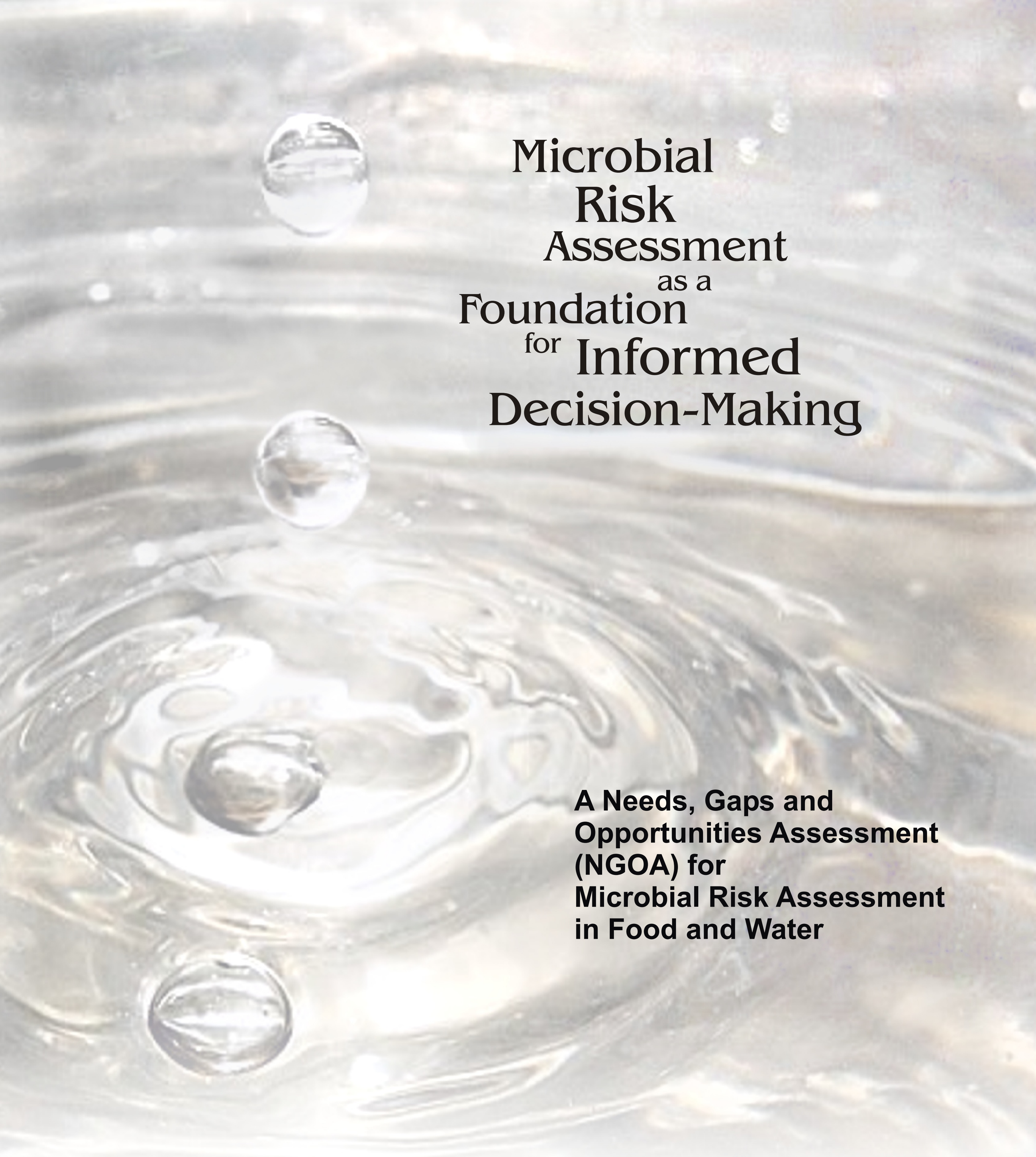

Microbial Risk Assessment as a Foundation for Informed Decision-Making

A Needs, Gaps and Opportunities Assessment (NGOA) for Microbial Risk Assessment in Food and Water

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Printed 2005

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1.0 Acknowledgements

The authors would like to acknowledge the Canadian Institutes for Health Research (CIHR), the Canadian Water Network (CWN) and the National Sciences and Engineering Research Council (NSERC) for funding this project.

We would also sincerely like to thank the participants at the expert consultation: Nick Ashbolt (*University of New South Wales, NZ*); Kevin Brand (*University of Ottawa, CA*); Mike Cassidy (*Ontario Ministry of Agriculture and Food, CA*); Ray Copes (*University of British Columbia / B.C. CDC, CA*); Robert de Valk (*Further Poultry Processors Association, CA*); Tom Feltmate (*Canadian Food Inspection Agency*); Leon Gorris (*Unilever, SEAC, UK*); Charles Haas (*Drexel University, USA*); Arie Havelaar (*National Institute of Public Health and the Environment of the Netherlands*); Sandra Honour (*Alberta Agriculture Food & Rural Development, CA*); Peter M Huck (*University of Waterloo / NSERC, CA*); Bruce McNab (*Ontario Ministry of Agriculture and Food, CA*); Diane Medeiros (*Health Canada*); Norman Neumann (*Alberta Provincial Laboratory of Public Health, CA*); Pierre Payment (*University of Quebec, CA*); Mark Powell (*US Department of Agriculture, ORACBA*); Andrijana Rajic (*Alberta Agriculture Food & Rural Development, CA*); Will Robertson (*Health Canada*); William Ross (*Health Canada*); Mark Servos (*University of Waterloo / Canadian Water Network*); and Frances Natress (*Agriculture and Agri-food Canada*); for taking time out from their busy schedules in order to provide valuable insight that clearly enhanced this product.

In addition, several reviewers: Robert Buchanan (*US Food and Drug Administration*); Sarah Cahill and Maria de Lourdes Costarrica (*Food and Agriculture Organization*) Jorgen Schlundt (*World Health Organization*); Joan Rose (*Michigan State University, USA*); and Karen Hulebak (*US Department of Agriculture*) took time to look over the report and provide feedback. This process improved the report significantly and is very much appreciated.

Significant gratitude and acknowledgement are due to: Jennifer Robertson at Health Canada, who provided excellent administrative support for this project including exploring the initial options for the expert consultation; providing research support throughout the project; and preparing the final webpage material; Maria Case, at the University of Guelph, who negotiated and made all the final arrangements for the expert consultation, as well as handling all the administrative and financial responsibilities both before and after the meeting; Elizabeth Cherevaty, who did a masterful job of conducting the literature search and impeccably documenting her strategy, as well as Judy Greig, Kristen Brown and Janet Harris who all provided additional research and editing support including searching through various web pages for risk assessment related researchers and information. Finally, thanks are due to Shari Orders of Decisionalysis Risk Consultants, who did a fantastic job of capturing and preparing a transcript of the comments and discussions at the expert consultation.

2.0 Executive Summary

International agencies and all levels of government are increasingly relying on, or at least recognizing the need to rely on, risk assessments for decision-making in public health protection, international trade, and to support cost-effective resource allocation and prioritization of research efforts. There are a number of forces behind the increasing use and discussion of risk assessment in food and water safety decision-making. These range from legislative mandates, accountability and external scrutiny, to scientific concerns and trade obligations.

However, as a relatively new discipline, risk assessment in microbial food and water safety remains poorly understood and under-utilized by risk managers and other decision-makers, the scientific community, and research funding agencies.

Microbial risk assessment (MRA) is a systematic analytical approach intended to support the understanding and management of microbial risk issues. The benefit of a structured risk assessment process lies in the ability to synthesize data and information, represent complex relationships, describe the probability and severity of adverse events and to inform the decision-making process.

The risk assessment process not only serves to analyze current data and knowledge about a risk issue, but can also provide a tool to identify data gaps and research needs, and a mechanism through which priorities for research needs can be assessed. Accordingly, it should be viewed as a tool that can contribute towards the identification of specific studies, or 'targeted research' and data collection, in areas critical to understanding the nature of microbial risks and how they arise. This particular contribution of risk assessment appears to be commonly overlooked or under-utilized.

Typically there can be several motivations for initiating a risk assessment, including:

- Collect and objectively evaluate information on a risk issue
- Facilitate channels of communication between impacted groups
- Assist in the understanding of complex processes to make them more manageable
- Provide a tool that can assist in the evaluation of proposed management strategies
- Highlight data and information gaps and identify research needs

The understanding of the role of microbial risk assessment has evolved significantly in its relatively short history. In the past, the primary purpose for doing a risk assessment was assumed to be simply a means to estimate risk in order to make decisions on acceptability and the need for regulation. A second stage of the evolution was the recognition of the ability to measure the risk reduction potential of various risk control options. As our understanding increases, and as we address more complex problems (e.g., antimicrobial resistance, global trade impacts, impacts of livestock operations on water quality), there is an increasing demand for tools whose primary contribution is to allow a more complete understanding of complex risk-generating systems. As a result, there has been an increasing appreciation that one of the more important strengths of risk assessment is in its contribution to the understanding of systems. Improved comprehension translates into more informed decisions regarding risk mitigation strategies, and an improved capacity to identify important knowledge gaps that can be addressed through targeted research.

A review of the current status of risk assessment as an integral part of decision-making processes led to the convening of a panel of experts from across Canada and the international community to assess the needs, gaps and opportunities in microbial risk assessment. The panel concluded that effective and routine applications of microbial risk assessment to inform decision-making requires the achievement of specific objectives. These include:

- Consistent quality in risk assessments
- Application of a prioritization process for microbial risk decision-making
- Incorporation of risk assessment to inform targeted research decisions
- An ability to assess new evidence rapidly for its impact on decision-making and policy
- The application of diverse and appropriate risk assessment approaches for short-, medium- and long-term decision-making
- The development and maintenance of comprehensive systems models for microbial risks in food and water
- An ability to incorporate costs and other decision-relevant evidence into the outputs
- Effective interaction between risk assessors, decision-makers and stakeholders to increase trust and credibility in risk assessment and risk management

Four key areas were identified in which there are specific opportunities to help achieve the objectives stated above, and several recommendations were formulated within each category, summarized as follows:

Key Recommendations to Advance Microbial Risk Assessment for Food and Water Safety

1. Coordination

- Prioritization and Co-ordination of Research and Information
  Risk assessment as a process, and its outputs, should be integrated into formulating research agendas set forth by funding agencies and governments. Formal research evaluation tools such as value-of-information techniques should be applied to compare the merits of various research directions as they pertain to policy-making needs and reducing uncertainty in weighing risk management options.

- Coordinated Development of Comprehensive Models
  The development of mathematical / simulation risk models must be viewed as a distinct and practical scientific activity with merits for funding on par with other scientific research activities.

- Improved Data and Analytical Tool Sharing
  Practical and effective processes and mechanisms that allow information sharing among government agencies, the scientific research community and industry are necessary. Initial steps to undertake include: evaluation of the costs and demand for data-sharing systems; what sharing arrangements currently exist; identify the barriers that prevent the sharing of certain types of information and potential approaches to overcoming these barriers.

2. Methodology and Tool Development

- Estimation and Attribution of the Burden of Illness
  The estimation and attribution of the burden of illness along both a pathogen and pathway basis is essential. This information is central to the establishment of an effective risk management strategy and the responsible allocation of risk mitigation resources. Current initiatives to establish the level of under-reporting of gastrointestinal disease in Canada should be extended to include the level of under-reporting for specific microbial pathogens and specific exposure pathways. Further, mechanisms to integrate diverse types and sources of evidence (molecular, phenotypical typing, survey data, etc.) are needed to support these initiatives.

- Development of Health Outcome Measures
  Comparison of human health risks from different types of hazards, both microbial and non-microbial, requires that health outcomes are measured in comparable terms of magnitude and severity. This is essential to help prioritize and focus resources on reducing those risks that present the greatest social and/or economic impacts. There are several existing health outcome measures, for example, Disability Adjusted Life Years (DALY), that should be evaluated and the most appropriate measure(s) adopted by health agencies. Subsequently, health outcome measures for specific microbial pathogens should be developed within readily accessible databases. It is also important to develop appropriate risk communication strategies for managers, communicators and assessors when conveying the complexity and potentially contentious nature of defining human health outcome measures.

- Development of New and Diverse Methods and Tools
  Microbial risk assessment is at a stage of development where there is a great need to promote diversity and innovation in the tools and approaches employed. Critical evaluation of the suitability, benefits and limitations of current and new methods must be ongoing. Strategically, it would be beneficial to match the techniques and tools that are developed to the types of decisions that are likely to benefit. Modeling tools and techniques in other fields should be investigated for their applicability to microbial risks. Development of user-friendly formats for risk modeling tools and methods is needed to encourage the uptake of risk assessments into management and research applications.

- Development of Tools for Analyzing Emerging Scenarios or Events
  An important area for development is risk assessment approaches to aid managers in dealing with new and/or emerging food safety issues. Potential areas of investigation include the application of failure analysis approaches, application of genetic sequencing information into predictive tools for emerging pathogens, and methods to assess the probabilities of rare or anomalous situations.

- Development of Tools for Rapid Risk-Based Decision-Making
  Many microbial risk decisions must be carried out and implemented within short turn-around times, frequently under circumstances of considerable uncertainty. However, the majority of risk assessments conducted to-date have been designed for longer-term decision-making. Rapid decision-support needs in situations typically faced by food and water risk managers must be identified, followed by the development of suitable and effective risk-based decision-making tools designed to address these needs.

3. Education and Infrastructure Development

- Guidance for Qualitative Risk Assessment
  Qualitative risk assessment is a descriptive form of risk assessment that is frequently applied in microbial risk decision-making. There is, however, a large variation and discrepancy in what constitutes a qualitative risk assessment. As a result, there is a need to assess the various qualitative methods of synthesizing information and to develop guidance on qualitative risk assessment that will ensure consistency in application and confidence in the decision-making advice that is provided.

- Guidance on Technical and Methodology Issues
  Technical documents are needed to support the growing microbial risk assessment community. For example, there are many recurring technical issues such critical evaluation of available data, simulations of rare events, treatment of 'non-detects' in laboratory data, that are basic to most quantitative risk assessments and for which authoritative guidance is needed.

