ILSI Europe
Report Series

Using Microbiological Risk Assessment (MRA) in Food Safety Management

Summary Report of a Workshop held in October 2005 in Prague, Czech Republic

Organised by the ILSI Europe Risk Analysis in Microbiology Task Force and the International Association for Food Protection (IAFP)

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USING MICROBIOLOGICAL RISK ASSESSMENT (MRA) IN FOOD SAFETY MANAGEMENT

by Anna Lammerding

SUMMARY REPORT OF A WORKSHOP HELD IN OCTOBER 2005 IN PRAGUE, CZECH REPUBLIC

ORGANISED BY THE ILSI EUROPE RISK ANALYSIS IN MICROBIOLOGY TASK FORCE AND THE INTERNATIONAL ASSOCIATION FOR FOOD PROTECTION (IAFP)

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FOREWORD

The evolution in food safety management has resulted in worldwide acceptance of systems such as hazard analysis critical control point (HACCP) operated in conjunction with good practices, such as good hygienic practice and good manufacturing practice. Over the last decades, governmental food safety control has shifted from management of hazards to management of risks. In support of risk-based food safety control, Codex Alimentarius, under the auspices of the parent organisations WHO and FAO and supported by governments around the world, has adopted risk analysis as the common operational framework. A prominent part of the risk analysis is microbiological risk assessment (MRA), the process of assessing and characterising the risk posed by a hazard in a food within a certain population. The two other component parts of risk analysis are risk management and risk communication. In the context of risk analysis, new ways of working and metrics for food safety have been developed. Both these aspects, as well as how to conduct risk assessment, risk management and risk communication, have been the subject of consultations initiated by FAO and WHO as well as of scientific workshops held by a variety of organisations. The scientific workshop "Using Microbiological Risk Assessment (MRA) in Food Safety Management", organised by ILSI Europe in collaboration with the International Association for Food Protection (IAFP), was convened in Prague (Czech Republic) on 12–14 October 2005. The aim was to explore the practical utility and validity of MRAs developed in different contexts in more depth and, where possible, to establish learnings and useful practices that can guide future developments. This report summarises the results of presentations and discussions at that workshop.

EXECUTIVE SUMMARY

Guidelines and principles for microbiological risk assessment (MRA) have been elaborated through the role of the Codex Alimentarius Commission as the recognised standard-setting body for safe foods in international trade. The focus of the workshop reported on here was to build up a good understanding (i) of the variety of microbiological risk assessment (MRA) approaches developed by different risk assessors since this methodology began to evolve (mid-1990s) and (ii) of the purpose and context of individual MRAs. Based on that understanding, the workshop intended to discuss two aspects that are important for an MRA to be useful: utility (related to the usefulness regarding the purpose an MRA has been developed for) and validity (the trueness or correctness of an MRA).

The workshop was held using a format of presentations in plenary sessions, providing case examples of different approaches to MRAs and different contexts/purposes for the development of MRAs, and break-out group discussions on specific aspects of utility and validity.

In general terms, the workshop concluded that MRA should be viewed as a flexible process, within a structured format, that is tailored to address the needs of a specific microbiological risk management (MRM) problem and generates results that are useful to support important decision-making tasks, regardless of scope or context. It was recognised that MRAs should be "fit-for-purpose", but needed to be undertaken within the given constraints of context and available resources. Risk managers, thus, must be clear about their needs and understand that resources are needed to deliver specific desired outputs from MRA.

The workshop recognised, importantly, that by deploying MRA the traditional strategies for management of food safety, informed mainly by science, are complemented with a more holistic view of the issue at hand by a variety of experts and stakeholders. This added value is the key for the future, when risk-based decision-making will be commonplace but will need to be firmly supported by transparent and open processes. To the scientific characterisation of an issue, MRA adds estimates of the two quantities of risk: (i) the magnitude of a potential adverse outcome and (ii) the probability that the adverse outcome will occur. This requires that the available evidence is processed, following rules of inference, to generate statements of the probability of individual events. These are then combined to determine the probability, together with the magnitude, of an undesirable final event. Depending on the context of the issue and given constraints (such as data, resources and time availability), different approaches can be followed in characterising the risk estimates. Some approaches are more descriptive (qualitative) while others are more quantitative. Mixed and tiered approaches may be used as well. Some quantitative approaches to MRA may provide additional insights useful for making decisions, e.g. about the uncertainty in factual information, the variability in one or more factors and/or the uncertainty and variability in the risk estimates.

In addition to MRA, other risk-based tools are being used for decision-making purposes. The "risk profile" is a structured narrative, a written description of the food safety problem and its context. It is prepared early in the MRM process to help decide the next steps, including whether an MRA is necessary or not. Risk profiles have also been used in a broader context to provide sufficiently detailed information for strategic planning in the absence of an MRA. Risk-ranking techniques may be valuable, for instance in prioritisation when comparing relative risks from multiple hazards or from different intervention strategies. Risk ranking can be based on expert elicitations, qualitative measures or, more recently, developed on the basis of sophisticated quantitative risk models. Other alternative approaches to MRA exist, and are needed, to address the range of different types of food safety issues faced by governmental risk managers or by food safety managers in industry.

The most appropriate type and construct of an MRA will vary depending on the nature of the risk problem, its context and complexity, the uptake of the MRA outcomes, the urgency of the risk management decision, the involvement of stakeholders and other factors. Often, the timeframe available will constrain the development of the assessment, but assessors must know what stringency needs to be built into an MRA. This stringency very much determines the utility and validity of the MRA. Those involved in commissioning and executing an MRA, the risk managers and risk assessors respectively, need to be clear about the implications of any undue constraints on the utility and validity of the MRA product that can be reasonably delivered.

The most important attribute of an MRA is that it is "fit-for-purpose"; i.e. that it answers the risk management question(s), improves the decision-making process and does so in a timely manner. Nevertheless, there are common characteristics, regardless of the rigour of the approach or the stringency built into the MRA product, which should be taken into account to ensure that the MRA has value in decision-making.

This report summarises considerations for validity and utility criteria for MRA in a broad scope of applications, and in areas where different types of MRAs need to be improved in order to optimise their use in MRM activities.

OBJECTIVES OF THE WORKSHOP

The workshop aimed to further advance the development of MRAs that are useful and valid for the purpose they are established for, working through the following practical objectives in the plenary sessions and break-out working group meetings:

1. Consider the different formats of MRA types and new food safety management concepts related to MRA application
2. Identify characteristics that contribute to the validity and usefulness of MRA
3. Identify what type of risk assessment is required to address different risk management questions
4. Explore the links between risk assessment and risk management decision-making, including:
   a. Setting and using the new types of criteria (i.e. appropriate level of protection (ALOP), performance and food safety objectives, performance criteria)
   b. Utility of MRA information in the absence of set criteria
5. Identify areas of future research to improve the use of MRA.

INTRODUCTION TO MICROBIOLOGICAL RISK ASSESSMENT

The establishment of microbiological risk assessment (MRA) as a structured systematic process to support food safety risk management has been largely driven by the international community. The Codex Alimentarius Commission (CAC) defines risk analysis as a process comprising risk assessment, risk management and risk communication. Integrating detailed scientific examinations and logical inferences (i.e. risk assessment) with socio-political/deliberative processes (i.e. risk management and risk communication), risk analysis is a major shift in thinking about the ways science and policy-making in food safety should interplay. As working principles, each of the three components of risk analysis should be developed and applied consistently, and should be open, transparent and well documented. In an effort to harmonise international trade issues, principles and guidelines documents have been elaborated for microbiological risk assessment and for microbiological risk management, incorporating definitions and ways of working (CAC, 1999; CAC, 2004; CAC, 2006; FAO/WHO, 1997; FAO/WHO, 2002). Work of the international community performed after the workshop has added to these resources (FAO/WHO, 2006).

Risk assessment of microbiological hazards in foods is now a well-recognised and accepted approach within food safety risk management. In 1999, Codex Alimentarius adopted the "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" (CAC, 1999). ILSI Europe has published the proceedings of a workshop held in 1999 entitled "Microbiological Risk Assessment" in a special issue of the *International Journal of Food Microbiology* (ILSI Europe, 2000).

