



Health
Canada

Santé
Canada

Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks

August 1, 2000

Canada 

Table of Contents

Preface	Page i
1. Introduction	Page 1
1.1 Why Revise the Current Approach?	Page 1
1.2 Developing a Revised Approach	Page 3
1.3 Underlying Principles	Page 4
1.4 Overview of the Framework	Page 10
2. Steps in the Decision-Making Framework	Page 13
2.1 Identify the Issue and Its Context	Page 14
2.2 Assess Risks and Benefits	Page 26
2.2.1 Assess Risks	Page 27
2.2.2 Assess Benefits	Page 37
2.3 Identify and Analyze Options	Page 40
2.4 Select a Strategy	Page 44
2.5 Implement the Strategy	Page 47
2.6 Monitor and Evaluate Results	Page 50
3. Overview of Guidance Documents	Page 53
3.1 Environmental Risk Assessment	Page 53
3.2 Socioeconomic Analysis	Page 54
3.3 Risk Communication	Page 55
3.4 Public Involvement	Page 55
3.5 Integrating Population Health and Risk Management Decision-Making	Page 55
3.6 Developing Health-Based Outcome Measures	Page 55
3.7 Priority Setting	Page 56
References	Page 57
Glossary	Page 61
Appendix A: Project Team	Page 75

Preface

Background

Canadians are among the healthiest people in the world. An important factor in achieving this success is our willingness to exploit opportunities provided by scientific discovery and technological innovation for improvement. Almost every aspect of our lives is affected by new technologies. These include the development of therapeutic and other health products, innovations affecting the quality and safety of our food supply, and the creation of new industrial and other consumer products. While our health and general standard of living has improved through technological advances, it is important to realize that all processes, activities and products have the potential to adversely affect our health. In fact, many of the modern challenges to health are a consequence of complex interactions between our physical and social environments together with our personal and life style choices. In order to properly address this complexity, maintaining and improving health requires a structured, analytical and deliberative approach to mitigating and controlling health risks. In Canada, maintaining and improving our health is a responsibility shared by individuals, communities, industry, and all levels of government.

Health Canada helps protect the health of Canadians with programs and regulatory measures concerning: the quality, safety and effectiveness of drugs, medical devices and pesticides; the safety of consumer products and workplace substances; the safety and nutritional quality of food; exposure to toxic substances in the environment; and the quality of air and water [Health Canada, 1998]. The Department also helps Canadians to prevent, and reduce the incidence and severity of disease, injury and disability, through for example, prevention and control programs for specific diseases (such as HIV, cancer or cardiovascular disease) and for groups or individuals at higher risk [Health Canada, 1998]. The assessment of health risks, and the selection and implementation of effective risk management strategies, form the basis for many of Health Canada's activities.

In 1993, Health Canada published a formal framework, which defined and described the risk assessment and risk management process in a structured way [Health Canada, 1993]. While the 1993 approach served its purpose well, in recent years there have been a number of changes in society, science and technology, that have prompted the Department and other public health agencies to reexamine the way that they deal with health risks. These changes have had an enormous impact on public health and the work of health protection. Health Canada has recognized the need to modernize its approach to risk assessment and risk management, to deal effectively with these new challenges. Much progress has been made over the past several years; however, there is currently no formalized, consistent approach, being applied across the spectrum of health protection issues.

Project Overview

In the summer of 1997, Health Canada launched a fundamental review of its health protection operations. This effort, known as “Health Protection Branch (HPB) Transition,” was aimed at helping Health Canada and its partners to better manage risks to the health of Canadians into the next century [Health Canada, 1998]. Through HPB Transition, Health Canada developed a decision-making framework and a number of documents that provide guidance in dealing with related considerations. Implementation of the framework, its underlying principles, and the associated guidance documents, will help the Department to deal with the challenges of the current environment, in a consistent, comprehensive and coordinated fashion, and consequently will improve the effectiveness of the risk management decision-making process across its health protection programs.

Contributors

Appendix A lists the members of the Risk Management Framework Project Team, who provided direction, coordination, technical expertise, and assistance for the project, and developed this document (or its earlier versions), based on a variety of input. An accompanying document lists the names and memberships of the numerous Groups that provided program-related input and developed guidance and other documents. A number of other individuals also provided comments that contributed to the development of the framework and guidance documents, through their participation in focus groups held in the winter of 1997/98, and comments on earlier drafts. Comments made during public consultations in the fall of 1998, and various presentations throughout 1999 also contributed to the development of this document.