- Training for Risk Assessors and Risk-Based Decision-Making
  Risk assessment, risk-based decision-making, and risk communication training are needed for decision makers, researchers and risk assessors. Currently, there is an apparent lack of entry-level individuals with the appropriate skills and knowledge to conduct quantitative microbial risk assessment. In addition, most managers are not familiar with the conduct of risk assessments, or how to evaluate and utilize the outcomes of risk assessments, particularly quantitative probabilistic models. A survey of training needs is warranted, to identify the current and future demands for individuals formally trained in microbial risk assessment, to establish the types of skills that might be lacking, and to develop a range of training opportunities, from graduate training to short courses and workshops.

- Development of a Practitioner Network

The sharing of resources, tools, information and strong collaborative personal networks among practitioners would strengthen microbial risk assessment in Canada. The microbial risk assessment community is currently relatively small, however, mechanisms and opportunities to promote interactions and synergy among risk assessors, both within and outside of national borders, must be encouraged and supported.

- Application of Peer Review Processes for Risk Assessment
  Protocols must be implemented to ensure rigorous peer review in microbial risk assessment. This includes review processes for scrutiny of the evidence and assumption base, accuracy of the representation of the food or water system, and the translation of these two components into a model.

4. Communication

- Effective Integration of Risk Communication into the Process
  The effectiveness of risk communication is often the critical deciding factor in the success or failure of any risk-based policy or decision-making process. Although a detailed analysis is beyond the focus of this current document, there is an urgent need to evaluate and assess risk communication strategies. These include: communications in the context of conducting risk assessments and the interactions between managers, assessors and stakeholders; how risk assessments are presented to stakeholders; how risk mitigation messages are conveyed to the public and their effectiveness (e.g., boil water advisories); how to deal with communication challenges that will inherently arise when prioritizing microbial and other risks based on technical ranking schemes. A 'needs, gaps and opportunities' assessment focusing on risk communication would provide significant benefits to direct future activities.

One of the goals of MRA is to provide policy and decision-makers with a process to translate their information needs into specific research directions that will support the formulation of effective risk management strategies. Conversely, researchers will benefit from a process that helps synthesize diverse findings into decision-support tools, and to enhance the uptake and utilization of scientific evidence for the applied management of microbial risks.

The success of incorporating research and risk assessment into decision-making processes for microbial food and water safety in Canada will be dependent on commitment to overcome the needs and gaps identified in this project and to make available the resources required to take advantage of the opportunities that exist. Advancements in the directions identified in this report will help promote risk assessment as an informative and effective linkage between researchers, their data and scientific information, with risk management, decision-making and policy development.

3.0 Introduction

3.1 Background

In 2002, the Canadian Institutes for Health Research (CIHR) Institute of Infection and Immunity, in partnership with the CIHR Knowledge Translation Branch, the Canadian Water Network (CWN) and the Natural Science and Engineering Research Council (NSERC) announced support for up to eight 'Needs, Gaps and Opportunity Assessments' (NGOAs). Microbial Risk Assessment (MRA), as it applies to food and water, was one of five areas specifically identified as being of interest to the partners in the original call for proposals (the others were: antimicrobial resistance; health impact of food and waterborne infections; real time diagnostics – new technologies; and global climate change and emerging infectious disease). This project began in the spring of 2003, with completion in 2004.

It is important to recognize at the onset that the primary purpose of MRA is to assist in the understanding and management of microbial risk issues. It is essentially a tool that synthesizes data and information in order to inform the decision-making process as objectively as possible. Given the understanding that MRA is applicable to any number of microbial issues, the spectrum of relevant needs, gaps and opportunities could conceivably be as broad as all the current and future microbial issues in food and water. Typically, an NGOA for a specific topic (e.g., one of the other four interest areas) would survey the literature with the intent of identifying areas for which data and information are lacking, or where knowledge is sparse and thus direct research into those areas. For MRA, depending upon the microbial risk issue under consideration, there may be a variety of data types that are relevant and that might exist at varying degrees of depth. In addition, the risk model(s) that might be appropriate for one issue would not necessarily be applicable to other microbial problems.

Early in the evolution of this study, it was recognized that boundaries were required around the task of cataloguing the needs, gaps and opportunities for microbial risk issues in food and water. This recognition was based on the consideration that, as MRA is intended to assist in the understanding of microbial risks, the risk assessment conducted for a specific microbial risk issue would constitute the best vehicle to identify the needs and gaps associated with that risk issue.

Hence, this report focuses on the field of microbiological risk assessment as a whole. The emphasis is on the needs, gaps and opportunities that exist for the advancement of the methodology in general rather than for specific areas of application, including its use by decision-makers. In turn, the advancement and improved application of MRA itself will contribute to the targeted research agenda. Ideally, this application will be iterative and continuously update the needs, gaps and opportunities for a specific risk issue.

Microbial risk assessment is generally acknowledged at the international, national and provincial levels as an effective and desirable tool to help make decisions on microbial risks in food or water. The overall objectives of this project are to identify and recommend a direction for the advancement of MRA from its current status as a recognized tool for decision-making but not yet exploited to its full potential, to a tool that is an integral part of the research and risk reduction strategies employed by decision-makers.

3.2 Approach

The results and recommendations developed and presented in this project were a product of four complementary influences:

- An environmental scan
- The MRA experience of the research team
- An expert consultation
- A peer review process

The environmental scan was composed of both a literature review and search of activities in risk assessment and individuals working in various facets of MRA. The literature review included both published resources, using structured keyword searches in citation databases, and unpublished information located by using a combination of internet-based searches and a large personal contact network to tap into other sources. The results of the literature scan, representing a comprehensive bibliography of MRA activities, are available at www.uoguelph.ca/OAC/CRIFS. The primary purpose for the review of current literature was to evaluate the status of risk assessment activities and to take stock of the direction in which activities were moving. A catalog of Canadian researchers and institutes that identified themselves as being involved in risk assessment activities applicable to food and water was also generated. The database of researchers is also available at www.uoguelph.ca/OAC/CRIFS, and is a relatively unfiltered grouping (i.e., no critical evaluation was made on the type or scope of risk assessment activity) of researchers that list risk assessment as a specific field of interest.

The applied experience of the authors was used to formulate the initial strategy for the advancement of MRA, which was concurrently informed by the environmental scan and subsequently enhanced by the expert consultation. The collective experience of the team included research in water and food microbial safety, generation of risk assessments, service on international expert panels, and provision of expertise towards the formulation of guidance documents for MRA, and represented a good cross-section of expertise upon which to base an initial strategy.

The expert consultation, held in Edmonton, Alberta, Canada, in November 2003, drew upon the experience of a substantial roster of both Canadian and international expertise in risk assessment (see Acknowledgements). The primary focus of the consultation was to tap into the experience and insight of the experts so as to ensure that the outputs from this product were in tune with a good cross-section of the risk assessment community. In addition, the intent was to get feedback on the completeness of the environmental scan to that point and to critically evaluate the advancement directions proposed. Finally, a wider circulation of the report in the form of a peer review taps into a larger pool of expertise and insight than was possible by relying upon the expert consultation alone.

The goal of the current report is that it is informative to a broad audience that includes: decision-makers in research, policy formulation and risk management, risk assessment practitioners, and researchers. The first part of this report: "Risk Assessment as a Basis for Decision-Making" provides important background information on current thinking with respect to the application of MRA for decision-making. The objective of this section is simply to ensure that the broad audience for which this report is intended all have the same frame of reference for the concepts used throughout the report. The second part of the report: "Recognition of the Need for Risk Assessment in Decision-Making", is a broad sweep at the international, national and provincial levels illustrating the acknowledgement and importance articulated in the mandates of organizations to rely upon risk assessment for decision-making. The objective in this section is to demonstrate that there is general agreement on the applicability of risk assessment as a foundation for decision-making, but it does not tend to be utilized in a formal sense as frequently as one would expect, hinting at the existence of a broad needs, gaps and opportunity applicable to the field as a whole. Finally, the last two sections of the report, "A Framework for Advancing Microbial Risk Assessment" and "A Detailed Review of Pathways", form the main body of the report. These sections identify the needs, gaps and opportunities that exist, in the form of advancements or improvements in the field of MRA, such that it can be applied more rigorously and frequently in decision-making, thereby ensuring that scientific data and information are represented as objectively as possible.

4.0 Risk Assessment as a Basis for Decision-Making

4.1 Introduction and Background

Microbial risk assessment is an analytical approach intended to support the understanding and management of microbial risk issues. The benefit of the tool lies in the ability to synthesize data and information, to represent complex relationships, to describe the probability and severity of adverse events and to inform decision-making processes.

The understanding of the role of MRA has evolved significantly in its relatively short history. In the past, the primary purpose for doing a risk assessment was assumed to be simply a means to estimate risk in order to make decisions on acceptability and the need for regulation. A second stage of the evolution was the recognition of the ability to measure the risk reduction potential of various risk control options. As our understanding increases, and as we address more complex problems (e.g., antimicrobial resistance, global trade impacts, impacts of livestock operations on water quality), there is increasing demand for tools whose primary contribution is to allow a more complete understanding of complex risk-generating systems. As a result, there has been an increasing appreciation that one of the more important strengths of risk assessment is in its contribution to the comprehension of systems. The improved comprehension translates into more informed decisions regarding risk mitigation strategies, and an improved capacity to identify important knowledge gaps that can be addressed with targeted research to collect and/or generate relevant information.

4.2 A link between research & decision-making

The risk assessment process provides a mechanism for the systematic compilation and analysis of the current data and knowledge about a risk issue. Significantly, it provides not only a tool to identify data gaps and research needs, but also a means through which priorities for identified research needs can be assessed. Accordingly, it should be viewed as a tool that can contribute towards the identification of targeted research areas. This particular contribution of risk assessment appears to be commonly overlooked or under-utilized.

Figure 1 shows how risk assessment provides a link between the arenas of research, which generates data and scientific information, and risk management. A defining characteristic is that each of the links flows in both directions. Through risk assessment, decision-makers have a mechanism to translate their needs into specific research directions. Similarly, researchers have a tool to synthesize diverse findings into decision-support tools to promote the uptake and utilization of scientific evidence into decision-making processes.

Figure 1: Risk assessment as a link between research and risk management

The following can be key motivations for initiating a risk assessment:

- Collect and objectively evaluate information on a risk issue;
- Facilitate channels of communication between impacted groups;
- Assist in the understanding of complex processes to make them more manageable;
- Provide a tool that can assist in the evaluation of proposed management strategies;
- Highlight data/information gaps and identify research needs.

4.3 The model in risk assessment

A fundamental component of the risk assessment process is in the development of a risk model. As food and water safety issues become more complex, contentious, and/or interdisciplinary, a model is increasingly essential to act as the 'thread' that integrates diverse information into answers for risk management questions. Theoretically, models can range from mental models to computer simulation models. Clearly, the utility of a mental model in satisfying questions arising from any one of the key motivations for risk assessment is limited. In this current context, we define a model as the result of a process of representing a real world system, ranging from small, focussed events to large complex processes, in a form that allows analysts and decision-makers to better understand and study the system's behaviour and potential response to proposed actions. Figure 2, adapted from Law and Kelton (1997), summarizes the stepwise progression that leads to an analytical or simulation-based mathematical model as a mechanism to understand and experiment with a system.

Models can serve as the primary vehicles in facilitating the two-way flow of information between research and decision-making functions. With this in mind, much of the discussion regarding advancements in risk assessment centers on the tasks of developing, interpreting, and communicating models.

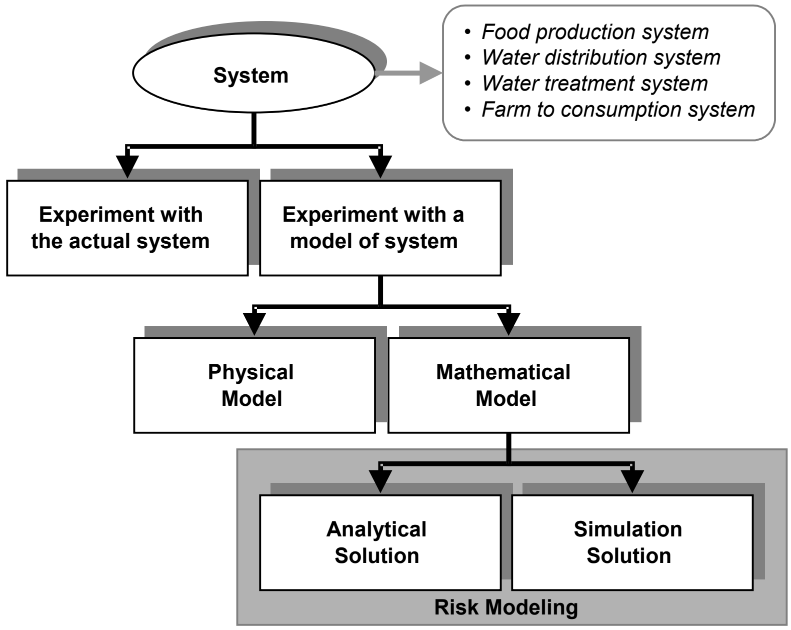


Figure 2: Modelling as a basis for gaining an understanding and experimenting with systems (adapted from Law and Kelton, 1997).

5.0 Recognition of the Need for Risk Assessment in Decision-Making

International agencies and all levels of government are increasingly relying on, or at least recognizing the need to rely on, risk assessments for decision-making in public health protection, international trade, and to support cost-effective resource allocation including prioritizing research directions. This section describes some of the rationale for adopting risk-based approaches in food and water risk management.

At the outset, it is worthwhile to consider what is implied by the commonly applied, yet rarely defined, qualifier, '*risk-based'*. Without knowing the exact motivation behind every use of the term, experience suggests that the qualifier *risk-based* is generally meant to imply one or more of the following attributes:

- With respect to an analysis: that a systematic attempt is made to consider the likelihood of occurrence and severity of an adverse outcome, rather than simply a finding of possibility, a generic review of evidence of the hazard, or a summary judgment on the acceptability of a risk.

- With respect to a decision: that a risk assessment was carried out and that the decision taken was contingent upon, even if not exclusively, the results of the risk assessment.

- With respect to a collection of risk control measures: that the allocation of effort and resources for inspection or some other control measure is allocated based on, even if not exclusively, an assessment of the risk and possibly, the potential to reduce it.

In this report, use of the term *risk-based* does not imply that a measure of risk, to the exclusion of all other factors, completely determines the risk management decision. It is understood that there are many other inputs into risk management decisions (e.g., jurisdictional considerations, legal obligations, collective bargaining agreements). At the same time, *risk-based* is often seen to imply a situation or future goal where, to the greatest extent possible, risk management decisions and resource allocations are strongly influenced by scientific assessments of risk, or are otherwise aligned to reduce risk.