A number of examples of microbiological risk assessment have been published over the intervening years by governments, international organisations, academia, research organisations and companies. Attention is now focussed on how microbiological risk assessment can best be utilised in food safety management to understand the magnitude of prevailing risk regarding a pathogen/product combination, to design risk intervention scenarios, when appropriate, and to help identify and select risk management options for implementation. Previous meetings on this topic have included the 2002 FAO/WHO joint consultation, which led to the report entitled "Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards, Guidelines and Related Texts" (FAO/WHO, 2002), and an ILSI Europe workshop held in 2003, from which the report "Food Safety Objectives – Role in Microbiological Food Safety Risk Management" was published (ILSI Europe, 2004). Selected workshop papers were published in a special issue of *Food Control* (De Swarte and Donker, 2005; Gorris, 2005; Stringer, 2005; van Schothorst, 2005; Walls and Buchanan, 2005; Zwietering, 2005).

Under the framework defined by the CAC, MRA is a science-based process consisting of the following steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. It is recognised within the CAC guidelines and principles that risk assessments can be either qualitative or quantitative, the former based on descriptive rankings or categories of risk, and the latter using numerical data to calculate risk.

Indeed, even within the international arena, the World Trade Organization's (WTO) Sanitary and Phyto-Sanitary (SPS) agreement specifies "SPS measures based on an assessment, as appropriate to the circumstances, of the risk to human health" (WTO, 1995).

As for MRA, the CAC has introduced a framework, principles and guidelines for the conduct of microbiological risk management (MRM) (CAC, 2006). The components of this process are:

- Preliminary MRM activities including identification of a food safety issue, development of a risk profile, formulation of an MRA policy and commissioning an MRA if warranted
- Identification and selection of MRM options
- Implementation
- Monitoring and review.

From within this context, new operational concepts have emerged. These include the definition of public health goals, including the articulation of an appropriate level of protection (ALOP), the expression of food safety objectives (FSO), performance objectives (PO) and performance criteria (PC), linked together with traditional parameters including product and process criteria and microbiological criteria. A risk-based management approach is a major step in advancing a science-based food safety system by linking food safety requirements and criteria to the public health problems they are designed to address (a link that is not always present in current regulations). This connection, particularly when expressed as a quantitative probability, would also provide a means to measure and compare the effectiveness of existing and new requirements or risk management interventions.

MRA has advanced relatively quickly within a short time span. The framework, guidelines and principles defined by Codex have been integrated into many efforts and the resulting documents are available in published literature or can be found on websites. Furthermore, different approaches have been formulated to characterise risk, demonstrating that the process can be flexible. This will vary between government and industry applications, international trade and national public health objectives. The approach taken will be dependent on the scope, resources available, the specific type of problem and the specific information needed.

Undertakings in MRA and the development of MRM guidelines and principles have, in a sense, progressed independently. This has probably occurred since MRA, as a largely scientific endeavour, is somewhat more straightforward than the philosophies underlying MRM. The challenges now lie in integrating these activities to optimise both the utilisation of MRA information and the strength of MRM decision-making, a primary consideration underlying the organisation of this workshop.

Workshop participants considered several case examples of different approaches that have been developed, debated their applications (e.g. to setting criteria, to help inform food safety risk managers about effectiveness of options/strategies) and defined what factors might be considered to ensure that an MRA is valid and the information useful for risk managers.

ADDED VALUE OF RISK ASSESSMENT OVER SCIENTIFIC CHARACTERISATION

Beyond a measure of human health outcomes, the process of conducting an MRA has value in that it is a structured, systematic approach to integrate and evaluate information from many diverse sources along the food chain. In this way, it can lead to enhanced understanding of the factors that influence risk, provide insights for risk management and identify critical knowledge gaps that hinder effective action in mitigating the risk of foodborne illness. Specifically, a quantitative MRA provides information that can (i) assist targeting potential control and risk reduction measures, (ii) form a basis for cost-benefit analysis of the relative merits of competing risk mitigation strategies and (iii) help to focus the direction of research programmes.

Several different formats and a range of different analytical approaches in MRA have been introduced, all of which can be informative for decision-makers for different circumstances. There is a need to allow flexibility in the approach chosen to evaluate the safety of foods and health impacts because of the characteristics of the safety issues to be dealt with and the available data, time, skilled resource, etc.

MRA can be viewed as an option that might be utilised for the scientific characterisation of a situation or threat. The spectrum ranges from narrative descriptions using observed evidence, experience and factual knowledge (e.g. literature reviews, hazard analyses, risk profiles) to MRA approaches that range from qualitative to increasingly more analytical and detailed quantitative analyses.

A fundamental concept considered by the workshop was the difference between scientific characterisation or advice and risk assessment (including risk-based analyses such as risk ranking and risk-based priority setting). In other words, what is the added value of risk assessment over scientific characterisation? The workshop recognised that, while scientific narratives of a situation provide what is currently known, and mainly keep to factual information, the probability and magnitude of any specific event occurrence or adverse outcome are typically not addressed. It is through using risk assessment that probabilities are explicitly described and quantified, and potential outcomes defined with some measure of magnitude. The primary value-added feature of MRA is in the inference of the probability of adverse outcomes by appropriately combining a formal representation of the risk-generating system (part of which is the food production system) with the rules of inferring probability.

Hence, MRA can be considered a subset of scientific characterisation with certain key distinctions:

- Evidence is processed in order to generate statements of probability of individual events, which are then appropriately combined to determine the probability of an adverse event of interest.
- Where there is a continuum of severity in the adverse events, the variation in probability along this continuum is explicitly recognised.
- Appropriate characterisation of a system for the purpose of inferring probability will, with few exceptions, require representing and incorporating the variability into the various influencing factors being considered, since this is known to be critical to estimating the probability of adverse events.
- Characterisation of the risk is done partly by describing the effects of evidence, assumptions and, often, potential intervention actions on the probability or severity of adverse outcomes.

It was acknowledged during the discussions that MRA is not necessarily the approach needed to address all food safety management questions; traditionally and in many circumstances today, sound scientific information and characterisation is entirely valid and sufficient to inform decision-makers. This also includes historical epidemiological data, which, although lacking the predictive value of (probabilistic) MRA, can provide relevant information for managers to consider in decision-making. Depending on the availability of suitable data and assuming appropriate data handling, risk assessment potentially can provide additional insights in situations of significant uncertainty, complexity and/or conflict, plus an objective basis for effectiveness and economic considerations relevant to decision-making when choosing a course of action.

APPLICATION OF MRA IN DIFFERENT CONTEXTS (UTILITY)

MRA is a valuable tool that can be applied to different purposes and problems in governments, industries and other organisations. As a result, different approaches and formats have arisen for MRA, while staying within the Codex framework of hazard identification, hazard characterisation, exposure assessment and risk characterisation. Traditionally, two broad categorisations are used: qualitative and quantitative. The first refers to an MRA that captures probabilities and impacts in descriptive classes or rankings. The latter provides numerical values for the calculation of a risk.

Government Perspective

Microbiological risk assessment serves as a useful tool for government in several areas. A significant driving force for the adoption of MRA has been the international dimension for the fair commerce of safe food between nations. Within a country, however, it serves to inform national policy and provide advice on issues of public health, and aids in the transparency of decision-making and communication. It can be used as a tool for horizon scanning or as an early warning to predict potential risks with emerging food safety issues. An example of the latter may be the introduction and dissemination of a newly recognised pathogen, such as the recently recognised *Salmonella* DT104 in the food supply. As a systematic process, MRA is also valuable in identifying gaps in information/knowledge, which can help to focus resources in priority areas for surveillance and research.

The MRA approach most useful for government applications will be defined by the nature of the food safety issue and the urgency for a decision and action taken. During the workshop discussions, three broad categories of activities were defined. First is in the management of food hazards, incidents and emergencies that require a rapid assessment and response. Here, the Codex framework can be helpful in ensuring that a structured process is used, although under these circumstances the MRA tends to be qualitative or semi-quantitative and relies heavily on existing, available knowledge. Predictive modelling tools and epidemiological data are informative for exposure assessments and for considering different risk intervention strategies, but relatively little time is available to deploy these. Risk profiles (discussed in more detail in a following section of this report) can be of great value as concise, consistent compilations of relevant information about a food safety issue, its context and the potential risk management options. These are essential for informing managers in time-constrained decision-making situations.