Purpose of the Framework and Guidance Documents

The purpose of this document is to provide a description of the key challenges which led to the development of the revised framework, the general principles that underlie the framework, a detailed description of the steps in the framework, and an overview of the considerations that are dealt with in various guidance documents.

A summary document is available, which includes only the key challenges, the general principles, an overview of the steps in the framework, and a limited glossary. Draft guidance documents dealing with the following considerations are also available under separate covers: conducting environmental risk assessments; conducting socioeconomic analyses; communicating risk-related information; involving interested and affected parties; integrating population health and risk management decision-making; developing health-based outcome measures; and setting priorities.

The framework and guidance documents are intended to provide a common, general basis for risk management decision-making throughout the Department. The documents in themselves are not intended to be implementation manuals; rather they can be used by individual programs to develop specifically tailored procedures to meet their particular needs.

Intended Audience

The framework and guidance documents are intended for use by Health Canada managers and staff, including scientists and public health professionals, who are responsible for, or involved in carrying out, various aspects of the risk management decision-making process. The documents will be of particular interest to those individuals responsible for developing program-specific implementation procedures.

Intended Application

The framework and guidance documents are intended to be applicable to the range of agents that fall within Health Canada's mandate. These agents include: diseases (both communicable and noncommunicable); substances (chemicals, radiation, microbes); and products (food, medical devices, drugs, tobacco, consumer products). In addition, a document has been developed to provide guidance for undertaking environmental risk assessments on products of biotechnology (as required due to legislative obligations).

1. Introduction

Risk: A measure of both the harm to human health that results from being exposed to a hazardous agent, together with the likelihood that the harm will occur.

1.1 Why Revise the Decision Making Framework?

A Decision Making Framework has two primary functions. First, it is a quality assurance tool which formalizes decision making as a consistent process with identifiable steps. Secondly it helps to identify the important principles and organizational values of decision making. In 1993, Health Canada published a formal *risk determination* framework, which defined and described the risk assessment and risk management process in a structured way [Health Canada, 1993]. Since that time, decision makers have been faced with a number of important challenges including: rapidly advancing health related technologies; changes in government organization, roles and responsibilities; and a rapidly expanding, diverse information and knowledge base.

Over the last decade, government decision making has come under increasingly critical scrutiny. In particular, the *Krever Commission of Inquiry on the Blood System in Canada (1997)* provided a detailed criticism of decision making as it related to the management of Canada's blood supply. In the summer of 1997, Health Canada launched a fundamental review of its health protection operations in response to these criticisms and to the new challenges in health risk management. This initiative (Health Protection Branch Transition) was designed to help Health Canada and its partners better manage risks to the health of Canadians into the next century [Health Canada, 1998].

Recommendations for improved decision making based on the national public health consultations held by HPB Transition and from various Health Canada working groups focused on several major themes, including:

The Examination of Health Risks Within a Broad Perspective

Traditional risk assessments typically focus on the results of biological, chemical, and physical studies involving the health effects resulting from exposure to a single agent. In recent years, there has been a growing recognition that a number of factors or determinants can affect health, and these determinants together with their interactions, can influence the level of risk for specific populations. There has also been a growing recognition that risks need to be viewed in their public health context to ensure that the most important risks are addressed and that key risks are not ignored because an issue has been defined too narrowly. Taking both of these things into account can lead to more complete and meaningful risk assessments, and to the development of risk management strategies that are more effective and that have fewer unintended adverse impacts.

Collaboration, Partnership and Team Work

To avoid duplication of services and to be cost-effective, governments at all levels are developing partnerships. Canada-wide health protection systems, non-governmental organizations and university research communities are capable of doing some of the work that is now being done within Health Canada. While some level of scientific and other collaborations have always existed, the nature of these collaborations and the extent to which they are undertaken, must increase in order to ensure that an appropriately broad range of information and expertise are taken into account when identifying, assessing, and managing health risks.

