

## 3. Risk Assessment

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

### 3.1. Introduction

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

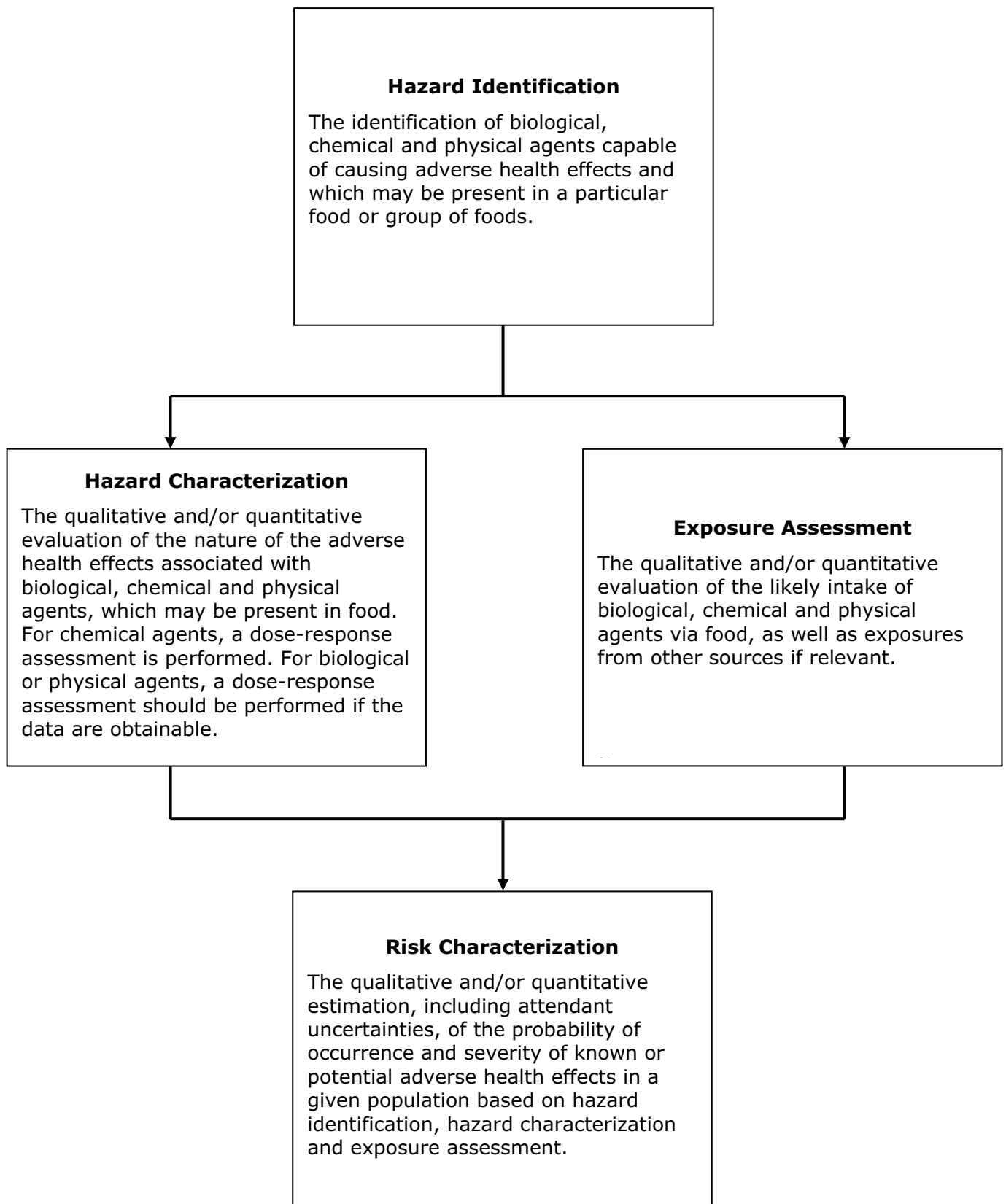
**Box 3.1. Examples of direct use of a risk profile to establish food safety standards**