The second activity is where groups of experts, panels or committees undertake a scientific review on a food safety issue in order to provide broad advice and recommendations to government agencies. The work may not be strictly constrained by time and there may be opportunities to have data generated to cover important knowledge/data gaps. Based on the elements of the Codex framework, the outputs of such risk assessments tend to be qualitative or (semi-)quantitative. Conducting the review or assessment may extend over weeks or years, depending on the nature of the questions asked of the experts. Such panels or committees often comprise experts from a cross-section of disciplines in non-government professions.

The third area where MRA is useful is to address broad-scoped, complex issues and such undertakings may be considered a part of strategic planning and the basis for future regulatory action, standard-setting, or prioritisation of essential research and/or surveillance. For example, MRA may be used to quantitatively evaluate risks of specific pathogen/food combinations (e.g. *Listeria monocytogenes* in cooked meats and poultry), assess multiple transmission pathways for a single pathogen (e.g. all routes by which a population may be exposed to *Escherichia coli* O157:H7 or norovirus, not necessarily all foodborne) or a pathogen-specific trait through single or multiple pathways (e.g. exposure to quinolone-resistant *Campylobacter* via a diversity of routes).

Industry Perspective

The food industry is responsible for the assurance of safety of the products they market. In both design of the product and design of the practical operations to manufacture and deliver a safe product to the consumer, industry relies on valid and well-recognised practices and principles to assure safety. Food industries manage the conditions of the particular local operation by (i) establishing the general hygiene and safety requirements for the production facility and the product group through good hygienic practice (GHP) and good manufacturing practice (GMP) and (ii) establishing the specific hygiene and safety requirements for the specific product and process through HACCP. The HACCP system dictates that all significant hazards possibly associated with the particular food are controlled to the extent required for it to constitute a safe product, and that control of the operations is monitored, documented and re-evaluated as needed. Generally, MRA is not necessary in industrial operations, as it is through established HACCP practices and safety assessments that the production of safe food products is assured, focussed on a single product and production site and using scientific knowledge and experience. Traditionally, the food production industries have been concerned primarily with assessing potential exposures (i.e. the presence, survival and growth of pathogens in foods) and have accumulated data, expertise and experience in safety assessment, including the use of predictive microbiological modelling in combination with appropriate testing.

However, applying the principles of MRA can also be of value and relevant for certain decision-making situations where variability and uncertainty exist. When a food industry elects to use quantitative MRA, it will have to balance investment of analytical expertise and resources to the value created as part of the normal cost of product innovation. For example, the larger the market opportunity or economical benefit or the more complex the aspect of food safety is, the more relevant it may be to use MRA in new product and process design. Hence, the development of an MRA by industry will be highly specific to the single food/process of interest. The endpoint of such analyses are generally not explicit estimations of "probability of an adverse health effect" in terms of public health statistics (e.g. number of illnesses per year in a population) but a measure of an adverse outcome in terms of pathogen survival or growth, or possibly a measure of economic corporate risk. Some examples of MRA applications include: evaluating the safety of adding non-processed ingredients to processed products at the retail phase; consumer safety of radical product innovation; simulating "safe" changes in heat processing; simulating "safe" shelf life for product innovations; evaluating effects of changes in extrinsic (e.g. time, temperature, atmosphere) or intrinsic (e.g. ingredients) factors. Such applications will help guide decisions about further investments, critical data gathering and necessary experimentation, etc., in a systematic and structured manner.

MRA techniques are yet another tool at the disposition of the food industry to refine and improve its ability to establish product and process designs. Some techniques allow for more realistic assessment of pathogen dynamics (e.g. by assessing levels/occurrence as distributions rather than single values) or better consideration of expert knowledge or safety rules in the calculations (e.g. by using influence networks.). They add to the suite of existing resources (i.e. data, expertise, experience, testing results) to provide input into decision-making.

MRA as developed by governments will evaluate the public health risks that are associated with food products on the national market and evaluate what could be done to mitigate undue risks. Some of the insights gathered in the MRA process can be used by industry to show compliance to governmental risk-based guidance or to refine and improve their GHP/HACCP systems. Other benefits can be realised, including that the MRA brings a systematic and structured framework for regulatory decision-making that is sufficiently transparent and open to allow discussion between stakeholders on a more-or-less level playing field.

MRAs conducted and used by governments in establishing policy and public health risk reduction targets will impact on industry in several ways:

- Industry has to comply with national policies and regulations, and when these involve FSO or PO levels specified by competent national authorities, the food industry must ensure and demonstrate that their food safety management systems comply with these standards.
- The food industry can use the information brought together in a broad-scoped MRA study (whether carried out by governments or by other credible institutions) to provide new insights on pathogens that may pertain to their own specific products/processes.
- Different partners in the food supply chain can use MRA information and insights to assure that the various management systems in the supply chain become more aligned and integrated to control hazard levels in accordance with FSO or PO standards.
- The food industry can and should be an active stakeholder in MRA and in setting standards at the governmental level and must be familiar with the concepts used in decision-making.

A small number of examples in the published literature demonstrate the potential uses of MRA for an integrated risk-based approach to the control of a pathogen in an industry setting. The MRA framework and process help to guide a multi-disciplinary approach incorporating several disciplines, help to foster stakeholder awareness and industry participation, and allow linking MRA with economics and spatial elements.

MRA APPROACHES ON AND ALONG THE "QUALITATIVE–QUANTITATIVE CONTINUUM"

In the field of food safety MRA, two categories of analysis are generally referred to: qualitative and quantitative MRA. In reality, there are no sharp lines defining these categories, nor gradations within these categories, as MRA methodologies represent a progression of increasing quantification and analytical sophistication. Correspondingly, there is typically an increase in the requirements for data, degree of detail in describing the system of concern, analytical expertise and time involved when utilising increasingly sophisticated methods of analysis. The characteristics, merits and limitations of these approaches are discussed here.

Defining the Problem: Risk Profiles

One of the newer tools introduced for MRM, prior to commencing a risk assessment, is termed a risk profile. The basis for sound MRM, including the MRA approach to be taken, is to focus on the relevant aspects that pertain to the risk issue or situation, however broad or narrow the scope of the problem. To aid in determining how to address a food safety issue, a first step is to clearly identify what is known about the situation.

The term "risk profile" has been adopted under the CAC risk analysis approach as part of the "preliminary risk management activities" and is "a description of the food safety problem and its context" (CAC, 2006). The information assembled presents in a concise form the current state of knowledge relevant to a food safety issue and the food safety policy context that will influence further possible actions. In this perspective, a risk profile may be considered a structured "narrative" type of evaluation, or a "preliminary risk assessment". However, in addition to scientific information, other considerations such as public perceptions, trade impacts and management/intervention options may also be included in the document. The purpose of the risk profile is to aid in providing a common understanding of the food safety issue at hand through the various parties having a stake in the decisions, either as those responsible for the decision or as those affected by it. This is particularly relevant in the use of risk profiles by government, where for instance a risk profile can be a suitable means of providing documentation in situations of urgency in decision-making on the priority for dealing with the issue. A risk profile may also be helpful for risk managers to decide whether a more detailed, quantitative risk assessment should be established or whether other management action needs to be taken. Risk profiles have become an integral part of the way the Codex Committee on Food Hygiene (CCFH) considers the need to develop new codes of international hygienic practice. Guidelines for the type of information that should be considered within a risk profile and its application have been elaborated by FAO/WHO (2002).

In a broader context, workshop participants suggested that the risk profile can be a complete end product in itself to provide a systematic summary of a food safety matter. Similar to a "feasibility study", the information provided can lead to a decision about the "next steps" that should be taken, even without considering an MRA. The risk manager or decision-maker(s) (and potentially, affected stakeholders) should determine the scope of information and amount of detail that should be considered within a risk profile so that it adequately addresses the objectives of the work. The resulting document may be only a few pages completed within a short time frame to address immediate issues, or the risk profile may be a comprehensive, detailed document for more strategic planning issues. As an example, the latter objective was the purpose of a project in Australia, where comprehensive, detailed risk profiles were compiled for all red meat commodities to identify priorities for management and further assessment as needed (Pointon *et al.*, 2006; Sumner *et al.*, 2005).

Qualitative and "Semi-quantitative" MRA

Qualitative MRA relies on descriptions or categorisations to estimate the magnitude of risk, and the impact of factors affecting risk. According to CAC (1999) such assessments "...are appropriate when the available data are inadequate to develop numerical estimates of risk but, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permit risk ranking or separation into descriptive categories of risk". A qualitative MRA might also be established before a quantitative assessment to give some idea of potential magnitude of risk, and to indicate whether or not a more detailed analysis is needed to better understand the issue.