Effective Risk Communication

The growing complexity of risk assessment and risk management, the increasing interest and demand of the public for more information, and the number of recent controversies related to the handling of specific risk issues (e.g. contamination of the blood supply; whether to permit use of recombinant bovine somatotrophin (rBST) in Canada), all contribute to the need for Health Canada to provide interested and affected parties with timely, relevant information, in a format that is useful to them. The public is no longer satisfied with merely being presented with the results of risk management decisions after the fact.

Public Engagement and Stakeholder Participation

In recent years, members of the public have become more interested in being involved in decisions that affect them, especially when it comes to their health. The reluctance of many individuals to rely on government to singularly make risk management decisions, requires that mechanisms be put into place to provide greater opportunities, not only for the exchange of information, but where possible, for participation in the risk management decision-making process.

Transparency

The growing complexity of risk assessment and risk management, and public expectation for information, make it critical that the risk management decision-making process be clear and understandable, in terms of the steps involved, the basis for decisions (including uncertainties, assumptions, and their impacts), and the roles, responsibilities, and accountabilities of participants.

Accountability

In recent years, there has been an increasing public demand for governments to demonstrate accountability for their actions, and to ensure the wise use of limited resources. This requires increased attention to priority-setting, and to selecting and implementing effective risk management strategies.

Flexibility and Ability to Adapt to New Situations in the Management of Health Risks

The need to deal with new health risks, new discoveries and technologies, a broad range of information and perspectives, and the greater involvement of multiple participants (including different levels of government), all must be factored into risk management decision-making. The current environment requires that a wider range of risk management options be considered, where possible, so that an optimal approach can be selected (i.e. one which is effective, has minimal negative impacts, and can be carried out at a reasonable

cost).

The emergence of these challenges has had an enormous impact on public health and the work of health protection. Health Canada has recognized the need to modernize the health protection system, including its approach to risk management decision-making, to deal effectively with such challenges. Much progress has been made over the past several years; however there is currently no formalized, consistent approach, being applied across the spectrum of health protection issues. There is clearly a need to make further progress in this area.

1.2 Developing a Revised Approach

Through HPB Transition, Health Canada is developing a decision-making framework, consisting of three components (issue identification, risk assessment, and risk management), and a number of documents that provide guidance in dealing with related considerations.

What's in a Name?

There is no standardized terminology when it comes to dealing with health risks. Various agencies and organizations use different terms to refer to the same process, and in some cases, the same terms to refer to different processes. This can present a problem in instances where these groups need to exchange information, collaborate, or ensure that legislated requirements or international agreements are adhered to.

For example, the term “risk analysis” is used in the area of food safety, by the Codex Alimentarius Commission, Health Canada’s Food Programme, and the Canadian Food Inspection Agency, the term “risk determination” is used in the 1993 Health Canada Framework, and the term “risk management” is used by the Canadian Standards Association, U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management, U.S. Environmental Protection Agency, International Standards Association, and Health Canada’s Therapeutic Products Programme.

Use of the term the general term *decision-making framework* is intended to avoid the difficulty of trying to reconcile terminology differences that exist, while recognizing that Health Canada needs to take the perspectives of various health protection agencies into account.

The revised approach:

- ! Maintains a focus on health and safety.
- ! Broadens the base of information used for decision-making.
- ! Supports an evidence-based approach.
- ! Provides clarity in terms of the process followed, information used, and decisions made.
- ! Provides sufficient flexibility to address a range of risk issues and situations.

- ! Strengthens the Department's ability to evaluate risk management strategies.
- ! Clarifies the roles, responsibilities, and accountabilities of participants.
- ! Provides greater opportunities for the involvement of interested and affected parties.
- ! Provides the basis for a systematic, comprehensive, coordinated Branch, and Department-wide approach.
- ! Serves as a tool at the center of a broader framework for policy development.

Consistency: A Key Advantage of the Revised Approach

Although the Department has had an "official" approach for assessing and managing health risks since 1993, the approach has been implemented to varying degrees across and even within various Branch programs. While programs have done well in meeting their own needs and dealing with many risk issues, there has been no coordinated effort to train individuals in applying a common approach, or to ensure that the approach is applied in a consistent and comprehensive manner. This is especially a concern for risk issues that cut across program areas (e.g. a chemical contaminant in air, water, and food), and has sometimes resulted in different risk assessment and management approaches being used, difficulties in information exchange and understanding, and difficulties in developing consistent Branch risk management policies.

