Recent Approaches in Risk Assessment of Foods

Farhana Masood, Samira Umme Aiman, Sana Khan, Showkat Ahmad Lone, and Abdul Malik

Abbreviations

ICMSF	International Commission on Microbiological Specification for Foods
MRM	Microbial Risk Management
SPS	Sanitary and Phytosanitary Measures
CCFH	Codex Committee and Food Hygiene
CAC	Codex Alimentarius Commission
USNACMCF	United States National Advisory Committee on Microbiological Criteria for Foods

1 Introduction

The objective of ensuring safe food for the World's constantly growing population has been a major preoccupation of governments, international organizations (e.g. WHO/FAO CODEX, ILSI, ISO, ICMSF, etc.) and professional and trade bodies over many years. Yet, in deprived areas of the world, there remains a basic need to ensure a reliable and safe food supply. In all countries, especially in developed consumer-oriented countries, the need is to ensure that foods do not present an unacceptable risk to the health and well being of the consumer. Throughout the world, the law imposes a duty of care and responsibility for the safety and quality of foods on those business organizations involved in the procurement, processing, distribution, and retail sale of the products. A risk analysis framework provides a

F. Masood • S.U. Aiman (✉) • S. Khan • S.A. Lone • A. Malik
Faculty of Agricultural Sciences, Department of Agricultural Microbiology,
Aligarh Muslim University, Aligarh 202002, India
e-mail: samiraummeaiman@gmail.com

A. Malik et al. (eds.), *Food Processing: Strategies for Quality Assessment*,
Food Engineering Series, DOI 10.1007/978-1-4939-1378-7_11

process to systematically and transparently collect, analyse, and evaluate relevant scientific and non-scientific information about a chemical, biological, or physical hazard possibly associated with food in order to select the best option to manage that risk based on the various alternatives identified.

1.1 Components of Risk Analysis

As a structured decision-making process, risk analysis includes three distinct but closely connected components: risk management, risk assessment, and risk communication (Fig. 1). Each of these components plays an essential and complementary role in the risk analysis process. Although, risk management and risk communication tended to receive less attention than risk assessment in the past, it is important to stress that risk analysis will only be effective when all three components are successfully integrated.

Risk analysis is a process consisting of three components: risk assessment, risk management, and risk communication. Risk assessment is scientifically based process and focus on estimating the risk that hazardous event or factor will negatively affect a population or subpopulation and consisting of the following steps: (1) hazard identification; (2) hazard characterization; (3) exposure assessment; and (4) risk characterization. Risk management is the process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering

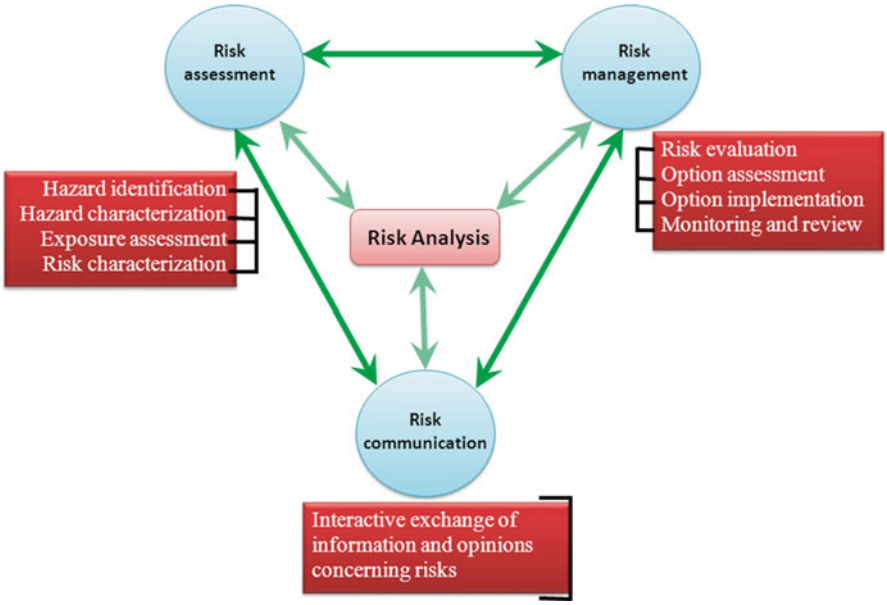

Fig. 1 Components of risk analysis

risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate implementation of prevention and control options. Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

