2. Purpose of microbiological food safety risk assessment

The purpose of MRA in the Codex framework is, at its most basic, "a systematic analytical approach intended to support the understanding and management of microbiological risk issues" (Fazil et al., 2005). In microbiological food safety, the outcomes of interest are usually the incidence of one or more types of human health effect attributable to a specific food, pathogen, process, region, distribution pathway or some combination. Those health effects include diarrhoeal illnesses, hospitalizations and deaths. In other microbiological risk assessments, other impacts, e.g. social, environmental and economic, might be considered as well.

Risk managers initially define the intended use of a risk assessment in their "preliminary risk management activities' (see FAO/WHO, 2002). They can then be expected to interact with risk assessors to refine the specific questions to be answered, or scope, focus or outputs of the risk assessment in an iterative fashion, possibly throughout the conduct of the risk assessment. Risk managers are expected to ask risk assessors to answer a specific set of questions, which, when answered, provide the managers with the information and analysis they need to support their food safety decision process.

The statement of purpose for a risk assessment should be clear and should guide the form of the risk assessment output such as number of cases of illness per year attributable to the product or pathogen, ranking of risk from one food compared with others, or expected reduction in risk if various interventions are implemented. If the risk assessment aims to find the best option to reduce a risk, then the statement of purpose should also identify all potential risk management interventions to be considered in the risk assessment. The questions and the statement of purpose will, to a great extent, guide the choice of the approach to be taken to characterize the risk. The data and knowledge collected in a specific risk assessment can be combined and analysed in different ways to answer a number of different risk management questions. Analogously, however, if the purpose of the risk assessment is not clear initially, inappropriate data and knowledge may be collected, or combined and analysed in ways that—while providing insight into some aspects of the risk—do not provide clear answers or insights to specific questions of the risk manager to assist in making a decision. Consequently, the purpose(s) of a specific risk assessment should be clearly defined and articulated to the risk assessors responsible for conducting the risk characterization prior to commencing the risk assessment so that the relevant data is gathered, synthesized and analysed in a way that provides answers to the risk manager's questions

It is imperative to have some understanding of the likelihood of different outcomes under different scenarios, such as alternative intervention strategies, for a risk manager to be able to make rational choices between them. Without addressing the probability component of a risk, the risk manager is faced with comparing outcomes that are simply 'possible'.

Risk assessment is a decision tool. Its purpose is not necessarily to further scientific knowledge, but to provide risk managers with a rational and objective picture of what is known, or believed to be known, at a particular point in time. Inevitably, a risk assessment will not have included all possible information about a risk issue because of limited access (for example, time constraints for the collection of data, or unwillingness of data owners to share information) or because the data simply does not exist, and in the process of performing a risk assessment one

usually learns which gaps in knowledge are more, and which are less, critical. Broad distribution of a draft risk assessment, in which the data gaps and assumptions are clearly pointed out, may, however, elicit new information.

Sometimes what is known at a particular time is insufficient for a risk manager to be comfortable in selecting an intervention strategy. If the risk manager's bases and criteria for making a particular decision (i.e. the 'decision rule') are well defined, a risk assessment carried out based on current knowledge can often provide guidance as to what, and how much, information would make the choice of the correct decision more clear. Another benefit of the risk assessment methodology is that it provides a basis for rational discussion and evaluation of data and potential solutions to a problem. Thus, it acts to create consensus among stakeholders around risk management strategies or helps to identify where additional data are required.