5.1 Basis for Advancing Risk-Based Policy Development

There are a number of forces behind the increasing use and discussion of risk assessment in food and water safety decision-making. The forces range from legislative initiatives, accountability and external scrutiny, scientific concerns and trade obligations.

5.1.1 Enabling Legislation

As an example, a potential trend in governance is found in the enabling legislation of the Canadian Food Inspection Agency (CFIA), which explicitly describes the role of risk in guiding the Agency's resource allocation:

> *"WHEREAS the consolidation of those services under a single food inspection agency will contribute to consumer protection and facilitate a more uniform and consistent approach to safety and quality standards and risk-based inspection system" (Government of Canada, 1997).*

It would seem likely that future or re-organized agencies and departments, particularly those that deal with public health, food, water, animals, plants, etc., will have such language formally included in their enabling documentation.

5.1.2 Scrutiny of Efficiency of Expenditures

Legislation requires that the Auditor-General of Canada provide an opinion on the statements of performance in the CFIA's Annual Report. Similar opinions are required when government auditors perform periodic value-for-money (VFM) audits of other government departments. These audits could be based on food or water safety responsibilities.

The CFIA is not alone in requirements to demonstrate a risk-based policy environment. At the request of Congress, the General Accounting Office (GAO) of the United States has issued several reports scrutinizing the efficiency and effectiveness of the U.S. food inspection system. The focus of these reports is the relative cost-effectiveness of inspection activities. From a perspective similar to that of the Auditor-General of Canada noted above, problems with relative cost-effectiveness are referred to as 'program risks' since a more cost-effective allocation of resources would provide more protection in the area of food safety and other goals.

> *"In summary, the highly fragmented federal food safety structure needs to be replaced with a uniform, risk-based inspection system under a single food safety agency. In the interim, the implementation of the Results Act's planning requirements may better facilitate the use of food safety resources across the federal government"* (US-GAO, 1999).

The GAO also noted inconsistent and illogical differences in inspection frequency resulting from jurisdictional decisions that would seem to deviate considerably from a risk-based concept of inspection delivery.

In addition, the U.S. Department of Agriculture (USDA) Reorganization Act of 1994 requires risk analyses for all major regulations before implementation to ensure that the proposed risk reduction strategies are cost-effective and those efforts to reduce foodborne illness promote the maximum net benefit to society (U.S.C., 1994).

5.1.3 Policy Scrutiny

In the early 1990's, leading academic institutions (e.g., the Center for Risk Analysis at the Harvard School of Public Health, Carnegie-Mellon University's Department of Engineering and Public Policy) and highly credible non-governmental organizations began to exert considerable influence on regulatory legislation and budgetary oversight functions in the United States. Large differences in the relative cost-effectiveness of various health protection regulations and medical interventions have been described (Tengs *et al.*, 1995). This contributed to the momentum behind various attempts at risk-based regulatory reform in the US, including executive orders directed at regulatory agencies.

Recent events, including a successful court challenge to USDA's pathogen performance standards, have spawned a number of initiatives in the U.S. related to the use of risk assessment in food and water policy. A panel of the U.S. National Academy of Sciences (NAS) recently reviewed a broad range of performance standards and criteria in the U.S. Food regulatory system (NAS, 2003). Among the panel's recommendations are the following:

- *"Minimize knowledge gaps by conducting pilot programs of the proposed performance standard, by maintaining data-bases of critical information, or by conducting risk assessments that can be used to develop performance standards, and by including science-based expertise if needed"* (p. 252).

- *"Microbial risk assessment may help find the most effective solutions for lowering consumer exposure to foodborne microbial hazards"* (p. 254).

Finally, the ability to demonstrate and measure the effectiveness of policies is being increasingly stressed at all levels of government. However, the ability to do this becomes difficult when dealing with complex and highly confounded issues where it is not possible to produce clear-cut cause-and-effect types of observable evidence. Risk modelling is now being recognized as one approach that can be used for the purposes of demonstrating and measuring the effectiveness of food and water safety policies in terms of risk reduction.

5.2 Basis for Advancing Foodborne Microbial Risk Management

5.2.1 International Trade Agreements

The assessment of risk has been established as fundamental to justify trade restrictions according to international agreements. The World Trade Organization (WTO) agreement, in effect since January 1, 1995, contains sub-agreements dealing with Sanitary and Phytosanitary (SPS) Measures (WTO, 1998). These agreements are designed to curb the use of unjustified sanitary measures for the purposes of trade protection. For the purpose of the SPS,

> *"A sanitary measure is defined as a measure applied to protect human or animal life or health within the territory of the member from risks arising from food additives, contaminants, toxins or disease-causing organisms in food, beverages and feedstuff."*

For foods, the agreements apply to all regulations and procedures including end-product specifications, processing and production methods, sampling procedures, and packaging and labeling requirements directly related to food safety.

The basic principles espoused in the WTO SPS agreements include the following:

- SPS measures must be the least trade-restrictive in accomplishing their objectives;
- SPS measures should be based on an assessment of the risks to human, animal or plant life or health. An importing country is not required to conduct a risk assessment itself, but it must be able to demonstrate that its measures are based on an "appropriate" risk assessment;
- SPS measures cannot be more stringent for imports than for agricultural goods and food products of domestic origin.

These measures could place elements of food policy developed in Canada on a world stage, with risk assessments being a focus of international scrutiny.

5.2.2 International Standard-Setting Bodies

The WTO assigns responsibility for standard setting and advice on the scientific aspects of risk to the Codex Alimentarius Commission (CAC) for foods, Office International des Epizooties (OIE) for animals and the Secretariat of the International Plant Protection Convention (IPPC), for commodities in international trade. Under the United Nations, both the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) have emphasized the value of risk assessment for managing microbial risks and provide leadership in the conduct of MRA. A recent expert consultation recommended that national governments provide adequate resources to conduct MRA (FAO/WHO, 1999). In addition, it was also recommended that countries should prioritize risk assessment-related activities, and conduct collaborative case studies between developing and developed countries to facilitate the transfer of knowledge and experience in MRA. The CAC also stresses that food safety risk management decisions should be based on risk assessment, including in the setting of standards or other criteria for foods in international trade
(CAC, 2003).

5.2.3 Expressed Intent in Canadian and U.S. Food Policy

Health Canada has expressed support for the use of MRA for policy decision-making and in the establishment of standards. For example, Health Canada's Raw Foods of Animal Origin (RFAO) Policy Committee recommends that policy decisions concerning RFAO should be based on the general principles of risk assessment following the Codex approach (Health Canada, 2001). Risk assessment is also becoming intertwined with legislative renewal initiatives at Health Canada, related to the proposed Canada Health Protection Act (CHPA):

> *"A risk-based approach to product regulation would mean the level of regulatory control exercised over a given product would be proportional to the risk posed by that product, rather than the statutory or regulatory definition that the product may fall under. Under such a framework, mechanisms would need to be developed to determine the categorization of products according to their class of risk. The proposals for a new CHPA [Canadian Health Protection Act] include sufficiently broad authority to move to a regulatory framework based on risk rather than product definition."* (http://www.hc-sc.gc.ca/iacb-dgiac/arad-draa/english/rmdd/rfp/rfp019.html)

The CFIA's 2002-2003 *Report on Plans and Priorities* (CFIA, 2003a) states that it "…remains committed to working with stakeholders to adopt risk-based control measures…" to manage food safety risks. One key to success, as stated in the report, is to use risk assessment "…as an essential component of … regulatory decision-making".

In the U.S.A., the President's Council on Food Safety recognized that assessment of food safety risks must play a critical role in setting priorities and determining the effective use of resources (PCFS, 2001). Similarly, the USDA acknowledged risk assessment as a valuable tool to help make public health decisions in both the nutrition and food safety areas (Woteki, 1998). In 2003, the U.S. Food and Drug Administration released a Strategic Plan containing a key element: to use "...efficient risk management..." by "...develop[ing] timely, first-rate integrated risk assessment..." for foods (USFDA, 2003).

In Canada, at the provincial level, the Ontario Ministry of Agriculture and Food (OMAF) has promoted risk assessment since 1995. The II&E Risk Management Framework states that "Integration of risk-based thinking into design of strategic policies, programs, and training..." is a "...fundamental requirement…and that it ...has or will implement risk assessment tools specific to program mandates" (OMAFRA, 2001).

The above are examples of what seems to be a clear trend at multiple levels of governance toward basing microbial food safety policy decisions on assessments of risk; in some cases this may include fundamental changes in organizational policy and regulatory approaches.

5.3 Basis for Advancing Water Quality Risk Management

The growing number of water quality parameters covered by drinking water guidelines has caused a dilemma for drinking water providers in terms of determining and maintaining priorities for assuring safe drinking water. For example, in some cases, drinking water outbreaks have occurred where chlorination was kept intentionally inadequate because of concerns over disinfection by-products (Hrudey *et al.*, 2002). Both the Walkerton and North Battleford inquiries revealed that water personnel were unaware of the critical role of disinfection and treatment performance in assuring drinking water safety. Furthermore, they were largely ignorant of the health risks posed by specific pathogens. Meanwhile, dozens of specific pesticides, disinfection by-products, other organic parameters and specific pathogens have been added to guidelines or have been under active consideration. Yet, individual treatment for every parameter and pathogen is not possible. As a result, drinking water risk management has needed some refocusing and a trend has emerged back towards emphasizing good practice and achieving effective, multiple barriers to assure drinking water safety rather than a narrow focus strictly on achieving numerical guideline targets. Sampling, analysis and reporting times will inevitably delay reactive risk management responses. Accordingly, and because risk management should be preventive in nature, control programs directed only towards monitoring numerical quality targets for finished product drinking water are likely to remain an ineffective approach to risk management. Microbial risk assessment can play a vital role in providing a valid means to simulate the pathogen removal achieved based on treatment performance indicators.

5.3.1 International Bodies

The WHO produced Guidelines for Drinking Water Quality in 1984-85 with a second edition published between 1993 and 1997. In part, the extended time spans for these publication dates reflects the expansion of the detail and the number of parameters being considered for water quality guidelines. The additional detail arose in part from the more extensive application of quantitative risk assessment approaches to setting guideline levels for chemical contaminants.

The third edition of the WHO Guidelines for Drinking Water Quality is now available in draft form (www.who.int/water_sanitation_health/dwq/guidelines/en/). A major restructuring of the WHO guidelines has been undertaken to achieve a more consistent approach between guideline levels for chemical contaminants and those for microbial pathogens. The proposed approach seeks to rationalize overall water quality targets to ensure that microbial pathogens receive the priority they deserve relative to chemical risks that have dominated the agenda in recent decades.

The new draft guidelines incorporate the concept of health-based targets developed from consideration of health outcomes. The latter are distinguished between two cases. In the first case, excess disease incidence or prevalence can be detected by epidemiological methods. In the second case, risks are too small to be detected by such methods and risk assessment must be used to set tolerable risk target levels. For microbial risks in developed countries, the second situation will be the norm. Accordingly, there is a clear need for development and application of credible MRA to support this new focus for the WHO drinking water quality guidelines. Microbial risk assessment is also useful for measuring the potential impact that water quality improvements would have on the burden of disease in the community compared with other interventions directed at microbial hazards such as improved sanitation or food hygiene.

The approach for achieving some compatibility between chemical and microbial risk has been to propose a reference level of risk, expressed in terms of losses in disability-adjusted life years (DALYs). This is necessitated by the diversity of health outcomes between acute gastrointestinal disease and chronic outcomes like cancer. The approach for applying DALYs to microbial risk is based on work by Havelaar (2003).

5.3.2 Canadian and U.S. Policies

In the U.S., a target of 1 in 10,000 annual risk of infection has been proposed for microbial risk from drinking water exposure (Macler and Regli, 1993; Regli *et al.*, 1991). In contrast to a DALY approach, this target does not support comparisons with chronic disease risks or among various pathogens because it does not consider severity of illness. However, this target has provided a reference point in relation to a number of MRAs that have been performed on various pathogens and scenarios (Gale, 1996; Gerba *et al.*, 1996; Gibson *et al.*, 1998; Haas *et al.*, 1993; Haas *et al.*, 1996; Haas *et al.*, 2000; Medema *et al.*, 1996; Mena *et al.*, 2003; Teunis *et al.*, 1997). Regulation of microbial risks under the U.S. federal Safe Drinking Water Act is done by specifying treatment and monitoring requirements based on predicted removal performance for *Cryptosporidium*.

In Canada, quantitative MRA has not played a substantial role in drinking water risk management to date. However, the recommendations arising from the Walkerton Inquiry, Part 2 (O'Connor, 2002) called for requiring a total quality management program for the water industry in Ontario that would include an external audit requirement. Implementation of this accreditation program over time, along with a continuing high profile of microbial pathogens will likely lead to more need for MRA in support of drinking water guidelines and for the evaluation of pathogen control technology at individual water treatment facilities. A particular need for MRA may emerge in the need to balance the risks and benefits associated with alternate disinfection technologies. In this domain, processes for setting guidelines for chemical hazards based on safety assessments (which are not necessarily risk assessments) are relatively well established. A balanced approach to address microbial hazards is not currently available or under development.

6.0 A Framework for Advancing Microbial Risk Assessment

Microbial risk assessment is clearly acknowledged, at all levels of governance, as a fundamental input into decisions regarding the management of food and water safety risks. However, in Canada, MRA tends to be viewed as more of an academic exercise, and hence the objectives of this report are to identify and recommend directions for the advancement of MRA such that it will become an integral part of the research and risk reduction strategies employed by decision-makers.

The conceptual framework shown in Figure 3 depicts the current status of MRA in Canada, specific objectives that must be achieved in order to advance MRA, and four categories of activities (pathways) that will help attain those objectives. The basis for the proposed framework is the motivation in needing to advance MRA from where we are today; that is to support:

> ***The application of rational risk-based decision-making for the comprehensive, efficient and effective management of microbial hazards***

In order to manage microbial risks, which are often complex and interrelated, it is essential that a *comprehensive* view be taken of the problems and their potential solutions. The application of finite resources available to manage specific risks must be apportioned *efficiently*. Inherently, a premium must be placed on establishing the *effectiveness* of management strategies.

It is acknowledged that there are many dimensions influencing the management of any one risk situation. These include legislative, jurisdictional, trade agreements and public perceptions, all of which may have an impact on the approach used to manage the risk issue. However, regardless of progress in such other dimensions, which are beyond the scope of MRA itself, the ultimate purpose, and value, of MRA is to deliver sound scientific information.