1.2 The Risk Analysis Process

Risk analysis focuses important factors that would enhance protection of human health and minimize the incidence of food-borne diseases through establishing control of food-borne hazards and framing food safety policies and its practical application. Risk analysis provides food safety regulators with the information and evidence they need for effective decision-making. The process normally begins with risk management, which, as a first step, defines the problem, articulates the goals of the risk analysis and defines the questions to be answered by the risk assessment. The science-based tasks of 'measuring' and 'describing' the nature of the risk being analysed (i.e. risk characterization) are performed during the risk assessment. Risk management and assessment are performed within an open and transparent environment based on communication and dialogue. Risk communication encompasses an interactive exchange of information and opinions among risk managers, risk assessors, the risk analysis team, consumers, and other stakeholders. The process often culminates with the implementation and continuous monitoring of a course of action by risk managers.

1.2.1 Essential Characteristics of Risk Analysis

Risk analysis is an iterative and ongoing process in which steps are repeated when needed. The process does not end once a decision is reached. Members of the risk analysis team regularly monitor the success and impact of their decision. Modifications are made as required—on the basis of new data or information or changes in the context of the problem—to achieve further reductions in adverse human health effects. It requires open and effective internal and external communication. Risk managers must interact and communicate frequently with risk assessors and other members of the risk analysis team (internal communication), as well as many different types of stakeholders (external communication) as often as needed.

Risk management has been defined as 'the process, distinct from risk assessment, of weighing policy alternatives, in the light of risk assessment in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed,

selecting appropriate prevention and control options (Codex). Risk management therefore plays a key role at the beginning of the risk analysis process in identifying food safety problems and considering the best ways to manage them. The consideration of different policy alternatives is a critical part of risk management. This requires a focus on the scientific aspects of the risk (i.e. the detail and the outcome of the risk assessment) as well as any associated economic, legal, ethical, environmental, social, and political factors that are important to people. Risk management is not a linear process. Like the rest of risk analysis, risk management is an iterative process. Therefore, any model for risk management should be flexible enough to enable the various activities to be reviewed, repeated, and adapted as necessary.

2 Food Safety Objectives and Risk Assessment

It confers appropriate level of protection, sanitary, and phytosanitary measures that should be adapted to protect human, animal, and plant life or health. Modern approaches to food safety include the identification of actual, or potential, hazards from microbial contamination, assessing the risk that such contamination may cause disease in the consumer, and then seeking to employ processes that will control and minimize such risks. '*Hazard*' can be defined as something that has the *potential* to cause harm, for instance the contamination of food by pathogenic bacteria. '*Risk*' is defined as the *likelihood* of harm in a defined situation; for instance, consumption of food contaminated with specific pathogenic microorganisms and/or their toxins. *Risk assessment* of foods is therefore concerned with assessing the potential risk that consumption of a food may cause harm to consumers. As is amply demonstrated by ICMSF (2002), risk assessment requires an understanding of microbial contamination per se and also that both food process operations and domestic food handling practices may reduce or increase the risk from a defined hazard for a defined group of consumers (infants, children, the aged, the immuno-compromised, etc.).