All risk assessments should be critiqued within the context of the decision question, i.e. which risk management strategies the risk manager wishes to select between, and what data are available to help in the evaluation of those strategies. For example, in the case of bovine spongiform encephalopathy (BSE), sufficient animal health surveillance data may be available to quantitatively characterize BSE prevalence in a cattle population, but the dose-response relationship for vCJD (the human form of BSE) is likely to remain unknown for the foreseeable future. Therefore, it would clearly be nonsense to criticise a BSE risk assessment for failing to include a dose-response component where there are insufficient data available on which to base a dose-response relationship. The purpose of a risk assessment is to help the risk manager make a more informed choice and to make the rationale behind that choice clear to any stakeholders. Thus, in some situations, a very quick and simple risk assessment may be quite sufficient for a risk manager's needs. For example, imagine the risk manager is considering some change that has no cost associated with it, and a crude analysis demonstrates that the risk under consideration would be 10-90% less likely to occur following implementation of the change, with no secondary risks. For the risk manager, this may be sufficient information to authorize making the change, despite the high level of uncertainty and despite not having determined what the base risk was in the first place. Of course, most risk issues are far more complicated, and require balancing the benefits (usually human health impact avoided) and costs (usually the commitment of available resources to carry out the strategy, as well as human health impacts from any secondary risks) of different intervention strategies.

There are two basic concepts concerning probability. The first is the apparently random nature of the world; the second is the level of uncertainty we have about how the real world is operating. Together, they limit our ability to predict the future and the consequences of decisions we make that may affect the future. Microbiological food safety risk assessment is most affected by uncertainty: uncertainty about what is really happening in the exposure pathways that lead humans to become infected or to ingest microbiological toxins, uncertainty about processes that lead from ingestion or infection to illness and that dictate the severity of the illness in different people, and uncertainty about the values of the parameters that would describe the processes of those pathways and processes. These are discussed in Section 2.5.3. Some of those uncertainties are readily quantified with statistical techniques where data are available, which gives the risk manager the most objective description of uncertainty. If, however, a risk assessment assumes a particular set of pathways and causal relationships that are incorrect, the assessment will be flawed.

2.1 Properties of risk assessments

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; and
- MRA should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment and Risk Characterization.

The last-named principle is discussed in greater detail below.

2.1.1 The need for the four components of risk assessment

As noted above, CAC (1999) prescribes four components for microbiological risk assessment:

1. *Hazard Identification*;
2. *Hazard Characterization*;
3. *Exposure Assessment*; and synthesis of these three elements into a
4. *Risk Characterization*.

The approach has a very appealing logic and is adapted from the US National Academy of Science system of evaluating chemical risks that has been applied by the US Environmental Protection Agency (US EPA) since the 1970s. Some flexibility is essential, however, in interpreting the need for these four components as separate entities.

All of these components are necessary in some form, but a key issue for risk assessors is the interpretation of exposure assessment and hazard characterization. CAC defines hazard characterization as

> "The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of Microbiological Risk Assessment the concerns relate to microorganisms and/or their toxins."

It elaborates by explaining

> "This step provides a qualitative or quantitative description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food. A dose-response assessment should be performed if the data are obtainable."

and

> "A desirable feature of Hazard Characterization is ideally establishing a dose-response relationship."

This has often been inaccurately interpreted as a necessity to determine a dose-response relationship. Clearly, if there is no means to define a credible dose-response relationship, or to determine the level of exposure that is combined with the dose-response relationship to estimate human health effects, an alternative approach should be sought. Sections 5.5.5 and 5.5.6 describe methods that allow exposure and risk to be related but without the need for the usual type of dose-response function yet which are perfectly valid for certain types of problem, e.g. estimation of relative risk. It has been pointed out (FAO/WHO 2002) that

> "in many cases, effective risk management decisions can still be made when only some of the components of [quantitative microbiological risk assessment] are available, notably exposure assessment."

2.1.2 Differentiating risk assessment and risk characterization

In several frameworks, risk assessment is broken down into a number of stages (CAC, 1999; OIE, 1999) but, in general, risk assessment is the 'umbrella' term used to describe the complete process of assessing a risk. In the Codex framework, risk assessment is the *process* of undertaking the four steps which enable an assessment of the risk. Analogously, risk characterization is the *process* of combining the information from the Hazard Identification, Exposure Assessment and Hazard Characterization to produce a 'risk estimate', the final expression of the risk, which is the output of both the risk characterization and the risk assessment processes. While the actual methods used to achieve a risk estimate may vary between quantitative and qualitative risk assessments, the relationship between the processes of risk assessment and risk characterization are the same.