Despite the terminology, many such assessments are actually qualitative expressions of essentially quantitative analyses, and may be described (although inexactly) as "semi-quantitative". Such an MRA may be derived from the synthesis of data and knowledge concerning factors that affect the probability and severity of an adverse event. Alternatively, it may rely on comparison to some other known, quantified risk or risk-affecting factor to infer the risk associated to the specific food safety issue at hand. As an example, a qualitative assessment of the risk from *L. monocytogenes* in processed meats was developed in New Zealand using reference to quantitative information (Lake *et al.*, 2002) (see Box 1).

Box 1: Qualitative MRA: Combining Qualitative and Quantitative Information

In an MRA study in New Zealand conducted for ready-to-eat meat products (Lake *et al.*, 2002) the following inputs were considered:

- Food surveys in New Zealand indicated a prevalence of contamination in ready-to-eat meat products similar to that found overseas
- A high level of consumption of these foods in terms of numbers of servings and serving sizes was observed
- An outbreak of non-invasive infection by *L. monocytogenes* where ready-to-eat meats were identified as the vehicle had occurred in New Zealand, and ready-to-eat meats had been identified as a transmission vehicle in reported episodes of invasive listeriosis
- The limited prevalence data for New Zealand suggested that contamination occurs across all types of ready-to-eat meats
- A US quantitative MRA suggested that pâté and meat spreads, along with deli meats, represent the highest relative risks in the ready-to-eat meat group, while fermented meat products have a lower relative risk (FDA/FSIS, 2003).

From these considerations, it was inferred that a significant proportion of listeriosis in New Zealand could be attributed to processed meats. This was achieved without the need to conduct a fully quantitative MRA for the New Zealand situation but by comparison to the factors affecting the risk from analogous products and processes in another country (USA) with similar dietary habits and for which the risk had been well characterised and quantified.

Qualitative MRA often relies significantly on the knowledge and opinions from experts, and care should be taken that this does not lead to the introduction of biases and errors by subjective estimations. This also applies, although to a lesser extent, to quantitative models, for instance when key data are lacking and need to be covered by surrogate data or assumptions. In part, biases and errors may be unavoidable, but by being aware of these potential pitfalls and using recognised elicitation practices to minimise subjectivity, the assessment can still produce valid results. Obvious biases are best made transparent and their possible effect on the risk characterisation made explicit.

Numerous qualitative risk assessment schemes have been developed in the form of risk assessment matrices, including several relevant to foodborne hazards. In general, these schemes rely on selecting from a range of descriptive levels of hazards and probabilities of exposure (such as high – medium – low). A table, or "matrix" is constructed with hazard levels in one dimension and the probability of exposure in the other. Where the selected values intersect on the matrix, a risk ranking or description is given, usually from a small range of descriptors. While these schemes are superficially attractive, experience suggests that for them to deliver a reliable assessment of risk the user must have a high degree of relevant and detailed knowledge of that risk and, conversely, that inexpert users would be unlikely to achieve consistent assessment of risk using such schemes. Challenges also arise in defining descriptive categories and appropriately combining discrete categories of probability and severity. Another limitation is that qualitative risk classifications in one assessment are unlikely to be comparable to another assessment, although widely accepted guidance such as the hazard classes established by the International Commission on Microbiological Specification for Foods (ICMSF) are helpful for standardising some of the practices in qualitative MRA (ICMSF, 2002).

Despite the caution needed to avoid and acknowledge such limitations, some of the simple schemes can provide a very effective method of communicating how a risk estimate was derived. As discussed in the workshop, however, there is a need to advance and refine these types of assessments. Some of the key elements that should be considered in developing qualitative or semi-quantitative MRA are summarised in Box 2.

Box 2: Advancing Qualitative Risk Assessment

The format, attributes and guidelines for robust qualitative expressions of risk have not been defined, and lack uniformity. The workshop participants discussed that future efforts in developing these types of MRAs should pay attention to certain key aspects:

1. Demonstration of quality of inference: clear description of how the conclusions were derived/ inferred from the data given
2. Clear definition of the meaning of descriptors (e.g. "negligible" means indistinguishable from zero)
3. Documentation of data sources and indication that the data were relevant and complete; explanation of why data were excluded
4. Explicit descriptions of assumptions and data gaps
5. Evidence that a broad range of people (whether by skills, culture, region, as appropriate) have been involved in the preparation and review of the document
6. Expression of the confidence the assessor/assessment team has in the conclusions of the assessment, the scope of applicability of those conclusions (particular company, type of food, region, entire country etc), as well as areas of uncertainty.

Quantitative MRA – Deterministic and Stochastic (Probabilistic)

There has been an increasing use of quantitative techniques, including mathematics and statistics, both to support established safety assessments and to extend the knowledge base to changing food supplies, new food products and a wide variety of different consumer behaviours. Quantitative MRA uses these techniques to help define and describe systems and relationships between the elements of a system to quantify outcomes. Although the mathematical representation of food safety systems sometimes seems abstract, and can cause confusion, most quantitative assessments aim to use a set of simple definitions and some fundamental rules to present essentially natural arguments in an organised fashion. For deterministic assessments, all variables are assigned a certain fixed value, for example, the mean value of a set of data on the initial contamination levels in a food, the average storage temperature of the food, and so on. The calculations result in a single number (which may be bounded by confidence intervals) as the risk estimate outcome. Once the relationships between the factors in a model are determined, e.g. how the storage temperature will affect the multiplication of the organism to give the final dose in the food consumed, deterministic models are relatively simple to calculate. However, even with consideration of confidence intervals, these do not provide much insight into how likely (or unlikely) it is that the adverse event will occur, nor give useful insights about the drivers of the risk.

However, generally the various data inputs to describe a system will not have one fixed value but will be variable (stochastic). In order to include this information, one needs the statistical distribution of the variables (the shape of the distribution curve and its parameters), resulting in a stochastic assessment. Stochastic models can incorporate both variability and uncertainty. Variability is the heterogeneity of a population: this can be inherent, biological, seasonal, localised variability or random fluctuations. Uncertainty on the other hand is the lack of exact knowledge (due to extrapolation, simplifications, estimations, parameter uncertainty, unknown phenomena). Combining distributions requires more expertise than for single numbers in an equation to calculate outputs. By using simulation software based on techniques such as Monte Carlo analysis, the effect of variability on intermediate results and the final outcome can be calculated. For every simulation (i.e. literally, to simulate what may occur in reality) a random value of each variable is selected, resulting finally in a dose at consumption. This results in a probability distribution of the exposure, which is then converted to a probability distribution of the risk through combining with a distribution for the dose–response relationship between pathogen and host.

Variability can often, although not always, be reduced by better control (e.g. process controls in the food production environment); uncertainty may be reduced by taking further measurements to better characterise the factor of interest. It is necessary to separate variability and uncertainty, since these are different things and need different treatments and interpretations. A difficulty with variability is the question of which variability to include, and which are the right distribution and parameters to use? A difficulty with uncertainty is that to a large degree uncertainty is inherently not known. Therefore, which distribution and parameters to use is totally arbitrary if this is handled as a statistical distribution. Often the running of some scenarios, using alternative (but plausible) values to give borders resulting from uncertainty, might be sufficient since complex simulations with many distributions might give a false impression of the exactness of this uncertainty. Further, calculations become less transparent and more difficult to interpret the more complex the simulation.

Complete Food Chain vs. Product–Process MRA

The scope of an MRA may be concerned with all steps in a production-to-consumption food chain or it may be focussed on a few or even a single step in the food chain. An example of the latter is where a food product prepared in a specific process is the topic of study and is investigated for an entire food commodity industry.