In order to achieve the objectives listed in Figure 3, certain activities must be undertaken. The activity categories are characterized as *pathways* because, conceptually, they represent the way forward from the current status toward a desired future status. The pathways can be interpreted as capturing the needs, gaps and opportunities that exist for MRA in the areas of: coordination, methodology, education and infrastructure, and communication.

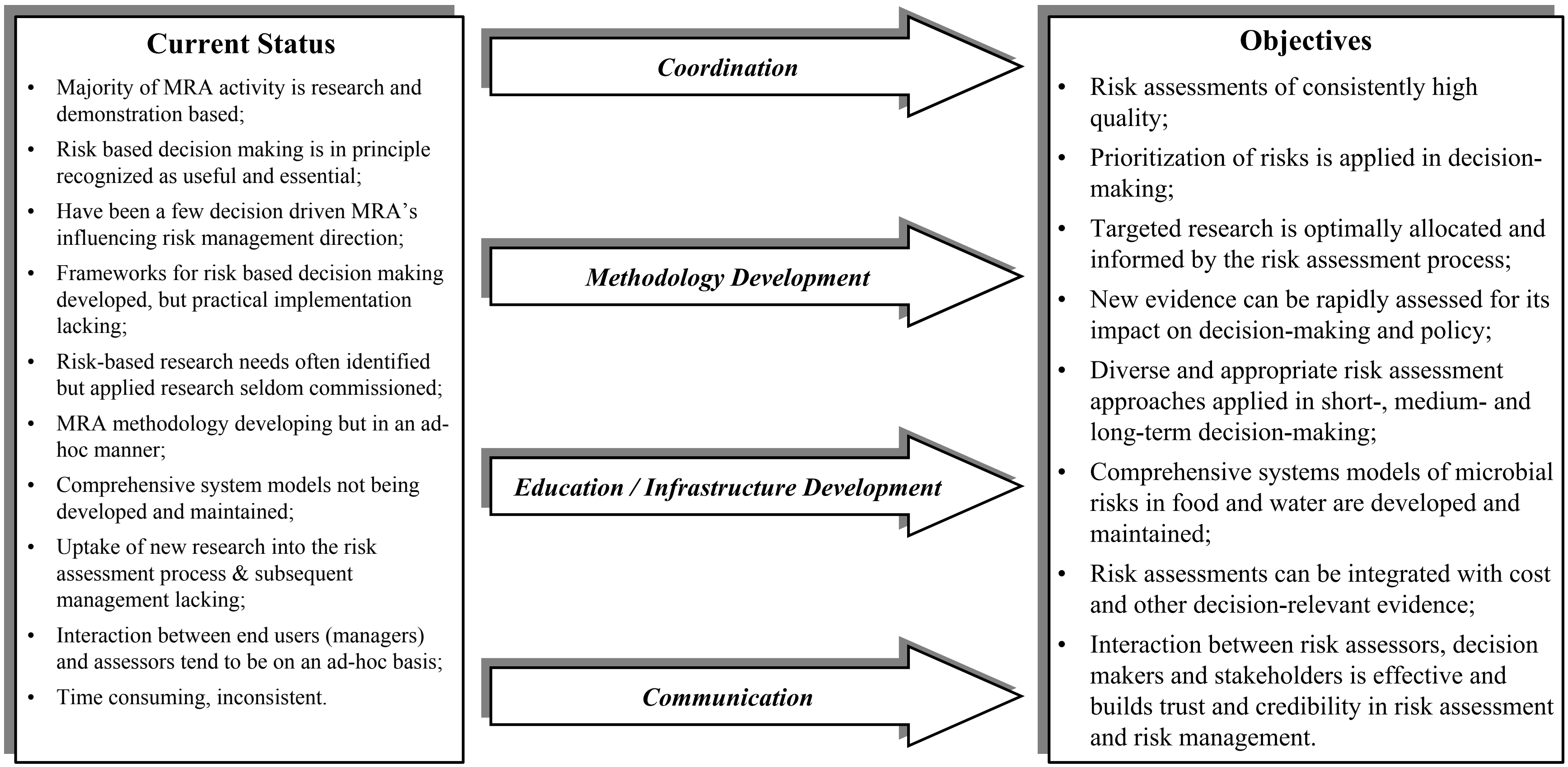
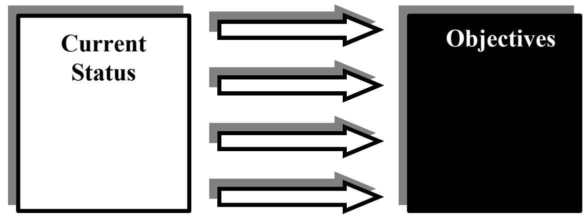


Figure 3: Framework for advancing microbial risk assessment (MRA) to support food and water safety risk-based decision-making in Canada.

6.1 Objectives for Microbial Risk Assessment



The objectives for MRA, introduced in the previous section, and explained in more detail in this section represent desired attributes of an environment that would foster the application of rational risk-based decision-making for the comprehensive, efficient and effective management of microbial hazards. These objectives constitute a target toward which efforts to advance from the current state of MRA can be directed.

- **Risk assessments are of consistently high quality**

  In the current context, *quality* refers to the use of appropriate data, models and methods, the treatment and processing of data and models in a sound manner, acknowledgement and measurement of variability and uncertainty to an extent that is sufficient to the problem, and the provision and effective communication of a balanced representation of the situation. Collectively, these attributes of *quality* determine the capacity of a risk assessment to effectively support the decision-making process. A continuously high quality of risk assessment practice is essential to ensuring its use in decision-making and the increasing and continued acceptance and trust of its outputs and recommendations. A few assessments of inferior quality can significantly affect a history of high quality assessments. Of note, the transparency that the risk assessment process strives to achieve means that the relative quality of assessments will become more evident.

- **Prioritization of risk is applied in decision-making**

  Decision-makers are typically faced with concurrent risks arising from microbial as well as other types of hazards. In any organization, there will never be sufficient resources to address all management issues simultaneously. This reality demands effective prioritization of risks to be addressed, and impacts both research and risk reduction priorities. Prioritization, by definition, implies that some risks will remain unaddressed. To ensure that the priorities are appropriate and can be effectively communicated, the prioritization needs to be done in a manner that is transparent, and that can be shown to reduce the overall risk most effectively and efficiently. Risk-based prioritization could aid decision makers with resource allocation and planning decisions. For a comprehensive review of this issue, see Graham (1997).

- **Targeted research is optimally allocated and informed by the risk assessment process.**

  Current targeted research directions are driven by various inputs. One common approach is to rely on expert consultations to provide such direction. These methods have their advantages, but need to be enhanced with a more concrete link to the actual data and information that exists on an issue. They need to be coupled with the value (for instance, in terms of added knowledge, or risk reduction, or the potential impact on the ranking of decision choices) that a particular research direction might hold. One of the important scientific contributions of risk assessment is the identification and potential prioritization of gaps in the state of scientific knowledge about an issue. Ideally, this output should play an important role in driving the targeted research agenda of governments, industry and research funding agencies.

- **New evidence can be rapidly assessed for its impact on decision-making and policy**

  The generation of new knowledge and the refinement of existing knowledge should have rapid uptake into the decision-making process. Research into issues related to microbial pathogens in food and water systems can range from very specific investigations at the micro level to much broader issues investigated at a macro level. The results from these research activities need to be quickly integrated into the characterization of the overall risk. In order for this to occur, and more specifically for this to occur in a reasonable time period, the results from research need to have a defined path through which they can be fed into the decision-making process. The application of a risk assessment approach for informing a decision can facilitate more timely and integrated uptake of new evidence into the decision-making process if it has an impact on the policy or management strategies.

- **Diverse and appropriate risk assessment approaches are applied in short-, medium- and long-term decision-making**

  In order to effectively manage microbial risks, the response to an issue needs to be appropriate and must occur within a reasonable period of time. The scope and varying degrees of complexity of microbial issues that have to be managed means that the risk assessment tools available also need to be appropriately varied. The selection of approaches and tools need to be applied in a discriminating fashion so that the balance between decision needs, time and resources is efficiently achieved. Comprehensive quantitative models that account for all forms of variability and uncertainty would be the preferred choice if the scope of an issue is broad and time allows for the development of a more complex management strategy. However, in other instances, issues can and should be effectively handled using simpler analysis tools. The linkages between decision-making, research information, and risk assessment must be strengthened so that the assessments are appropriately tailored to meet the decision-making needs. It is important to note that although the methods that are employed could at times be simpler, it is essential that they still employ a structured approach that fosters iterative improvement and transparency.

- **Comprehensive systems models of microbial risks in food and water are developed and maintained**

  Food and water systems are complex, and require comprehensive and long-term strategies in order to effectively manage and reduce the microbial risks associated with them. An approach that facilitates the understanding of these complex, frequently non-linear and dynamic systems needs to be pursued. A systems model approach maps out hazard influences and describes relationships between the components of a large inter-related system. The approach can be qualitative or descriptive at first, but by identifying research needs, requirements and priorities, a more quantitative description should evolve and be maintained. Ideally, this would form the centerpiece of a comprehensive risk management and research strategy.

  The coordinated development and maintenance of these systems models facilitates the management of complex microbial problems with a longer term and broader vision. Several current issues (e.g., antimicrobial resistance, manure management, wastewater and drinking water management) would seem to be strong candidates for a more systems-oriented approach to their investigation and management.

- **Risk assessments can be integrated with cost and other decision-relevant evidence**

  To effectively select and differentiate between candidate risk management strategies, and to ensure that options are fairly evaluated, it is important that costs as well as other decision-relevant evidence (such as risk reduction efficiency, time requirements, method acceptability, technology effectiveness, etc.) are considered in the decision (Garber, 1998; Gurian *et al.*, 2001; Montgomery, 1998). Ideally, assessments should be structured to be compatible with this type of information or ideally, to directly incorporate the capacity to integrate the information into the decision support tool.

  In the end, the utility of a risk assessment is in its input to the decision-making process. As a result, interpreting the mandate of the decision-maker, and aligning the evidence in a way that is most useful to the decision-maker are essential parts of the risk assessment process. The principle in this objective is not necessarily to create risk assessments that incorporate all the factors that might influence the decision-making process, but rather to create assessments that, to the greatest extent possible, accommodate analyses of other factors to arrive at a well-balanced, and well-informed decision.

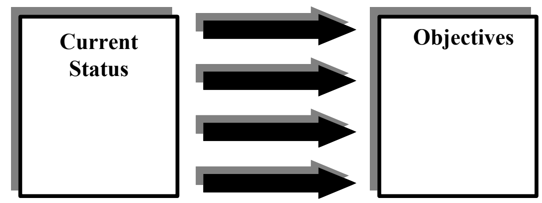
- **Interaction between risk assessors, decision-makers and stakeholders is effective and builds trust and credibility in risk assessment and risk management**

    In the field of risk management, there is consensus regarding the need to improve the communication of risks and to foster more timely and effective communication during the entire decision-making process. There are many relationships (e.g. risk assessors and risk managers, risk managers and stakeholders, risk managers and public) that can be critical to the success or failure of any risk-based policy initiative.

    In addition to the communication of risks, it is essential that the risk assessment data, models, assumptions and outcomes are communicated or made available in a format appropriate for a broad audience. Full integration of the discipline of risk communication into the risk management process is required.

    Many of the issues involved in selecting tools for use in risk assessment are technical and relate to software cost, compatibility with other tools and the user's comfort with them. However, an important consideration in these tools is the capacity of others to understand, review, and contribute to their development. Improved communication and interaction between risk assessors and risk managers would result from the use of more user-friendly and transparent risk assessment tools. This would also lead to improved understanding of the limitations and implications of risk assessment findings and outcomes, and ultimately more informed and acceptable decision-making processes.

6.2 Pathways to Achieving Microbial Risk Assessment Objectives



The core of this project lies in defining the pathways that will advance MRA and contribute towards achieving the defined objectives. Each of the four major pathways identified Figure 3 encompasses needs, gaps and opportunities that exist along a common theme. These are grouped as follows:

Major Pathway: Coordination

- Prioritization and Co-ordination of Research and Information
- Coordinated Development of Comprehensive Models
- Improved Data and Analytical Tool Sharing

Major Pathway: Methodology and Tool Development

- Estimation and Attribution of the Burden of Illness
- Development of Health Outcome Measures
- Development of New and Diverse Methods and Tools
- Development of Tools for Analyzing Emerging Scenarios or Events
- Development of Tools for Rapid Risk-Based Decision-Making

Major Pathway: Education and Infrastructure Development

- Guidance for Qualitative Risk Assessment
- Guidance on Technical and Methodology Issues
- Training for Risk Assessors and Risk-Based Decision-Making
- Development of a Practitioner Network
- Application of Peer Review Processes for Risk Assessment

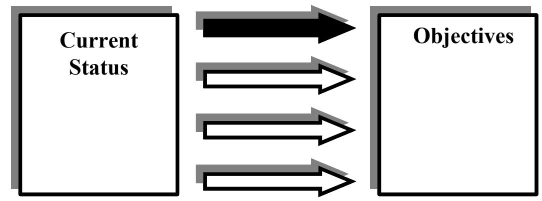
Major Pathway: Communication

- Effective Integration of Risk Communication into the Process

Examining the components of each pathway, in the following section, reveals directions and activities that will support advancement of MRA.

7.0 Detailed Review of Pathways

7.1 Major Pathway: Coordination



7.1.1 Prioritization and Co-ordination of Research and Information

Current Status

In Canada, and in most countries, there are many groups conducting research at various levels (government, academic or private) and on various issues, driven by many different agendas, with numerous sources of funding directing research along many different pathways. Unfortunately, there is a lack of an overarching integrated research strategy to guide these activities and to specify how their results will inform the overall microbial risk knowledge base. In addition, apart from a general encouragement to collaborate on new research, there is an absence of a system to coordinate work such that complementary research can be quickly synthesized and duplication of effort avoided.

Research can typically be separated into exploratory or 'hypothesis-driven' research, and 'targeted' research driven by risk management/policy needs. Exploratory research is vital to advancement of science; determining an appropriate strategy to guide allocations for these types of endeavors is outside the scope of this report. Targeted research, on the other hand, is well within the scope of this NGOA. Organizing and allocating resources to these types of studies requires some method to focus activities, determine direction, prioritize and select among alternatives. Considerable resources are expended to obtain scientific information (e.g., laboratory experiments on responses of pathogens in various environments and to various challenges, surveillance systems for illness and levels of food or water contamination, consumption surveys, comparative assessments of new technologies). Given the magnitude of the effort involved and the great demand for information, careful targeting of research is critical to overall effectiveness.