The International Commission on Microbiological Specifications for Food (ICMSF) introduced the concept of '*Food Safety Objectives*' (FSOs) that was adopted subsequently by CODEX (CCFH) as part of its MRM document. An FSO provides a means to convert public health goals into parameters that can be controlled by food producers and monitored by government agencies. It is defined (ICMSF 2002) as, '*the maximum frequency and/or concentration of a microbial hazard in a food considered tolerable for consumer protection*'. ICMSF (2002) notes that FSOs are '*typically expressions of concentrations of microorganisms or toxins at the moment of consumption*'. Concentrations at earlier stages of the food chain are considered to be performance criteria. Hence, an FSO seeks to take account of hazards arising both during commercial processing and from unpredictable effects associated with retail and domestic food storage and handling. By contrast, performance criteria relate to the requirement to control hazards at earlier stages of the food chain. So, the FSO is defined as '*the maximum likely level of hazard that is acceptable*' following the integration of several stages in food processing, based on knowledge of microbial associations of foods, processing hurdles

(Leistner and Gould 2001; ICMSF 2005) which may result in death or inhibition of microorganisms and of the likelihood of re-contamination and/or re-growth of organisms during subsequent storage and handling. Thus the FSO concept relates also to the use of the Hazard Analysis and Critical Control Point (HACCP) concept for controlling the effectiveness of food processing operations.

CODEX has now published a Guide for National Food Safety Authorities (Anon 2006) that explains the whole concept of Food Safety Risk Analysis. This report covers all aspects of risk assessment for foods including providing guidance on the four stages of a risk management procedure. Microbiological risk assessment is based on the use of 'quantitative *microbiological metrics*' as a risk management option. 'Quantitative metrics' is defined as the '*quantitative expressions that indicate a level of control at a specific step in a food safety risk management system … the term 'metrics' is used as a collective for the new risk management terms of food safety objective (FSO), performance objective (PO) and performance criteria (PC), but it also refers to existing microbiological criteria'*.

2.1 Understanding Risk Assessment

Codex defines risk assessment as a scientifically based process consisting of four steps: (1) hazard identification; (2) hazard characterization; (3) exposure assessment; and (4) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

Several aspects of this definition are important to highlight. Firstly, risk assessment is a systematic and science-based process, which involves four major steps. Secondly, risk assessment explicitly addresses uncertainty (i.e. what is not known about the risk) in a logical, transparent, and well-documented manner that is clearly indicated to everyone involved in the risk analysis process. Finally, risk assessment can be descriptive or narrative, qualitative, semi-quantitative, or quantitative. Both qualitative and quantitative risk assessments are important in different circumstances and there is nothing inherently superior or inferior about either.

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

Quantitative risk assessment is based on numerical data and analysis. It can be deterministic (e.g. food additive safety assessment) or probabilistic (e.g. microbial risk assessment). Quantitative risk assessments should describe uncertainty in numerical terms with uncertainty distributions determined by various statistical methods. A quantitative risk assessment can address risk management questions at a finer level of detail than a qualitative risk assessment. There is no one way to perform a food safety risk assessment. Different models for food safety risk assessment

exist and the process will vary according to the type of risk, the model used, and the questions to be answered. Indeed, in some cases (e.g. when the risk management response is obvious and acceptable to all the parties concerned or when there is insufficient data), it may either be unnecessary or impossible to perform a full risk assessment according to Codex guidelines.

2.1.1 Hazard Identification

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

2.1.2 Hazard Characterization

During hazard characterization, risk assessors develop a complete profile of the nature and extent of the adverse health effects associated with the identified hazard. The impact of varying amounts of the hazardous material on human health can be considered quantitatively (in a dose–response relationship) and/or qualitatively in a narrative fashion (Table 1).

2.1.3 Exposure Assessment

The exposure assessment provides scientific insight on the presence of the hazard in the product(s) consumed. It combines information on the prevalence and concentration of the hazardous material in the consumer's food supply and environment and the likelihood that the consumer will be exposed to various quantities of this material in their food. Information on the prevalence and concentration of the hazard could

Table 1 Examples of hazards

Biological	Chemical hazards	Physical hazards
Bacteria	Naturally occurring toxins	Metal, machine filings
Toxin-producing micro-organisms	Direct and indirect food additives	Stones
Moulds	Pesticide residues	Glass
Parasites	Residues of veterinary drugs	Insect parts
Viruses	Chemical contaminants	Jewellery
Other biological hazard		Tools

include estimates of the number of pathogens in a serving of food or the amount of a food additive consumed daily by a representative consumer. Depending on the nature of the problem, exposure assessment takes into account the relevant production, storage, and handling practices along the food chain.