Capturing a single product/process in an MRA may be somewhat more straightforward than describing multiple steps in a food chain, each with their own variability. The workshop noted that the complexity inherent to complete food chain MRAs is best dealt with by taking a quantitative MRA approach. MRAs that describe and quantify microbiological hazards within different food safety management systems, beginning at primary production through to consumption for an entire commodity class, have been constructed for priority pathogens such as *Campylobacter* spp., *E. coli* O157:H7, *L. monocytogenes*, *Salmonella* spp. and *Vibrio* spp. Two examples were presented during the workshop: the CARMA (*Campylobacter* Risk Management and Assessment) project carried out in the Netherlands and the UK Food Standards Agency assessment of the contribution of poultry to the number of human quinolone-resistant *Campylobacter* infections *(*see Box 3*).*

Box 3: Quantitative MRA: Examples of Modelling the Food Chain

1. The *Campylobacter* Risk Management and Assessment (CARMA) project was carried out in the Netherlands with the objectives of providing advice to the government about the effectiveness and efficiency of control measures aimed at reducing campylobacteriosis in the population (see: http://www.rivm.nl/carma). A farm-to-consumption risk assessment model for *Campylobacter* in the broiler chicken meat chain was constructed to assess the existing human risk related to the consumption of chicken breast fillets prepared at home and consumed in a meal with a potentially cross-contaminated salad. Next, the relative risks of the interventions were calculated. The model was combined with economic analysis and epidemiological data, which allowed a cost–benefit analysis of the interventions. The outcomes of the work underlined the importance of quantitatively characterising the variability in numbers of *Campylobacter* at primary production, on carcasses and in the food products. Consumer risks were mainly associated with highly contaminated products and product batches and, by running scenario analyses the estimated risk was significantly lowered by interventions, either on-farm or at later stages, that reduced the concentrations of the pathogen on the meat. The MRA was used to assist in developing risk-based sampling schemes to eliminate highly contaminated lots from the fresh meat supply, i.e. to achieve a defined performance objective, and to link microbiological criteria to a public health outcome measure, e.g. an ALOP.

2. In the UK, MRA was used to assess the risk of illness from (fluoro) quinolone-resistant *Campylobacter* (QRC) attributable to various pathways: food, the environment and "human" sources, i.e. foreign travel, human use of ciprofloxacin (VLA, 2005). As part of this work a farm-to-consumption risk model was developed to assess and compare the risk of QRC infection from conventional, free-range, organic and non-UK chicken. For the conventional chicken model, the exposure assessment quantified three scenarios where QRC colonisation/contamination may occur during on-farm broiler chicken production and/or during transport. It also simulated the impact of processing, cross-contamination events and undercooking during preparation in the consumer's home. These aspects were also considered in the free-range, organic and non-UK chicken risk assessments, but these models commenced at the point of retail due to the better quality of data at this stage. The risk estimation for each source included the risk of illness, the number of QRC cases and the number of excess illness days due to patient treatment failures because of pathogen resistance. A number of risk management strategies were modelled to estimate potential risk reductions. Although not specified in the risk question at the beginning of the work, the farm-to-consumption risk model could, with some modification, be used to assist in the setting of targets such as performance objectives and estimating the resulting public health outcomes.

The data requirements for complete food chain MRAs are extremely large, and large degrees of variability and uncertainty must be considered. The models rapidly become complex and modelling methodology is still under development. However, such comprehensive MRAs can be greatly beneficial to risk managers since these allow control strategies at different stages of the farm-to-consumption pathway to be investigated and compared. An additional benefit to be realised in the development of a food chain MRA is its use as a basis to aid in the setting of broad risk management options, such as the specification of metrics such as food safety objectives, performance objectives and other criteria for an industry. It was noted during the discussions that before beginning, or in the early stages of MRA work, it is necessary to define the desired information outcomes and, for instance, to make explicit whether decisions about establishing metrics need to be made such that the MRA will indeed include the relevant elements for that decision.

Typically, the narrower the scope and the more uniform a food safety management system is (e.g. homogeneous product characteristics, controlled production, handling and manner of consumption) the more precisely the variables within the system can be described. The more uniform the product and extrinsic factors to which it is exposed, the more precisely the behaviour of the pathogen can be predicted. When a product–process MRA is undertaken by a single manufacturer, it will be limited to those parameters under its control, i.e. beginning with the raw materials and modelling the processing stages. Many uncertainties in the system can then be minimised, if necessary, by taking representative measurements of the variables within the system. The MRA itself, or simply using the framework to guide an investigation, will often be useful to identify which specific experiments might be needed to fill in data gaps (see Box 4).

Box 4: Quantitative MRA: Examples of Specific Product/Process MRAs for Single Manufacturers

1. **Modified-atmosphere packaged sliced chicken roll:** A company was producing a safe product under current processing conditions. A risk model was developed to assess the effects of process modifications on increasing retail shelf life without increasing the consumer risk.

   Key elements of the MRA process:
   - Detailed definition of scope, including motivation and expected outputs
   - HACCP flow diagram as the basis for process description
   - Preliminary analysis to identify critical risk-related factors that might be altered by introduction of process changes, and to focus more detailed data gathering on these factors
   - Mathematical modelling of time–temperature histories, bacterial death, time to toxin production; variability and uncertainty quantified
   - Implicit consideration of dose–response/human health risk: presence of toxin at time of consumption considered unacceptable risk.

   Form of outputs:
   - The estimated probability that a pack contains at least one spore of *Clostridium botulinum*
   - The residual lag time (for spore outgrowth and formation of toxin) at time of consumption, expressed in days under commercial storage conditions, with and without product/process changes.

   Key findings:
   - Systematic analysis led to improved understanding of the process by industrial personnel
   - Quantitative modelling identified factors where large data uncertainties (e.g. for predicting behaviour of pathogen) led to large uncertainty in absolute risk, which thus could be considered in the manager's decision-making
   - Identified magnitude of change in relative risk associated with process changes
   - Demonstration of equivalence of process to existing regulatory criteria.

Box 4 continued

2. **Specification and handling of an ingredient categorised as "high care":** A company could realise increased cost-savings if reduced stringency did not compromise safety.

Key elements of the MRA process:

- The initial steps were similar to the preceding example, with implicit consideration of dose–response/human health risk: recovery of *Salmonella* after storage of ingredient was considered to be an unacceptable risk. The initially defined outputs were differences in risk compared to other "high care" and "low care" categories of ingredients. However, by using the systematic MRA process for data compilation, preliminary analysis led to identification of a critical risk-determining factor that could be addressed by targeted routine testing, eliminating the need for further mathematical risk modelling.

Risk Ranking

Risk ranking is one set of the risk assessment tools that has emerged as a means for considering more objectively the relative risks associated with multiple hazards when decisions must be reached regarding the priorities for committing limited resources to the control of hazards. Synonymous or similar procedures are hazard ranking, risk attribution, risk-based priority setting and comparative risk assessment. Initially developed as a qualitative or semi-quantitative technique for comparing risks, in recent years the degree of sophistication has expanded to a point where highly complex, probabilistic risk-ranking models have been developed to consider microbiological foodborne hazards, for example, *L. monocytogenes* in ready-to-eat foods (FDA/FSIS, 2003; FAO/WHO, 2004). The meeting noted that risk-ranking techniques have evolved into a highly flexible group of risk assessment tools that range from reasonably rapid qualitative techniques making use of expert elicitation data to the detailed quantitative consideration of a broad array of highly complex data and relationships. Thus, an appropriate risk-ranking technique can be used to match the analytical needs and time/resource limitations typically faced by risk assessors and risk managers. However, efforts are needed to enhance the applicability of this approach *(see Box 5).*

Risk ranking may be based on quantitative data-rich food chain MRAs, but can also be based on risk profiles or more qualitative analyses. Therefore, the descriptions of risk profiles, qualitative or quantitative MRA and risk ranking should not be considered mutually exclusive.

Box 5: Risk-Ranking Challenges

Managing the microbiological safety of foods is a complex process that requires consideration of a broad array of risks, foods, primary production settings, food processing options, distribution systems, marketing environments, home preparation methods and mitigation strategies. The likelihood that a microbiological entity will cause disease is dependent on the interaction of three broad, highly variable factors: the micro-organism, the human host and the food matrix. Objectively prioritising multiple food safety issues is a necessary activity, and risk-ranking methodologies are needed to achieve this goal.

- A wide variety of risk ranking approaches and needs exist, and solutions are quite varied. In some cases, risk ranking is a relatively qualitative process or expert-opinion driven. A few quantitative examples exist. Generic MRA models for risk-ranking purposes would be useful, and it is noted that a number of projects in this area are currently underway. The complexity of a risk-ranking MRA inevitably increases as the diversity and number of hazards and types of risk situations that are to be compared.
- Risk can encompass many attributes in the context of decisions to be made, including inherent or controlled risk, economic factors (cost of implementation, litigation), the need to respond to urgent issues, perception as well as public health risk. Even public health risk can be measured in different ways (numbers of cases, economic burden etc).
- A significant problem is the definition of a common risk metric by which to compare impacts of different types of risks. Disability-adjusted life year (DALY) and quality-adjusted life year (QALY) values have been advocated to facilitate comparison of all types of health outcomes. Acknowledging that there is some complexity and debate about the value choices and underlying epidemiological data involved in calculating DALYs and QALYs, these metrics have been useful in public health decision-making.