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

**3.2.1. Risk assessment**

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

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



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

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

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

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

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

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

### 3.2.2. Use of ranking tools

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

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

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

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

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

### **3.2.3. Epidemiology**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.5.1.1. Hazard identification

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

3.5.1.2. Hazard characterization

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



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

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

#### 3.5.1.3. Exposure assessment

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

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

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

#### 3.5.1.4. Risk characterization

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

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

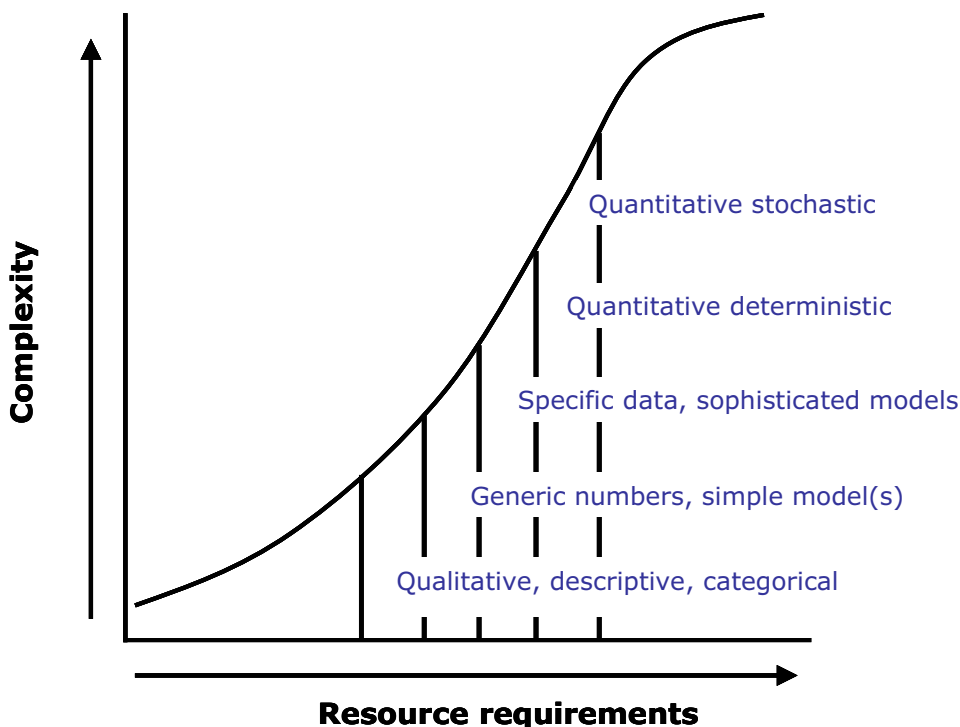
### 3.5.2. Qualitative or quantitative?

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

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

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

Figure 3.2. Continuum of risk assessment types



#### 3.5.2.2. Stochastic (probabilistic) approaches

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### 3.5.3.3. Exposure assessment