2.1.4 Risk Characterization

During risk characterization, all the evidence from the previous three steps is combined in order to obtain a risk estimate (i.e. an estimate of the likelihood and severity of the adverse health effects that would occur in a given population with associated uncertainties) and respond to the questions posed by the risk managers. In general, the risk characterization includes a summary description of the consequences of exposure to the hazard, as well as an estimate of the likelihood of the adverse consequences of interest in a risk estimate. The outputs of a risk characterization should clearly identify important data gaps, assumptions, and uncertainties in order to help risk managers judge how close the characterization might come to describing reality. Risk characterization rarely gives more than a reasonable estimate or an informed view of the risk in reality.

2.2 Chemical and Microbial Risk

Food safety risk assessments are undertaken in response to identified chemical or microbial risks to human health. Chemical risk assessments focus on the presence of chemicals such as food additives, food contaminants, or residues of veterinary drugs. Some chemicals, such as food additives and colourings, are deliberately added to food in small amounts to make food look or taste better, to maintain or improve nutritive value, to help processing or preparation, to maintain freshness, or to help preserve food (direct additives). In addition, indirect additives or 'contaminants' can enter food accidentally during handling, processing (through equipment), or packaging (through migration) or can be generated through chemical processes in the food itself ('chemical reaction'). Technical aids used in primary production (such as pesticides or veterinary drugs) can also remain as residues in food products. As the number of direct and indirect additives to food has increased, so too has public concern about the type and amount of these additives and their potential to cause cancer or other illnesses in people. A microbial risk assessment evaluates the likelihood of adverse human health effects occurring after exposure to a pathogenic microorganism or to the medium in which the organism occurs. The hazard in microbial risk assessment is fundamentally different from the hazard in a chemical risk assessment. In particular, the hazard in a microbial risk assessment is alive, which reorients the focus of the risk assessment significantly. One of the most unique aspects of a living hazard is that the levels of pathogen in a food can change radically over time. Most microbial hazards can grow, decline or die many times before a food is consumed (Table 2).

Table 2 Characteristics of microbial and chemical hazards

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

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

3 Techniques Used in Food Safety Risk Assessment

Food safety risk assessment must be based on sound scientific evidence. Food safety regulators must have access to appropriate scientific data, information, and expertise in order to assign a risk assessment. Depending on the nature of the hazard and circumstances in which it occurs, various scientific experts (including biologists, chemists, medical experts, geneticists, epidemiologists, toxicologists, microbiologists, agronomists, botanists, entomologists, zoologists, and others) may be involved. The exact combination of analytical tools and techniques used in qualitative and quantitative risk assessment will vary according to the specific context and type of the risk assessment. In order to apply these techniques and perform risk assessment, certain basic infrastructure (including laboratories, scientific equipment, technology, and research facilities) will be essential.

3.1 Statistical Techniques

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

assessment. Knowledge of the following basic techniques is required for successful risk assessment:

- Descriptive statistical techniques to extract useful information from scientific data and evidence
- Inferential statistical techniques to obtain information about populations from samples
- Different statistical tests to establish the most likely explanation of the observed phenomena

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

3.2 Probability

Probability encompasses variability and uncertainty, both of which are always present in the context of food safety risk assessment. Risk assessors need a good command of basic probability concepts and techniques, including the ability to make basic probability calculations, in order to perform most kinds of quantitative risk assessment. Probabilistic risk assessment also requires a solid understanding of probability distributions and their characteristics since variability and uncertainty are both frequently described using probability distributions.

3.3 Monte Carlo Process

The Monte Carlo process has been applied to a large range of complex problems that involve random behaviour. It is a procedure that generates values of a random variable based on one or more probability distributions. It has been used extensively in microbial risk assessment and is increasingly being applied in other types of quantitative risk assessments, e.g. for intake assessment of chemicals in food. The Monte Carlo process encompasses two steps: (1) a random number is generated over the [0,1] interval (2) that number is transformed into a useful value using a probability distribution specified by the individual responsible for the model.