If the only criterion used to judge allocation of funding was based on the question: "Does this increase our knowledge regarding the risks associated with a pathogen of concern?" the list of potential research and data gathering activities would be virtually endless. The appropriate use of resources therefore requires a critical review of the comparative benefits associated with various research and data gathering activities.

Within the decision sciences, the comparative benefit of sources of information is referred to as a value-of-information (VOI) assessment. This approach typically measures the expected value of the gain associated with decision-making given the new information, compared to making a decision without it. While VOI methods can be quite structured and mathematically demanding, less formal, surrogate approaches exist, i.e. semi-quantitative metrics. Hammitt and Cave (1991) illustrate the application of both quantitative and qualitative approaches to measuring the value of information associated with various toxicological hazards in food.

Research prioritization to support MRA is essential, due to the considerable number of points in the continuum of food production and drinking water provision where the risk can be amplified or attenuated. There are many players, many disciplines and many potential 'observation', or data collection, points in food and water systems. For example, the presence of *E. coli* O157:H7 in beef begins with the many sources of the organism for cattle, including water. Thereafter, the risk is modulated and potentially mitigated at every point in the food processing system all the way through to individual consumer behaviors and person-to-person transmission. This same scenario could be further complicated by the possibility that, should human illness result, the pathogen will be resistant to antimicrobial treatment. By comparison, for a chemical hazard in the same commodity, beef (e.g., dioxins, veterinary drug residues, nitrates), although the risk may be attenuated (e.g., through dilution or degradation) or amplified (e.g., bio-concentration in fat, metabolism to more toxic forms), there would seem to be far fewer opportunities for modulation and mitigation of these risks along the entire continuum.

One result of the multiple elements and highly complex chain of causality influencing microbial risks is that there are typically a large number of possible observations, matched by a large number of potential intervention points. Risk managers (depending upon jurisdiction) often must consider any number of possible mitigations, ranging from drinking water standards for food-producing animals to consumer food advisories, increased surveillance and outbreak response capacity. Analogously, for drinking water, risk managers could intervene at any number of points along the water supply continuum including source water protection, diverse treatment technologies, testing, distribution system upgrades and maintenance, or residential at-the-tap devices. Given the numerous options, coordinating and setting priorities for research and information gathering pose substantial challenges for decision-makers.

From a purely decision-theoretic perspective, there is no need to distinguish research from more routine data collection activities. Value, in this context, is decision-centric and not necessarily related to the value placed on a project by the research community. There will often be a conflict of goals (and potentially, of interests) between the desire to carry out what may be labeled 'important' research (e.g., publishable advancements of a more general nature) and the need for more straightforward, perhaps mundane and often non-publishable, data gathering. From the perspective of VOI, the preference among competing projects is adjudicated by the likelihood of benefit with respect to decisions with and without the additional information.

<u>The Way Ahead</u>

A risk assessment, when completed, represents a detailed evaluation and survey of the state of knowledge about an issue. It produces, as one of its outputs, an identification of specific research needs and can provide a basis upon which to direct and prioritize research according to its impact on managing the microbial risk.

Currently, the research identification outputs of risk assessments are not incorporated into the process of informing research direction. Risk assessment outputs do not have to be the only inputs into determining research directions, but they should be considered, and as such need to be integrated into the research agenda set forth by funding agencies and governments. In order for risk assessment objectives to be achieved, a substantial effort is required through leadership from governments together with coordination and guidance by funding agencies. Such a coordinated approach offers an opportunity to develop a framework and a system that facilitates the funding of targeted research, more effective information uptake, and ultimately, better informed decisions in reducing the risk from microbial pathogens in food and water.

To compare and appropriately fund targeted research areas that may contribute to the overall microbial risk decision-making arena, some variation upon VOI techniques should be considered. A key barrier to the full application of formal, and even informal, assessment techniques is the requirement for somewhat explicit knowledge of the decision-makers' options, associated costs, and decision rules. Given that a large proportion of public policy decisions are not formalized, and are influenced by many important, but typically non-transparent factors, the potential to explicitly measure the VOI may be constrained. There is a need to explore the feasibility of applying VOI techniques for microbial risk decision-making, and to study and propose ways that such approaches can be incorporated into current research frameworks.

As it is recommended that the determination of specific research directions needs to be done in a structured and transparent manner, the NGOA expert consultation did not propose targeted data collection and research areas. In addition, the experts at the consultation generally agreed that:

- There are key data issues that need to be addressed to improve the quality and applicability of microbiological risk assessments, and
- There exists great potential for wasteful ("black-hole") spending of resources on research when measured in terms of actual contribution to informed decision-making.

As examples for the application of VOI principles, two elements were examined that are commonly identified in MRAs as needing more research and data collection: dose-response relationships, and consumption data for exposure assessments. These represent examples of two very different types of information. Dose-response information can, theoretically, be derived from a combination of animal studies (Haas and Madabusi-Thayyar, 1999; Haas *et al.*, 2000; Raybourne, 2002), tissue-based studies (Daniels *et al.*, 2000), development of mechanistic models that simulate behavior after ingestion (Coleman *et al.*, 1996), and/or improved epidemiological investigations that report information such as the number of organisms consumed during an outbreak (Buchanan *et al.*, 1997; Maijala *et al.*, 2001; WHO/FAO, 2002a; WHO/FAO, 2002b; WHO/FAO, 2003). In the case of consumption surveys, the acquisition of improved data is widely considered to be important for managing risks, with benefits beyond just microbial hazards in food and water.

Example: Dose-Response Models

Any risk assessment that attempts to measure the concentration (and subsequently an ingested dose) of pathogens in either food or water will inevitably employ a dose-response model to convert the predicted dose into a health outcome. For many pathogens, including priority pathogens such as E. coli O157:H7, there remains considerable uncertainty regarding the probability of illness associated with varying levels of ingested dose. In some cases, this uncertainty can dominate the total uncertainty in the estimate of risk. At the same time, various barriers exist to the improvement of dose-response models including those with an ethical basis (i.e., human feeding trials), those derived from fundamental scientific questions (e.g., extrapolation from animal studies to humans), and the sheer complexity of potential interactions between host properties (e.g., age, immune status), the internal environment (e.g., the impact of the food or water matrix, antacid use) and the pathogens themselves (e.g., differences among strains or serovars of the same species).

While there is consensus that all of these three elements (host, pathogen, environment) are important, the critical missing piece has in fact been a coherent framework for improving the ability to predict risks through research and methodology development for the dose-response relationship. It is relatively simple to delineate a long list of potentially researchable topics that chip away at the uncertainty in dose-response relationships. However, making the case that any one particular project will reduce the total uncertainty in the risk assessment, such that a different decision might result from the research findings, is a considerably greater challenge. A comprehensive review of uncertainty reduction through dose-response assessment and its impact on decision-making is therefore required before a coherent research agenda can be established.

Example: Consumption Data

Another main category of data requirements that was front-and-center in the minds of the participants of the expert consultation was consumption data. A key point of discussion was the availability of consumption data and issues related to the difficulty in sharing data among institutions, jurisdictions, and so on.

While there is clear benefit in knowing which foods and how much are being consumed, what people do with their foods, how long they store *them, how they cook it and what they do with leftovers, what is the value of the incremental contributions from larger, more detailed, or more frequent consumption or similar surveys? Given the total uncertainty in many risk assessments, the reduction in uncertainty in the estimate of the number of servings in a population or the duration of storage may not appreciably reduce the total uncertainty and as a consequence have no impact on the ultimate decision. On the other hand, there may be important consumption information that could in fact have an impact on the decision. It is very difficult to assess the potential benefit of data in reducing risks through reliance on mental heuristics. As well, given the strong disciplinary biases that accompany research valuation, it becomes even more evident that a structured and traceable process is needed.*

Coordination of research and data collection, specifically in addressing risk assessment/risk management needs, is something everyone agrees is critical, and its merits are often cited. However, effective coordination requires time and resources, and hence such activities must be assigned an importance and priority on the list of things to be done. However, it is at this stage that coordination typically gets relegated to a secondary role at best. Improved coordination contributes to the efficiency and quality of the relationship between evidence-generators (researchers) and evidence-users (risk assessors). It would be beneficial if researchers would understand, that, from a risk assessment perspective, certain standard methods for collecting and summarizing microbiological data might not be appropriate. An excellent example of this problem is that of processing and summarizing microbial data on the log-scale. While the log-scale is convenient (i.e., much easier to average, graph, think about), the arithmetic scale is usually that which is relevant, and proportionate to risk. The use of the mean of log-scaled numbers can be quite misleading with respect to the risk, and the calculation of this statistic can actually result in a net detriment due to corruption of conclusions based on an inappropriate parameter.

Finally, it is understood that a purely decision-centric approach cannot be used to establish all research priorities. Clearly an appropriate balance of exploratory or hypothesis-driven and targeted research will continue to be required in science. However, whatever component of research funding is justified by contributing to current and medium-term policy-making, there is a need to conduct a risk-informed assessment of the value of those projects towards decision-making. Microbial risk assessment can provide a mechanism for direct policy input as well as a basis for determining research priorities by demonstrating the magnitude of uncertainty and the impact on decision options of reducing that uncertainty.

Summary
Prioritization and Co-ordination of Research and Information

- The process of risk assessment and its outputs need to be integrated into the research agenda set forward by funding agencies and governments;
- Formal research evaluation tools such as value-of-information techniques need to be applied to compare various research areas;
- The merits of coordination are often cited, however to be effective it needs resources and effort, and thus an assignment of importance and priority;
- A purely decision-centric approach cannot be used to establish all research priorities and an appropriate balance of basic and targeted research will continue to be required;
- Research funding, justified as being in the service of policy-making, needs to be evaluated in terms its value in service of decision-making. Microbial risk assessment has an important role to play here by providing a mechanism for both direct policy input as well as demonstrating the magnitude of uncertainty and the impact of reduced uncertainty on decision options.

7.1.2 Coordinated Development of Comprehensive Models

Current Status
The development and application of systems models as vehicles to incorporate data and information in a coherent manner becomes increasingly relevant as the complexity of the risk issue increases. All participants in the NGOA expert consultation emphasized this view. Currently, there is no process in place to commission, coordinate the development of, or maintain comprehensive models that describe food and water systems. There are a few existing risk assessment models that describe either a food or water system and which would be of value if they could be used as a starting point for further refinement with new knowledge or new applications. However, the majority of these are generally not sufficiently comprehensive, and were not originally intended nor designed to support long-term management strategies that include identifying risk mitigations and areas for research.

It is important to recognize that risks arising from microbial pathogens in either food or water are typically not independent. Frequently, pathogens posing a risk via water will have a source(s) that is also likely to affect foods, and vice-versa. For example, *E. coli*

O157:H7 and *Campylobacter* spp., both found in the water supply that which caused the Canadian Walkerton outbreak (Grey Bruce Health Unit, 2000) are isolated commonly from food animals, and the food supply. Food production, processing and handling typically require large volumes of water, which may be contaminated, in turn contaminating food. In order to fully understand and manage food and water safety, appropriately integrated, and hence complex, system models must be developed.

The Way Ahead

As in the case of a coordinated approach to research, the development of systems models that are comprehensive, integrated and up-to-date requires collaboration and coordination across government, industry and academia. In order to be successful however, something more concrete than the typical calls for collaboration and coordination is required. First, the development of accurate and comprehensive system models is a unique and practical scientific endeavor, and should be considered for research funding on par with other types of scientific activities. Second, the development of systems models does not have to occur all at once, but rather, can evolve in a modular fashion, with different assessment/modeling individuals or groups developing unique parts of the model, just as research is conducted piece-wise, with all the segments together forming the bigger picture. The selection of which systems to begin the modeling process with should pass through a vetting process, just as targeted research should be prioritized. To be effective, it is likely that some degree of ownership of the product would be required, and that the task of maintenance and incorporation of new evidence and new components would need to be the responsibility of an individual or group of scientists who would be accountable to the appropriate government departments and research funding agencies.

Summary
Coordinated Development of Comprehensive Models

- The development of computational/mathematical microbial system models needs to be viewed as a distinct and practical scientific activity with merits for funding on par with other scientific research activities;
- The coordinated development of models needs to evolve in a modular fashion, with different groups developing unique parts of the system model, just as research is conducted piece-wise with all the pieces forming a bigger picture.

7.1.3 Improved Data and Analytical Tool Sharing

Current Situation

A substantial amount of information is continuously generated on microbial hazards in food or water, including data collected as a routine part of industry practice for in-house analysis, through government surveillance activities, or as an academic research endeavor. Often, much of this information unfortunately remains invisible to the typical scientific literature databases (e.g., journal abstracting services). This is compounded by the journalistic bias to publish only positive research results and 'novel' findings in the scientific literature. The absence of a legitimate process or venue to make negative research results available to the scientific community is being increasingly recognized as an important issue in all areas of scientific endeavor (Knight, 2003). The impact may be more significant in the field of risk assessment, where evaluating the "weight-of-evidence" is central to the process.

Comprehensive MRAs represent a substantial collection and analysis of both published and unpublished data, evidence and information. However, the assessments themselves are typically not published in scientific journals, and only occasionally are they readily available to individuals outside of the group that conducted or commissioned the work. The field is at a stage where there is a need for the development/adaptation of analytical tools that can be used for general and recurring risk issues. However, the general case is that each time an assessment is conducted, new tools and techniques are developed, often at considerable expense of resources and timeliness of the analysis, and, like the data and information necessary for risk assessment, are often unavailable to other assessors in a readily usable form.

The Way Ahead

Sharing and coordination of information, data sources and tools, are the basic elements of this pathway. It is acknowledged that, prior to the coordination of information, sharing arrangements need to be established. The distribution of information is often driven by political issues among organizations and is subject to the confidentiality concerns of governments, academics, and industry. The need for data sharing is an issue that is often raised, and the importance of negotiating and arranging a structure or framework that will allow data and information to be more readily accessed/exchanged was echoed in the NGOA expert consultation. Clearly, some of the barriers that exist today (e.g., legal, proprietary) are unlikely to be overcome in the near term and it is suggested that incentives, beyond reliance on simple goodwill, must be considered.