2.2 Risk characterization measures

In assessing foodborne 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., as discussed in Chapter 7 and Appendix 1. 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.

2.3 Purposes of specific risk assessments

Various types of probability models and studies of risk issues have been labelled as 'risk assessments' (see Box 2.1). 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.

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

Box 2.1 Examples of risk assessments developed for different purposes

- Danish *Salmonella* risk assessment apportioned human cases to different food animal sources.
- Health Canada *E. coli* O157 in ground beef, Dutch RIVM STEC O157 in steak tartare – all risk assessments for research and instruction.
- US FDA *Listeria* risk assessment for risk attribution to food categories.
- FAO/WHO *Enterobacter sakazakii* in powdered formula for evaluation of interventions
- USDA *E. coli* O157 and *Salmonella* Enteritidis risk assessments for intervention strategies.
- US FDA-CVM FQ-resistant *Campylobacter* risk assessment for human health impact estimation.

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.

Risk assessment of the types described here can be used for purposes that might be considered 'internal' or 'external', depending, in part, on the range of stakeholders. The internal purposes might include activities such as setting priorities, allocating resources, and so on, within an organization, and the risk assessment not made public. External uses of risk assessment might be those that affect more stakeholders, such as those that result in changed regulations, or are undertaken as academic exercises, or as demonstrations of new or improved approaches to risk assessment. These are usually made public and are subject to peer review. Such assessments are frequently published in professional journals or made available on Web sites, or both.

2.3.1 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 foodborne 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.

A closely related activity is risk attribution, which apportions an identified risk among competing causes. This might involve apportioning food risks among pathogens, apportioning the risk associated with a specific pathogen among different food groups, or among different types of behaviour, like eating at barbecues or in restaurants. Risk attribution of a specific pathogen from different food sources could be used to rank food sources by the risk they pose. This helps the managers to identify the most important food or food source to control in order to most efficiently and cost effectively control the disease.

2.3.2 Comparing risk management strategies

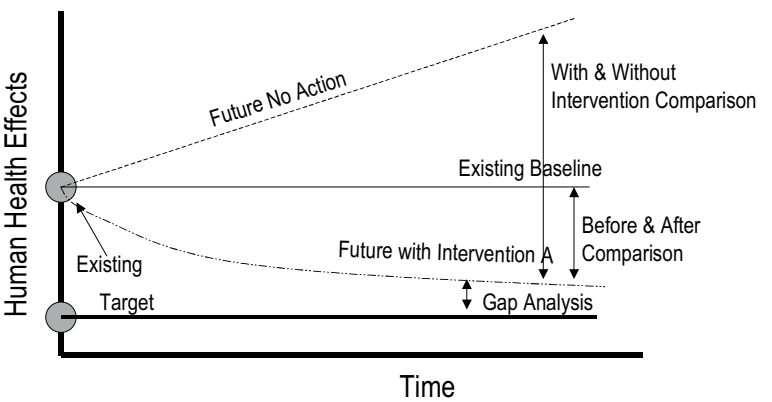
Risk assessment is commonly undertaken to help risk managers understand which, if any, intervention strategies can best serve the needs of food safety, or if current risk management actions are adequate. Ideally, agencies with responsibility for safety of foods would consider all possible risk management 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. As discussed elsewhere, some risk assessments may be undertaken to ascertain whether existing food safety regulations and existing intervention strategies are adequate, or most appropriate, and if they require review.

Evaluations of putative risk management actions are often based on comparisons of a baseline risk estimate with a forecast risk that could result from pursuing various alternative strategies. These are sometimes called 'what-if' scenarios (see Box 2.2). One includes a future with no new intervention, the other a future with a new intervention. Initially, a baseline model (i.e. the 'without intervention' scenario) is constructed and run to give a baseline estimate of risk. Then selected model parameters are changed to determine the probable effect of the putative intervention(s) (see Box 2.3 for examples of interventions). The differences between the two risk estimates offer strong indications of the public health benefits of the proposed intervention(s) and, if possible, could also indicate the costs required to attain them. Combinations of interventions can be investigated in a similar fashion, to determine their joint effect, in an effort to find the optimal strategy

