.
- Text and video presentations

It is not unusual for a probabilistic scenario analysis to combine several different tools such as an event tree and the Monte Carlo Process. Probabilistic scenario analysis has been used in most of the quantitative microbial risk assessments completed to date.

Figure 5: An example of a probabilistic event tree



5.5.5 Knowledge elicitation techniques

Although risk assessment is based on a scientific and evidence-based approach, it will sometimes be necessary to obtain professional judgements and expert opinions to address data gaps and uncertainty in decision-making processes. Data gaps are encountered frequently during risk assessment. When the missing data are considered important to the decision-making process, risk assessors must try to close the existing data gaps as far as possible. In cases where there is sufficient time and resources, additional research can be undertaken to produce the necessary data. However, in other cases where it is impossible to locate or produce new data, risk assessors can use other techniques – such as knowledge elicitation techniques – to address data gaps.

In many cases, experts are not used to describing what they know or how they know it. Knowledge elicitation techniques are used to reveal expert knowledge in these circumstances and help to make expert opinions as evidence-based as possible. A wide variety of techniques can be used to elicit knowledge from experts, and improve the quality and transparency of the knowledge gathering process. Traditional methods include the Delphi method, the nominal group approach, scenario analysis, scientific heuristics, rational consensus, indirect elicitation, the direct method, parametric estimation, self-scoring, collective scoring, surveys and questionnaires, interviews and case studies. Many new knowledge elicitation techniques have been developed in recent years. These include cognitive approaches, contextual approaches and ethnography. Domain knowledge has also recently been elicited using card sorting, laddering, proximity scaling techniques, protocol analysis, using multiple experts, focus groups, repertory grids, automated techniques and machine learning.

5.5.6 Ranking tools

Ranking is a common technique in qualitative risk assessment. Ranking helps risk assessors to prioritize risks. For example if a country is concerned with food-borne illnesses associated with poultry consumption but there are over 20 pathogens associated with poultry in that country, ranking can determine which pathogens should be addressed first.

Various kinds of ranking techniques exist. The multi-criteria decision-making literature is rich in methods to rank and sort problems. However, other simpler techniques can also be useful. For instance, criteria and their subjective weights can be used to sort and rank various alternative options. The choices of criteria and weights should be based on as much scientific evidence as possible to make the process as evidence-based as possible.

5.5.7 Sensitivity analysis

A good risk assessment uses sensitivity analysis to clearly identify and address uncertainty. Sensitivity analysis enables managers to understand how answer(s) to question(s) might change under different conditions or assumptions. It helps risk assessors to systematically investigate and discover which variables have the greatest influence on the outcomes of the risk assessment. A sensitivity analysis can illuminate the option assessment process for risk management by identifying those inputs with the greatest positive and negative effects on outcomes.

Complex risk assessments may have dozens of input and output variables that are linked by calculations, systems of equations, assumptions, and so on. Risk assessors and risk managers must understand the relative importance of the various components of a risk assessment and the influence of these variables on the results of the risk assessment. Some outcomes and decisions are sensitive to minor changes in assumptions and input values. However, it is not always immediately obvious which assumptions and uncertainties most affect outputs, conclusions and decisions. Therefore, thorough, rational decision-making requires an explicit examination of such sensitivities.

A good sensitivity analysis will aid the risk assessment by revealing the most important variables in the assessment. It will provide insight into the conditions that contribute the most to good and bad outcomes. Once the key inputs are identified, assessors can focus their attention on addressing the uncertainty in these variables or carefully describing their variability. Therefore, sensitivity analysis helps to focus an assessor's attention on the most important inputs. Typically a few key model inputs account for most of the variation in the output. One of the most useful insights gained from a sensitivity analysis is a sense of how much each model input contributes to the uncertainty and variability in the output.

Box 19: One-at-a-time analysis

A common and popular approach to sensitivity analysis holds all input values at their expected value or some other representative value, and then varies a single input to examine its effect on the target output. However, this approach can be as dangerous as it is sometimes useful.
Suppose two variables A and B have a high positive correlation. Now suppose A is held constant and B is allowed to vary. The effect of the correlation is lost.
Or suppose the following function relates these variables. If $A<50$, then

$C = B + 1$, else $C = B^{100}$. In this case a one-at-a-time analysis will yield unrealistic and misleading results. Great care must be taken to assure the sensibility of the chosen sensitivity analysis.

Many different sensitivity analysis techniques exist. One popular approach uses parametric variation of the values of input variables to examine its effects on one or more output variable. This variation is done in a variety of ways that include:

- Deterministic one-at-a-time analysis of each input under consideration
- Deterministic joint analysis
- Scenario analysis
- Subjective estimates
- Parametric analysis of a range of values
- Importance analysis (regression or correlation of inputs and outputs)

Considerable knowledge of the risk assessment itself may be required to conduct a proper sensitivity analysis, given the need to identify candidate parameters and inputs for investigation, as well as to select an appropriate approach for sensitivity analysis (see Box 19).

5.6 Characteristics of a good risk assessment

A good risk assessment helps food safety regulators and other officials to make transparent, science-based decisions about a food safety risk. It improves the quality of the decision-making process and informs the decision for which it was prepared. Although there is not one particular type of 'best' risk assessment, a good risk assessment has a number of essential characteristics:

- ***Clearly identifies the questions to be answered***
  A good risk assessment ensures that both the questions asked and the responses identified are the most appropriate ones. Although the questions to be answered by the risk assessment come from the risk managers, risk assessors must spend time understanding, defining and, if necessary, clarifying and refining them together with risk managers. The questions to be answered should be documented and understood by all members of the risk analysis team.

- ***Is a collaborative and interdisciplinary team effort***
  A good risk assessment involves a range of scientific experts working together in order to respond to the questions asked. The best teams are interdisciplinary ones where the roles of experts are complementary and their contributions together exceed the sum of their individual parts. In some cases, non-scientific experts (e.g. communication specialists) can also contribute to the work of the risk assessment team.

- ***Has adequate resources***
  A good risk assessment has adequate resources (time, money, personnel and expertise) that reflect the importance of the food safety problem under consideration and that are sufficient to answer all the questions posed.

- ***Is based on scientific evidence and sound assumptions***
  A good risk assessment is based on scientific evidence and clearly formulated, unbiased assumptions. Sound assumptions are important to help bridge data gaps. Risk assessors should try to clearly formulate implicit assumptions (i.e. ones that are not expressed explicitly but reside inside thoughts or actions) as well as explicit ones (i.e. assumptions made knowingly). The assumptions used should be rigorously challenged and should clearly identify any weaknesses. Good assumptions are revised or discarded as necessary, and are based on the most likely outcomes rather than the worst-case scenarios.

- ***Uses the best available data***
  A good risk assessment uses high-quality, accurate and reliable quantitative, qualitative and/or semi-quantitative data. Risk assessors need to be able to transform facts and evidence into useful information, which can be used to support, inform and guide decision-making. They should pay adequate attention to the collection, analysis and mining of data, and ensure the use of good conceptual and computer models. Risk assessors should also ensure that analysis is explicitly tied to existing evidence, clearly presented, and supported by references and bibliographic information.

- ***Explicitly acknowledges, identifies and addresses uncertainty***
  A good risk assessment explicitly acknowledges, identifies, describes and addresses the magnitude, importance, types and sources of uncertainty. It seeks to eliminate uncertainty or reduce it to a minimum, and to address any remaining uncertainty by the most appropriate means (e.g. expert knowledge, primary research, and qualitative and quantitative techniques such as sensitivity analysis, probabilistic techniques and Monte Carlo analysis). If necessary, variability is addressed separately and explicitly.

- ***Considers all the relevant risks***
  A good risk assessment considers all the explicit and implicit risks that are relevant in any particular situation. It identifies and quantifies residual risks (i.e. the risk that remains after a management action is taken) as far as possible, and puts them into perspective. A good risk assessment also takes account of changes or transformation in risks due to management measures. For instance, chlorine in the water supply reduces microbial risks but increases chemical risks. Banning the use of antibiotics in animal feed reduces risks of antibiotic resistance but may increase the risk of food-borne illness. Risk assessors must ensure that when risks are transformed they are carefully explained so that proper risk-risk trade-offs can be made.

- ***Is objective, unbiased and transparent***
  A good risk assessment is honest, unbiased, clear and objective. It should be based on a scientific approach and carried out with objectivity and neutrality. Opinions or value judgements (for instance on economic, political, legal or environmental aspects of the risk) should not be allowed to influence the outcome of a risk assessment. A good risk assessment should explicitly and openly identify and discuss any controversies in the science or uncertainties in the analysis.

- ***Its results are validated***
  A validation step should be part of any risk assessment protocol

- ***Is clearly and comprehensively documented***
  A good risk assessment should clearly document the assumptions, logic, models used, calculations, and results obtained so that they are comprehensible to risk managers and other stakeholders despite their complexity. The risk assessment process should produce a coherent narrative report that puts risks into a proper perspective and explains how they should be managed and why. It should be comprehensive and detailed enough to meet all the risk managers' needs for decision-making.

- ***Is revaluated as appropriate***
  A risk assessment stands as a justification for a management decision at the time the decision is made. However, with additional information, such as that which can reduce the uncertainties identified in the risk assessment, the assessment can be reopened

- ***Has educational value***
  A good risk assessment helps mangers to understand food safety problems and learn about related issues. It helps managers to identify the limits of knowledge and enables resources to be directed towards narrowing information gaps. Good risk assessment is conducive to learning and the process is as important as the result.

5.7 Suggestions for further reading

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6. Risk Communication

6.1 Introduction to this chapter

Risk communication is an integral part of risk analysis together with risk management and risk assessment. Risk communication provides timely, relevant and accurate information to members of the risk analysis team, as well as external stakeholders, in order to improve knowledge about the nature and effects of a specific food safety risk. Successful risk communication is a prerequisite for effective risk management and risk assessment

This chapter introduces the concept of risk communication and describes the principles for its success. It explains why it is important to engage stakeholders in two-way dialogue about the risk in question, and how to do this. A step-by-step strategy for risk communication is elaborated.

Box 20: Key points about risk communication covered in this chapter

- Risk communication should facilitate an open and interactive exchange of information, facts and opinions about food safety risks.
- Internal risk communication takes place among members of the risk analysis team.
- External risk communication occurs between the risk analysis team and external stakeholders.
- Science and emotion define risks, and risk communication must address both aspects. Although food safety experts focus on science, the general public is usually more concerned about the emotional aspects of the risk.
- Risk communication should always have a clear goal.
- Responsibility for risk communication should be clearly defined and assigned to one or more members of the risk analysis team.
- Risk communication provides a platform to actively involve external stakeholders as soon, and as meaningfully, as possible in the risk analysis process.