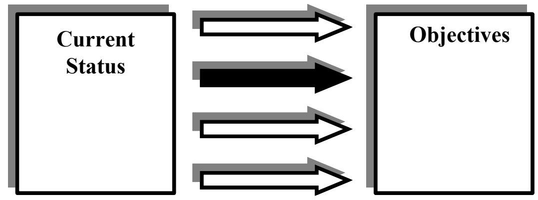
The sharing of information relevant to risk assessments, either data and/or analytical methods, will only occur if the means to achieve it are practical. The Food Safety Risk Analysis Clearinghouse (www.foodriskclearinghouse.umd.edu), a collaborative effort between the University of Maryland and the US Food and Drug Administration, could potentially serve as a model for the development of a joint, modified, or enhanced central risk assessment database/repository in Canada. Information exchange agreements with industry, academia and governments, and linkages to external resources should be explored.

The complexity and scope of the problem of developing an appropriate structure and mechanism for the sharing of information, data, tools and techniques is such that studies are warranted to investigate alternative means and options. The studies need to focus on: evaluating the sharing arrangements that currently exist in this and other fields; the barriers that prevent the sharing of certain types of information and potential approaches to overcoming these barriers including an exploration of incentives to encourage the sharing of information even if it is negative; the protocols for the types of data that could be most informative to the process; the mechanisms through which the inclusion of data into the clearinghouse is decided; the groups that would need to be involved; and the technology or mechanisms that could be used to foster this sharing. Given the potential scope of the project, proceeding in a stepwise fashion is recommended, beginning with a comprehensive scoping study to establish costs and demand for the system. Input received during the course of this assessment suggests that the demand for such a system is currently strong and would be expected to grow as risk assessment becomes more ingrained in decision-making.

Summary
Improved Data and Analytical Tool Sharing

- Information and data sharing arrangements need to be established;
- Initiate a scoping study to evaluate amongst other things: the costs and demand for the system; the sharing arrangements that currently exist; the barriers that prevent the sharing of certain types of information and potential approaches to overcoming these barriers; the mechanisms through which the inclusion of data is decided; and the technology that could be used to foster this sharing;
- Development of an effective process and mechanism to allow information sharing to take place in a practical manner.

7.2 Major Pathway: Methodology and Tool Development



7.2.1 Estimation and Attribution of the Burden of Illness

Current Situation

In order to better prioritize research, risk assessment and policy activities, there is a need to improve estimates of the burden of illness associated with food- and water-borne microbial pathogens. Although summary reports are produced in Canada (Health Canada, 1998), the categorization of illnesses is relatively crude and does not adequately capture specific microbial pathogens, nor even foodborne and waterborne diseases as separate categories. In addition, the nature of most food- and waterborne diseases is such that the under-reporting associated with them is likely to be significant. However, it is worth noting that, as in other countries, work is now underway to attempt to estimate under-reporting rates through the Canadian National Studies on Acute Gastrointestinal Illness (NSAGI) initiative (http://www.hc-sc.gc.ca/pphb-dgspsp/nsagi-enmga/info_e.html).

The absence of information is more evident, and arguably more critical, in attempts to derive estimates for the portion of the burden of disease *attributable* to various exposure pathways. The inability to provide basic attribution estimates, however uncertain such estimates may be, is a fundamental barrier to effective risk management. It remains unclear why managers responsible for assigning resources to manage risk tolerate this lack of information. Numerous technical means (e.g., molecular typing, surveillance schemes) are justified on the basis that these will provide information pertaining to sources of microbial risk, however, as yet, there is no concrete evidence that these have yielded specific risk attributions in Canada. One example of informative attribution work in can be seen in Payment (1997), where an attempt is made to determine the fraction of gastrointestinal and respiratory disease attributable to tap water in Canada. A model to consider for implementation is the relatively large research effort to measure and apportion the burden of disease underway in the U.S. (FSRC, 2004). Another model is the work in Denmark to attribute cases of salmonellosis to specific food animals (e.g., poultry vs. pork vs. beef; Hald *et al.*, 2004).

The Way Ahead

It is acknowledged that reporting of infectious diseases will never be entirely complete and accurate. As a result, an estimate of the magnitude of under-reporting of diseases will continue to be required. Furthermore, such an estimate is likely to be specific to a country, and possibly even to a region, state, or province within a country. The Canadian NSAGI program is clearly a step in a positive direction towards establishing under-reporting for gastrointestinal illness in general, but this needs to be expanded to determine under-reporting of specific microbial pathogens. In the short term, it may be possible, and useful, to derive under-reporting rates for individual pathogenic species (and subtypes) using rates estimated for other countries and modifying those with information from the NSAGI initiative as it becomes available.

One of the fundamental parts of trying to attribute the burden of disease along various pathways is the collection of baseline data to measure the prevalence and level of contamination in various foods and water. Baseline data contributes to other areas as well by providing a basis upon which to verify risk management strategies and to measure performance.

A significant effort is required to begin the process of identifying the burden of illness attributable to specific exposure pathways. Examples include: what proportion of disease are; food- vs. waterborne; drinking water vs. recreational water; home food preparation vs. prepared retail foods. A key element of the required research is to develop mechanisms for integrating diverse sources of evidence (e.g., molecular, microbial, surveillance, mechanistic reasoning, trends analysis) to arrive at attribution estimates. Such estimates will, in most cases, remain highly uncertain, but they are nonetheless critical to current and future risk management of microbial illnesses.

Summary
Estimation and Attribution of the Burden of Illness

- Expansion of initiatives attempting to establish under-reporting for gastrointestinal illness in general, to under-reporting for specific microbial pathogens;
- Initiate research to estimate the attribution of the burden of illness to specific exposure pathways;
- Develop approaches to integrate diverse sources of evidence (molecular, microbiological, surveys, mechanistic reasoning, trends, etc.) to arrive at attribution estimates.

7.2.2 Development of Health Outcome Measures

Current Situation

There are many important decisions in food and water risk management that require the ability to compare risks from different hazards. This is particularly important in MRA due to the considerable diversity in the severity of health outcomes that can result from foodborne illness. There is substantial research documenting the range of outcomes; for concise summaries, see Lindsay (1997), McDowell and McElvaine (1997). Default approaches such as simply counting 'cases' as a basis for priority-setting are not appropriate and do not ensure that protection is proportionate to societal values regarding the avoidance of severe and irreversible outcomes. Without explicit recognition and application of some metric that captures variable severity in outcomes, an important dimension of risk management decision-making remains uninformed.

In addition, to be truly effective at reducing the overall societal risk, an essential skill is the capacity to compare the relative risks and benefits of exposure to all types of hazards, i.e., chemical, microbial, nutritional, etc. (Havelaar *et al.*, 2000a; Odom *et al.*, 1999; Regli *et al.*, 1999). Although difficult to prove, it would seem that in recent decades microbial illnesses, and especially foodborne and waterborne diseases, have been assigned less weight in their importance in public health as compared to toxicological hazards, and more specifically, carcinogens. This may be driven by an inaccurate mental model of microbial pathogens as being exclusively associated with mild, temporary illnesses. The specter of severe, irreversible health outcomes and fatalities in the Walkerton and North Battleford outbreaks (Hrudey et al., 2002) may have updated this mental model to some extent.

The importance of having common human health outcome measures to compare hazards can be seen using an example from the derivation of chlorination by-product guidelines. In establishing these guidelines it would be ideal if there were a consistent basis upon which to compare the risk on the exposed communities from the disinfection by-products vs. the microbial pathogens that the disinfectant attempts to control. However, a lack of appropriate quantitative metrics to compare risks from these different hazards prevents this from being done. In the end, we are left with a situation that can be interpreted to be a one-sided risk evaluation with important information on tradeoff risks being unavailable to risk managers. A very similar example, (though exactly the opposite with respect to the imbalance in risk assessment), can be seen in chicken processing operations where chlorine may be added at extremely high levels to significantly reduce the microbial loading on the finished product. However, the competing risk from chlorination by-products as a result of this practice remains unassessed. As an example, Hardalo and Edberg (1997) provide a case study in which disinfection by-products could pose a potentially greater risk than the microbiological hazards being controlled.

Health outcome measures typically attempt to synthesize the quality and the quantity of life into a single measure for the purposes of comparative decision-making. There are many different measures that have been developed, and each has specific strengths and weakness that make them more or less suitable for certain applications and likely to place more or less weight on certain types of outcomes.

<u>The Way Ahead</u>

There are three components for which research in this area is warranted. The first component should focus on methodological work to analyze existing health outcome measures to determine the most appropriate one for the purpose. As mentioned previously, there are many measures and approaches that exist (Quality Adjusted Life Years (QALY), Disability Adjusted Life Years (DALY), etc.), and the development of new approaches does not seem warranted in the absence of overwhelming evidence that the existing approaches are inadequate. The second component should focus on the actual task of applying the appropriate health outcome measures to begin building a database for microbial pathogens. And finally, a third area is to address the communication challenges that undoubtly will arise when such measures are considered in decision-making. In addition to a degree of complexity, controversy is inevitable given the value-laden nature of assigning a weight to human life, pain and suffering. Consideration of communication issues will be important to the use of such measures in formal priority-setting processes, and in the establishments of performance standards (e.g., water quality guidelines, establishing food safety objectives).

Some work is already in progress on the use of quantitative health outcome measures for some food and water microbial pathogens. As an example, DALY estimates have been developed for *Campylobacter* spp. (Havelaar *et al.*, 2000b). Priority-setting exercises in government, industry or international agencies would all greatly benefit from the development and availability of appropriate quantitative and qualitative measures of the health outcomes associated with the full spectrum of microbial hazards.

Summary
Development of Health Outcome Measures

- Critical analysis, selection and adoption of health outcome measures for Canadian decision-making purposes;
- Apply appropriate health outcome measures, and generate a database of measures for microbial pathogens;
- Address risk communication challenges resulting from the complexity and contentious nature of relative health measures.

7.2.3 Development of New and Diverse Methods and Tools

Current Situation

As an emerging field, many of the seminal MRAs have used similar technology and modeling techniques. Duplication and adoption of existing approaches continues because, in many cases, microbial risk assessors must address mathematical and computational challenges in the midst of pressing timelines. These situations often result in following a path of least resistance, and drawing upon a relatively small tool chest of previously applied methods, regardless of their efficiency. For example, many of the risk assessments performed to-date have used Monte Carlo simulation tools as add-ins to spreadsheet applications (Cassin *et al.*, 1998a; Fazil *et al.*, 2002; Duffy and Schaffner, 2002; Hope *et al.*, 2002; Lindqvist and Westoo, 2000). Alternative tools and quite different approaches are available with potentially unique advantages. Examples include analytical approaches, belief networks and causal modeling (Barker *et al.*, 2002; Carlin *et al.*, 2000), stand-alone simulation software, and alternate non-probabilistic methods of propagating variability and uncertainty. Most of these have not been sufficiently explored nor applied in the field.

Similarly, in post-simulation analyses such as sensitivity and uncertainty analysis, the diversity of approaches applied is much less than what is available. Commonly, the uncertainty and sensitivity analysis techniques used are those that are packaged with off-the-shelf risk assessment software. However, some recent advancements have been made with the development of guidelines on selection of tools and techniques for sensitivity analysis specific to MRA (Frey *et al.*, 2003; 2004; Frey and Patil, 2002).

In general, there is a relative lack of academic attention to methodological development relevant to MRA. In addition, attention to such methodological developments is not currently fostered by regulatory agencies since methodological work is not likely to be a priority amidst the demands for immediate advice for risk management purposes.

<u>The Way Ahead</u>

A potential trap to avoid is that of constantly developing new methods to do the same or similar things. However, the alternative of ignoring the development of innovative methods for MRA to better handle specific scenarios and technical challenges is equally problematic. The MRA field is currently at a stage where there is a need to promote diversity and innovation in the tools and approaches that are available, and to apply these to solve more diverse types of problems. As a first step, a critical review of the variety of techniques available is needed, and the types of decisions or circumstances that would most likely benefit from each technique. A novel approach to test out the practical application of alternative methods would be to pose defined MRA problems to several groups working independently and using different approaches. Results could then be compared to evaluate the potential strengths and weaknesses of each strategy, and, most importantly, to determine if different decisions would have been taken depending upon the techniques employed. It is acknowledged, however, this might be a challenge to arrange, and to separate the capacity of the tool from the capability of the analyst applying it.

On the computational front, many of the challenges faced by microbial risk assessors are related to issues such as dealing with rare events, the highly non-linear phenomena of microbial growth and inactivation, the discrete nature of exposure to microorganisms (often only a small number of organisms), and the inherent complexity of the systems being described. Arguably, given sustained attention, these and other technical problems are manageable and could be solved outside of the pressures of a time-critical decision-making environment. It would be valuable if these mathematical and computational challenges could be surveyed, prioritized and studied with solutions offered. In addition, there is a growing inventory of risk assessment models that describe relevant biological or processing phenomena in a mathematical format (Cassin *et al.*, 1998b; Den Aantrekker *et al.*, 2003; Fazil *et al.*, 2002; Gale, 1998; Hartnett *et al.*, 2002; Jordan *et al.*, 1999; Petterson and Ashbolt, 2001; Rosenquist *et al.*, 2003; Tian *et al.*, 2002). The development and cataloguing of these models into a modular library, such that they could be applied with slight modification for specific risk assessment issues, could help alleviate some of the time constraints associated with the quantitative risk assessment process.

Recognizing the progress made by Frey and co-workers (2002; 2003; 2004) in cataloguing the various approaches that are available and in providing direction on the selection of techniques, the task at hand for post simulation analysis (uncertainty and sensitivity analysis) should focus on translating the tools and methods for post-simulation analysis into formats that encourage uptake into application. The most likely direction for this is through the development of software tools that make application of the techniques more user friendly. These user-friendly tools would have considerable value both within and outside the field of MRA.

Technical challenges and solutions in MRA for food and water overlap with those in related fields. These include infectious disease modeling, animal and plant health risk assessment, watershed management, groundwater modeling, water treatment design, public health program analyses, behavioral psychology, economic modeling, and complex systems simulation. A survey would be useful to generate a database of common phenomena and the corresponding analytical techniques that are being applied in other fields. The goal of this activity would be to detect promising opportunities for methodology cross-fertilization and could be achieved by cataloging the techniques, the area of application in other fields, and the comparable or potential application in MRA for food and water.

