UNIT 7 RISK ASSESSMENT

Structure

7.0 OBJECTIVES

After studying this unit, we shall be able to:

- describe risk assessment in the context of SPS agreement;
- define key terms related to key risk assessment terms;

- explain scientific approaches for assessing risk;
- describe generic Codex risk assessment framework;
- identify general characteristic of risk assessment; and
- explain basic components of risk assessment.

7.1 INTRODUCTION

Risk assessment can generally be described as assessment of intensity and frequency of the potential adverse effects to life and health resulting from exposure to hazards over a specified time period. It is well recognized internationally that increased scientific, legal and political demands are being made on the standards, guidelines and other recommendations elaborated by international setting organizations like Codex Allementrius Commission. This is, in part, due to increased consumer interest in food safety, the WTO's SPS and TBT Agreements, harmonization initiatives, calls for increased scientific rigour and the need for transparency. To respond to these increasing demands, the greater application of risk assessment in the standard decision-making process is essential. Risk assessment is the central scientific component of risk analysis and has evolved primarily because of the need to make decisions to protect health with the available scientific knowledge and prevailing scientific uncertainty. Risk management and risk assessment are separate but closely linked activities, and ongoing, effective communication between those carrying out these separate functions is essential. As described in Unit 6, risk managers applying the risk management framework must decide whether a risk assessment is possible and necessary. If this decision is affirmative, risk managers commission and guide 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. 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 7.7.1), 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[1] and economics are likely to be most useful to risk managers trying to integrate and balance risks and benefits.

7.1.1 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 study material 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 necessary and scientifically justified.
- 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 is the essence of the explanation of a "risk-based standard" presented in Unit 6 (Box 6.8).

7.1.2 Relative Positions of Risk Assessment and Risk Management

The place occupied by risk assessment during an application of the risk management framework by risk managers is described in Unit 6. Although risk managers commission and guide the risk assessment and evaluate its outputs, the risk assessment itself is generally an external product, independently produced by scientists.

7.2 DEFINITIONS RELATED TO RISK ASSESSMENT

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Risk assessment policy: given in Unit 6.

Risk profile: given in Unit 6.

Risk characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk estimate: The quantitative estimation of risk resulting from risk characterization.

Hazard identification: The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

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

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

7.3 PRINCIPLES OF FOOD SAFETY RISK ASSESSMENT

Principle 1- Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

Principle 2- Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.

Principle 3- There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach.

Principle 4- Risk assessment should use available quantitative information to the greatest extent possible and risk characterizations should be presented in a readily understandable and useful form.

Check Your Progress Exercise 1

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) Define the following term as per Codex
   - Hazard identification
   - Hazard Characterization
   - Dose response Assessment
   - Exposure Assessment

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2) Enumerate various general principles of food safety risk assessment?

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7.4 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 6.4.1, Step 3). While this unit is focused on risk assessment as an input to the risk management framework, 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 Section 7.1.3) cannot be realized in such scenarios; nevertheless, choices to apply other scientific approaches are likely to be reasonable and appropriate in their own right.

It is important to recognize that a range of approaches can lead to a risk based standard. This brings flexibility to the issue of the level of risk assessment rigour needed in low-risk situations.

In developing an approach to use of risk assessment methodology, the risk management framework process should always include a risk profile of some sort. In applying the risk management framework, risk managers may directly use the information in the risk profile to identify and select food standards. Present example(s) 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 given below. 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.

Example 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.

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 *Listeria 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 *Listeria 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 directly 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 for further information.

7.4.1 Risk Assessment

Risk assessment incorporating, in one way or another, the four analytical steps described by Codex (see Fig. 7.1) is the main focus of this unit. The way those steps are applied differs somewhat for microbiological and chemical hazards. 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.

In contrast, for chemical hazards, "safety evaluation[3]" is a standard risk assessment methodology. 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 7.8.6

[3] 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.