6.2 Understanding risk communication

Risk communication has been defined as an interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions (Codex). Risk communication is a powerful yet neglected tool in helping people make more informed choices about risks.

Risk communication encompasses a continuous and interactive exchange of information and opinions between risk assessors, risk managers, consumers, industry, academic institutions and other interested stakeholders throughout the risk analysis process. Risk communication should involve a two-way dialogue. Risk communicators must provide external stakeholders

with clear and timely information about the food safety risk and measures to manage it; this information should be communicated in a way that stakeholders can easily understand and using a media that they can easily access. In addition, it is essential for risk communicators to solicit feedback from external stakeholders and listen to their opinions in order to refine the key message communicated and to fully and adequately address stakeholder concerns.

Risk communication can focus on internal and/or external audiences:

- Internal risk communication takes place among different groups in the risk analysis team including risk assessors, risk managers and risk communicators. For instance, communication between risk assessors and managers is essential to ensure coordination and the effective implementation of activities at different stages of risk analysis.
- External risk communications (the focus of this chapter) focuses on communication between the risk analysis team and external stakeholders including the general public.

6.3 Purpose of risk communication

The fundamental goal of risk communication is to provide meaningful, relevant and accurate information, in clear and understandable terms, targeted to a specific audience. Risk communication may not resolve all the differences between parties, but it should lead to a better understanding of those differences. Risk communication should also lead to more widely understood and accepted risk management decisions. Effective risk communication should have goals that build and maintain trust and confidence. It should facilitate a higher degree of consensus and support by all interested parties for the risk management option(s) being proposed. The goals of risk communication are presented in Box 21.

Box 21: Goals of risk communication

1. Promote awareness and understanding among all participants of the specific issues under consideration during the risk analysis process.
2. Promote consistency and transparency in arriving at and implementing risk management decisions.
3. Provide a sound basis for understanding the proposed and/or implemented risk management decisions.
4. Improve the overall effectiveness and efficiency of the risk analysis process.
5. Contribute to the development and delivery of effective information and education programmes, when they are selected as risk management options.
6. Foster public trust and confidence in the safety of the food supply.
7. Strengthen working relationships and mutual respect among all participants.
8. Promote the appropriate involvement of all interested parties in the risk communication process.
9. Exchange information on the knowledge, attitudes, values, practices and perceptions of interested parties concerning risks associated with food and related topics.

Source: 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. Food and Nutrition Paper No. 70.

6.4 Models for risk communication

Food safety regulators have learned several lessons about risk communication during recent years. One of the most important lessons is that risk communication does not occur automatically during risk assessment and risk management. Risk communication must be carefully planned, implemented and managed to ensure effective results. Responsibilities and objectives should be clearly identified at the outset. Mechanisms that facilitate the ongoing participation of all the interested parties throughout the risk analysis process should be created. In best practice, risk communication professionals contribute to the design and implementation of the communication process.

Two main models are currently used to manage the risk communication component of risk analysis. In the first, one member of the risk management team is responsible for the overall coordination of risk communication tasks, usually carried out by others. In the second model, one or more risk communication experts are responsible for planning, designing and implementing the risk communication process as part of the risk analysis team. Whatever the model used, it is essential to clearly define and delineate the responsibilities for risk communication from the outset. In addition, it is vital to ensure meaningful participation of relevant stakeholders and that incoming and outgoing messages are clearly received and understood.

6.5 Identifying and engaging stakeholders

Stakeholder participation provides opportunities to bridge gaps in language, process, understanding, perceptions and values. It provides an opportunity for affected groups to hear, consider and respect the various opinions, ideas and recommendations about the risk in question. Experience has shown that stakeholder participation enhances the outcomes of the risk analysis process. An honest exchange of information, ideas and opinions about risks, risk assessment results and risk management options enhances transparency. Risk assessments conducted with stakeholder involvement meet less opposition; stakeholders who have been able to review and comment on the risk assessment plan are more likely to understand and accept the results than those excluded from the process. Similarly, risk management decisions made in collaboration with stakeholders tend to be better received, more effective and more sustainable.

Many different kinds of individuals and groups involved in all aspects of the food chain from farm to fork (including production, processing, distribution, sale and consumption) are affected by food safety risks (see Box 22). Risk communicators, with the help of risk assessors and managers, should make an explicit effort to identify all the relevant stakeholders in the risk analysis process as soon as possible. Answering the following questions can help to identify important stakeholders[9]:

- Who might be affected by the risk management decision (including groups that already know or believe they are affected, as well as groups that may be affected but as yet do not know it)?
- Who has information and expertise that might be helpful?
- Who has been involved in similar risk situations before?

[9] The Presidential / Congressional Commission on risk assessment and risk management. 1997. Final report, Volume 2.

- Who has expressed interest in being involved in similar decisions before?
- Who might be reasonably angered if not included?

Box 22: Types of stakeholders

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

While some stakeholders will proactively make known their interest in the risk analysis and actively endeavour to contribute to the process, others may seek to protect their interests and try not to become involved. Although identifying stakeholders takes time and effort, the results are worthwhile. Sometimes, incentives (for instance, childcare or transportation expenses) will be necessary to enable certain groups of stakeholders to participate. Countries are likely to have their own statutory or policy regulations concerning how and when stakeholders can participate in public decision-making processes.

6.5.1 Stakeholder roles

Different types of stakeholders can play different roles in the risk analysis process. Some stakeholders can play an instrumental role in framing the problem and identifying potential issues to be addressed or sources of information. Stakeholders can also contribute to the development of risk assessment questions or provide comments on the results of a risk profile. The nature and extent of stakeholder involvement will depend on a number of factors including:

- the complexity, uncertainty, impact and level of controversy associated with the decision to be made;
- the urgency with which the problem must be addressed; and

- the extent to which participants can have a genuine influence on the decision – if the decision is not really negotiable, then stakeholders' time should not be wasted.

The risk communication strategy should consider the optimal way to involve the various stakeholders at different stages of the risk analysis process. Many different ways to involve stakeholders exist as illustrated in Box 23. In general, large public meetings have not been the most effective in facilitating the transparent two-way exchange of information that risk communication seeks to achieve. Information and communication technologies provide new methods for stakeholder engagement. For instance, web discussion boards and chat rooms can be used to provide access to information. Call-in television and radio programmes enable members of the general public to share views and concerns, or obtain information from experts and decision-makers.

Box 23: Examples of tactics to engage stakeholders

Meeting Techniques	Non-Meeting Techniques
• Public hearings	• Interviews
• Public meetings	• Hotlines and toll-free numbers
• Briefings	• Web sites
• Question and answer sessions	• Advertising and flyers
• Town hall meetings	• Television and radio
• Panel discussions	• Reports, brochures and newsletters
• Focus groups	• Booths, exhibits and displays
• Workshops	• Contests & events

6.6 Communicating analytical and emotional aspects of risk

Perception of risk is both analytical and emotional. Risk communication therefore needs to consider technical or analytical dimensions of risk, as well as non-technical or emotional dimensions. Technical aspects of food safety risk include the nature and extent of the human health effects, and the options and costs of mitigation (the facts about the hazard). Non-technical aspects focus on the emotional response to the risk (the outrage).

Risk communication should understand and respect both the analytical and emotional factors that influence how people make risk judgements. While it is important to communicate scientific or technical information about the risk, communication that addresses emotional aspects of a risk is also crucial since people do not generally respond to controversial risks on the basis of technical judgements. Non-technical information about the broader context of the risk – often emphasised by the media, industry or consumer groups – is often of most interest to the general public. Therefore, risk communication that addresses the emotional factors that underlie people's concerns, rather than dismissing such perceptions as 'irrational' because they are not solely fact-based, is likely to be more successful in helping people to make more informed choices about the risk they face.

The perceived level of risk has an important effect on the extent of risk management considered necessary to make risks acceptable. In general, the greater the perceived risk, the greater the desired reduction of that risk. The ideal level of risk is zero; however, this is not an option. An acceptable level of risk is defined as a level that is good enough, where 'good

enough' means stakeholders think the advantages of increased safety are not worth the costs of reducing the risk by restricting or otherwise altering the risk producing activity.

The acceptability of the appropriateness of risk management measures is closely related to public perception of risk. For instance, in some cases the proposed measure (e.g. irradiation) to reduce a particular risk is perceived by the public to be more harmful than the risk itself. Therefore, it is essential for risk managers to ensure that the risk communication process uncovers information about the general public's perception of the risk in question. Some of the factors that influence people's perception of risk are presented in Box 24.

Box 24: Factors that influence perception of risk

Dread: Hazards that provoke a risk that is perceived as dreadful tend to evoke stronger fears than something seen as less dreadful.

Control: When an individual feels as though she/he has some control over the process determining the risk faced, that risk usually seems smaller than if it was decided by a process over which the individual had no control.

Natural or human-made: Natural risks (e.g. sun radiation) are usually perceived as less worrying than human-made risks (e.g. anthropogenic sources of radiation) even when facts show that the former present greater risks.

Choice: A risk that an individual chooses usually seems less risky that a risk that is imposed.

Children: Research has shown that risks to children are perceived as worse than the same risk to adults.

New or old: A risk that is new tends to be more frightening than the same risk after people have lived with it for some time and been able to put it into perspective.

Awareness: Greater awareness of a risk increases conscious concern about that risk.

Personal exposure: Any risk seems larger if an individual thinks they or someone they know could be a victim. This helps explain why statistical probability is often irrelevant to people and an effective form of risk communication.

Risk-benefit trade-off: When people perceive a benefit from a certain behaviour or choice, the risk associated with it seems smaller (e.g. the benefits of a vaccination are perceived to outweigh the risk of the side effects). If there is no perceived benefit, the risk seems larger.

Trust: Research has shown that the less people trust the institutions that are responsible for exposure to the risk or communication about the risk, the more they will be afraid. In comparison, increased trust reduces fear.

Source: Harvard Center for Risk Analysis. Risk in Perspective. June 2003. Volume 11, Issue 2 (available at: http://www.hcra.harvard.edu/pdf/June2003.pdf).

6.7 Strategies for risk communication

Risk communication occurs in many different contexts. Experience demonstrates that to be most effective, the strategy used for risk communication should be tailored to stakeholders' particular characteristics and concerns. Although there are many similarities, the strategies needed during a food safety emergency will differ from those needed to engage the public in dialogue during non-emergency situations (for instance about the risks and benefits of new food technologies) or during chronic low-level food related risks.