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

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

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

#### 3.5.3.4. Risk characterization

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

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

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

#### 3.5.3.5. Application of toxicological guidance values

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

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

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

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

#### 3.5.4.1. Hazard identification

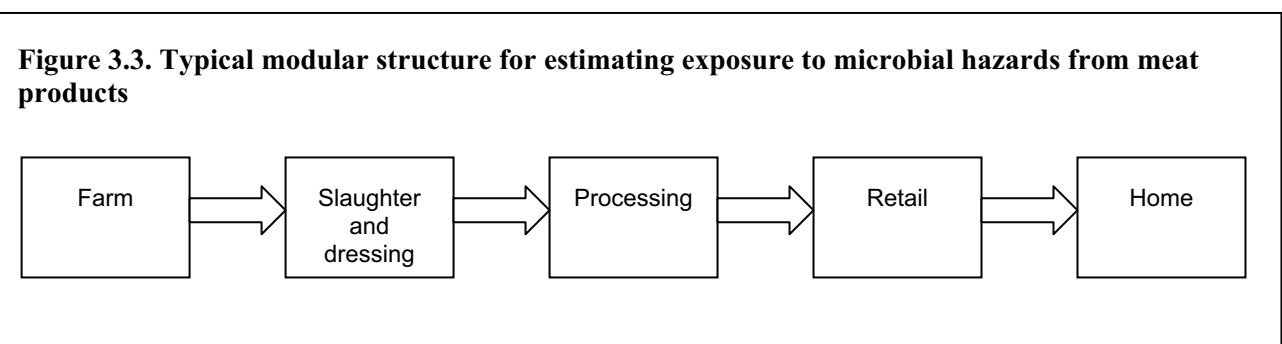
A wide range of biological hazards can cause food-borne illness. Long-familiar hazards include microbes, viruses, parasites and toxins of biological origin, but new hazards are continually being identified, such as *E. coli* O157:H7, the prion agent of BSE, and multi-

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

#### 3.5.4.2. Hazard characterization

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

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



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

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

#### 3.5.4.3. Exposure assessment

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

#### 3.5.4.4. Risk characterization

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

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

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

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

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

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

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

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

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

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

### **3.5.6. Sensitivity analysis**

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

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

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

### **3.5.7. Validation**

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

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

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

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

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

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

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

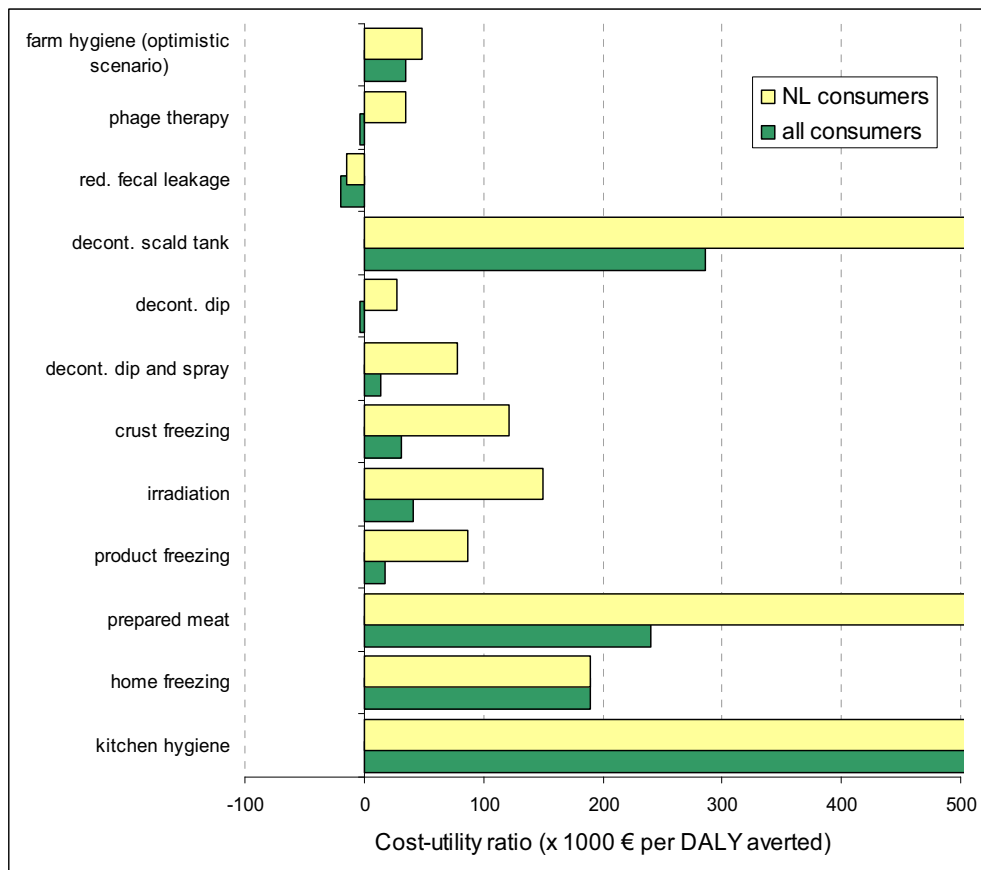
As both risk assessment and economic assessment suffer from uncertainty, there are real benefits in integrating the two disciplines to gain more realistic descriptions of the consequences of decisions that may be made by risk managers. The common element is being able to create a single matrix for decision-making.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