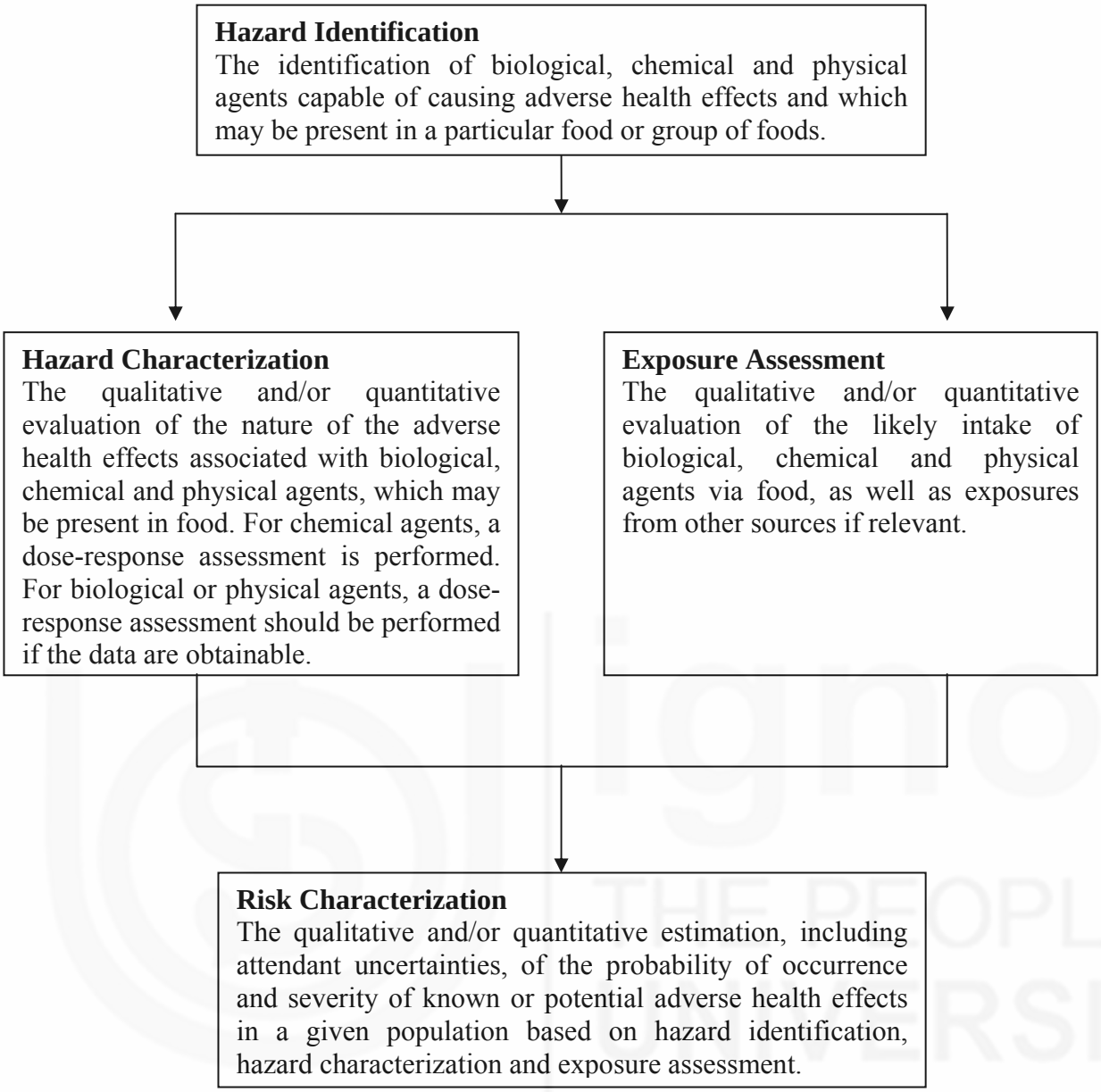

Fig. 7.1: Generic Description of the Components of Risk Assessment

7.4.2 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 (given below). 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 record, and food user sub-population.