Box 2.2 'With' and 'without' intervention scenarios and changes in risk over time

There are many ways to approach an evaluation of risk management options, including gap analysis, before and after comparison, and with and without comparison (as illustrated in this example). The risk estimates, special studies, economic and environmental analyses, opinion surveys, analysis of the legal implications of proposed actions, and the like will vary from case to case. Not all of these elements are within the domain of risk assessment, but a few generic steps in the process can be identified. These include:

- Describe the existing baseline risk condition, i.e. the current state of the risk, given the intervention strategies already in place.
- Describe the most likely future condition in the absence of a change in risk management intervention, i.e. the 'without' condition. Every option is evaluated against this same 'without' condition, labelled 'Future No Action' below. This future may exhibit an increasing, decreasing, flat or mixed trend.
- Describe the most likely future condition anticipated with a specific risk-management intervention in place, i.e. the 'with' condition. Each intervention has its own unique 'with' condition: in the example below, it is labelled 'Future With Intervention A'.
- Compare 'with' and 'without' conditions for each intervention option.
- Characterize the effects of this comparison: not all effects are equal in size, some are desirable, others are not.



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 one-hundred-fold, but if this risk was negligible at the start, then reducing it one-hundred-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 foodborne 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.

Box 2.3 Examples of Microbiological Risk Management Interventions

- Vaccination of farm animals.
- HACCP and similar approaches during processing.
- Refrigeration and specification of 'use by' or 'best before' dates.
- Establishment of microbiological criteria.
- Use of 'Hurdle Concept' to limit pathogen growth.
- Product labelling for traceability.
- Consumer education, e.g. for 'at-risk' consumers.

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 foodborne 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.

2.3.3 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.

In some instances risk managers are labouring in ignorance about the nature of a food safety problem. In this case, a risk assessment may be commissioned to simply expand the knowledge base.

Research is needed to do good risk assessment, but risk assessment is also a very useful aid in identifying where gaps in knowledge exist and thus where additional information is needed. A risk assessment may be undertaken specifically or incidentally to identify research needs, to establish research priorities, and to design commissioned studies.

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.

2.4 Choosing what type of risk assessment to perform

Risk assessments methods span a continuum from qualitative through semi-quantitative to fully quantitative. All are valid approaches to food safety risk assessment, but the appropriateness of a particular method ultimately depends on the ability of the risk assessment to match the desirable characteristics listed in Section 2.1. Chapters 3 to 5 describe and provide examples from this continuum. While the chapter headings and examples might imply the existence of three strict categories of risk assessment methodology, the three terms are descriptions only and are used simply for convenience for organization of the document, and any risk assessment might include elements of any combination of these approaches. A benefit of risk assessment as a whole is that solutions to minimize risk often present themselves out of the formal process of considering risk, whether the risk assessment that has been conducted is qualitative, semi-quantitative or quantitative.

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."

The Australian National Health and Medical Research Council note (NHMRC, 2004: 3–6) cautions that:

> "Realistic expectations for hazard identification and risk assessment are important. Rarely will enough knowledge be available to complete a detailed quantitative risk assessment. ... A realistic perspective on the limitations of these predictions should be understood by staff and conveyed to the public."

The decision on the appropriate balance of the continuum of methods from qualitative to quantitative will be based on a number of factors, including those considered below.

Consistency

A desire for consistency can work both for and against a decision to apply qualitative risk assessment. On the one hand, qualitative and semi-quantitative risk assessment can be made simple enough to be applied repeatedly across a range of risk issues, whereas quantitative risk assessment is more driven by the availability of data and may have to employ quite disparate methods to model different risks. Subjectivity can occur in quantitative risk assessments, e.g. in approaches to the selection and analysis of data, but the basis of these judgements can usually be documented in a way that enables others to replicate the results. Nonetheless, comparison of

assumptions and data quality may be difficult. On the other hand, qualitative risk assessment is more prone to subjective judgements involved in converting data or experience into categories such as 'high', 'intermediate' and 'low' because it may be difficult to unambiguously define these terms, so repeatability of an analysis by others is less certain.