The Need for Flexibility in MRA Approaches

MRAs discussed at the workshop varied in many aspects relating to the food safety issue studies, the skills and capacities of the risk assessment experts, the requirements and constraints set by the risk manager, etc. Together the MRAs nicely described the continuum between descriptive and straightforward calculations and highly sophisticated quantitative probabilistic types of analyses. An MRA will often include both descriptive and quantitative elements because not all data are available in a numerical fashion or because data gaps exist that are covered by a description. The scope of an MRA may encompass an entire commodity industry, from production to consumption, or may focus on a single product–process in a certain part of the food chain. It even may concern a single manufacturer. It all depends on the purpose of the MRA and the context that the MRA develops the insight for. Endpoints of an MRA may characterise population health risks in different ways, such as the number of predicted cases of illness in a year and/or a per-meal risk. Other adverse endpoints may also be measured, and linked to, for example, the likelihood and impacts of economic risks. Outside of public health measures and consumer protection, other adverse outcomes of interest for a manager are also valid. For example, in a food processing business, focus will be on potential exposure. In such cases human health impacts are implied, but not quantified through use of a dose–response relationship.

FACTORS RELATING TO MRA VALIDITY

The workshop discussed that the value of an MRA, in part, depends on how valid the MRA is for the food safety issue at hand, and that validity depends on many factors, including the chosen MRA approach, data selection, modelling methods and interpretation of outcomes. The accuracy to which an MRA represents a risk situation is a result of a number of factors and, beyond the scientific issues, it will be influenced by the context/situation of the risk management issue. In circumstances where an MRA has formal standing such as evidence, for example in trade dispute resolution tribunals, the stringency for adherence to a rigid set of specifications is driven by international legal requirements, which would not necessarily be requirements in other circumstances. With the exception of illogical and improper errors fundamental to the conclusions of the assessment, the validity of an MRA is multi-dimensional and can be defined on a continuous scale rather than in discrete categories. As the degree of detail and sophistication of the MRA method increases from qualitative to quantitative, there is increased quality and transparency in evidence and inference; however, there is also an increased demand for the length of time needed to carry out the work and the resources (software, data, expertise) required. In addition, although the "apparent" transparency of inference increases (i.e. the logic of reasoning dictated in quantitative MRA by mathematical rules for appropriately combining data), transparency may also, in reality, be lost to all but those in the MRA community who can truly understand the highly complex analyses. Then the question arises about the validity of an MRA that is not understood, and possibly for that reason not useful and thus not accepted, by the majority of potential users.

The factors influencing MRA validity were presented during the workshop discussions in four categories, as follows:

• *Quality and Treatment of Data*

As for any sound scientific investigation, MRA requires the proper selection and scrutiny of input data (including numerical data and other types of information and knowledge that might not be numerical; also including assumptions covering data gaps) relevant to the risk issue, regardless of the approach (qualitative or quantitative) selected. One of the more challenging aspects within MRA is the characterisation of variability associated with the input data and among elements in the model of the risk-generating system.

• *Timeliness*

An MRA must be timely to be valid. In pursuit of timeliness, analysts tend to choose the approach that is most readily available to them with the greatest certainty of satisfying the decision-maker's needs by the imposed deadline. Inevitably, there will be trade-offs in the degree of detail and analytical modelling when timeframes pose constraints.

• *Quality of Inference of Probability*

As an essential element of MRA, the quality of the inference of probability will always be a key to validity. Any MRA approach is inherently a simplified representation of reality; however, failure to appropriately incorporate variability and uncertainty and illogical or inappropriate simplifications may lead to misrepresentations of the system or to flawed data and analysis. This then clearly weakens the validity of MRA by compromising the quality of inference of probability.

Due to the multiplication and/or inactivation characteristics of microorganisms, there is typically exponential variability in multiple factors in the risk model, i.e. values will range across orders of magnitude. In addition, a significant fraction of the risk can be generated by combinations of events that tend towards the extremes of their true distribution ranges. Overlooking the influence of variability in driving a risk outcome by choosing single values to represent the phenomenon then becomes a serious distortion of the system. However, to a degree the selection of single values can take account of known variability (e.g. by not taking a mean value but a high-end input value representing more of a "worst-case" input). However, it is critical that the choices of values and their consequences are made explicit as part of the risk characterisation.

Qualitative MRA relies on narrative descriptions of the reasoning that was involved in analysing information, defining likelihoods and arriving at judgements of magnitude of risk. Therefore, there is typically very little constraint, and hence little strength, in the inference of probabilities by the analyst. In addition, the vagueness of words chosen as descriptors, for which there are generally no uniform interpretations, can significantly bias the estimate of risk in both the analyst's mind and in the mind of the reader.

Semi-quantitative MRA can potentially infer probability in a valid manner. However, many of the simplifications made in semi-quantitative analyses may lead to errors. A common example of this is the use of additive scoring schemes, where the combination of scoring elements would more appropriately be multiplicative. Another example is arbitrary choices in the ranges of scales leading to inappropriate weighting of evidence that affects the final risk score.

Quantitative MRA is generally preferred with respect to the ability to properly infer probability. However, there are unforeseen difficulties that can interfere with the inference of probabilities. Errors are easy to introduce into large spreadsheets, calculations and in the logic of inference. In simulation models, specific issues arise, such as running enough simulations for risk estimate convergence and the ability to represent rare events. However, although many errors are possible, specific references and resources are available, such as Haas *et al.*, (1999), Vose (2000) and general texts on probability and statistical inference that provide guidance on how to avoid certain types of errors in quantitative MRA, which is currently lacking for qualitative and semi-quantitative approaches.

• *Transparency*

Transparency in a risk assessment requires that the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the risk estimation are fully and systematically stated, documented and accessible (CAC, 2004). As for any type of scientific characterisation, the full breadth of input data used in MRA must be clearly presented, as should be other parts of the factual evidence relating to the issue at hand. More often overlooked, however, is transparency in the inference of probabilities – the logic used and the pathway(s) linking the individual pieces of evidence to the conclusions reached. Again, qualitative MRA lacks uniformity and precision in the language and logic of deriving conclusions. In semi-quantitative approaches, although a transparent scoring system may be provided, the combining of values in the system may be arbitrary, less transparent and, in reality, meaningless. Quantitative MRA uses mathematical and statistical logic rules of inference; however, in complex systems the complexity of calculations make them difficult to interpret (and ideally reproduce) except for perhaps a few analysts. Hence, realistically, transparency in MRA should imply that the particular audience of concern will be able to follow the arguments with a reasonable level of effort. This will enable decisions to be made with a level of confidence, as well as allow various stakeholders to understand the MRA study and any estimates or scenarios developed in it, and to be able to engage as active participants in the risk analysis process.

CRITERIA FOR MRA VALIDITY AND UTILITY

In selecting an MRA method, or in evaluating the important and "desirable" characteristics of an MRA, workshop participants identified criteria in terms of which elements are important for the validity of an MRA, and which elements are important for its utility, i.e. usefulness for decision-makers (Tables 1 and 2). While these criteria are distinguished separately, in reality validity and utility are both multi-dimensional and overlapping aspects of MRA and are best considered in conjunction. Timeliness is probably the factor that would dictate the stringency of meeting the "desirable" properties of an MRA; an assessment must be timely to be both useful and valid.