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.

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.

7.4.3 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 (see given below). The usefulness of epidemiology depends on the availability of data.

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 *Escherichia 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, travelers, 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.

7.4.4 Combination of Approaches

Distinctions are drawn in this Unit 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.

7.5 RESPONSIBILITIES OF RISK MANAGERS IN COMMISSIONING AND GUIDING A RISK ASSESSMENT

The decision to proceed with a risk assessment is to be taken by risk managers based 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, and
- 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, and
- there is a need to verify that an interim (or precautionary) regulatory response to an urgent food safety problem is scientifically justified.

Risk managers, in consultation with risk assessors, should fulfil several tasks when commissioning a risk assessment and seeing it through to completion (given below) as per steps given below.

General responsibilities of risk managers in commissioning and guiding 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:
  - identify food safety issue including purpose and scope of the risk assessment;
  - prepare risk profile;
  - develop questions that need to be addressed by the risk assessment;
  - establish a risk assessment policy; and
  - specify form of the outputs of the risk assessment.
- Risk managers should ensure that sufficient time and resources are available to complete the risk assessment.

7.5.1 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. A large-scale risk assessment generally requires a multidisciplinary team that may include, as appropriate, experts with biological, chemical, food technology, epidemiological, medical, statistical and modelling skills, among others.

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.

Risk managers need to take care to ensure that the assembled team satisfies the general criteria that require that the team is:

- objective, balanced in terms of scientific perspectives;
- free from undue biases and conflicts of interest; and
- free from potential financial or personal conflicts of interest that could bias an individual's scientific judgment.

7.5.2 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). 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 (see Unit 5, Section

5.3.3) and other pre-existing scientific efforts on relevant subjects before they commission new work). 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.

7.5.3 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 given below. The questions asked by the risk managers can have an important influence on the choice of risk assessment methodologies used to answer them.

Examples of questions to be addressed by risk assessors

In the example of Campylobacter in broiler chickens used in Unit 6, risk assessors could be asked to address any of the following questions:

- Quantify relative impacts of specified food safety controls for *Campylobacte*r 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 per cent?).
- 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).

While risk assessment is fundamentally an objective, scientific activity, it inevitably contains some elements of policy and subjective scientific judgment. For example, when scientific uncertainty is encountered in the risk assessment, gaps in scientific knowledge are 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. Below

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.

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.

7.5.4 Specification of Form of the Outputs

Outputs of a risk assessment may be sought in non-numerical (qualitative) or numerical (quantitative) form (see also Section 7.7.2). 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 (see Section 7.6.5) and are presented as a distribution reflecting more real-life situations.

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

7.5.5 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.

Check Your Progress Exercise 2

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) State various basis used in risk ranking tools? Give one example using any of these basis.

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2) What are the specific tasks of risk managers while commissioning risk assessment?

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3) Who is responsible for ensuring sufficient resources in terms of time and funds for carrying out risk assessment?

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7.6 GENERAL CRITERIA OF RISK ASSESSMENT

Irrespective of the context, risk assessments generally share a number of basic criteria (given below). 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 criteria 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.

General criteria 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 interactive 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.

7.6.1 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.
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, and
- where possible, make assessments available to the public for comment.

7.6.2 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. 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 Unit 6). In such cases, particular attention should be

devoted to ensuring that the risk assessment meets the criteria. Communication between risk assessors and risk managers is also a critical element in the process, as described in more detail in Unit 8.

7.6.3 Structured Process

Risk assessments should follow a structured and systematic process; see Section 7.7 on risk assessment methodology.

7.6.4 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 (given below). 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 (see Unit 5, Section 5.3.3). These assessments are also used by risk assessors and risk managers at the national level.