3.4 Probabilistic Scenario Analysis

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

values and how those input variables are related. Probabilistic scenario analysis is used to generate different scenarios and undertake a probabilistic analysis of the most likely scenarios and their outcomes. The worst-case scenario is often used in deterministic risk assessment. Scenarios can and have been considered deterministically. However, because of the extent of variability and uncertainty in the world, it is often difficult to identify the full range of possible outcomes of any risk management decision with just a few carefully circumscribed scenarios. It is not unusual for a probabilistic scenario analysis to combine several different tools such as an event tree and the Monte Carlo Process. Probabilistic scenario analysis has been used in most of the quantitative microbial risk assessments completed to date.

3.5 Knowledge Elicitation Techniques

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

Knowledge elicitation techniques are used to reveal expert knowledge in these circumstances and help to make expert opinions as evidence-based as possible. A wide variety of techniques can be used to elicit knowledge from experts and improve the quality and transparency of the knowledge gathering process. Traditional methods include the Delphi method, the nominal group approach, scenario analysis, scientific heuristics, rational consensus, indirect elicitation, the direct method, parametric estimation, self-scoring, collective scoring, surveys and questionnaires, interviews, and case studies. Many new knowledge elicitation techniques have been developed in recent years. These include cognitive approaches, contextual approaches and ethnography.

3.6 Ranking Tools

Ranking is a common technique in qualitative risk assessment. Ranking helps risk assessors to prioritize risks. Various kinds of ranking techniques exist. The multicriteria decision-making literature is rich in methods to rank and sort problems. However, other simpler techniques can also be useful. For instance, criteria and their subjective weights can be used to sort and rank various alternative options. The choices of criteria and weights should be based on as much scientific evidence as possible to make the process as evidence based as possible.

3.7 Sensitivity Analysis

A good risk assessment uses sensitivity analysis to clearly identify and address uncertainty. Sensitivity analysis enables managers to understand how answer(s) to question(s) might change under different conditions or assumptions. It helps risk assessors to systematically investigate and discover which variables have the greatest influence on the outcomes of the risk assessment. A sensitivity analysis can illuminate the option assessment process for risk management by identifying those inputs with the greatest positive and negative effects on outcomes. Complex risk assessments may have dozens of input and output variables that are linked by calculations, systems of equations, assumptions, and so on. Risk assessors and risk managers must understand the relative importance of the various components of a risk assessment and the influence of these variables on the results of the risk assessment. Some outcomes and decisions are sensitive to minor changes in assumptions and input values.

A good sensitivity analysis will aid the risk assessment by revealing the most important variables in the assessment. It will provide insight into the conditions that contribute the most to good and bad outcomes. Once the key inputs are identified, assessors can focus their attention on addressing the uncertainty in these variables or carefully describing their variability. Therefore, sensitivity analysis helps to focus an assessor's attention on the most important inputs. Many different sensitivity analysis techniques exist. One popular approach uses parametric variation of the values of input variables to examine its effects on one or more output variable.

4 Characteristics of a Good Risk Assessment

A good risk assessment helps food safety regulators and other officials to make transparent, science-based decisions about a food safety risk. It improves the quality of the decision-making process and informs the decision for which it was prepared. In general, risk assessments should be as simple as possible whilst meeting the risk manager's needs and should strive to balance greater detail and complexity (e.g. through addressing more questions or alternative scenarios) against having to include the greater set of assumptions that this would entail because more assumptions decrease the reliability of the conclusions. Codex Guidelines (CAC 1999) for microbiological risk assessment contains a list of general principles of microbiological risk assessment, including that:

- Risk assessment be objective and soundly based on the best available science and presented in a transparent manner
- Constraints that affect the risk assessment, such as cost, resources or time, be identified and their possible consequences described
- Microbiological risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be the output

- 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 be specifically considered
- Data should be such that uncertainty in the risk estimate can be determined
- Data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized
- MRA should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment and Risk Characterization