Table 1. Criteria Relevant to Validity

Characteristic	Comments
Timeliness	In response to the decision-maker's needs; will determine approach and stringency
Quality and treatment of data	Validity of science and logic; current, relevant and sufficient data; rationale for inclusion/exclusion of data
Inference of probability	Appropriate assigning and propagation of probabilities; appropriate choice of distributions; adequate number of iterations in a simulation model to detect rare events of concern In semi-quantitative or qualitative MRA, clear definition of the meaning of "descriptors" such as negligible, low, medium, high; logic in combining semi-quantitative values; clear description of how conclusions are derived and magnitudes of probability and severity are assigned
Internal consistency	Sound logic and inference; systematic reasoning; particularly important in assigning values for risk ranking and other non-mathematical evaluations
Appropriateness of assumptions, expert opinion, scientific support	Logical soundness of premises or underlying assumptions in scientific justification, in terms of theoretical arguments or empirical results, and in methodological assumptions
Epidemiological and biological credibility	Outcomes should not be inconsistent with observed data; although not necessarily in agreement should be within plausible limits and account for all observations
Transparency	Systematic development of the MRA steps and the MRA structure; the models used to describe the food supply chain, processes and microbiological dynamics; the data used and those disregarded as well as pertinent data gaps; the use of alternatives to close data gaps (e.g. expert knowledge, surrogate data, assumptions); the uncertainty in the models, data, assumptions as well as in the risk estimates and for the different "what-if" or mitigation scenarios developed; the process of reasoning to arrive at conclusions in qualitative MRA; documentation in adequate detail for appreciation by the variety of stakeholders
Peer-review[1]	Independent review of data, logic, scientific interpretation, models and analysis; may require different experts for different aspects of the MRA; staggered process for complex MRA – review of model at early stages of assessment process; guidance given to reviewers in the form of directed questions, access to model
Stakeholder involvement	As appropriate for inputs of data and knowledge about the risk situation; for government – to ensure MRA reflects broad scope of an industry or public segments
Trustful outcome	Confidence level associated with results

1. Generic guidance documents to help direct the peer-review process for risk assessments have been elaborated by different agencies, including the World Organization for Animal Health (OIE), the US Food and Drug Administration and the US Environmental Protection Agency

Table 2. Criteria Relevant to Utility

Characteristic	Comments
Addresses the MRM question(s), timely, responsive	MRM "process" related, i.e. importance of communication and understanding between managers and assessors, clear definition of problem statement and scope, ultimate application of outputs; iterative interactions before and during the MRA
Stringency and detail	MRA approach/method and scope (e.g. qualitative or quantitative; food-chain vs. specific stage) and form of outputs should be appropriate for the importance of the task or decision required
Clarity for different audiences	Tiered series of reports for more than one group of people, ranging from complete analytical documentation to interpretive summaries aimed at non-technical audiences
Explicit statement of limitations	Clear description of constraints relevant to the accuracy, interpretation and application of results
Objectivity	Avoidance of language/conclusions that imply what the risk manager's decision should be
Proactive	Findings help to decrease risk, prior to product being released in the marketplace
Reactive	Findings help to understand how and where risks arose with products already in marketplace
Identification of risk-determining steps, knowledge gaps and conflicting evidence	Helps decision-makers to focus on important factors in the food chain for intervention, and informs both decision-makers and scientists about important data collection/data generation needs
Inclusion of "what-if" scenarios, evaluation of potential risk reduction strategies	Requires defining scenarios together with risk manager(s) prior to and/or during the conduct of the MRA (may also include economists at some early stage for cost–benefit/utility analysis considerations); iterative and interactive
Aids in prioritisation	Results inform decisions about where to allocate resources for optimal risk mitigation
Database of knowledge	A comprehensive compilation of data, information and assumptions relevant to a pathogen, food, host and exposure pathway(s), which can be updated with new knowledge
Applicable to stakeholders	The MRA enhances understanding of the food safety risk issue, and can inform participants (industry or trading partners) involved at different stages along the food chain; new information or insights may be used by stakeholders for other purposes; helps to promote communications
Adaptable to other countries	Particularly relevant for government and international (e.g. FAO/WHO) MRA; may be feasible for countries with comparable industries and host populations to adopt or adapt as is appropriate using local national data

Workshop participants generally agreed that the same criteria should be considered for all MRA approaches (i.e. whether qualitative, semi-quantitative or quantitative), whether for government or within a food company, although the degree of stringency may vary and specific constraints or situations will dictate the extent to which criteria can be adhered to more or less stringently.

A fundamental consideration in the meeting related to the decision-making environment and that the MRA has to be "fit-for-purpose" to be useful. In other words, that the MRA indeed answers the risk manager's questions such that it produces information that appropriately informs the risk management process, and does so in a timely manner. The rigour and stringency applied to the MRA may need to be aligned with the urgency to deal with a risk and/or the likely magnitude of risk and consequences of decisions based on the MRA outcomes.

It was noted that an MRA is a model of a system and thus is similar to a scientific hypothesis. In this context, the rules applied to accept, reject or modify hypotheses should apply equally to MRA, e.g. does the model describe the known data, does the model rely on known principles, does the model generate testable hypotheses and, if so, does it correctly predict outcomes?

It may be perceived that constraints such as time, resources and/or in the data produce "conflicts" in the degree to which an MRA is either valid and/or useful. However, in reality, these are factors that must be considered by managers, together with assessors, to define which approach is the most appropriate for the situation. Constraints should be acknowledged before beginning the process and, to the extent possible, openly discussed between managers and assessors. In the MRA document any issues that impact the final outcomes and limitations of the assessment should be made explicit for the reader. The development of concise risk profiles during the initial stages, prior to conducting MRA studies, can be useful in identifying potential challenges to what can be achieved through a more detailed analysis *(see Box 6).*

Box 6: Validity of Risk Profiles

Codex guidelines provide a suggested format for a risk profile document (CAC, 2006). However, because risk profiles are relatively ill defined, except within the Codex framework, the main attribute of validity is that these suit the application for which they are intended. The purpose needs to be clearly specified, and will be dictated by the needs or desires of the risk manager and the situational context.

Attributes of good risk profiles

The 2002 Kiel 2 Consultation Report (FAO/WHO, 2002) identifies the descriptive elements, using information that is relevant and readily accessible, that may be included in a risk profile, briefly noted here:

- A concise description of the food safety issue
- Information about the hazard
- Any unique characteristics of the pathogen/human relationship
- Information about exposure to the hazard, e.g. routes of exposure, prevalence, characteristics of the hazard, levels of hazard throughout the food chain, possible control measures and their feasibility and practicality
- Information on the types and severity of adverse health effects on humans, subsets of populations at increased risk, prevalence and incidence data from public health surveillance
- Other information relevant to risk management decision-making, e.g. adequacy of the data, perceptions of the issue, practical considerations (economic, technical, political, legal), possible actions and expected consequences (public trust in the decision-making process, distribution of risks and benefits)
- Potential risk management questions to be answered by risk assessors.

Additional attributes that should be considered are:

- Clear specification of the context of the food safety issue
- The anticipated lifetime of the document, or the time when it was last updated
- The size of the document, scope and time for completion should be specified, initially prior to the work but also within the document itself to identify any constraints or limitations for the reader.

It was also noted that a risk profile undertaken for industry might have a more limited scope than one done for government or Codex, as it would typically only relate to matters that the company has some degree of control over.

A major criticism of many, if not the majority, of quantitative probabilistic MRA undertakings is that they are multi-year projects and very resource-intensive. An important consideration is the question of whether such an MRA is still relevant upon completion – does it reflect the current situation and/or technologies "today", when the work began two or three years previously? It was acknowledged that a large project team for data collection is inevitably needed to ensure the information is up-to-date and incorporated into the final product; this also implies that the risk model must be constructed in such a way to readily allow for modifications of data inputs and analysis.

However, developments are already being realised that will help to overcome these challenges. The current unfamiliarity with, and limitations of, this still-evolving field contribute to lengthy timeframes in conducting the work, but are being overcome as training opportunities and expertise become more widely available. Efforts are being made to develop readily available, user-friendly interfaces, tools and databases. The increasing accessibility of models included in website repositories (e.g. http://www.cost920.com; http://www.foodrisk.org) will aid in reducing the time quantitative MRAs require, as well as be informative for other applications. Increased refinements of models and literature databases, particularly for the priority pathogens present in most regions of the world, will provide improved formats that may be readily shared between experts and, where possible, tailored to applications specific to the particular country or product.

Nevertheless, it is acknowledged that the nature of some food safety issues will unavoidably demand extensive time and other resources. For complex problems that require an integrated strategic approach (for example if considering multiple interventions in the food chain, evaluating multiple exposure vehicles/pathways, or multiple-pathogen models), risk managers must realise that these will be longer-term undertakings.

Discussion at the workshop regarding the quality of inference of probability led to questions such as:

- What is the appropriate way to develop a model that is not overly complex, nor over-simplified?
- To what extent should variability and uncertainty be included, and how should their impacts on risk outcomes be estimated?