Expertise

Quantitative risk assessments typically require that at least part of the assessment team have rigorous mathematical training. If this resource is in limited supply, this may make qualitative risk assessment more appropriate, as long as the risk question is amenable to this approach. Note that, though qualitative risk assessments may not be demanding in terms of pure mathematical ability, they place a considerable burden of judgement on the analyst to combine evidence in an appropriate and logical manner, and the technical capability necessary to collate and interpret the current scientific knowledge is almost the same.

Theory or data limitations

Quantitative risk assessments tend to be better suited for situations where mathematical models are available to describe phenomena and where data are available to estimate the model parameters. If either the theory or data are lacking, then a more qualitative risk assessment is appropriate.

Breadth of application

When considering risks across a spectrum of hazards and pathways, there may be problems in applying quantitative risk assessment consistently across a diverse base of theory and evidence, such as comparing microbiological and chemical hazards in food. The methodologies and measurement approaches may not yet be able to provide commensurate risk measurements for decision-support where scope is broad.

Speed

Qualitative and semi-quantitative risk assessments generally require much less time to generate conclusions compared with quantitative risk assessment. This is particularly true when the protocols for qualitative and semi-quantitative risk assessments have been firmly established with clear guidance in the interpretation of evidence. There may be some exceptions where the process of qualitative risk assessment relies on a process of consultation (e.g. when relying heavily on structured expert elicitation) that requires considerable planning, briefing, and scheduling.

Transparency

The desire for transparency can favour all methods, depending on the type of transparency that is desired. Transparency, however, is not the same as 'accessibility'. Transparency, in the sense that every piece of evidence and its exact impact on the assessment process is made explicit, is more easily achieved by quantitative risk assessment. However, accessibility, where a large audience of interested parties can understand the assessment process, may be better achieved through qualitative or semi-quantitative risk assessment. Quantitative microbiological risk assessment often involves specialized knowledge and a considerable time investment. As such, the analysis may only be accessible to specialists or those with the time and resources to engage

them. Strict transparency is of limited benefit where interested parties are not able, or find it excessively burdensome, to understand, scrutinize and contribute to the analysis and interpretation. Qualitative or semi-quantitative approaches may be easier to understand by a larger range of stakeholders, who will then be better able to contribute to the risk analysis process

Stage of analysis

Qualitative and quantitative risk assessment need not be mutually exclusive. Qualitative risk assessment is very useful in an initial phase of risk management to provide timely information regarding the approximate level of risk and to decide on the scope and level of resources to apply to quantitative risk assessment. As an example, qualitative risk assessment may be used to decide which exposure pathways (e.g. air, food, water; or raw versus ready-to-eat foods) will be the subject of a quantitative risk assessment.

Responsiveness

A major concern often expressed in regulatory situations is the lack of responsiveness of risk characterization measures or conclusions when faced with new evidence. Consider a situation where a risk assessment has been carried out with older data indicating that the prevalence of a pathogen is 10%. After the risk assessment is published, it is found that the prevalence has been reduced to 1%. In most quantitative risk assessments, there would be a clear impact of the reduced prevalence on the risk characterization. In some qualitative risk assessments, this impact may not be sufficiently clear. Qualitative risk assessments, particularly where the link between evidence and conclusion is ambiguous, may be considered to foster or support this lack of responsiveness. The unresponsiveness can generate mistrust and concern for the integrity of the risk assessment process.

2.5 Variability, randomness and uncertainty

Variability, randomness and uncertainty are frequently confused because all three can be described by distributions. However, they have distinct meanings, and a common understanding between the risk manager and risk assessor of these concepts can greatly help in the risk assessment process. These topics are also considered in Section 5.4, but in the context of quantitative risk assessment and mathematical modelling approaches.