In general, strategies for risk communication should pay attention to the following activities:

1. Collect and analyse background information about the food safety risk, perceptions of different stakeholders, context, and so on

- Anticipate potential and emerging food-related public health hazards before they become serious.
- Understand the scientific basis of the risk(s) and related uncertainties.
- Identify the different types of stakeholders that are currently or potentially affected by the risk.
- Determine stakeholder perception and knowledge of the hazard, and their resulting behaviour about the risk involved.
- Identify the types of risk information stakeholders consider important and want to receive.
- Identify and be sensitive to related issues that may be more important to some stakeholders than the risk itself.

2. Develop and disseminate key messages targeted at particular audiences

- Develop key messages targeted at particular stakeholders that address both the analytical (i.e. how the risk is determined, how it can be monitored and how individuals can control or reduce it) and emotional aspects of the risk. The types of information that should be communicated to stakeholders will depend on the particular nature and context of the risk (see Box 25 for examples).
- Identify the most appropriate media to disseminate information to, and communicate with, different types of stakeholders.
- Emphasise the human side of the risk, in addition to the scientific aspects, in order to attract and maintain interest.
- Explain the process used to assess risk including uncertainty.
- Ensure openness, transparency and flexibility in all communication activities.
- Increase awareness of the benefits resulting from a particular behaviour or choice associated with the risk.

3. Engage stakeholders in dialogue about the risk

- Identify and implement a range of tactics and methods to engage stakeholders in an interactive dialogue about the risk in order to identify, understand and respond to their concerns and increase awareness about the risk and the best way to respond to it.

- Establish contacts with, and provide additional information to, key media (television, radio, press, etc.)
- Make use of existing channels for education and outreach (e.g. health education, agricultural extensionists) to enhance dialogue with people and communities.
- Ensure coordination and collaboration with other institutions/groups that also have credible information related to the risk.

4. Monitor and evaluate the outcomes of the risk communication

- Test the clarity and impact of key messages on a representative segment of the target audience before messages are disseminated.
- Integrate activities to monitor and evaluate the effectiveness of key messages, the communication channels used, and the outcome of risk communication activities so that they can be adapted and improved as required.

Box 25: Elements of effective risk communication

Nature of the risk

- Characteristics and consequences of the hazard
- Magnitude and severity
- Urgency of corrective actions
- Trends in severity (increasing or decreasing in importance)
- Distribution and spread
- Nature and size of population(s) at risk
- Profile of high-risk groups
- Probability of exposure
- Amount of exposure that constitutes a significant risk

Nature of the benefit associated with a certain behaviour or choice

- Actual or expected benefit(s) associated with a particular behaviour or choice
- Who benefits and in what ways
- Trade-off between risk(s) and benefit(s)
- Scale and importance of benefit(s)
- Total benefits to all affected populations

Uncertainties in risk assessment

- Methods used to assess the risk
- Importance of each of the uncertainties
- Weaknesses or inaccuracies in available data
- Assumptions on which estimates are based
- Sensitivity of the estimates to changes in assumptions
- Effect of changes in the estimates on risk management decisions

Risk management options

- Action(s) taken to control/manage risk
- Action(s) individuals may take to reduce personal risk
- Reasons for choosing a specific risk management option
- Effectiveness of a specific risk management option
- Benefits of a specific risk management option
- Costs of managing the risk including who pays for management
- Risks that remain after a risk management option is implemented

6.8 Principals for risk communication[10]

6.8.1 Know the audience

Before formulating risk communication messages, analyse the various stakeholders and audience(s) to understand their particular motivations and opinions. Get to know the stakeholders in order to understand their concerns and feelings, and to maintain an open channel of communication with them.

6.8.2 Involve scientific experts

Scientific experts, in their capacity as risk assessors, must be able to explain the concepts and processes of risk assessment. They need to be able to explain the results of their assessment and the scientific data, assumptions and subjective judgements upon which it is based, so that risk managers and other interested parties clearly understand the risk. They must also be able to clearly communicate what they know and what they do not know, and to explain the uncertainties related to the risk assessment process. In turn, the risk managers must be able to explain how the risk management decisions are arrived at.

6.8.3 Establish expertise in communication

Successful risk communication requires expertise in conveying understandable and usable information to all interested parties. Risk managers and technical experts may not have the time or the skill to perform complex risk communication tasks, such as responding to the needs of the various audiences (e.g. public, industry, media, etc.) and preparing effective messages. People with expertise in risk communication should therefore be involved as early as possible. This expertise may have to be developed by training and experience.

6.8.4 Be a credible source of information

Information from credible sources is more likely to influence public perception of a risk than information from sources that lack credibility. Trust and credibility must be nurtured rather than eroded or lost through ineffective or inappropriate communication. Efforts should be made to provide accurate and timely information about the risk from competent and expert sources that are viewed as trustworthy, fair and unbiased. Disseminating consistent messages from multiple sources will reinforce the credibility of the message. Communications should acknowledge current issues and problems. Care must be taken to avoid exaggeration, omissions, distortion or self-serving statements. Above all, information should be disseminated as soon as possible, with frequent and ongoing updates, so that the audience does not become focused on the suppression of facts rather than the management of the risk itself.

6.8.5 Share responsibility

The roles of different types of institutions in risk communications should be recognized. Regulatory agencies of governments (at the national, regional and/or local levels) have a fundamental responsibility given their leading role in managing public health risks. Government agencies need to determine what the public knows about the risk in question and what the public thinks of the various options being considered to manage those risks in order

[10] 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. Food and Nutrition Paper No. 70.

to ensure that risk management decisions are appropriate. The media also plays an essential role in the communication process. Industry also has a responsibility for risk communication, especially when the risk is as a result of their products or processes. All parties involved in the risk communication process (government, industry and media) have joint responsibilities for the outcome of that communication even though their individual roles may differ.

6.8.6 Differentiate between scientific and value judgement

It is essential to separate 'facts' from 'values' in considering risk management options. At a practical level, it is useful to report the facts that are known at the time as well as what uncertainties are involved in the risk management decisions being proposed or implemented. The risk communicator bears the responsibility to explain what is known as fact and where the limits of this knowledge begin and end. Value judgements are involved in the concept of acceptable levels of risk. Consequently, risk communicators should be able to justify the level of acceptable risk to the public. Making the basis for this determination clear is an important function of risk communication.

6.8.7 Assure transparency

The risk communication process should be transparent if the public is to accept the outcome of the risk analysis process. While respecting legitimate concerns to preserve confidentiality (e.g. proprietary information or data), transparency in risk analysis consists of having the process open and available for scrutiny by interested parties. Effective two-way communication between risk managers, the public and interested parties is both an essential part of risk management and a key to achieving transparency.

6.8.8 Put the risk into perspective

One way to put a risk in perspective is to examine it in the context of the benefits associated with the technology or process that poses the risk. Another approach that may be helpful is to compare the existing risk with other similar and more familiar risks. However, this can create problems if it appears the risk comparisons have been intentionally chosen to make the risk in question seem more acceptable to the public. In general, risk comparisons should not be used unless:

- both (or all) risk estimates are equally sound;
- both (or all) risk estimates are relevant to the specific audience;
- the degree of uncertainty in all risk estimates is similar;
- the concerns of the audience are acknowledged and addressed; and
- the substances, products or activities themselves are directly comparable including the concept of voluntary and involuntary exposure.

6.9 Suggestions for further reading

FAO/WHO. 1999. The application of risk communication to food standards and safety matters. Report of a Joint FAO/WHO Expert Consultation in Rome, Italy, 2–6 February 1998. FAO Food and Nutrition Paper No. 70 (available at: http://www.fao.org/DOCREP/005/X1271E/X1271E00.htm#TOC).

Fischoff, B. 1995. Risk perception and communication unplugged: twenty years of process. *Risk Analysis*, 15: 137-145.

Harvard Center for Risk Analysis. Risk in Perspective. June 2003. Volume 11, Issue 2 (available at: http://www.hcra.harvard.edu/pdf/June2003.pdf).

Joint Institute for Food Safety and Applied Nutrition. Food safety risk communication resources. A joint project between the University of Maryland and the United States Food and Drug Administration (available at: http://www.foodriskclearinghouse.umd.edu/risk_comm_foodsafety.cfm).

Sandman, P.M. 1994. Risk communication. In: Encyclopaedia of the Environment, Eblen, R.A. & Eblen, W.R. (eds.). 1994. Boston, MA: Houghton Mifflin, pp. 620-623.

University of Maryland. Food safety risk communication primer.

Annex 1: Glossary[11]

Acceptable Daily Intake (ADI)	An estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg). JECFA 2003 (available at: http://jecfa.ilsi.org/).
Codex Alimentarius Commission	The Codex Alimentarius Commission is a subsidiary body of the Food and Agriculture Organization of the United Nations and the World Health Organization. It is entrusted with the elaboration of international food standards to protect the health of consumers and ensure fair practices in international trade in foods. Available at: **www.codexalimentarius.net**
Dose-Response Assessment	The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).
Exposure Assessment	The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.
Hazard	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
Hazard Characterization	The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical risk assessments, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.
Hazard Identification	The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.
Maximum Residue Limit	The maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or mg/kg on a fresh weight basis) that is acceptable in or on a food. It is based on the type and amount of residue considered to be without toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as

[11] Unless otherwise indicated, definitions are from the 13th Edition of the Procedural Manual of the Codex Alimentarius Commission. Joint FAO/WHO Food Standards Programme. 2003 (available at: www.codexalimentarius.net/procedural_manual.stm).

	well as food technological aspects and estimated food intakes. JECFA 2003 (available at: http://jecfa.ilsi.org/).
Quantitative Risk Assessment	A Risk Assessment that provides numerical expressions of risk and indication of the attendant uncertainties (stated in the 1995 Expert Consultation definition on Risk Analysis) (CAC GL 30[12]).
Qualitative Risk Assessment	A Risk Assessment based on data, which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk (CAC GL 30).
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Risk Analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk Assessment Policy	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.
Risk Characterization	The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.
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 Estimate	The quantitative estimation of risk resulting from risk characterization.

[12] CAC. 1999. Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL 30 (available at: http://www.codexalimentarius.net/standard_list.asp).