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 (see Unit 8, Section 8.5.1).

* 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.

7.6.5 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.

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 (given below).

Examples of uncertainty and variability in risk assessments

- ***Methylmercury in fish:*** 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 Tolerable Daily Intake (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 Provisional Tolerable Weekly Intake (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 food:*** 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.

The risk estimate should, wherever possible, include a numerical expression of uncertainty, and this must be conveyed to risk managers by the risk assessors in a readily understandable form so that the full implications of the range of uncertainty can be included in decision-making.

7.6.6 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 approaches and other judgements have been used can yield useful insights.

Check Your Progress Exercise 3

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) What are the general characteristics of risk assessment?

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2) State various sources which can be used for scientific information for risk assessment?

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3) How risk assessment can be more transparent?

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7.7 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.

Differences in risk assessment methodology are most apparent for chemical compared with microbiological hazards (see Section 7.4.1). This is partly due to intrinsic differences between the two classes of hazards (given below). 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. Use of these chemicals can be regulated or restricted suitably so that residues at the point of consumption do not result in risks to human health. Microbial hazards, in contrast, are very common 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.

Some characteristics of microbial and chemical hazards that influence the choice of risk assessment methodology

Microbial Hazard	Chemical Hazard
• Hazards can enter foods at many points from production to consumption.	• Hazards usually enter foods in the raw food or ingredients, or through certain processing steps (e.g. acrylamide or packaging migrants).
• The prevalence and concentration of hazard changes markedly at different points along the food production chain.	• The level of hazard present in a food after the point of introduction often does not significantly change.
• Health risks are usually acute and result from a single edible portion of food.	• Health risks may be acute but are generally chronic.
• Individuals show a wide variability in health response to different levels of hazard.	• Types of toxic effects are generally similar from person to person, but individual sensitivity may differ.

7.7.1 Basic Components of a Risk Assessment

The risk assessment process is generally represented as consisting of four steps, described by Codex (see Fig. 7.1 in section 7.4.1 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.

a) **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 Unit 6); 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.

b) **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.

c) **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 heat treatment, and cross-contamination at the time of final preparation for consumption may add to the complexity of the evaluation.

d) **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 Unit 6, Section 6.6.5). 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 7.8.4 below).

7.7.2 Qualitative or Quantitative?

Risk assessment outputs can range from qualitative (non-numerical) to quantitative (numerical) with various intermediate formats (see Fig. 7.2). 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.

Factors influencing the type of risk assessment undertaken: The most common factors which are considered by risk managers (see Fig. 7.2) before deciding the type of risk assessment to be carried out are (a) time available; (b) resources; (c) resolution of out put. Essentially, the good risk assessment is one that answers the risk questions within these constraints- i.e. it is fit for purpose.