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



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

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



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

### 3.7. Suggestions for further reading

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<http://www.who.int/ipcs/publications/jecfa/en/index.html>
- JEMRA: [http://www.fao.org/ag/agn/jemra/riskassessment\\_en.stm](http://www.fao.org/ag/agn/jemra/riskassessment_en.stm)  
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## 4. Risk Communication

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

### 4.1. Introduction

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

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

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

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

## 4.2. Understanding risk communication

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

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

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

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

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

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

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

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

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

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

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

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

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

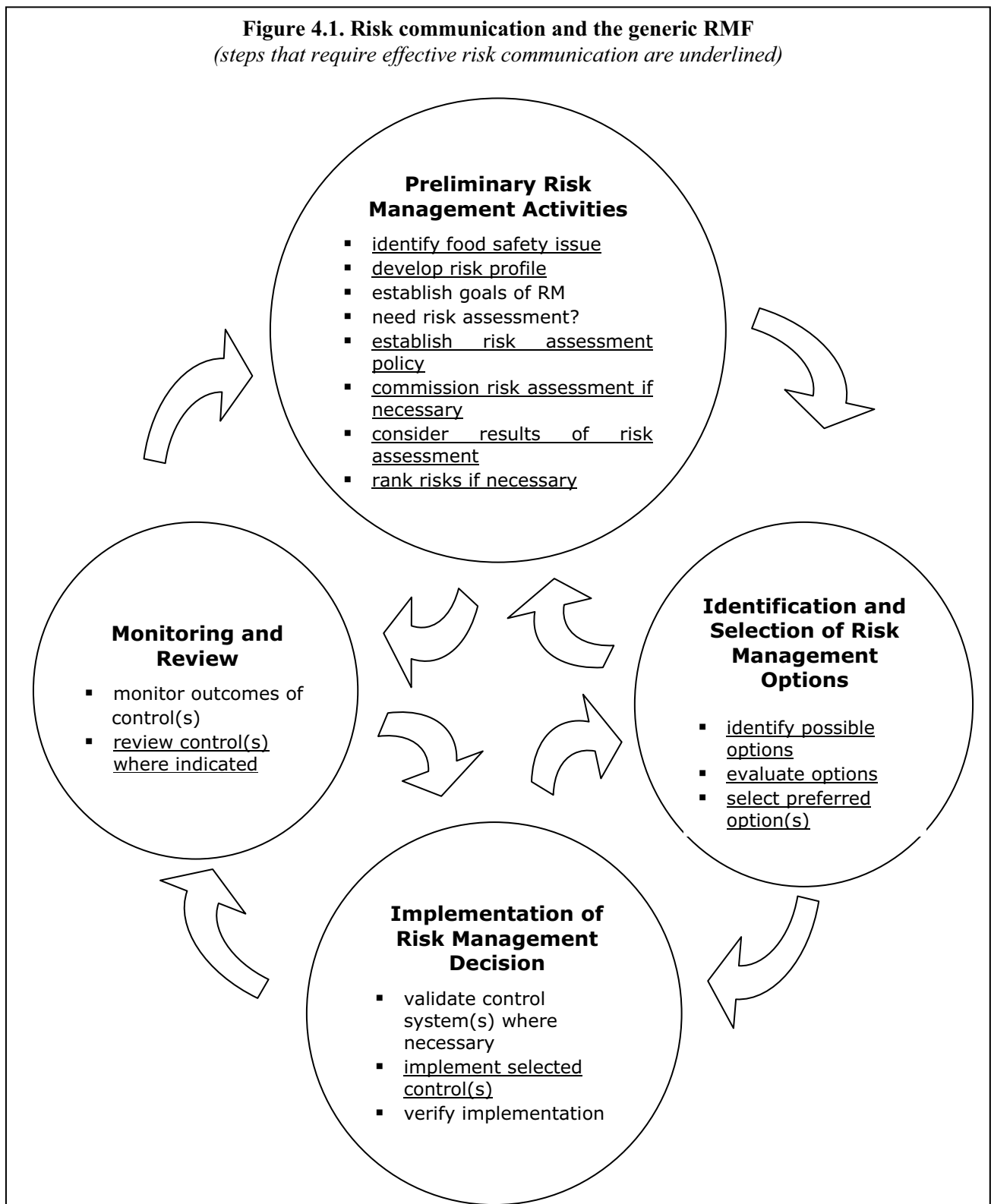
#### ***4.3.3. Establishing risk management goals***