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 Profile	The description of the food safety problem and its context.
Sensitivity analysis	A method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes to its inputs (CAC GL 30).
Transparent	Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review (CAC GL 30).
Uncertainty analysis	A method used to estimate the uncertainty associated with model inputs, assumptions and structure/form (CAC GL 30).

Annex 2: Food Additive Safety Assessment

Food additives are chemicals and colourings deliberately added to food in small amounts to improve the colour or flavour of food, maintain or improve nutritive value, maintain freshness or assist with processing or preparation. Public concern about the types and amounts of food additives and their potential relationship to various illnesses has increased significantly in recent years as the use of food additives has grown.

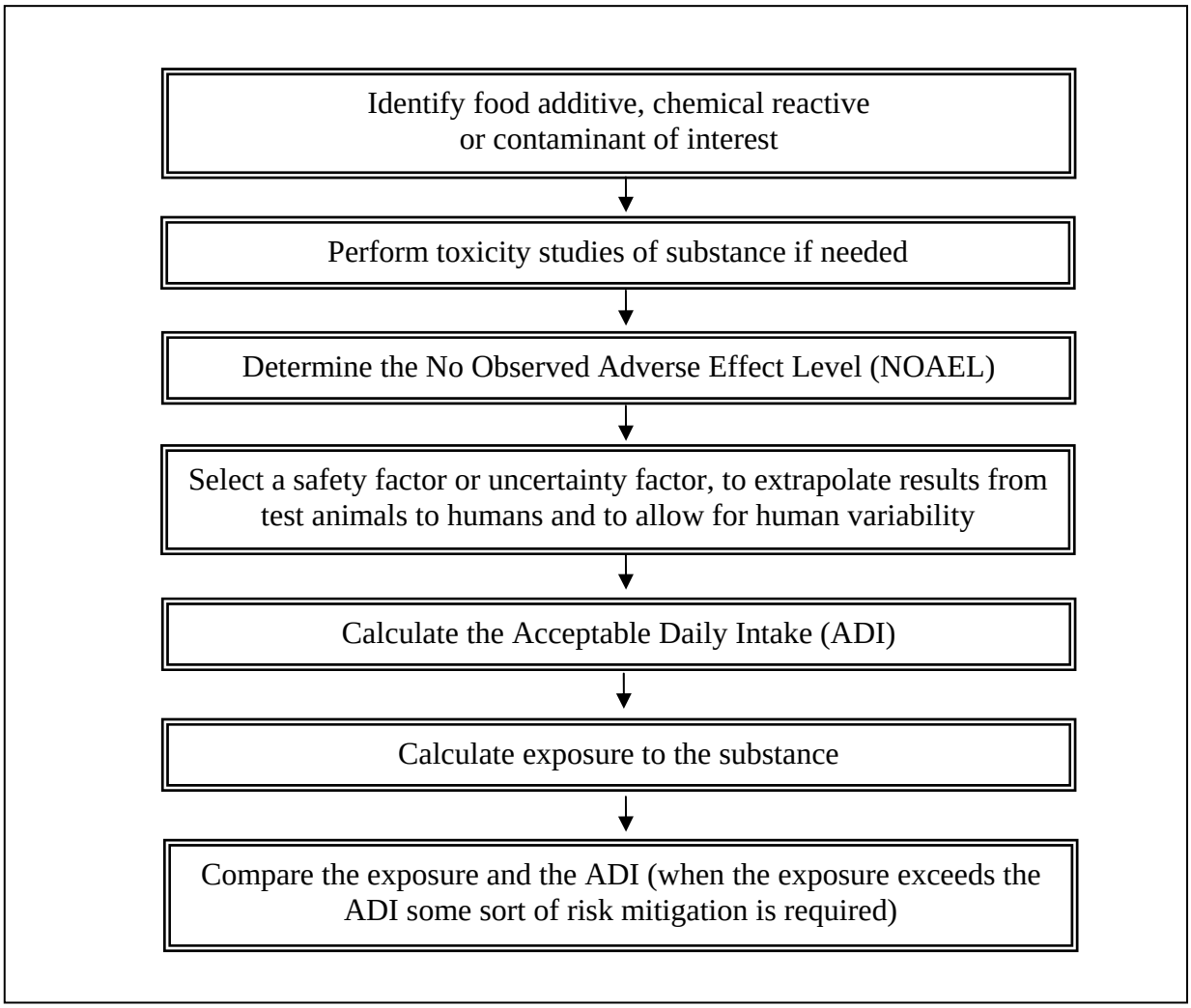
I. Process for a food additive safety assessment

A food additive safety assessment is an example of a chemical risk assessment. As described in Chapter 5, a chemical risk assessment for food safety is based on:

- hazard identification
- hazard characterization (including a dose-response assessment if appropriate)
- exposure assessment
- risk characterization

The basic tasks in a food additive safety assessment are illustrated in Figure 6. The steps in an assessment of indirect additives or chemicals in food (such as contaminants, allergens, pesticide or veterinary residues) will be similar.

Figure 6: Steps in a food additive safety assessment



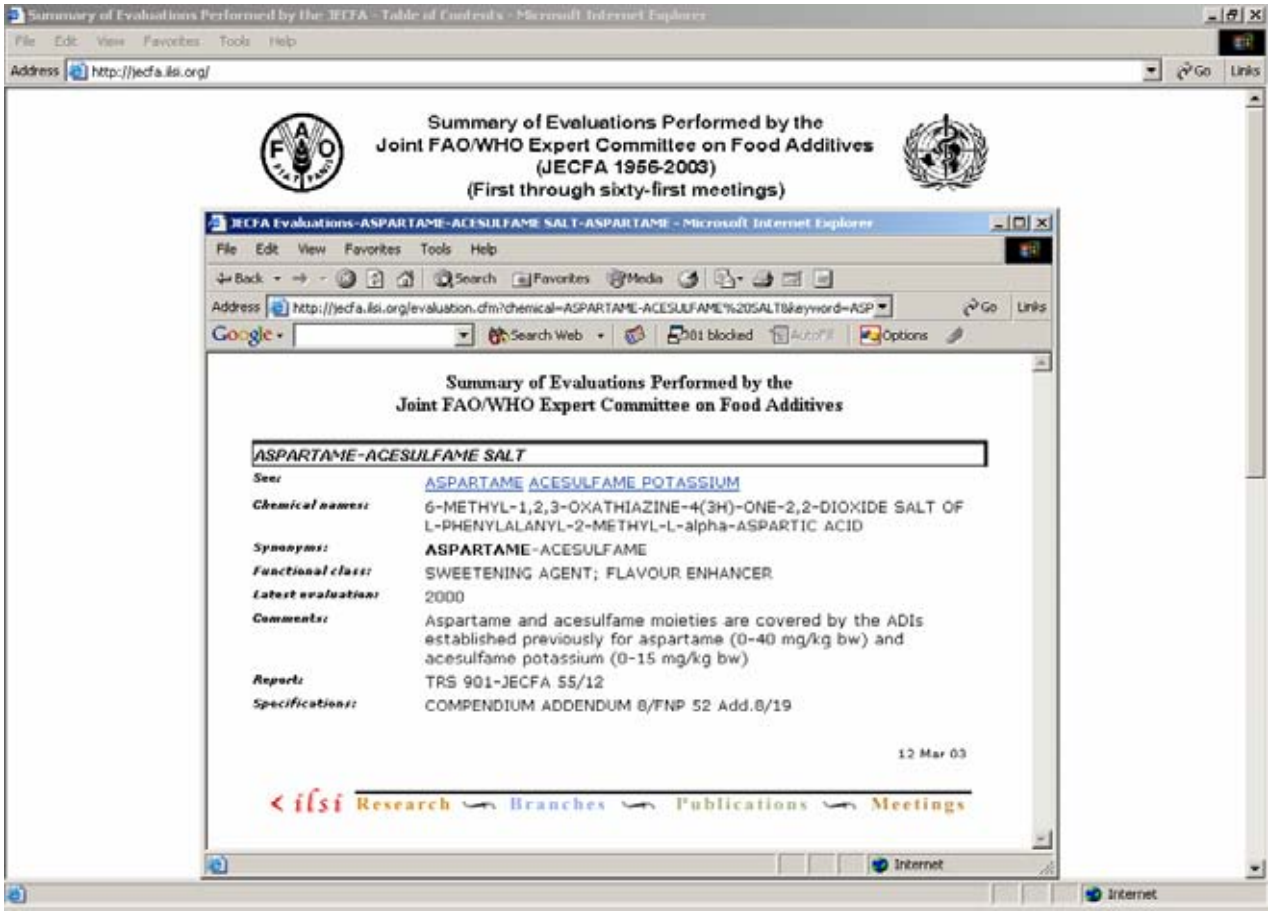
A case study of a chemical risk assessment for aspartame in presented in an accompanying volume to this Manual (Part II).

II. Information on food additives

Information on many of the known food additives is now widely available, which eliminates the need for countries to perform their own toxicological studies. Much of this information is freely available on the Internet and is adequate for many safety assessment purposes.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) provides a unique global mechanism for the safety assessment of food chemicals. Over the last 50 years, JECFA has evaluated more than 1 500 food additives, approximately 40 contaminants and naturally occurring toxicants, as well as residues of approximately 90 veterinary drugs. JECFA has also developed principles for the safety assessment of chemicals in food that are consistent with current thinking on risk assessment and take account of recent developments in toxicology and other relevant sciences. JECFA provides online access to summaries of all evaluations performed on food chemicals on the Internet (available at: http://jecfa.ilsi.org/) as illustrated in Figure 7. The *JECFA Compendium of food additive specifications* is available on the Internet (at http://www.fao.org/es/ESN/jecfa/database/cover.htm) and in hard copy (as FAO Food and Nutrition Paper 52 (plus addenda). In many cases, JECFA has also established an acceptable daily intake. JECFA summaries are also available in hard copy upon request.

Figure 7: JECFA summary evaluation for aspartame



JECFA has also developed *Principles for the safety assessment of food additives and contaminants in food*, which provide guidance on:

- determining chemical and toxicological test requirements for individual chemicals that are added to or occur in food;
- assessing analytical methods that should be applied; and
- updating test procedures and methods of assessment as science progresses.

These principles are available on the CD-ROM that accompanies this Manual and on the Internet (at **http://www.who.int/pcs/jecfa/ehc70.html#FOREWORD**).