2.5.1 Variability

Variability, also sometimes referred to as inter-individual variability, refers to real differences in values of some property of a ‘population’ over time or space of between individuals, whether the population refers to people, units of food, a species of foodborne pathogen etc. Examples of variable factors relevant to microbiological risk assessment include the storage temperatures of food products, seasonality of different food preparation methods (e.g. barbecuing), culinary practice, susceptibility to infection across subpopulations, consumption patterns across a region, differences in virulence between strains, and product handling processes across different producers.

In some cases, some of the variability in the population can be explained by observable individual attributes. For example, while the human population is heterogeneous; there may be discernable differences in risk between identifiable subpopulations because they are for some reason less frequently exposed, or less susceptible, to the hazard of interest. Or there could be

three different methods of storing a food product, e.g. three different temperatures and corresponding humidity, leading to different potential for microbiological growth, and the fractions of the food item that are stored in each manner.

When there are discernable differences in risk due to known factors, 'stratification' of some type can be a practical method of addressing the population variability by recognizing those populations as discrete within the risk assessment. The properties of each subpopulation may still be described as a variable quantity, but with a different mean value and spread of values. There are many ways of stratifying a human population based on demographic, cultural, age and other variables, but foodborne pathogen risk stratifications are usually done in one of two ways. One is based on differences in exposure and the other is due to differences in susceptibility. These strata may also overlap. Within the population of interest, evidence should be sought of differences in susceptibility and of any likelihood of food-associated differential exposure patterns. If any differences found are likely to either significantly affect the risks or the potential safeguards, consideration should be given to stratifying the risk characterization based on these differences.

Variability is, in principle, described by a list of the different values that the variable takes. Often however, there are such a large number of values (for example, some characteristic about a human population, which will have millions of individuals) that it is more convenient to describe the variation using a frequency distribution.

2.5.2 Randomness

Randomness is due to the effect of chance inherent in the real world, and has also been described as aleatory uncertainty and stochastic variability.

There is debate about whether randomness actually exists, or simply reflects our imperfect knowledge of the real world, but for practical purposes the residual variation not explained by a model (i.e. a description embodying our understanding) is often treated as inherent randomness (Morgan and Henrion, 1990). An example of randomness in the context of MRA is given in Section 5.4.1, which also illustrates the interplay between variability, randomness and the use of stratification, as discussed above.

2.5.3 Uncertainty

Uncertainty is due to lack of knowledge regarding the true value of a quantity, and is also termed epistemic uncertainty, lack-of-knowledge uncertainty, or subjective uncertainty. It is often stated that variability and randomness are properties of the system being studied, whereas uncertainty is a property of the analyst. Different analysts, with different states of knowledge or access to different datasets or measurement techniques, will have different levels of uncertainty regarding the predictions that they make. An understanding of uncertainty is important because it provides insight into how lack of knowledge can influence decisions. When the range of uncertainty is large enough that there is ambiguity as to which decision alternative is preferred, then there may be value in collecting additional data or conducting additional research in order to reduce uncertainty.

Uncertainty is associated not only with the inputs to an assessment model, but also regarding the scenarios assumed for the assessment and the model itself. Sources of scenario uncertainty include potential misspecification of the harmful agents of concern, exposure pathways and vectors, exposed populations, and the spatial and temporal dimensions of the problem. Sources of model uncertainty include model structure, detail, resolution, validation or lack thereof, extrapolation, and boundaries of what is included and what is excluded from the model. Morgan

and Henrion (1990) and Cullen and Frey (1999) provide examples of sources of uncertainty in risk assessment, including the following:

- *Random error.* This is associated with imperfections in measurement techniques or with processes that are random or statistically independent of each other. Random measurement error leads to uncertainty that can be reduced by additional measurements, and is inversely related to *precision*. Precision refers to the agreement among repeated measurements of the same quantity.
- *Systematic error.* The mean value of a measured quantity may not converge to the "true" mean value because of biases in measurements and procedures. Such biases may arise from imprecise calibration, faulty reading of meters, and inaccuracies in the assumptions used to infer the actual quantity of interest from the observed readings of other quantities.
- *Lack of empirical basis.* Risk assessment often involves questions for which direct testing and observation is neither practical nor possible so that assumptions must be made based on available evidence. The validity of these assumptions cannot be assessed empirically. This type of uncertainty cannot be treated using conventional statistical techniques, because it requires predictions about something that has yet to occur or to be, tested, or measured. An example is the use of surrogate data when data are not available for the population of concern. Uncertainty about how well the surrogate data represents the population of concern can be characterized using expert judgements.
- *Dependence and correlation.* When there is more than one uncertain quantity, it may be possible that the uncertainties may be statistically or functionally dependent. Failure to properly model the dependence between the quantities can lead to uncertainty in the result, in terms of improper prediction of the variance of output variables.
- *Disagreement*. Where there are limited data or alternative theoretical bases for modelling a system, experts may disagree on the interpretation of data or on their estimates regarding the range and likelihood of outcomes for empirical quantities. In cases of expert disagreement, it is usually best to explore separately the implications of the judgements of different experts to determine whether substantially different conclusions about the problem result. If the conclusions are not significantly affected, then the results are said to be robust to the disagreements among the experts. If this is not the case, then one has to more carefully evaluate the sources of disagreement between the experts. In some cases, experts may not disagree about the body of knowledge. Thus, the differences in expert opinion may be reduced to clearly identified differences in inferences that the experts make from the data.

2.6 Data gaps

All risk assessments require data and knowledge (of processes, interactions, etc.), irrespective of whether they are qualitative or quantitative. Data (and knowledge) gaps influence the assessor's confidence in the risk characterization and the robustness of the estimate. The form of a risk assessment is determined primarily by looking at what decision questions need to be answered. Then a search is done to see what data and knowledge are available that would help construct a logical risk-based argument (the risk assessment) that answers these questions. A balance is generally needed: taking a particular risk assessment approach may not be able to answer all questions, but may provide a better quality answer. Data may not be available to answer the question at all. Thus, defining the form of a risk assessment may require considerable dialogue between assessor and manager.

This process will often lead to a better understanding of the value of other information that is not currently available. One can ask what else could be done if some specific data could be found. Depending on the time left until a decision has to be made, and on the resources available, the risk manager may consider it worth waiting, or expending the resources to acquire those data, and hopefully be able to make a more informed judgement as a result.

It is tempting to plan out the structure of a risk assessment that will answer all the risk managers' questions, and then attempt to find the data required to 'populate' the risk assessment. However, in the food safety arena this may not be a practical approach. Food safety management is beset by a lack of data, so writing a wish list of all the data one would like will inevitably lead to disappointment. Other approaches, such as building simplified model-based reasoning to describe the system or process before considering the data availability, have been proposed as preliminary activities to aid in determining the form of the risk assessment. More complete discussion of data gaps can be found elsewhere (Fazil et al., 2005; FAO/WHO, 2008), but a brief list of reasons for such gaps includes:

- it has not previously been seen to be important to collect these data;
- data are too expensive to obtain;
- data are impossible to obtain given current technology;
- past data are no longer relevant;
- data from other regions are not considered relevant; or
- the data have been collected or reported, or both, in a fashion that does not match the risk assessment needs.

Data that has not previously been seen to be important often arises in contamination studies with infrequent positive data. Such data are not usually valuable for scientific journals; therefore researchers have less interest in conducting such studies. However, negative data are important for risk assessment, e.g. to estimate prevalence.

Using the risk assessment framework, it may be possible to determine which gaps have the most influence on being able to address the risk management questions. This identification process can be used to set priorities for future data collection and experimental research.

2.6.1 The use of expert opinion

It may be necessary to elicit expert estimates for parameter values in the pathway model where there is a critical lack of data, and where for pragmatic reasons it is essential to assess that risk in the relatively near future. Problems here include, for example, decisions on identification and selection of experts, the number of experts required, techniques for eliciting information, overcoming bias, etc., and methods are developing in this area (see, for example, Jenkinson, 2004).