4.1 Risk Characterization Measures

In assessing food-borne microbiological risks we are principally concerned about the effect of the identified hazard on human health, of which there are a number of possible results from exposure to microbiological pathogens. In any specific individual, there may be no effect, or no measurable effect. However, to be considered a pathogen, there must be possible an adverse health effect in at least a proportion of the exposed population as a result of ingestion of the pathogen or its toxins. Adverse health effects from exposure to pathogens include illnesses of varying severity (morbidity) and duration, ranging from mild self-limiting illness to those requiring hospitalization, or leading to chronic diseases, through to death (mortality). To date, risk assessments have tended to measure risks of microbiological food poisoning or infection as a direct result of exposure to food contaminated with pathogens or their toxins. In population terms, however, the development of asymptomatic carriers of the pathogen may also be classified as an adverse health effect, since this may lead to multiplication, excretion, and spread of the organism, eventually causing illness or death in others (i.e. secondary spread). In addition, there may be adverse health effects of interest specifically at the population level, for example epidemics and pandemics. Risks estimates can be made on an individual risk basis, e.g. risk of illness per serving, or on a population basis, e.g. 'cases per annum'. While the Codex risk assessment framework focuses on severity and probability of disease, measures to compare disease severity are required. The burden of disease can be measured in terms of individual or national economic loss, if required, via probable numbers of days or years of working life lost, cost of treatment, etc. However, the measurement of loss of quality of life is harder to quantify, although various attempts have been made, resulting in the concept of equivalent life years lost through specific types of disability, pain, or other reduced quality of life. This allows the comparison of one health state with another and with mortality itself. Thus it is possible to quantify the adverse health effect of any occurrence in terms of life year equivalents lost and estimate the risk of this from any specified source. Integrated health measures provide information to put diverse risks into context.

There are many potential adverse health effects that a risk manager might be interested in, in addition to those about which the affected individual is directly concerned. This, in turn means that there are many possible ways to measure and express the magnitude of the risk (sometimes called the 'risk metric') that might be selected as the required output from a risk assessment. The selection of the particular measure of risk to be used is therefore not necessarily straightforward and must be discussed between the risk manager, the risk assessor, and other interested stakeholders. In addition, for quantitative modelling, the unit or units required must be defined whilst taking into account the practical aspects of modelling so that the outputs can be produced and reported in those units. Various types of probability models and studies of risk issues have been labelled as 'risk assessments'. FAO/WHO, OIE, and other guidelines advocate decision-making based on a risk assessment. Codex risk assessment guidelines and recommendations have legal significance in terms of what satisfies the food safety risk assessment requirements under the WTO Sanitary and Phytosanitary (SPS) Agreement. Thus, it is of both technical and legal importance to be able to determine whether a particular piece of work can be categorized as a risk assessment.

4.2 Risk Assessment Approaches

This section describes three categories of work that are often labelled 'risk assessment' and discusses when each type of study conforms to the necessary requirements. The three approaches are presented as examples, and other approaches to risk assessment are possible. No 'correct' approach can be recommended or specified: the choice of approach depends on the risk assessment question, the data and resources available, etc. The three categories considered are:

- Estimating an unrestricted or baseline risk
- Comparing risk intervention strategies
- Research-related study or model

4.2.1 Estimating 'Unrestricted Risk' and 'Baseline Risk'

An 'unrestricted risk' estimate is the level of risk that would be present if there were no safeguards; and a 'baseline risk' estimate is the current, standard or reference status, i.e. the point against which the benefits and costs of various intervention strategies can be compared. The concept of unrestricted risk has been most widely used in import-risk analysis, in which it has more obvious utility. A common and practical starting point for a risk assessment is to estimate the existing level of risk, i.e. the level of food safety risk posed without any changes to the current system. This risk estimate is most frequently used as the baseline risk against which intervention strategies can be valued, if desired. This baseline risk may, for example, have utility in determining an Appropriate Level of Protection (ALOP). Using the current risk as a baseline has a

number of advantages, among them being that it is the easiest to estimate the effect of changes by estimating the magnitude of the risk after the changed conditions relative to the existing level of risk, i.e. it may obviate the need to explicitly quantify the risk level under either scenario. This approach implicitly accepts the starting point of any risk management actions as being changes to the current system. For some purposes, a baseline other than the existing level of risk might be used as a point of comparison. For example, the baseline risk could be set as that which would exist under some preferred (e.g. least costly) risk management approach and the risk under alternative approaches compared with that.