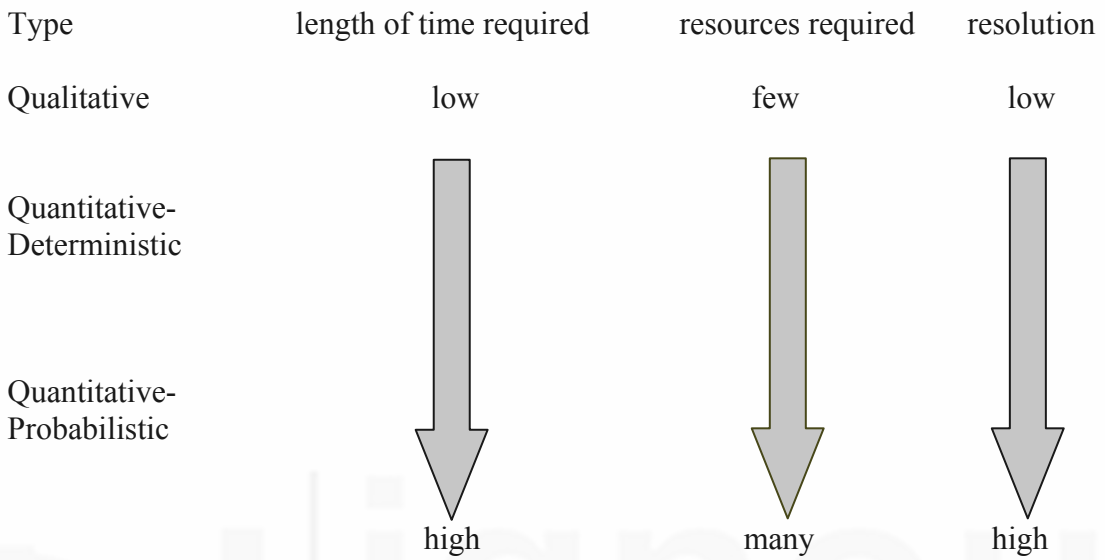

Fig. 7.2: Illustrations of the Factors that Influence that Decision to Undertake a Particular Type of the Risk Assessment

7.8 RISK ASSESSMENT FOR CHEMICAL HAZARDS

Chemical hazards in foods include food additives, environmental contaminants such as lead, mercury and dioxins, natural toxicants in food, such as glycol alkaloids in potatoes and aflatoxins in peanuts, acrylamide, and residues of pesticides and veterinary drugs. Adverse health effects are usually predicted for long-term exposure to chemicals. For certain chemicals, such as some mycotoxins, marine toxins, pesticides and veterinary drugs, both acute and chronic health effects need to be considered.

7.8.1 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.

7.8.2 Hazard Characterization

Hazard characterization describes and evaluates dose-response relationships for the most critical 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 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.

7.8.3 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. 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. Such point estimates are referred to as deterministic models. Some exposure models are emerging, such as for intake of pesticide residues, that takes 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. If the level of exposure as determined by the exposure assessment is lower than the ADI or TDI, the chemical in foods is within safe limits.

7.8.4 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." 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.

7.8.5 Application of Toxicological Guidance Values

Toxicological guidance values can be Acceptable Daily Intake (ADI) for food additives, pesticides and veterinary drugs, and Tolerable Daily Intake (TDI), Provisional Tolerable Weekly Intake (PTWI) and Provisional Tolerable Monthly Intake (PTMI) for other contaminants.

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.

7.9 RISK ASSESSMENT FOR BIOLOGICAL HAZARDS

Biological hazards are generally assessed in terms of a single exposure resulting in an acute health risk[4]. 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.

7.9.1 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 *Escherichia 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.

7.9.2 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.

7.9.3 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 (Fig. 7.3).

[4] Note that many natural toxins such as mycotoxins and marine toxins need insight into biology as well as chemistry for their risk assessment.

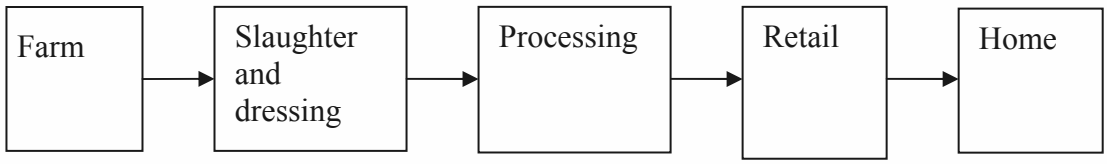

Fig. 7.3: Typical Modular Structure for estimating Exposure to Microbial Hazards from Meat Products

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.

7.9.4 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. 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. Due to this, 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.

7.10 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.

7.11 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 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.

7.12 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.

7.13 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 Unit 6. Developing and evaluating specific, quantitative microbiological metrics, such as performance objectives and performance criteria were described in Unit 6, and these can be can be incorporated in regulations.

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

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

Check Your Progress Exercise 4

Note: a) Use the space below for your answers.
b) Check your answers with those given at the end of the unit.