For quantitative MRA, mathematical techniques are available to separate and analyse the influence of variable and uncertain parameters in the model, but considerable expertise is required and the analyses are demanding in terms of the time needed. It is useful to identify the important elements that influence risk, and consider only these in detail. For example, an initial tiered characterisation of the evidence using qualitative models of the system might aid in identifying the potentially important risk-related factors, or segments of the system that must be carefully examined. The use of simplified model-based reasoning to describe the system before considering the data is suggested, as the available data will not necessarily (or very infrequently) reveal the rare distribution "tails" that one needs to be cognitive of (and which are the factors that most heavily influence the magnitude of the risk). These preliminary activities will also aid in determining whether uncertainty in the available data and/or about the system is too great to have any value in doing a detailed probabilistic MRA, and whether a deterministic or less quantitative approach might be more appropriate. Under some circumstances some large amount of uncertainty may be acceptable, for example if the purpose of the MRA is to identify significant data gaps or to examine emerging food safety problems for potential effects.

RECOMMENDATIONS

The workshop discussions evolved the following recommendations relating to the validity and utility of MRA:

1. A formal, detailed written Statement of Purpose prior to beginning an MRA is essential and should include the context, the intended use of the MRA information (e.g. to establish food safety measures, including targets such as FSOs, POs and other criteria; for international trade disputes; to identify research directions; to support cost–benefit analyses) and who will be affected by risk management decisions. The questions to be addressed must be formulated clearly and provide adequate detail, possibly including the types of scenario analyses to be developed and on what point(s) in the food chain the MRA should focus. Timeframes and other constraints or expectations from risk managers should be clearly understood by the risk assessment experts. All these considerations will influence the decisions on the most appropriate MRA approach and stringency of criteria for validity and utility. To achieve these objectives, risk assessors, risk managers and stakeholders must engage in open discussions prior to and, as necessary, during the conduct of an MRA.

2. Quantitative MRA is a promising development and a necessary process for rational food safety risk management. However, it can be time and resource intensive, and requires adequately skilled and experienced experts. These and other requirements present challenges for many countries to overcome. International collaboration is important for sharing expertise and avoiding duplication of efforts.

3. Although poorly defined qualitative MRA is not necessarily a "poor relation" in the risk assessment continuum. The completion of a qualitative MRA is not always quicker, and the hallmarks of a reliable qualitative approach are not dissimilar to those of any other risk assessment. However, efforts are needed to better define the format, attributes and guidelines for sufficiently robust qualitative expressions of risk.

4. Food-chain quantitative MRA is still in development as a tool for quantifying health risks, for comparing routes of exposure and for assessing the effects of control measures proposed by risk managers. Significant progress has been made in recent years, but additional efforts are needed to further develop the modelling methodologies and find the appropriate balance between simplicity and complexity.

5. Risk managers need to be aware of the potential benefits, ask the right questions and be able to interpret and understand the results and limitations of different approaches to developing MRAs. This is particularly true as food safety targets and criteria explicitly linked to defined public health outcomes become the standard for setting regulations and as the basis for trade.

6. Good MRA and MRM practices must be adopted to effectively benefit from MRA. The expectations of managers (e.g. "desirable" results, preference for "certainty" in conclusions) may often be unrealistic. Addressing such expectations should be balanced through transparency, acknowledging uncertainties and limitations, and through using clear language that is appropriate for the target audience(s) of the MRA documentation.

7. Risk managers and risk assessors alike need to be aware of obstacles for MRA such as data quality, data availability and lack of data quality control and how they impact on MRA utility and validity. This is particularly relevant in comprehensive quantitative MRAs that consider inputs from production to consumption.

8. For food chain or process–product MRAs developed either in a public or private context, the same criteria for validity and utility should be considered. Ideally, independent review should be part of the process, particularly for complex analyses. Data entry into large spreadsheets, complex calculations and, often, the logic of inference are prone to errors. An individual(s) who is knowledgeable but also objective and independent of the MRA team should carry out the review.

CHALLENGES AND FUTURE DIRECTIONS

The past decade has seen the rapid development of risk-ranking tools and their application to microbiological food safety concerns. It is anticipated that such advances will continue as industry, national governments and international organisations have to make informed decisions about where their limited food safety resources will have the greatest impact on improving public health. However, the limitations as well as the advantages of such approaches need to be recognised, and methods developed to overcome those limitations.

The use of MRA and the type of MRA (i.e. qualitative, deterministic, probabilistic) that is appropriate to establish metrics such as FSOs, POs, and other criteria are topics currently under international debate and discussion. Similarly discussed is the issue of whether targets such as an FSO or PO should be single numerical values not to be exceeded (i.e. a "shiny bright line") or are targets to be met within a certain statistical confidence (given a known standard deviation around the target value).

For consideration, the following points illustrate some of the challenges ahead:

- It is not feasible to simply derive the specific metrics or criteria from an MRA, including probabilistic models, because of variability and uncertainty. Any defined exposure parameter and model will have variability and uncertainty. The same holds for any dose–response relationship. Where possible, additional data might be generated to establish actual distributions of pathogens in a food. Deriving such parameters from different types of MRA, especially probabilistic MRA, is an area of science that needs careful attention.

- MRAs are used to inform risk management decisions and, ultimately, it is the risk managers who will establish the guidelines. In this regard, qualitative MRA may be as useful as quantitative methods. However, quantitative probabilistic MRA models can be used to evaluate in detail what the effects of setting specific criteria in the food chain will have on exposure and health risks, using scenario analysis to "test" potential targets. In this way POs, FSOs and public health outcomes, including a nation's ALOP, can be directly linked.

- MRA studies are becoming increasingly multidisciplinary, including socio-economics, epidemiology, etc., to provide risk managers with a broader range of information for decision-making. Cost–utility analysis as part of the MRA process has been found to be valuable for managers (for example, in the CARMA project; see Box 3). Producer and consumer behaviours, usually driven by social and/or economic factors, affect risk creation, risk management effectiveness and risk acceptance or rejection. Risk managers will realise that they need to be aware of the socio-economic "drivers" that may be relevant to a risk issue and will provide resources and access to appropriate experts. MRA modellers may then integrate these aspects and work with expertise in these fields during the process, rather than carry out the work without regard for eventual consideration and importance of such factors.

CONCLUSIONS

The most important attribute of an MRA is that it is "fit-for-purpose"; i.e. that it answers the risk management question(s) in a timely manner, providing the information required by the risk manager to make an informed decision about the food safety issue at hand. For an MRA to be valuable, in any situation, its documentation will need to be defensible, reliable and rigorous. Codex guidelines indicate that the resources invested in the MRA should be commensurate with the importance of the decision. If there is little debate about an issue among stakeholders an extensive MRA may not be needed. In such a circumstance a decision might be made on the consensus of experts, particularly for a matter where little ground for doubt exists. An issue that does not carry a large negative impact if the resulting management decision is wrong may also not require extensive resources and time.

It is also recognised that, depending on purpose, endpoints of a risk assessment will characterise population health impacts in different ways, such as number of predicted cases of illness or risk per meal. However, outside of human health risk measures, the adverse outcome of interest for a manager might be a measure of exposure, where human health impacts are considered but not necessarily through the use of an explicit dose–response relationship, or in terms of adverse economic impacts or other endpoints.

In the future, increasingly more governmental decisions will be based on MRA, and industry should strive to become a more active partner in the MRM process, encourage development of robust MRAs and be trained in understanding the concepts.

Innovation, with suitable rigour, is still needed to further advance the repertoire of MRA methods and applications. Transparency and good communications between managers and assessors will always be fundamental to the value MRA can bring to decision-making situations. Consistent, good MRA practices and consideration of the characteristics that enhance the validity and utility of any type of MRA are equally important to advancing this field.

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ABBREVIATIONS

ALOP	Appropriate level of protection
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
DALY	Disability-adjusted life year
FAO	Food and Agriculture Organization of the United Nations
FSO	Food safety objective
GHP	Good hygienic practice
GMP	Good manufacturing practice
HACCP	Hazard analysis critical control point
IAFP	International Association for Food Protection
ICMSF	International Commission on Microbiological Specifications for Foods
MRA	Microbiological risk assessment
MRM	Microbiological risk management
SPS agreement	Agreement on the application of sanitary and phytosanitary measures of the World Trade Organization
PC	Performance criterion
PO	Performance objective
QALY	Quality-adjusted life year
WHO	World Health Organization of the United Nations
WTO	World Trade Organization

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