In addition to information provided by JECFA, other sources of information also exist. For instance:

- The Toxicology and Environmental Health Information Programme provides free online access to an integrated system of toxicology and environmental health databases (available at: http://toxnet.nlm.nih.gov/).
- WHO has developed estimates of dietary intake of pesticide residue and contaminants in five regional diets as part of the WHO Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme (GEMS/Food). Although these estimates were not designed to meet the needs of food additive intake surveys, they nevertheless provide a useful source of data on food intake (additional information is available at: http://www.who.int/foodsafety/chem/gems/en/).

Despite the availability of free information, it is important to emphasize that systems to collect data on diet and food chemical concentrations are an important part of national risk assessment infrastructure given differences in consumption of food additives across countries.

III. Estimating the acceptable daily intake (ADI)

The Acceptable Daily Intake (ADI) of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical (Codex). The ADI is expressed in milligrams of the chemical per kilogram of body weight. Experts apply a rigorous process to establish the Acceptable Daily Intake (ADI) of a substance. Box 26 provides an example.

Toxicity studies are used to establish a No Observed Adverse Effects Level (NOAEL) . These tests generally involve studies on animals using relatively large doses of the substance being tested. However, it is challenging to extrapolate and apply these results to humans and to extrapolate from high doses to low doses. Differences in diets and eating habits can make it difficult to apply ADIs in all countries. There are often data gaps in intake studies and food chemical concentration data, especially in developing countries.

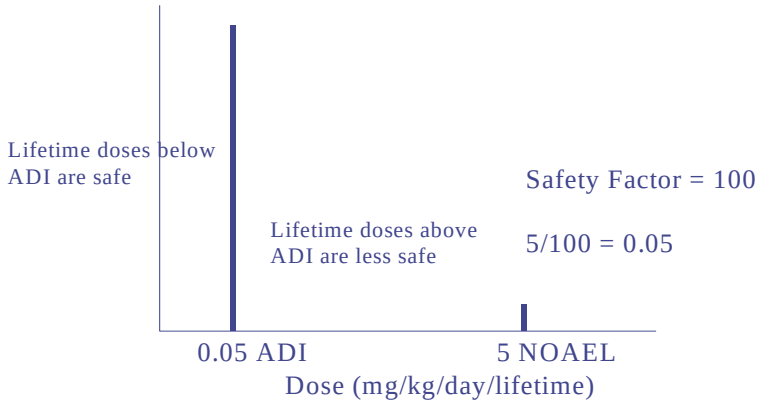
Safety factors are identified to account for these and other uncertainties. JECFA has used safety factors since its inception. The use of a safety factor is intended to provide an adequate margin of safety for the consumer by assuming that the human being is ten times more sensitive than the most sensitive test animal, and that the difference of sensitivity within the human population is in a ten-fold range. In determining an ADI, a safety factor is applied to the NOAEL determined in an appropriate animal study.

Recently, JECFA has adopted the use of Chemical Specific Adjustment Factors (CSAPs) instead of uncertainty or safety factors. CSAPs are factors based on quantitative, chemical specific, toxicokenetic or toxicodynamic data which replace some or all of the default uncertainty safety factors.

Box 26: Calculating an acceptable daily intake

The example below with a NOAEL of 5 mg/kg bw/day/lifetime has combined two factors for an overall safety factor of 100 yielding an ADI of 0.05 mg/kg bw/day/lifetime

ADI = NOAEL/Safety Factor



IV. Calculating exposure

Different kinds of calculations are used to estimate exposure to food additives. In general, the results are expressed as an intake summarised in mg/kg of bodyweight per day for a lifetime. Some estimates are calculated on the basis of an average or mean consumer, while others are based on a high-end consumer (for instance a 90th percentile level of consumption). Codex estimates exposure in three main ways:

- Per capita estimates: This is an estimated value of the exposure level if a food additive or contaminant were equally distributed across a population. A per capita intake may be calculated by dividing the total yearly production volume (corrected for imports and exports) of a chemical used in food within a nation by the national population.
- Estimates from dietary food intake surveys: Dietary surveys may be performed on foodstuffs consumed by a representative population sample over a short period of time (e.g. 1 to 14 days). The intake of an additive or contaminant per food type can be calculated by multiplying the usual additive or contaminant level in each type of food by the dietary intake of the food.

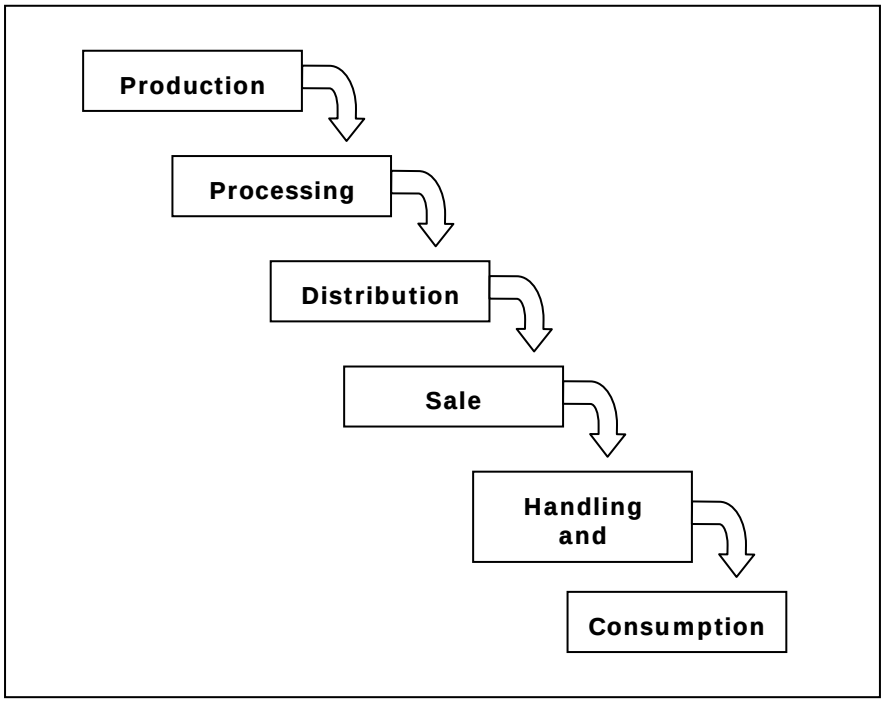
Analytical values from market-basket or total-diet surveys: This involves an analysis of representative diets for the usual level of the additive or contaminant in the diet (for instance using WHO estimates of dietary intake of pesticide residue and contaminants in five regional diets outlined above).

Annex 3: Microbial Risk Assessment

Introduction

A microbial risk assessment evaluates the likelihood of adverse human health effects occurring after exposure to a pathogenic microorganism or to the medium in which the organism occurs. Microbial risk assessments may be carried out for a number of different purposes including to support research, quantify or estimate a food safety risk, identify the causes of risks, attribute illnesses to specific risks, or support comprehensive risk management. The purpose of the risk assessment will obviously have an important effect on the scope and comprehensiveness of the assessment. While some microbial risk assessments will need to focus on the entire farm-to-table food chain (illustrated in Figure 8) in order to respond to the questions posed, others may have less ambitious objectives and may restrict their focus to a particular part of the food chain.

Figure 8: Components of a generic farm-to-table risk assessment



Some of the main purposes of microbial risk assessments are presented below

Purpose of Risk Assessment	**Probable Scope**
1. To carry out basic research to expand the knowledge base and increase understanding about a particular risk.	Will usually merit a thorough and complete assessment of the entire farm-to-table chain.
2. To produce a baseline risk estimation that describes the risk in quantitative or qualitative terms.	Will not normally need to consider the entire food chain.
3. To attribute risk (i.e. to assign a portion of a known risk among competing causes such as pathogens or foods).	An assessment of the entire farm-to-table chain may not always be needed.
4. To support regulatory decision-making.	In general, should cover that part of the food chain that is subject to the authority of the regulatory agency.
5. To facilitate comprehensive risk management in response to an identified food safety risk.	Should focus on the entire food chain in order to identify and investigate all the possible options to reduce the risk along the farm-to-table continuum and engage all the relevant stakeholders in risk management.
6. To produce information that can be used to support the establishment of international food safety standards	The scope of the assessment will vary according to the particular context.

Models for microbial risk assessment

The specific circumstances and elements of a microbial risk assessment are too unique to lend themselves readily to a standardised approach as has generally been achieved for chemical risk. Microbial risk assessment is also relatively new and as a result agreement on a particular conceptual model does not exist. Several frameworks exist for microbial risk assessment. Some of the best known models are:

- Codex. 1999. Principles and guidelines for the conduct of microbiological risk assessment CAC/GL 30 (see summary below)
- FAO/WHO. 2003. Hazard characterization for pathogens in food and water. Guidelines. Microbiological Risk Assessment Series, No. 3 (available at: ftp://ftp.fao.org/docrep/fao/006/y4666E/y4666E00.pdf).
- FAO/WHO. In press. Exposure assessment of microbiological hazards in foods: Guidelines. Microbiological Risk Assessment Series, No. 7.
- International Life Science Institute (ILSI). 2000. Revised framework for microbial risk assessment (available at: http://www.ilsi.org/file/mrabook.pdf).

Although the Codex guidelines and ILSI framework differ in how the elements of a microbial risk assessment are grouped and organized, they nevertheless share a number of common fundamentals.