Summary
Development of New and Diverse Methods and Tools

- Microbial risk assessment is at a stage of development where there is still a need to promote diversity and innovation in the tools and approaches;
- A critical review should be conducted of the techniques available and the types of decisions or circumstances most likely to benefit from each technique;
- Mathematical and computational challenges should be surveyed, prioritized and studied with solutions offered;
- Risk assessment models describing relevant biological or processing phenomena should be catalogued into a modular library thereby facilitating application and alleviating time constraints associated with quantitative risk assessments;
- Adapt tools and methods for post simulation analysis into a more user friendly format to encourage uptake into application;
- Conduct a survey of comparable phenomenon being described in other fields and the corresponding techniques being applied.

7.2.4 Development of Tools for Analyzing Emerging Scenarios or Events

Current Situation

Risk assessment methodology tends to focus on estimating the risks of existing hazards and prevailing exposure scenarios. Assessing the risk related to emerging hazards and events requires the development of new ways to approach and solve the problem. The environmental scan found no obvious methodological research activity underway to address the decision-making problems posed by emerging pathogens or new exposure scenarios.

The Way Ahead

Although the field is untapped and likely to benefit from researchers approaching the problem with a clean slate, there are some directions that appear promising. One direction is to explore techniques such as failure analysis to study the food and water systems currently in place (Agarwal *et al.*, 2001). Here, the intent would be to consider the barriers that exist in food and water systems in order to generate a profile of the characteristics of emerging pathogens that would be capable of overcoming these barriers. Emerging pathogens exploit weaknesses in our current approaches (such as the development of antimicrobial resistance, or cryptosporidium's elevated resistance to chlorination). An analysis of current systems in this way might provide some degree of warning as well as an awareness of potential surveillance markers related to the identified vulnerabilities in current systems. Ultimately, the development of predictive tools linked to genetic sequencing information would offer the potential to develop more precise predictive tools for emerging pathogens.

Given that many food and waterborne outbreaks result from a sequence of events and failures (as opposed to a single event or failure), the development of analysis tools designed to assess the probabilities of rare or anomalous situations would be a beneficial area of study. There has been some interesting work in this area focused on the evaluation of data collected during food processing (Gonzalez-Martinez *et al.*, 2003).

Summary
Development of Tools for Analyzing Emerging Scenarios or Events

- This focus area will benefit from researchers approaching the problem with a clean slate;
- Investigate the potential to apply approaches such as failure analysis techniques to study the robustness of food and water systems to emerging hazards;
- Explore the development of analysis tools linked to genetic sequencing information to develop predictive tools for emerging pathogens;
- Develop tools designed to assess the probabilities of rare or anomalous situations.

7.2.5 Development of Tools for Rapid Risk-Based Decision-Making

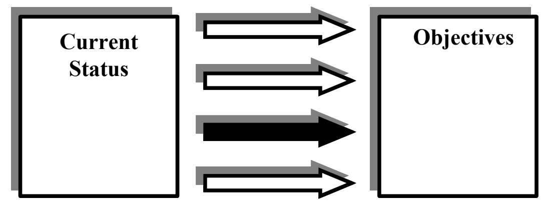
Current Situation:
Many microbial food safety risk assessments consider all segments of the production-to-consumption pathway (Cassin *et al.*, 1998a; Hartnett *et al.*, 2001; Hope *et al.*, 2002; Nauta *et al.*, 2000; Rosenquist *et al.*, 2003). Such comprehensive assessments are valuable, however, they are resource-intensive, and can take years before their results are available for decision-makers (USDA, 2001). There is a largely un-met need for decision-support tools that provide feedback in time-critical situations. For foods, urgency is called for in situations of dealing with imported commodities, product recalls, outbreak investigations, detection of intentional contamination, and potentially compromised products within the production environment. Rapid prediction of risk is critical in cases of water treatment failures, naturally- or intentionally-compromised source waters, issuing and rescinding boil water advisories, as well outbreak detection and investigation. A key criterion for the types of decision-support tools used in these situations is that they lead to reliable decision-making under conditions of considerable uncertainty and duress.

The Way Ahead
The development of tools in this area should be demand and decision-driven. Expert-based query systems, pre-simulated exposure scenarios in accessible databases, and probabilistic belief networks are examples of decision-making tools that might be developed, and later customized, for crisis situations. Efficient prioritization and development of such tools would be greatly facilitated by a detailed analysis of the rapid decision-support situation that are typical in food and water risk management. In order to characterize these needs and produce appropriate specifications for the support tools, there should be very close collaboration between researchers and the actual decision-makers responsible in time-critical situations.

Summary
Development of Tools for Rapid Risk-Based Decision-Making

- Conduct an evaluation of the rapid decision-support needs typical in food and water risk management and develop risk-based decision-making tools in response.

7.3 Major Pathway: Education and Infrastructure Development



7.3.1 Guidance for Qualitative Risk Assessment

Current Situation

Most routine food and water risk assessments may be best described as qualitative rather than quantitative, i.e., descriptive rather than numerical evaluations of risk. Qualitative risk assessments, by virtue of their relative simplicity and speed, do satisfy some of the needs of decision-makers, and such assessments are frequently conducted by Health Canada. The CAC, whose standards and guidelines are considered by the WTO as benchmarks for foods in international trade, cites the use of either quantitative or qualitative risk assessments as appropriate in substantiating trade dispute issues. It is interesting to note, however, that in animal health trade issues, there have been disputes regarding the nature and potential strengths and weakness of qualitative methods (WTO, 1998). The relative equality of the two approaches in terms of the quality of support for decisions is an issue of current debate. The primary contention is that most qualitative risk assessments tend be primarily literature reviews with a non-transparent and non-traceable progression to a judgment on the level of risk. At the NGOA expert consultation, it was evident that there is still debate among experts on the basic issue of whether a purely qualitative assessment can indeed be considered to be a risk assessment at all.

Such debates are a consequence of the lack of guidance and best practices for qualitative approaches, in contrast to the numerous prescriptive documents for the conduct of quantitative risk assessments. There is considerable uncertainty regarding what can and cannot be considered a qualitative risk assessment, and whether there are any clearly identifiable elements of good, or bad, practice for these types of assessments. Just as quantitative risk assessments can contain logic and mathematical errors, qualitative risk assessments may be construed on basic flaws in inference and treatment of evidence. However, without structured methodologies and techniques for translating and synthesizing qualitative information in a consistent and transparent fashion, little scrutiny or discipline is applied to the qualitative logic. Even an experienced practitioner of qualitative risk assessment would have little formal basis on which to assess the quality of his or her own, or another analyst's qualitative assessment. Without guidance on common pitfalls and key methodology considerations in qualitative risk assessment, a significant proportion of current risk-based decision-support is largely unaddressed in terms of initiatives to improve the state of practice.

The Way Ahead

There is a need formalize and improve the practice of qualitative risk assessments to address the needs of decision-makers in a consistent and scientifically sound manner. The creation of carefully evaluated guidance materials would be a considerable service to the advancement of MRA since properly constructed qualitative assessments can have substantial utility in many risk management activities. Towards these goals, specific activities that would be informative include the following: critical review of representative qualitative risk assessments in terms of quality of outputs for decision-making; assessment of scoring schemes or other methods of synthesizing information that might be used in qualitative risk assessments in order to determine associated strengths, weaknesses and pitfalls; establishment of the characteristics of a good qualitative risk assessment (e.g., defining best practices, case studies).

As an initial step, it would be useful to compile examples of good quantitative risk assessments and determine if similar conclusions could have been reliably reached using non-quantitative methods. Early in 2004, FAO and WHO began work on formulating a guidance document for qualitative and semi-quantitative risk assessments. The scope of the work, however, is likely to be of a more general nature than the specific approach advocated as a way forward here.

Summary
Guidance for Qualitative Risk Assessment

- Critically review current qualitative risk assessments on the basis of their decision-making advice;
- Assess qualitative methods of synthesizing information to demonstrate strengths, weaknesses and limitations;
- Analyze examples of applied quantitative risk assessments, to determine if similar conclusions and direction could have been reliably reached using non-quantitative approaches;
- Develop guidance materials on qualitative risk assessment, to ensure consistency in application and confidence in decision-making advice provided.

7.3.2 Guidance on Technical and Methodology Issues

Current Situation:
Microbial risk assessment guidance documents currently available tend to cover basic methodological issues, and are typically written in a format that provides a general overview, but do not go into any degree of detail on specific technical issues (WHO/FAO, 1999; WHO/FAO, 2003; and other series in preparation at www.who.int/foodsafety/micro/jemra/guidelines, and www.fao.org/es/ESN/food/risk_mra_guidelines_en.stm). These documents, and the

associated analyses, tend to be directed at a broad audience that includes decision-makers, risk managers, and individuals looking for a basic introduction to the field. They are not instructive in the analytical details of conducting a quantitative assessment. There are a few books that deal with the details of risk assessment as a whole (Bedford and Cooke, 2001; Covello and Merkhofer, 1993; Vose, 2000), and at least one that covers MRA specifically (Haas *et al.*, 1999). It is difficult however, in a reference book format, to go into specific details about the entire spectrum of issues (technical and methodological) that are relevant from a MRA practitioner's viewpoint.

Way Ahead:
There is a need for guidance documents that are focused, specific, and have a treatment of the technical issues at a level targeted at microbial risk assessors. In order to become adopted into best practice, the development of such guidance documents would eventually have to have a broad expert consensus. However, there are many activities, including research and background analysis in specific topic areas that must be done before reaching the point of discussing consensus. Examples of relevant issues include: the appropriate treatment of data in MRA (e.g., distinguishing 'good data' from 'bad data'); appropriate treatment of 'non-detects'; issues in estimating risk-based performance standards with a rigorous treatment of uncertainty and variability; simulating rare events; examples of model simplifications with known limits of applicability. Recent guidance documents for uncertainty and sensitivity analysis by Frey and co-workers are good illustrations of the level of detail and rigorous treatment that is required.

Summary
Guidance on Technical and Methodology Issues

- Development of detailed guidance documents on specific technical issues targeted at microbial risk assessors is needed;
- Specific topic areas for guidance include: appropriate treatment of data in microbial risk assessment; appropriate treatment of 'non-detects'; issues in estimating risk-based performance standards (with a rigorous treatment of uncertainty and variability); simulating rare events; and examples of model simplifications with known limits of applicability.

7.3.3 Training for Risk Assessors and Risk-Based Decision-Making

Current Status
The education and training issues associated with this pathway requires progress in two complementary directions: education and training for decision-makers, and training for

practitioners. In order to be truly effective, a risk assessment should address risk management questions. A few quantitative MRAs have been undertaken in Canada for food (Cassin *et al.*, 1998a; Farber *et al.*, 1996; Fazil *et al.*, 1999; Health Canada, 2000b), and internationally for water (Casman *et al.*, 2000; Crabtree *et al.*, 1997; Gale, 1998; Gale, 2000; Gerba *et al.*, 1996; Teunis and Havelaar, 2002; Teunis *et al.*, 1997). The majority of these can be characterized as research-oriented since they are not responding or providing direct input to a specific decision-making need. The lack of decision-driven risk assessments seems unlikely to be due to a lack of decisions needing input, nor absence of recognition for the need to use risk assessment in decision-making (Section 5 highlighted this recognition at the international, national and provincial levels). Accordingly, a more likely cause for the absence of decision-driven risk assessments is the lack of capacity to practically integrate risk assessment into the decision-making processes. Timeliness is an important component of this integration capacity, hence the importance of the needs described in Section 7.2.5 for tools for rapid risk-based decision-making.

The absence of quantitative MRAs applied to decision-making, is more pronounced when Canadian activities are judged on a comparative basis with nations such as the United States, Australia, New Zealand, and many countries in Europe. Ironically, Canadian researchers were the first to publish a comprehensive quantitative MRA for application to food safety (Cassin *et al.*, 1998a). Many Canadian scientists in food and water safety have served as participants and expert panel members for international bodies including the CAC, FAO and WHO, to help advance risk assessment applications in member countries.

In addition to the decision-maker level, researchers and scientists at the data-generation level also have some misunderstanding of the capabilities and reasons for doing a risk assessment. Of note, risk assessment has relevance in the research field along three fronts: as a tool to facilitate the uptake of research results into decisions and policy, the application of the systems modeling approach to help in the understanding of complex systems; and finally, as a method to guide research direction.

Formal MRA is a relatively new discipline in food and water safety. As a result, practitioners in the field, both in Canada and internationally tend to come from a variety of backgrounds with no formal training in MRA nor in the principles of decision analysis or systems analysis. There is, in general, a reliance on personal interest, adaptation of techniques from other fields and enrollment in an occasionally offered workshop or training session to gain the necessary tools and skills to make advancements in the field. Typically, individuals graduating from universities with microbiological specializations have not acquired the necessary quantitative and analytical skills. Conversely, those graduating from programmes that provide more quantitative and analytical skills will not have the necessary microbiological knowledge. It is generally acknowledged (but with a lack of supporting evidence), that the pool of human resources available are insufficient to meet the demand for decision-driven risk assessments that seems to be implied by the environmental scan. However, there is some question of the level of commitment (or 'real' demand) for risk assessment. It remains unclear whether there is a circular supply-demand paradox for risk assessment, where concrete demand is suppressed due to an apparent lack of a readily available supply of expertise.

The Way Ahead

There is a need for education and training for all contributors to the assessment and management of microbial risks. Some training in risk assessment and risk-based decision-making would benefit scientists, managers, and those responsible for implementing intervention strategies. Discussions at the NGOA expert consultation indicated that some priority should be given to initially developing programs that target decision-makers. This will provide an impetus from the top down, to structure risk assessments that have a problem-solving focus and to drive compatible research towards that end. Training and educational opportunities are needed to better inform laboratory/surveillance researchers on the concepts of risk assessment, but more importantly, to provide insight on the types, outputs and nature of research that are relevant to assessing risk.

A first step that would be beneficial in increasing the understanding and application of risk assessment for food and water safety would be to hold a series of very focused, application-oriented workshops. The workshops would be targeted at risk managers, risk assessors and researchers/data generators, with the objective of bridging the ‘disconnect’ among these groups. Ideally, the workshops could be structured around actual case studies, developed through consultation with affected stakeholders. Successful outcomes from this training would be that the risk manager gains an appreciation for the types of assessments that can be used in formulating decisions, the risk assessor gains an understanding for the types of decisions managers are faced with, and that the data generator gains a recognition for the types of information that would readily contribute to the risk assessment and decision-making process. At the same time, each group of individuals should also come to understand some of the limitations and constraints of each discipline.