Estimation of an unrestricted risk, i.e. the level of risk that would be present if no deliberate actions were taken to control the risk, sometimes referred to as inherent risk, may have a role in determining the efficacy of existing microbiological food safety risk management approaches compared with entirely new systems. Over time, as knowledge of the causes of infectious diseases grew, many controls to minimize food-borne illness have been implemented at the level of both consumers and the industry. While it is difficult to imagine being able to realistically assess the risk level in a hypothetical world where all those controls were removed, the principle is valid and takes as its point of departure a 'raw' risk that has been identified, and now quantified, and for which there are many combinations of options to choose from to control the risk. It would, in principle, enable reassessment of what combination of controls (both those in place and new possible interventions) would give the most efficient protection. In practice, one can attempt to estimate a risk where some of the more obvious, and perhaps more costly, interventions currently in place are removed, and then re-evaluate how to address the risk. Using the current risk level as the point of comparison does not encourage one to review the many layers of risk reduction activities that are already present and have evolved over time in the absence of monitoring to evaluate their efficacy and to improve their efficiency. For example, control measures introduced before good information existed about a problem might be expected to be highly conservative. With improved knowledge, better targeted approaches could possibly be devised to deliver the same health protection with fewer disadvantages to consumers or producers.

Estimating a baseline or unrestricted risk may not be for the immediate purpose of managing the risk so much as to measure or bound the severity of a food safety problem. Whilst in theory it may not be necessary to determine a baseline risk in order to evaluate intervention strategies, it is nonetheless almost always carried out in practice.

4.2.2 Comparing Risk Management Strategies

Risk assessment is commonly undertaken to help risk managers understand which, if any, intervention strategies can best serve the needs of food safety, or if current risk management actions are adequate. Ideally, agencies with responsibility for safety of foods would consider all possible risk management interventions along the food chain without regard to who has the authority to enact them, and this objective

has led to the creation of integrated food safety authorities in many nations and regions. A farm-to-table model may be most appropriate for this purpose. In practice, however, the scope of the assessment may be limited to those sections of the food chain within the risk manager's area of authority, but a more comprehensive risk assessment might identify relationships outside that area of authority that would motivate the risk manager to seek the new authority required to intervene effectively or to request others with authority to take appropriate actions. For some risk questions, analysis of epidemiological data or a model of part of the food chain may be adequate. In some cases it is possible to estimate the change in risk without producing an estimate of the baseline risk, but caution must be used in these cases. For example, a risk assessment might determine that it is technically feasible to reduce a particular risk 100-fold, but if this risk was negligible at the start, then reducing it 100-fold may not be a worthwhile course of action.

The 'proximity' of a risk is commonly considered in risk analysis applied to management of large construction projects, and in certain circumstances will also be an important factor in food safety risk assessment if unplanned or uncontrolled factors could be expected to change the risk over time, e.g. the increase in average age of populations in many nations is expected to increase overall population susceptibility to many disease, including food-borne diseases, leading to increased incidence. In other situations the risk may be seasonal, or arise only after natural disasters, or be linked to some specific event involving a very large gathering of people, etc. 'Proximity' describes the period or interval of time during which the risk might affect the stakeholders. A natural tendency is to focus on risks that are immediate when we may have a limited ability to manage them: assessing risks that could arise in the future might enable risk management steps to be implemented at a fraction of the cost of that for an emergency response when the risk has been realized.