Codex principles and guidelines for microbiological risk assessment

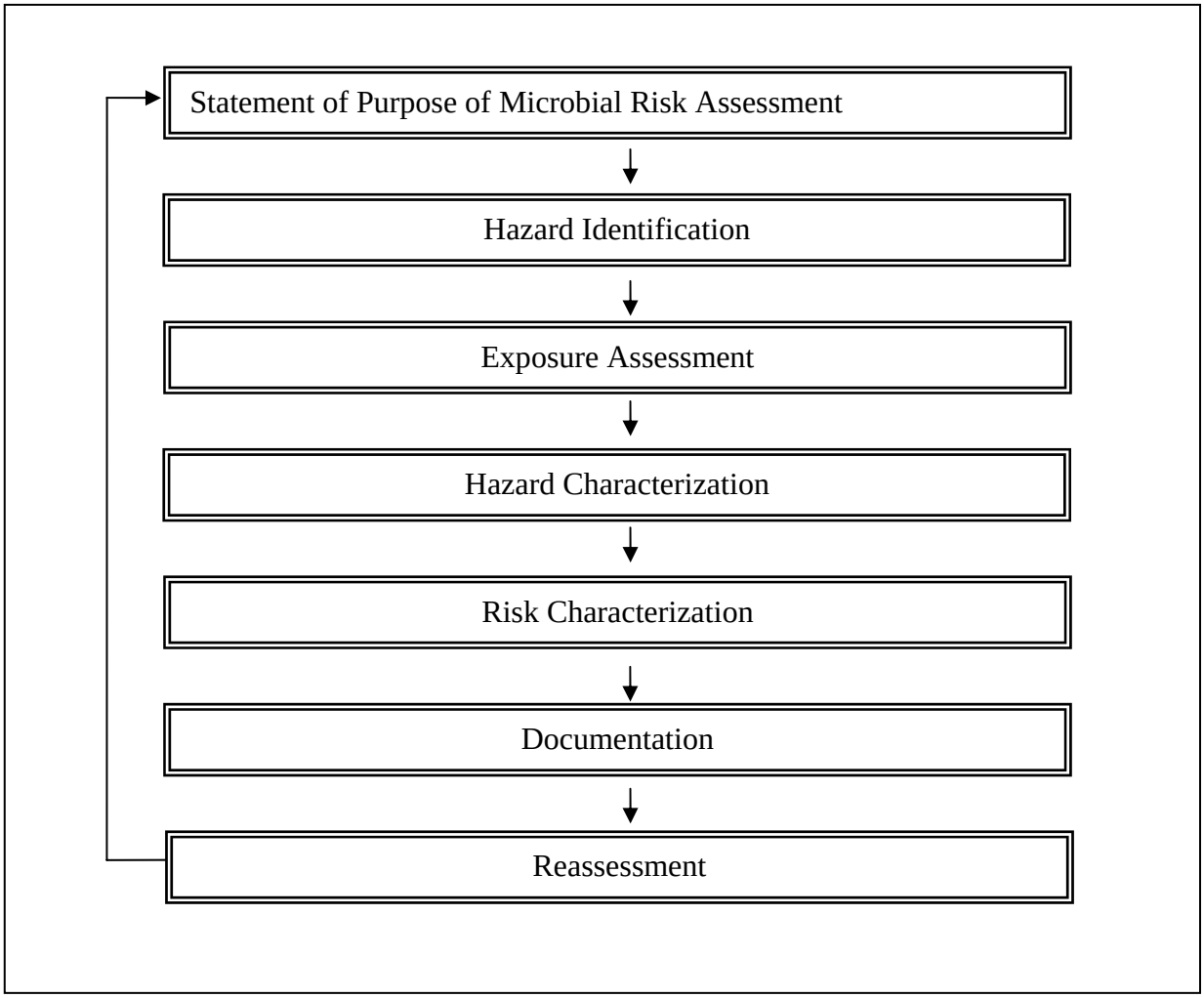
Codex has articulated a set of principles (see Box 27) and provided guidance on steps required for a microbial risk assessment (Figure 9).

Box 27: Codex principles for microbial risk assessment

1. Microbiological risk assessment should be based on sound science.
2. There should be a functional separation between risk assessment and risk management.
3. Microbiological risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.
4. A microbiological risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be the output.
5. The conduct of a microbiological risk assessment should be transparent.
6. Any constraints that impact on the risk assessment such as cost, resources or time, should be identified and their possible consequences described.
7. The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.
8. Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimised.
9. A microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.
10. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
11. A microbiological risk assessment should be reviewed as new and relevant information becomes available.

The steps in the process for a microbial risk assessment proposed by Codex clearly reflect the four components of the risk assessment process (hazard identification, exposure assessment, hazard characterization and risk characterization) explained in Chapter 5. The Codex process and guiding principles also encourage participation of relevant stakeholders to improve the quality of the assessment process, and the effectiveness and acceptability of its outcomes.

Figure 9: Process for microbial risk assessment (Codex)



At the beginning of a microbial risk assessment, the specific purpose and scope of the risk assessment should be clearly articulated. The microbiological risk assessment may require a preliminary investigation phase. If so, evidence to support the farm-to-table modelling of risk might be structured or mapped into the framework of the risk assessment.

Hazard identification

The identification of hazards in a microbial risk assessment will resemble the typical hazard identification process described in Chapter 5. For microbial agents, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern, as well as the associated food(s). Relevant information could be obtained from:

- clinical studies;
- epidemiological studies and surveillance including outbreak investigations;
- laboratory animal studies;
- investigations of the characteristics of microorganisms;

- interaction between microorganisms and their environment through the food chain from primary production up to and including consumption;
- studies on analogous microorganisms and situations.

Exposure assessment

As described in Chapter 5, exposure assessment identifies the extent of actual or anticipated human exposure to a hazard. Various factors influence exposure assessment for microbial risk as illustrated in Box 28. Exposure assessment should specify the unit of food that is of interest, usually the portion size in most cases of acute illness. Factors that should be considered for exposure assessment include the frequency of contamination of foods by the pathogenic agent and its level in those foods over time.

Since microbial pathogen levels can change dramatically with proper handling or abuse, the exposure assessment often describes the pathway from production to consumption. Scenarios can be constructed to predict the range of possible exposures. The scenarios might reflect effects of processing, such as hygienic design, cleaning and disinfection, as well as the time/temperature and other conditions of the food history, food handling and consumption patterns, regulatory controls and surveillance systems.

Box 28: Factors influencing exposure assessments for microbial risk

- Characteristics of the pathogenic agent
- Microbiological ecology of the food
- Initial contamination of the raw material
- Regional differences and seasonality of production
- Level of sanitation and process controls
- Methods of processing, packaging, distribution and storage of foods
- Preparation steps such as cooking and holding
- Patterns of consumption
- Consumers (socio-economic, cultural, ethnic, demographic, food consumption preferences and behavioural characteristics, etc.)
- Role of food handler as source of contamination
- Amount of hand contact with product
- Potential impact of abusive environmental, time or temperature relationships

Foods can be categorized in various ways during the exposure assessment stage. For instance, according to the likelihood that the food will be contaminated at the source, whether the food can support the growth of the pathogen of concern, whether there is significant potential for abusive handling of the food, or whether the food will be subjected to a heat process. The presence, growth, survival or death of microorganisms, including pathogens in foods, are influenced by processing and packaging, and the storage environment, which includes the time and temperature of storage, the relative humidity of the environment, and the gaseous composition of the atmosphere. Other relevant factors may include pH, moisture content or water activity (aw), nutrient content, the presence of antimicrobial substances, and competing microflora. Predictive

microbiology can be a useful tool to simulate the growth, survival or death of microorganisms in an exposure assessment.

Hazard characterization

Hazard characterization provides a qualitative or quantitative description of the severity and duration of adverse human health effects that may result from the ingestion of a microorganism or its toxin in food, as well the likely causes. A number of different factors influence hazard characterization for microbial risk as illustrated in Box 29.

Box 29: Factors influencing hazard characterization for microbial risk

- Microorganisms replication
- Host and environment – can cause virulence and infectivity to change
- Genetic material (e.g. antibiotic resistance, virulence factors) can be transferred
- Secondary and tertiary transmission
- Delayed onset of clinical symptoms
- Persistence in individuals leading to continued excretion of microorganism and risk of spread of infection
- Low doses can cause a severe effect
- Attributes of food (e.g. high fat content) may alter pathogenicity
- Genetic factors (e.g. Human Leucocyte Antigen type)
- Increased susceptibility (e.g. breakdowns of physiological barriers)
- Age
- Pregnancy
- Nutrition
- Health and medication status
- Concurrent infections
- Immune status
- Previous exposure history
- Population immunity
- Access to and use of medical care
- Persistence of organism in population

Dose-response relationships are desirable when data are available to develop them. When establishing a dose-response relationship, the different end points (such as infection or illness) should be taken into consideration and carefully defined. In the absence of a known dose-response relationship, risk assessment tools such as knowledge elicitation techniques could be used to consider the various factors necessary to characterize the hazard. Ratios of cases to eating occasions are also useful hazard characterization tools in some risk assessments.

Risk characterization

Risk characterization brings together all of the qualitative and quantitative information generated during the previous steps to provide a reliable estimate of the risk for a given population, and respond to the specific questions posed by the risk managers. The resulting estimate gives an approximation (numerical or descriptive) of the likelihood and expected severity of the adverse effects, which could occur in a given population due to the risk in question.

The risk estimate should include an indication and explanation of any uncertainties and assumptions inherent in the risk estimate. The degree of confidence in the final estimation will depend on the variability, uncertainty and assumptions identified. Differentiating between uncertainty and variability may be important in subsequent selections of risk management options.

Documentation

The entire risk assessment process should be systematically and clearly documented, and communicated to risk managers and other interested groups. The risk assessment documentation should clearly identify and explain the outcomes and results of the risk assessment, as well as the nature of any assumptions, expert judgements, uncertainties, limitations or weakness in the process or its conclusions. The output of the risk assessment process must provide risk managers with a clear and comprehensive basis to inform and guide their decision-making process on strategies for risk management.