It is beneficial, when developing new techniques and methods in an evolving field, to draw upon individuals with varied backgrounds and specialties, and who do not have pre-established and constrained approaches to solving problems. However, without an appropriate number of individuals entering the field with the necessary skills to build on the foundations established, a great deal of time is devoted to finding and training individuals. Universities need to consider that this field requires a set of skills, including analytical and decision-making, that is currently underdeveloped, and likely to be even more in demand as the adoption of these problem-solving methods become increasingly integrated into public and private decisions. As a result, there may be an opportunity to develop appropriate training programs at the university level so that new graduates are ready to contribute to the field of MRA by the time they graduate.

The principal investigators of this report, as well as the experts assembled at the NGOA expert consultation, were divided on the existence of a tangible shortage in supply of individuals trained in quantitative skills, and the demand for these skills. As a result, it is recommended that the most appropriate course of action along this pathway would be to initiate a ‘market study’ of training and development needs. The purpose of this would be to investigate if there actually is a substantial un-met demand for personnel who have been formally trained in MRA. Alternatively, or in addition, a study of this kind could be designed to identify the types of skills that might be lacking, as perceived by governments, industry and academia to help determine the most appropriate means of providing the training and education required.

It would clearly be prudent to phase-in any university-based risk assessment educational initiative. This could begin with scholarships for PhDs to do research in applying MRA to problems with development of new tools and techniques, and/or incorporating risk assessment models as part of a broader research focus. Microbial risk assessment requires interdisciplinary skills, abilities, and knowledge; as a result, it is not recommended that graduate programs confer degrees in MRA per se, but rather degrees in established programs (e.g., microbiology, epidemiology, engineering) with formal exposure to MRA and incorporation of the concepts within the research program.

The goal at the undergraduate level should be to develop personnel with the multi-disciplinary skills that can be applied to microbial food and water safety risk assessment, and are also easily portable to a variety of career paths. Canadian universities do not have programs in place for individuals with microbiological and epidemiological training to become familiar with, for example, the quantitative decision sciences. One recommendation, if supported by the results of the ‘market study’ mentioned, would be to develop a stream of study that exposes students to the field of policy, risk assessment, decision-analysis, epidemiology and microbiology. A complementary co-operative program could then be developed to enrich the training of these students and the exposure of other workers to the techniques. Eventually, the maturity of the program could open up opportunities for continuing education initiatives to provide scientists with exposure to the policy-making mechanisms and thus allow them to better translate their research into risk assessment and risk management processes.

Summary
Training for Risk Assessors and Risk-Based Decision-Making

- Develop risk assessment and risk-based decision-making training programs for decision makers, researchers and risk assessors with initial priority given to programs targeting decision makers to encourage a top-down approach;
- Develop workshops structured around case studies with attendance representative of risk managers/policy makers, risk assessors and researchers;
- Conduct a “market study” of training and development needs to establish if a substantial un-met demand exists for individuals formally trained in microbial risk assessment, or to establish the types of skills that might be lacking from the perspective of government, industry and the research field.

7.3.4 Development of a Practitioner Network

Current Status

In Canada, the network of individuals practicing risk assessment, chemical, microbial or otherwise, is not well coordinated. At the international level, there is very little knowledge or awareness of MRA activities taking place in different countries. There are pockets of international collaboration on risk assessment activities, and arguably, there may be far more international collaborations than domestic collaborations, particularly pertaining to food safety. There is also a chasm between the food and water MRA communities due, in part, to quite different regulatory and jurisdictional arrangements, and to academic separation of food and water disciplines. At present, there is no means by which one could communicate or coordinate with all of those dealing in MRA activities, either directly or indirectly, in Canada.

The Way Ahead

The practice and development of MRA in Canada would benefit from the availability of a set of collaborative communication vehicles (e.g., conferences, listservs, websites) that would allow practitioners to share resources, tools and experiences, and to maintain awareness of the activities of peers and other developments of common interest. The Canadian Water Network, given its mandate, could serve as one champion for bringing scientists together in venues that would foster this sort of collaboration. In addition to formal networks, the NGOA expert consultation concluded that there is potentially a need for 'seed funding' to support opportunities for students and/or scientists for training or to work on collaborative risk assessment projects. The funds would be geared towards covering expenses, such as travel and accommodations, and would be intended to foster the development of linkages through face-to-face meetings with other specialists (e.g., economists, social scientists, epidemiologists, microbiologists, engineers) as a way to build strong collaborative and personal networks.

Summary
Development of a Practitioner Network

- The practice and development of microbial risk assessment in Canada would benefit from the availability of a set of communication vehicles (conferences, listservs, websites, etc.) that allow practitioners to share resources, tools, and maintain awareness of activities;
- There is a potential need for 'seed funding' opportunities that foster the development of linkages to develop multidisciplinary proposals incorporating risk and decision sciences and to build strong collaborative personal networks.

7.3.5 Application of Peer Review Processes for Risk Assessment

Current Status

Risk assessments can be complex products that integrate a considerable amount of information and contain inferences that are often difficult to assess and evaluate. The risk assessment approach is often advocated for important and complex decisions, and peer review adds an additional level of quality control to the decision-support process. Useful peer review requires both an adequate process and competent reviewers. At present, there is no clearly identified process for the peer review of MRAs, either in Canada or internationally. In addition, although there are potentially many experts who can evaluate the scientific aspects concerning a food or water safety risk issue, and determine if all the appropriate references have been tapped, there is a lack of individuals who are adequately experienced and can evaluate *both* the content and the mathematical and inference tools used in the overall product. This can be critical, because the synthesis and inference applied to the evidence is at the heart of the risk assessment process.

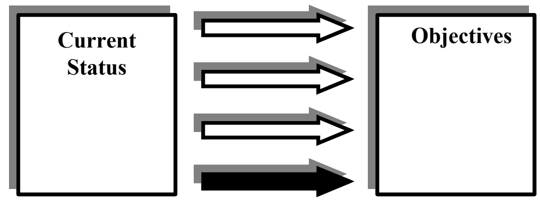
The Way Ahead

Microbial risk assessment peer review is required on three fronts. First, the evidence and assumption base used must be scrutinized to assess the validity of the decisions made to include, exclude, or process evidence. Any scientific assumptions not strictly linked to evidence should be carefully reviewed. Second, assumptions and data that relate to the characterization of the food or water system need to be reviewed for the accuracy of the representation. Third, the translation of these two evidence bases into a model should be evaluated. From past experience, the authors note that MRA peer reviews have tended to focus on evidence scrutiny, with less attention paid to the modeling, inference and risk characterization aspects. The 'value-added' dimension of quantitative MRA lies primarily in the accurate integration of evidence to generate complex joint probabilities leading to a characterization of risk, and hence warrants careful scrutiny. Guidelines should be developed to ensure an adequate peer review process that considers all three aspects. In the longer term, the appropriate availability of expert resources to achieve the quality of review required is likely to be an issue if adequate training and education is not made available in Canada (Section 7.3.3).

Summary
Application of Peer Review Processes for Risk Assessment

- Rigorous peer review process for microbial risk assessment is needed along three fronts: scrutiny of the evidence and assumption base; accuracy of the representation of the food or water system; translation of these two components into a model.

7.4 Major Pathway: Communication



7.4.1 Effective Integration of Risk Communication into the Process

Current Status:
It is recognized in most risk analysis frameworks that communication should be occurring throughout the problem-solving cycle as an integral and iterative part of the process (CFIA, 2002; CFIA, 2003b; Covello and Merkhofer, 1993; Health Canada, 2000a; OMAFRA, 1997; PCCRARM, 1997a; PCCRARM, 1997b; WHO, 2000; WHO/FAO, 1999). The recognition of its importance in a framework, and its actual implementation in practice are, however, two very different things. There is a general consensus within the risk assessment community that risk communication can always be improved. At present, the most obvious work in this area revolves around retrospective studies evaluating the communication performance in high profile events (e.g., the Walkerton outbreak (Kennedy, 2003), and funds are being made available to evaluate the performance of Health Canada's risk communication strategies surrounding SARS. These retrospective studies provide a measure of performance, but there needs to be more effort applied in actual development of techniques, approaches, and importantly, training and implementation of good risk communication principles for everyday use.

Risk communication is a field of study in its own right, and it would be a disservice to suggest that the needs and gaps appropriate to the field can be determined as a subset of risk assessment pathways. At the same time, there are some risk communication issues that can be addressed within the current scope. First, it is prudent to differentiate risk communication into a few different general forms. The most obvious form, and the one that most technical people would think of as risk communication, is the translation of risk estimates or other outputs such as uncertainty measurements into a form that is understandable to policy makers, risk managers or the public. Risk communication also includes the communication that occurs before and throughout the risk assessment process with decision makers, researchers and stakeholders in order to appropriately structure, modify or edit the assessment such that it satisfies the needs of all the stakeholders. Finally, risk communication can also be the vehicle through which the risk is mitigated. Here, the primary purpose of communication is not to inform stakeholders about the level of risk; rather it is primarily intended to communicate actions that can alter the risk. For instance, a "boil water" advisory is an example of risk communication designed to mitigate risk. In the food arena, food handling advice for specific products, or advice directed to highly susceptible individuals are examples of risk communication specifically designed to mitigate risk.

Way Ahead:

A detailed scan of the risk communication field by experts in the area is needed. Similar to the current project, this work should be initiated to determine where knowledge or capacity is lacking, where application would have a significant impact, and what barriers exist to the advancement and improvement in the field in general. It would be beneficial to conduct a detailed study of the means by which communication methods could be used to improve the role of MRA in public policy. A risk communication study for microbial risks needs to go beyond generic statements (e.g., 'communication is good, do it early, do it often, talk to everyone all the time, be open, be honest') toward the determination of key points of failure and their impacts in order to provide concrete solutions that can be implemented to improve the practice.

A specific area, for which the authors feel a study would be warranted, is one that looks into the communications issues that should be considered in attempting a ranking of microbial hazards, or other rankings based on a technical ranking scheme. Ideally, such a study would provide advice on perceptual properties of presenting the risk rankings. This is important, because while science and risk measures can dictate that certain risks are more important than others, the ability to convey this message in a form that is acceptable and understandable by stakeholders is often lacking especially with respect to microbial risks. The importance of risk ranking and prioritization has been stressed earlier in the report, however the ultimate success of the technical efforts depends upon the ability to inform the real prioritization process, which includes multiple decision-makers and stakeholders in complex consultative processes.

Another area of research in risk communication that would be highly beneficial is work focusing on determining the efficacy of risk communication strategies intended to mitigate risk. These studies should attempt to quantify the effectiveness of these communication methods, and how to improve them. An improved capacity to estimate risk reduction behavior, in terms of response and reaction rates, of issuing various types of warnings (e.g., warnings requiring rapid response such as boil water advisories and food contamination recalls, or longer term risk management strategies such as instructing people on cooking practices and product labeling) would be useful in formulating risk management strategies. In many cases of time-critical risk management, risk communication is the only risk mitigation tool available. Accordingly, the ability to understand the impact of this form of risk communication should be given a level of research funding in keeping with its importance as a direct risk reduction tool.

Summary
Effective Integration of Risk Communication into the Process

- Experts in the area of risk communication should conduct a detailed and critical scan of the field of risk communication;
- Study the means by which communication methods could be used to improve the role of MRA in public policy to determine the points of failure and their impacts, and to provide concrete and practical solutions;
- Analyze the communications issues associated with attempts to rank microbial hazards, or other rankings based on a technical ranking scheme;
- Determine the efficacy of different types of risk communication strategies intended to mitigate risk (e.g., warnings requiring rapid response such as boil water advisories, or longer term risk management strategies such as instructing people on cooking practices and product labeling).

8.0 Summary and Conclusions

According to the U.S. National Science Foundation (NSF), risk analysis becomes useful to society when its findings are translated into actions. This can only occur if the findings are accessible to decision makers and are regarded by them as an important source of guidance (NSF, 2002). At present, there are deficiencies in the translation of findings into actions. A workshop organized by the NSF made two interesting and important conclusions. First, scientists "…have significantly advanced our capacity for risk analysis and decision-making during recent decades". Second, "…the empirical findings and analytic tools produced by decision and risk sciences are not used in policy and other societal decisions as much as they could be".

To advance microbial risk assessment as a foundation for informed decision-making about food and water safety in Canada, this report outlines a framework identifying current needs, gaps and opportunities. The thesis proposed is that effective and frequent application of microbial risk assessment in risk management requires the field to strive towards achieving certain objectives. These objectives include: the need for consistent quality in risk assessments; the application of a prioritization process for microbial risk decision-making; the incorporation of risk assessment to inform targeted research decisions; the ability to assess new evidence rapidly for its impact on decision-making and policy; the application of diverse and appropriate risk assessment approaches for short-, medium- and long-term decision-making; the development and maintenance of comprehensive systems models for microbial risks in food and water; the ability to incorporate costs and other decision relevant evidence into the outputs; and the effective interaction between risk assessors, decision makers and stakeholders to increase trust and credibility in risk assessment and risk management.

The means to attain these objectives are grouped into four broad categories, or pathways, with recommendations for specific efforts in several defined areas. The key components are summarized here.

Pathway: Coordination

- Prioritization and co-ordination of research and information;
- Coordinated development of comprehensive models;
- Improved data and analytical tool sharing.

Pathway: Methodology and Tool Development

- Estimation and attribution of the burden of illness;
- Development of health outcome measures;
- Development of new and diverse methods and tools;
- Development of tools for analyzing emerging scenarios or events;
- Development of tools for rapid risk-based decision-making.

Pathway: Education and Infrastructure Development

- Guidance for qualitative risk assessment;
- Guidance on technical and methodology issues;
- Training for risk assessors and risk-based decision-making;
- Development of a practitioner network;
- Application of peer review processes for risk assessment.

Pathway: Communication

- Effective integration of risk communication into the process.

The successful incorporation of research, risk assessment and decision-making is dependent on progress being made to address the different needs, gaps and opportunities identified in this project. With advancements in each of these areas, risk assessment can serve as an integral and critical linkage between research and risk management, decision-making, and policy development. Policy and decision-makers will have a more effective mechanism than currently exists to translate their needs into specific research directions that will aid in the formulation of sound risk management strategies. Researchers will have a means to synthesize diverse scientific information into decision-support tools that will promote the uptake and utilization of evidence in the applied management of microbial risks in foods and water.

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