4.2.3 Research-Related Study or Model

It has already been stated that risk assessment is a decision tool, not a scientific or research tool. Some research-based risk assessments have been produced with the intention of expanding our knowledge and tools for evaluating risks. They may be based on hypothetical or on genuine decisions questions and evaluate the assessment results according to how they respond to those questions. However, they are not always initiated by a 'risk manager'. There are a number of large microbiological food safety models in existence that have been initiated as academic exercises. These models have helped advance the field of microbiological risk assessment by allowing us to see what techniques are necessary, developing new techniques, and stimulating research that can now be seen to have value within a risk assessment context. In some situations, those models have subsequently been used by risk managers to assist in risk management decisions. Such models have also made apparent the changes in collection and reporting methods for microbiological, epidemiological, production, dietary, and other data that would make the data more useful for risk assessment. Early experience with microbiological risk assessments has proven

these assessments to be valuable in aiding our understanding of complex systems. The very process of systematically investigating a food chain has contributed to our ability to both appreciate and understand the complexity of the systems that make up the food chain.

The importance of matching the type of risk assessment to its purpose has been emphasized previously. The USA National Advisory Committee on Microbiological Criteria for Foods noted (USNACMCF 2004): 'Risk assessments can be quantitative or qualitative in nature, but should be adequate to facilitate the selection of risk management options. The decision to undertake a quantitative or qualitative risk assessment requires the consideration of multiple factors such as the availability and quality of data, the degree of consensus of scientific opinion, and available resources'.

5 Assessing the Reliability of the Results the Risk Assessment

Every risk assessment has some degree of uncertainty attached to its results. Complying with all the requirements of transparency, of describing model and parameter uncertainties, and all the explicit and implicit assumptions, does not necessarily communicate to risk managers the degree of confidence that the risk assessor has in the results of the risk assessment or limitations in its application. Thus, risk assessors must explain the level of confidence they feel should be attached to the risk assessment results. All assumptions should be acknowledged and made explicit in a manner that is meaningful to a non-mathematician. For example, it would be insufficient to say that 'illnesses were assumed to follow a Poisson process': a better explanation would be 'illnesses were modelled as a Poisson process, which means that each illness is assumed to occur randomly in time, independently of each other, and that the risk of an illness is either constant over time or follows some repeated seasonal pattern'. This type of explanation enables the risk manager to better understand the assumptions, and perhaps pose more informed questions about the effect of any violation of the assumptions. Deciding whether a food is safe or not is a difficult task. Food can never be proven to be entirely safe nor entirely hazardous. It can only be proven to be hazardous to some degree under certain conditions. While demanding completely safe food is unrealistic, it is possible to have food in which potential hazards have been reduced.

6 Conclusions

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

negotiations based upon a risk assessment. It is important to communicate this fact to the public and thus signal that scientific evidence is only one of the determinants of Codex international food safety standards, albeit a very prominent one. The possible trade-offs between economic and political interests on the one hand and public health interests on the other hand, could become more tangible if the outcome of a Codex risk assessment was a 'menu of policy options'. Existing Codex procedures already allow for this furthermore risk assessors play a more important role in defining the range of policy options to be analysed. Risk analysis will only be effective if it takes place in an environment in which government, industry, academic institutions, and consumers recognize value and participate in the process. Risk analysis must have the support of food safety regulators at the highest level of government. Industry must find value in the results of risk analysis. Academic institutions must produce information that meets the needs of risk analysis. Consumers and businesses must be able to recognize and derive clear benefits from the risk analysis process. Similarly, mechanisms must be in place to enable stakeholders to participate in the development of risk analysis policy, as well as in the various activities performed during risk analysis.

References

Anon (2006) Food safety risk analysis: a guide for national food safety authorities. FAO food and nutrition paper 87. WHO/FAO, Rome

CAC/GL 30 (1999) Principles and guidelines for the conduct of microbiological risk assessment

ICMSF (2002) Microorganisms in foods. 7. Microbiological testing in food safety management. Kluwer Academic/Plenum, New York

ICMSF (2005) Microorganisms in foods. 6. Microbial ecology of food commodities. Kluwer Academic/Plenum, New York

Leistner L, Gould GW (2001) Hurdle technology: combination treatment for food stability, safety and quality. Kluwer Academic/Plenum, New York

USNACMCF (US National Advisory Committee on Microbiological Criteria for Foods) (2004) Response to the questions posed by FSIS regarding performance standards with particular reference to raw ground chicken, Atlanta, GA, USA