Reassessment

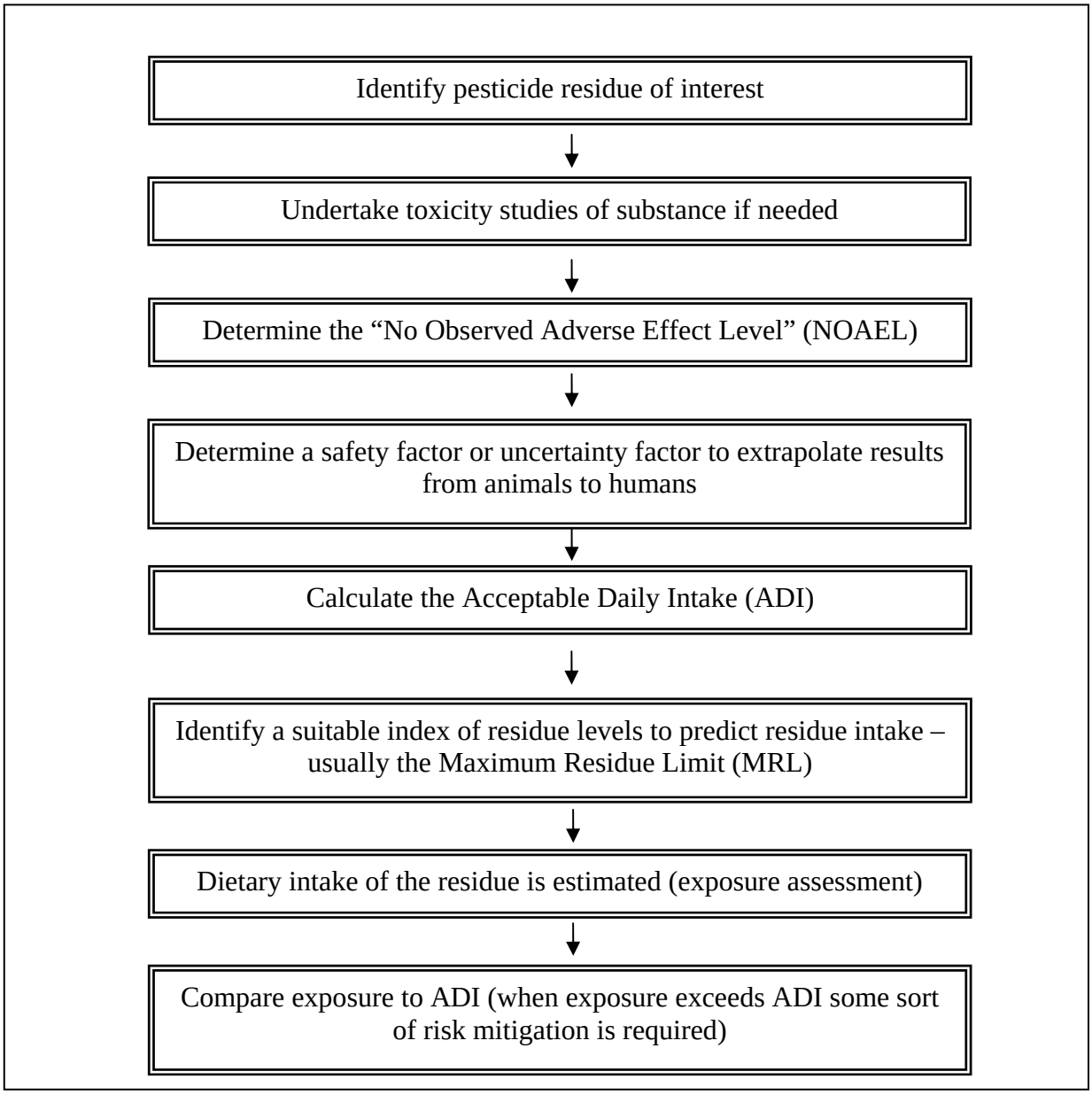
Continuously monitoring and reassessing risks is an essential part of microbial risk assessment to ensure that the selected risk management options continue to produce the best results. Surveillance programmes are useful and necessary to reassess the public health risks associated with pathogens in foods, particularly as new data and information becomes available.

Annex 4: Pesticide Residue Risk Assessment

Introduction

Pesticide residues are substances that remain in or on food, animal feed, soil, air or water following the use of a pesticide. For regulatory purposes, residues include the parent compound and any specified derivatives such as degradation and conversion products, metabolites and impurities considered of toxicological significance. The possible effect of pesticide residues on human health is an issue of concern. Pesticide residue risk assessment therefore provides an important means to evaluate the nature and extent of such risks, and identify appropriate risk management strategies. The steps in a pesticide residue risk assessment are outlined in Figure 10.

Figure 10: Pesticide residue risk assessment process



Pesticide residue risk assessment follows the main steps in the basic chemical risk assessment model, notably: hazard identification, hazard characterization, exposure assessment and risk characterization.

The main purpose of a residue risk assessment is to develop an index to predict pesticide residue intake in order to protect consumer health and/or facilitate international trade. The maximum residue limit (MRL) is the most commonly used index to predict pesticide residue intake. Maximum residue levels are primarily intended as a check that good agricultural practices (GAP) are being followed. The MRL is the maximum concentration of a pesticide residue expressed as mg/kg that can be legally permitted in food commodities and animal feeds. The MRL is established at a level that does not exceed that which would result from use of the pesticide in accordance with good agricultural practice. Neither the MRL nor the ADI is permanently fixed but vary based on the best judgement of a group of experts.

Box 30: International advice on pesticide residues

The Joint Meeting on Pesticide Residues (JMPR) is an expert body, administered jointly by FAO and WHO, whose primary task is to provide scientific advice on pesticide residues in food, such as establishing an ADI or ARfD and recommending MRLs, to the Codex Committee on Pesticide Residues.

An exposure assessment must be completed in order to determine whether the MRL and the underlying GAP are acceptable on public health grounds. The dietary intake of a pesticide residue is calculated by multiplying the residue level in the food by the amount of the food consumed. Total dietary intake is calculated by summing these products for all foods containing the residue of interest. The estimated dietary intake of the residue should be less than the established ADI.

The NOAEL is usually based on the most sensitive toxicological parameter in the most sensitive species of experimental animal. The safety factor for pesticide residues takes into account the type of effect, the severity or reversibility of the effect, and problems of inter-species and intra-species variability in establishing an ADI for humans. In 1996, the Joint Meeting for Pesticide Residues (see Box 30) considered the significance of interactions of pesticides. It concluded that while interactions were possible, the outcome of these factors could not be reliably predicted given the dependence of these interactions on many factors. In view of these uncertainties, JMPR concluded that the safety factors used to establish the ADI should provide sufficient margin of safety to account for potential synergies. JMPR generally uses safety factors of 100.

The risk characterization step in a pesticide residue risk assessment is slightly different from that in a food additive safety assessment. Because the actual residue levels in most foods are well below the corresponding MRLs, a Theoretical Maximum Daily Intake (TMDI) is used to separate residues of no concern for long-term intake from those that require further consideration. The TMDI is an overestimate of the true pesticide residue intake. When the TMDI is compared to the ADI for a person of 60 kg (or other appropriate size), values less than one indicate it is highly unlikely that even high intake consumers will exceed the ADI. However, because of the conservative bias inherent in the TMDI, a TMDI in excess of the ADI does not 'prove' that the MRL for the proposed residue is unacceptable.

An Estimated Daily Intake (EDI) can be used to obtain a better estimate of the actual residue intake when appropriate information is available. International Estimated Daily Intakes (IEDI) and National Estimated Daily Intakes (NEDI) can be prepared for use by risk managers.

Comparisons of the EDI and the ADI are similar in nature to the comparisons carried out for food additive safety assessment. An EDI is measured as mg/kg of body weight daily for a lifetime.

An Acute Reference Dose (RfD) has been developed for pesticide residues to assess acute hazards associated with short-term exposure to acutely toxic residues, using the same basic principles and methods used to derive the ADI. A NOAEL is established for acute effects and an appropriate safety factor is applied. Subgroups of populations are sometimes considered for acute exposures.

Annex 5: Risk Assessment for Genetically Modified Foods of Plant Origin

Introduction

Biotechnology has been used to genetically modify foods to increase production, improve nutrient content and/or produce better processing and storage characteristics. The food safety considerations for genetically modified foods are similar in nature to those that might arise from conventional breeding. Concern about the potential risks posed by certain aspects of biotechnology focuses on the effects on human and animal health. For instance, there is anxiety about the risks of transferring toxins from one life form to another, of creating new toxins or of transferring allergenic compounds from one species to another, which could result in unexpected allergic reactions. Given this concern, there is a need to develop a scientific approach to:

- objectively address concerns for the biosafety of each product or process prior to its release;
- evaluate possible effects on food safety;
- determine the extent to which the benefits of the product or process outweigh the assessed risks; and
- carefully monitor the post-release effects of these products and processes to ensure their continued safety to people.

The general risk assessment model presented in this Manual cannot be applied directly to the risk analysis of genetically modified foods since there is not necessarily a chemical or microbial hazard in the food. Rather, it is the whole food itself that is of potential concern. Whole food risk assessment is a very new concept and there this little agreement on how it is best performed. Whole food risk assessment currently includes a safety assessment designed to identify a hazard, nutritional or other concern present in a food derived from biotechnology.

Codex has developed principles and guidelines to conduct food safety assessments of genetically modified foods[13].

- CAC. 2003. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology Codex Alimentarius Commission (CAC). CAC/GL 44-2003.
- CAC. 2003. Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants. Codex Alimentarius Commission (CAC). CAC/GL 45-2003.
- CAC. 2003. Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms. Codex Alimentarius Commission (CAC). CAC/GL 46-2003.

[13] These principles and guidelines are available on the Internet at: http://www.codexalimentarius.net/web/standard_list.do?lang=en

Assessing safety based on substantial equivalence

The concept of substantial equivalence was first introduced into the discussion of safety evaluation of food from genetically modified organisms (GMOs) in 1993. It has subsequently been adopted in many countries as a basis for safety evaluation of a new food. Substantial equivalence means that a genetically modified plant, or food derived from one, is equivalent to its conventional counterpart and can be treated in the same manner with respect to safety as the conventional counterpart. Establishment of substantial equivalence is not a safety assessment in itself, but a dynamic, analytical exercise in the assessment of the safety of a new food relative to an existing food. The assessment of the safety of GMOs must address both intentional and unintentional effects that may result as a consequence of the genetic modification of the food source.

Although there is still discussion about the exact methodology to perform substantial equivalence, it is understood to include a comparison of the genetically modified food and its conventional counterpart. This comparison identifies the differences and similarities between the genetically modified food and its conventional counterpart. It attempts to account for the intended and unintended effects of the genetic modification by identifying new or altered hazards, as well as any other changes relevant to human health in key nutrients of the food. The comparison should take place as close to the species level as possible. It should, at a minimum, examine molecular characterization, phenotypic characteristics, key nutrients, toxins and allergens.

The safety assessment to determine substantial equivalence in a genetically modified food considers a number of factors related to the food including:

- Identity
- Source
- Composition
- Effects of processing and/or cooking
- Transformation process
- Recombinant DNA (stability of insertion; potential for gene transfer)
- Protein expression of the novel DNA
- Effects on function
- Potential toxicity
- Potential allergenicity
- Possible secondary effects from gene expression or the disruption of the host DNA or metabolic pathways (including compositions of critical macro- and micro-nutrients, anti-nutrients, endogenous toxicants, allergens and physiologically active substances)
- Potential intake and dietary impact of the introduction of the genetically modified food

If the available data are insufficient for a safety assessment, animal testing may be deemed necessary. The safety assessment is usually determined on a case-by-case basis and, consequently, there is no such thing as a ‘typical’ safety assessment.

Three outcomes are possible from a safety assessment to determine substantial equivalence in a genetically modified food. The products analysed can be shown to be:

i. Substantially equivalent to existing foods or food components

Products, which are demonstrated to be substantially equivalent to an existing counterpart are regarded as being as safe as that counterpart, and no further safety considerations than for the counterpart are necessary.

ii. Substantially equivalent to existing foods or food components except for defined differences

When a food product is determined to be substantially equivalent to an existing counterpart except for defined differences, it is concluded that further safety assessment should focus only on those defined differences.

iii. Not substantially equivalent to existing foods or food components

Until now, there have been few, if any, examples of foods or food components produced using genetic modification which could be considered to be not substantially equivalent to existing foods or food components. Lack of equivalence does not mean a food is unsafe. Rather, it means that its safety cannot be established on the basis of a comparison with a conventional food.