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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



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

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

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

**4.3.8. Ranking risks and setting priorities**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### ***4.3.10. Implementation***

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

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

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

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

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

## 4.4. Some practical aspects of risk communication

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

### 4.4.1. Goals of communication

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

#### 4.4.4. *Methods and media for communication*

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

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

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

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

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

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

#### 4.5. **Suggestions for further reading**

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



1998. FAO Food and Nutrition Paper No. 70 (available at: <http://www.fao.org/DOCREP/005/X1271E/X1271E00.htm#TOC>).

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

**Joint Institute for Food Safety and Applied Nutrition.** Web site of the Food Safety Risk Analysis Clearinghouse. A joint project between the University of Maryland and the United States Food and Drug Administration. Collection of resources related to food safety risk communication (available at: [http://www.foodrisk.org/risk\\_communication.cfm](http://www.foodrisk.org/risk_communication.cfm)).

**National Research Council.** 1989. *Improving Risk Communication*. Washington, DC: National Academy Press.

**National Research Council.** 1996. *Understanding Risk: Informing Decisions in a Democratic Society*. Washington, DC: National Academy Press.

**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.

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

**University of Maryland.** Food safety risk communication primer. Available on the web site of the Joint Institute for Food Safety and Applied Nutrition (see above).

**WTO.** 2002. Operating the SPS Enquiry Point. Chapter 4 in *How to Apply the Transparency Provisions of the SPS Agreement. A handbook*. WTO Secretariat (available at: [http://www.wto.org/english/tratop\\_e/sps\\_e/spshand\\_e.pdf](http://www.wto.org/english/tratop_e/sps_e/spshand_e.pdf)).

## **Annex 1: Glossary**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **HACCP**

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

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

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

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

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

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

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

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

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

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

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

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

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

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## **Sources**

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

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

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

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

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

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

## Annex 2: Case Study of Methylmercury in Fish

### Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

## **Risk Assessment**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **Risk communication aspects**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

### Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

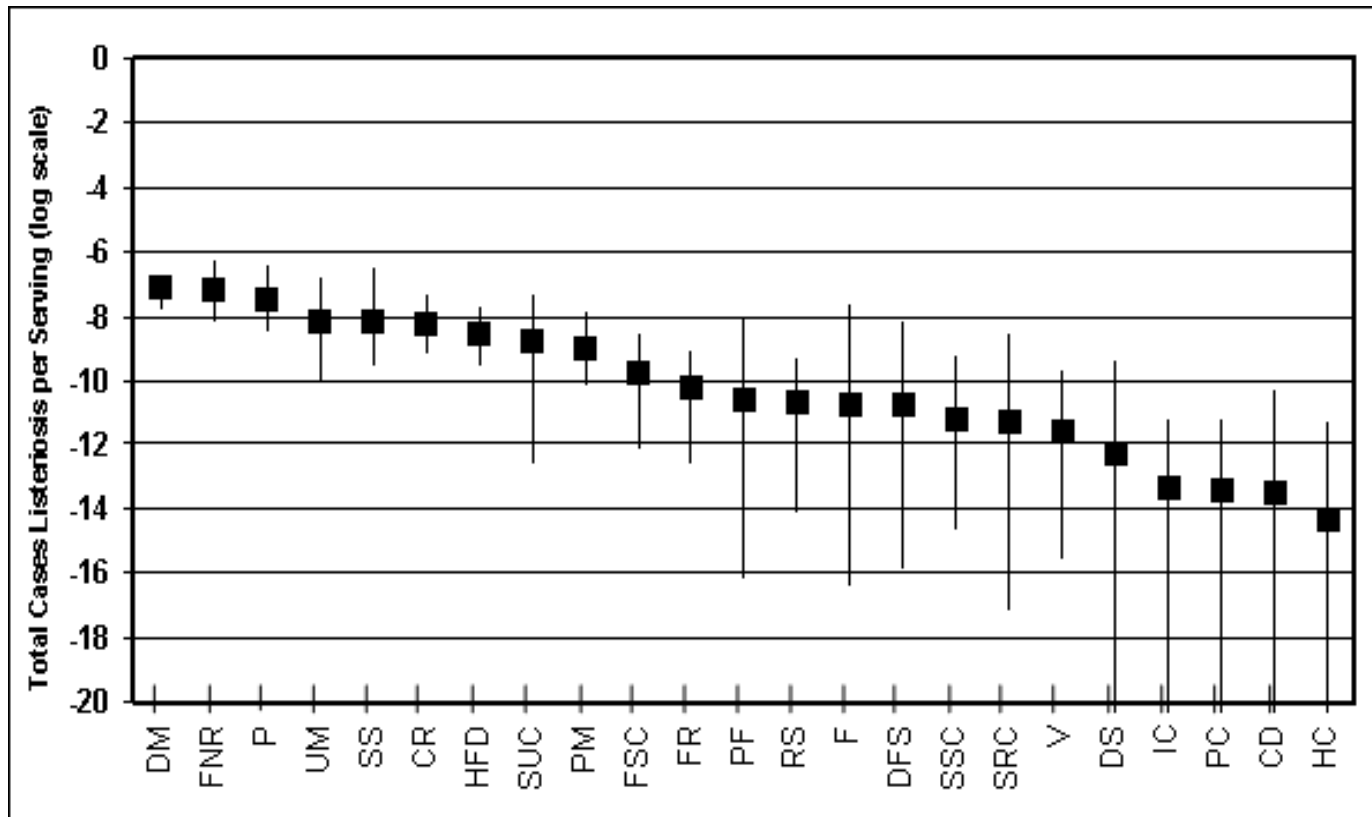
**Risk characterization:** Individual food category data and the dose-response model were used to estimate the number of cases of illness per serving and per year for each food category and each population group. This allowed foods to be ranked according to two different measures of relative risk. An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

**Step 8: Rank risks**

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **Risk communication**

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

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



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

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

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

## FAO TECHNICAL PAPERS

### FAO FOOD AND NUTRITION PAPERS

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Risk analysis offers a tool that national food safety authorities can use to make significant gains in food safety. Encompassing three major components (risk management, risk assessment and risk communication), risk analysis provides a systematic, disciplined approach for making food safety decisions. It is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied. Risk analysis can support and improve the development of standards, as well as address food safety issues that result from emerging hazards or breakdowns in food control systems. It provides food safety regulators with the information and evidence they need for effective decision-making, contributing to better food safety outcomes and improvements in public health. FAO and WHO have developed this guide to assist food safety regulators' understanding and use of risk analysis in national food safety frameworks. The primary audience is food safety officials at the national government level. The publication provides essential background information, guidance and practical examples of ways to apply food safety risk analysis. It presents internationally agreed principles, a generic framework for application of the different components of risk analysis and wide-ranging examples rather than prescriptive instructions on how to implement risk analysis. It complements and is aligned with other documents that have been produced or are being developed by FAO, WHO and the Codex Alimentarius Commission. This guide is the first of a two-part set. The second part will comprise a number of educational elements for capacity building, and include a slide presentation for use in training, a collection of up-to-date FAO and WHO tools and training materials related to food safety risk analysis, and specific examples and case studies of risk analysis carried out at the national and international level. Both parts will also become available on CD-ROM.

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