When expert opinion is required, the problems and methods of selection, overcoming bias, etc., up to this point are likely to be similar for qualitative and quantitative risk assessments. Details on these methods are discussed elsewhere in the FAO/WHO guidelines (FAO/WHO 2003, 2008). It is accepted that ideally a 'sufficient number' of experts should be utilized. Techniques like the Delphi method (Linstone and Turoff, 1975), which aim to achieve consensus among a panel of experts, can help produce more reliable estimates from the available information. However, there are situations when there truly are very few, and on

occasions perhaps only one, expert in the specific topic worldwide. Sometimes there are no true experts. This leads to the use of inputs with very wide levels of uncertainty, whatever the risk assessment type, which is far from ideal but may on occasion be the only option in the short term.

In a quantitative risk assessment, it is necessary to convert expert opinion into a numerical input, and once again various methods exist and are being actively developed (see, for example, Gallagher et al

., 2002). Even in a qualitative risk assessment, these methods may also be used to convert expert opinion into numerical values for specific model steps, and this is, where time allows, the preferred method. As noted earlier, when used to describe approaches to risk assessment, the terms quantitative or qualitative do not refer to formally defined categories of risk assessment. An alternative and less sophisticated way of using expert opinion in qualitative risk assessments, however, may be to ask directly for an opinion on the probability of a specific step in narrative terms of, for example, high, low, negligible, etc. The meanings of these words will have the same subjectivity problems as has is discussed for qualitative risk assessments in general (see Chapter 3), and the reader's evaluation of the results will need to be based on their evaluation of the experts selected. In principle, such a method should be only a temporary measure until improved data are available.

2.7 The role of best- and worst-case scenarios

As a filtering technique in risk assessment, e.g. as part of a risk profile, it may be useful to evaluate the best- or worst-case scenario to get a sense of 'how good could it be' or 'how bad could it be'. The worst case scenario is usually used to filter out whether a risk or an exposure pathway is worth worrying about. No further analysis is necessary if the most pessimistic estimate shows the risk level to be below some threshold of interest (e.g. a negligible-risk level).

Conversely, a best-case scenario can be used as a preliminary filter of possible risk management options. The risk manager can discount any options for which the most optimistic estimate of the benefits the options could offer does not justify the cost of that option

Best- and worst-case scenarios operate somewhat like extreme 'what-if' scenarios. Where there is considerable but quantified uncertainty about a model parameter, a value is used that gives the required extreme. This will usually be an extreme value from the uncertainty distribution of the parameter, like its 1^{st} or 99^{th} percentile. However, when there is not a monotonic relationship between the parameter value and the risk estimate (i.e. that the magnitude of the risk estimate only increases/decreases as the parameter value increases/decreases or, conversely that the magnitude of the risk estimate only decreases/increases as the parameter value increases/decreases), the extreme estimate of risk may occur more towards the centre of the parameter's uncertainty distribution.

Where there is uncertainty about exposure pathways and risk attribution, the extreme risk estimate is achieved by picking the most pessimistic (or optimistic) pathway: for example, 'imagine that all salmonella came from chicken'.

Potential problems with worst-case analyses include that the analysis usually focuses on the consequences of the worst case, without the context of the probability of that worst-case scenario occurring, and that it is difficult to specify the conditions that might lead to the worst (or best) case: absolute extremes may be limited only by our imaginations. Conversely,

wherever parameter values or exposure pathways are known with considerable certainty, they should be used to avoid exaggerating the extreme scenario beyond what is feasible.

Evaluating best- and worst-case scenarios can be considered as a risk assessment if the information about the extreme probability is credible and sufficient for the decision-maker.

2.8 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.

The risk characterization should include a description of the strengths and limitations of the assessment along with their impacts on the overall assessment. The risk characterization should also say whether the risk assessment adequately addresses the questions formulated at the outset of the exercise. It is important to try to devise explanations of the effect on assumptions on the assessment's validity. Bounding arguments can be useful in this regard, e.g. 'if assumption X were to be incorrect the risk still could not logically be greater than Y, providing all other assumptions were true'.

Chapter 6 provides detailed advice on assuring the quality of risk characterizations and of assessing their robustness and credibility.