1) How various characteristics of hazards influence choice of risk assessment methodology?

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2) Describe various components of risk assessment?

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3) How hazard characterization is carried out for chemical hazards?

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7.14 LET US SUM UP

Risk assessment is the scientific foundation of risk analysis. This Unit 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 guiding 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.

7.15 KEY WORDS

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

Exposure Assessment : The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

Hazard Characterization : The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Hazard Identification : The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Risk Characterization : The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk Estimate : The quantitative estimation of risk resulting from risk characterization.

7.16 ANSWERS TO CHECK YOUR PROGRESS EXERCISES

Your answer should include following points:

Check Your Progress Exercise 1

1)
- ***Hazard Identification***: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.
- ***Hazard Characterization***: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.
- ***Dose-Response Assessment***: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).
- ***Exposure Assessment***: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

2)
- ***Principle 1-*** Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.
- ***Principle 2-*** Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.
- ***Principle 3-*** There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach.
- ***Principle 4-*** Risk assessment should use available quantitative information to the greatest extent possible and risk characterizations should be presented in a readily understandable and useful form.

Check Your Progress Exercise 2

1) Risk arising out of type of food, type of food preparation, type of business, compliance record, and food user subpopulation are ranked based on their

severity. For more details may see details given in section 7.4.2. Example of risk ranking tools.

2) a) Forming the risk assessment team
   b) Specification of purpose and scope
   c) Questions to be addressed by risk assessors
   d) Establish risk assessment policy
   e) Specification of forms of outputs
   f) Time and resources

3) Risk manager is responsible for providing necessary time and resources for carrying out risk assessment.

Check Your Progress Exercise 3

1)
- 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.

2)
- 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.

3)
- 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.

Check Your Progress Exercise 4

1) The most common characteristics of microbial and chemical hazards that effect the choice of risk assessment are:
   a) The point of entry of hazard in food chain.
   b) The changes in level of hazard during processing.
   c) Whether the hazard has acute or chronic effect on health.
   d) Response factor in human due to presence of hazard.

2) a) Hazard identification
   b) Hazard characterization
   c) Exposure assessment
   d) Risk characterization

3) Details of hazard characterization as described in Section 7.8

7.17 SUGGESTED READING

European Food Safety Authority. 2006. *Transparency in Risk Assessment carried out by EFSA: Guidance Document on Procedural aspects*. EFSA Journal (2006) 353, 1-16 (available at: http://www.efsa.europa.eu/en/science/sc_commitee/sc_documents/1494.html).

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).

FAO/WHO. 2002. *Risk assessments of Salmonella in eggs and broiler chickens*. Microbiological Risk Assessment Series, No. 2 (available at: ftp://ftp.fao.org/docrep/fao/005/y4392e/y4392e00.pdf).

FAO/WHO. 2003. *Hazard Characterization for Pathogens in Food and Water*. *Guidelines* Microbiological Risk Assessment Series, No. 3 (available at: ftp://ftp.fao.org/docrep/fao/006/y4666E/y4666E00.pdf).

FAO/WHO. 2004. *Risk Assessment of Listeria Monocytogenes in Ready-to-eat Foods*. Technical Report. Microbiological Risk Assessment Series, No. 5 (available at: http://www.fao.org/ag/agn/jemra/listeria_report_en.stm).

FAO/WHO. Risk Assessments Reports and Other Publications of JECFA, JEMRA and JMPR are available on the FAO and WHO websites:

JECFA: http://www.fao.org/ag/agn/jecfa/index_en.stm

http://www.who.int/ipcs/publications/jecfa/en/index.html

JEMRA: http://www.fao.org/ag/agn/jemra/riskassessment_en.stm

http://www.who.int/foodsafety/micro/jemra/en/index.html

JMPR: http://www.fao.org/ag/agp/agpp/pesticid/

http://www.who.int/ipcs/publications/jmpr/en/