Annex 6: Plant Pest Risk Assessment

Introduction

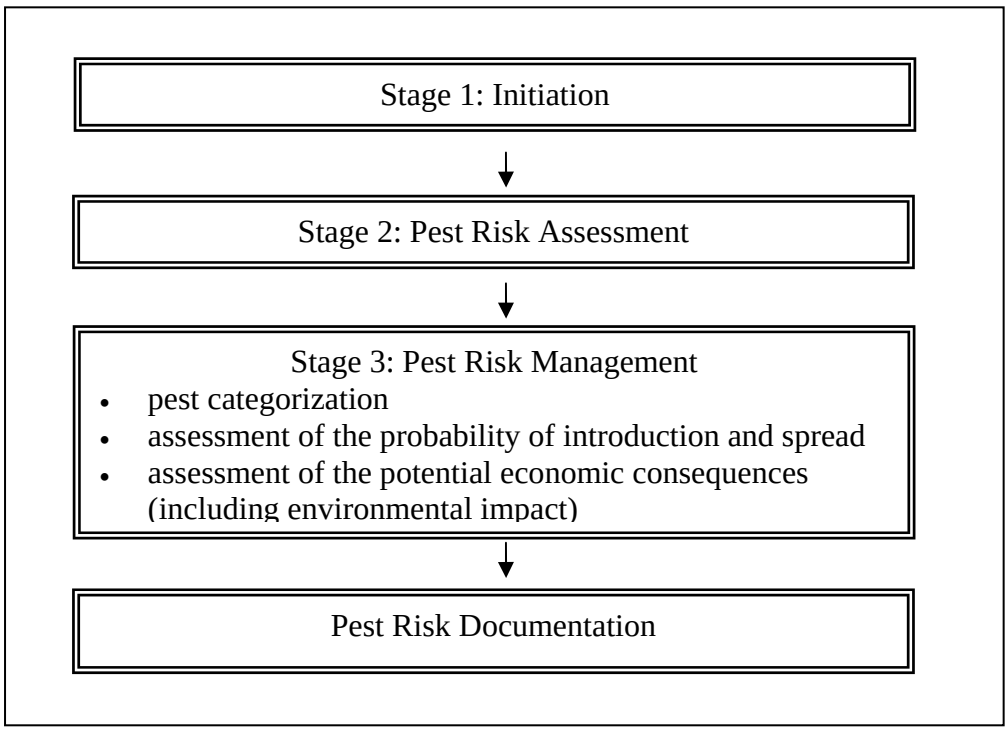
Plants can be threatened by pests, diseases or disease-causing organisms. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) enables countries to restrict trade in order to protect plant life and health (phytosanitary), as well as human or animal life and health (sanitary). The International Plant Protection Convention (IPPC) is a multilateral treaty for international cooperation in plant protection with more than one hundred contracting parties. It seeks to ensure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control in accordance with the SPS agreement.

Both the IPPC and the SPS Agreement call on members to base their phytosanitary legislation on transparency, minimal impact, non-discrimination, harmonization of measures, equivalence and scientific evidence. The IPPC's scope extends to plant pests that include: diseases and weeds, plants, plant parts, unprocessed plant products, storage places, conveyances and containers, and other objects or materials capable of harbouring or spreading pests.

Model for pest risk assessment

Pest risk assessment provides a process to evaluate biological/scientific and other economic evidence to determine whether a pest should be regulated and, if so, to establish the strength of any phytosanitary measures to be taken against it. The IPPC model for pest risk analysis (see Figure 11) differs from the Codex model introduced earlier in this Manual.

Figure 11: Model for pest risk analysis (IPPC)



Various international standards for phytosanitary measures exist including:

- Guidelines for pest risk analysis (International Sanitary and Phytosanitary Measure 2)
- Pest risk assessment for quarantine pests (International Sanitary and Phytosanitary Measure 11)
- Guidelines for assessing environmental hazards
- Pest risk assessment for living modified organisms
- Pest risk assessment for regulated non-quarantine pests

Initiation

The purpose of the initiation stage is to identify the pest(s) and pathways of quarantine concern that will be considered for risk analysis. The pest risk assessment (PRA) process may be initiated as a result of:

- the identification of a pathway that presents a potential pest hazard;
- the identification of a pest that may require phytosanitary measures; or,
- the review or revision of phytosanitary policies and priorities.

At the end of Stage 1, the pests and pathways of concern and the PRA area will have been identified. Relevant information is collected from any combination of official sources, databases, scientific and other literature, or expert consultation.

Pest risk assessment

At the outset of the pest risk assessment it may not be clear which pest(s) identified in Stage 1 require a PRA. The pest categorization process examines for each pest whether the criteria in the definition for a quarantine pest are satisfied. Quarantine pest categorization includes the following primary elements:

- identification of the pest;
- its presence or absence in the PRA area;
- its regulatory status;
- its potential for establishment and spread in the PRA area;
- its potential for economic consequences (including environmental consequences) in the PRA area.

An assessment of the probability of introduction and spread of a pest of quarantine concern comprises an assessment of both the probability of entry and the probability of establishment. Assessing the probability of introduction requires an analysis of each of the pathways with which a pest may be associated from its origin to its establishment in the PRA area. The probability of entry of a pest depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. The higher the number of pathways, the greater the probability of the pest entering the PRA area. In order to estimate the probability of establishment of a pest, reliable biological information (life cycle, host range, epidemiology, survival, and the like) should be obtained from the areas where the pest currently occurs. The situation in the PRA area can then be compared with that in the areas where it currently occurs

(taking account also of protected environments such as glass- or greenhouses) and expert judgement can be used to assess the probability of establishment.

Assessing the probability of spread of a quarantine concern pest is based primarily on biological considerations similar to those for entry and establishment. Examples of the factors to consider are:

- Suitability of the natural and/or managed environment for natural spread of the pest
- Presence of natural barriers
- The potential for movement with commodities or conveyances
- Intended use of the commodity
- Potential vectors of the pest in the PRA area
- Potential natural enemies of the pest in the PRA area.

Whenever possible in the assessment of potential economic consequences, quantitative data that provides monetary values should be obtained. In many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences, including environmental consequences.

Pest risk management

In the third stage, managers decide whether risk management is required and the strength of measures to be used. Because zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources. The uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option.

Documentation

The whole process of pest risk analysis should be adequately and transparency documented so that when a review or a dispute arises, the sources of information and rationale used in reaching the management decision can be clearly demonstrated. The IPPC requires countries to make available, on request, the rationale for their phytosanitary requirements. Documentation should include information on the following:

- Purpose of the PRA
- Pest, pest list, pathways, PRA area, endangered area
- Sources of information
- Categorized pest list
- Conclusions of risk assessment
- Probability
- Consequences
- Risk management
- Options identified
- Options selected

Annex 7: Animal Health Risk Assessment

Introduction

In addition to risk assessments for food and food products, risk assessment can also be performed for animal health. Importing animals and animal products involves a degree of disease risk to the recipient country. Import risk analysis therefore enables importing countries to assess, in an objective and justifiable way, the disease risks associated with the importation of animals, animal products, animal genetic material, feed stuffs, biological products and pathological material.

The World Organization for Animal Health (OIE) is recognized by the SPS Agreement as the international organization responsible for the development and promotion of international animal health standards, guidelines and recommendations affecting trade in live animals and animal products.

Steps in an animal import risk analysis

The components of an animal import risk analysis, as defined by the OIE, are similar to the components of risk assessment described earlier in this Manual:

1. Hazard identification
2. Risk assessment
3. Risk management
4. Risk communication

Hazard identification, which precedes the risk assessment in the OIE model, identifies the pathogenic agents that could produce adverse consequences associated with the importation of a commodity. The importing country should identify which potential hazards are already present in the importing country. The evaluation of the veterinary services, surveillance and control programmes, zoning and regionalization systems of the exporting country are important to assessing the likelihood of hazards being present in an animal population. An importing country may decide to permit importation based on the appropriate sanitary standards recommended in the International Animal Health Code, thus eliminating the need for a risk assessment.

Risk assessment estimates the risk(s) associated with a hazard. For many diseases, there are well-developed, internationally agreed upon standards and broad agreement concerning the likely risks. In such cases it is more likely that a qualitative assessment is all that is required.

According to OIE procedures, risk assessment has four steps: i) release assessment, ii) exposure assessment; iii) consequence assessment; and iv) risk estimation[14]. A release assessment describes the biological pathway(s) necessary for an imported animal or animal product to release or introduce pathogenic agents into a particular environment, and includes a qualitative or quantitative estimate of the probability. The exposure assessment describes the biological pathway(s) necessary to expose animals and humans in the importing country to the pathogenic agents released from a given risk source. It also estimates the probability of exposure to the

[14] OIE. 2004. Guidelines for import risk analysis. *In* Chapter 1.3.2 of the International Animal Health Code (available at: http://www.oie.int/eng/normes/mcode/en_chapitre_1.3.2.htm).

identified hazards with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation or insect bite), and the number, species and other characteristics of the animal and human populations exposed.

Consequence assessment describes the adverse health or environmental consequences, which may in turn lead to socio-economic consequences that can result from the evaluated exposures. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. Risk estimation integrates the results of the release assessment, exposure assessment and consequence assessment to produce an overall measure of the risks associated with the hazards identified at the outset of the risk analysis. A quantitative risk estimate might include one or more of the following elements: estimated numbers of herds, flocks, animals or people likely to experience health impacts of various degrees of severity over time; probability distributions, confidence intervals, and other means for expressing the variance of the risk estimation output; and a sensitivity analysis to rank the inputs as to their contribution to the uncertainties in these estimates.

Risk management is the process of deciding upon and implementing measures to achieve the member country's appropriate level of protection, while at the same time ensuring that negative effects on trade are minimized. The objective is to manage risk appropriately to ensure that a balance is achieved between a country’s desire to minimize the likelihood or frequency of disease incursions and their consequences, and its desire to import commodities and fulfil its obligations under international trade agreements. The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards. The analysis should be transparent so the exporting country can be provided with clear evidence-based reasons for the imposition of import conditions or the refusal to import.

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