The development of a revised approach for risk management decision-making (including the framework, its underlying principles, and associated guidance documents) together with a coordinated implementation effort across and within various programs, will provide the Branch with a common, consistent, and comprehensive means of dealing with risk issues. Working together can increase efficiency, effectiveness, and consistency of decisions, reduce duplication of effort, identify gaps in science and policy, and help to ensure that resources are used effectively.

1.3 Underlying Principles

A number of principles underlie the risk management decision-making process, and provide a general basis for decisions made and actions taken. A key difference between the revised approach and that embodied in the 1993 framework, is the formalization of a number of such principles, and the more consistent integration of these principles into the steps of the decision-making process.

The principles described below reflect Health Canada's current risk management decision-making philosophy. The principles respond to the changes in our operating environment, noted earlier, as well as other values that have been emphasized both in internal and external consultations. Some of the principles are based on ideas from other sources [European Commission, 1998; Hrudey, 1998; Light and Hrudey, 1998; Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997 a, b; Hattis, 1996; National Research Council, 1996]. The principles are inter-related and must be applied in a cohesive fashion.

In practice, many of these principles have been evolving over the last several years, as Health Canada has strived to continuously improve the policy development and decision-making process. Further some principles have already been applied when dealing with certain health protection issues. Defining these principles in an explicit way, as a key element of the revised approach, can help to ensure a common understanding among individuals who participate in, are interested in, or affected by, the risk management decision-making process, and that the principles are implemented in a more consistent manner across all health protection programs.

While every attempt should be made to apply the various principles below to specific risk issues and situations, it should be noted that their application may be limited in certain instances due to legislative or other requirements or restrictions.

Underlying Principles

- ! Maintaining and Improving Health is the Primary Objective
- ! Involve Interested and Affected Parties
- ! Communicate in an Effective Way
- ! Use a Broad Perspective
- ! Use a Collaborative and Integrated Approach
- ! Make Effective Use of Sound Science Advice
- ! Use a “Precautionary” Approach
- ! Tailor the Process to the Issue and its Context
- ! Clearly Define Roles, Responsibilities, and Accountabilities
- ! Strive to Make the Process Transparent

Maintaining and Improving Health is the Primary Objective.

Give health and safety precedence in making risk management decisions, over economic and other considerations. Balance Health Canada’s mandate to protect the health and safety of Canadians, with the right of individuals to make personal choices. Where these two interests are at odds, decisions must always favour the former over the latter.

Involve Interested and Affected Parties.

Provide adequate opportunities for affected and interested parties to be involved in the risk management decision-making process [Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997 a, b; Canadian Standards Organization, 1997]. This includes the decision as to whether to apply a precautionary approach and which provisional risk management strategy should be implemented.

Involvement means providing individuals and groups with access to relevant information, and with an opportunity to express their views and to influence policy decisions. It does not mean that unelected and

unaccountable members of the public or other groups can make decisions for which Health Canada is accountable. The nature and extent of involvement may vary depending on a number of factors including whether there is a need for a quick response (e.g. in an epidemic) and the level of resources available, and may range from active participation, to ensuring that concerns are sufficiently addressed, to the provision of information. Providing opportunities for involvement can build trust, lend credibility to decisions, and provide access to critical information. In order to be effective, the process for involvement must be clear and explicit, and carried out in a systematic way.

Communicate in an Effective Way.

Provide clear, accurate, relevant information to interested and affected parties in a timely manner, using a format that is useful and easily accessible to them [Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997 a, b; Canadian Standards Organization, 1997]. Communication is a two-way process and includes developing an understanding of the needs of interested and affected parties, reacting to concerns and informing, consulting, and educating. An important aspect of effective communication is providing individuals with enough information to allow them to contribute to the decision-making process in an informed way. The specific nature and extent of communications varies as does the nature and extent of public involvement.

Health Canada has a responsibility to inform and educate Canadians about risks to their health, and the process that is being used to assess and manage these risks. This includes helping individuals to understand that every choice brings with it some degree of risk and that certain risks are shared by society as a whole. It also includes providing information that allows individuals to make their own decisions on matters which concern their health, particularly when the degree of risk is low and the information is readily accessible. When possible, it also includes providing opportunities for individuals to contribute to the risk management decision-making process by expressing their concerns and perspectives, and by providing knowledge and expertise that can help to shape the process and decisions made.

Effective communication is especially important in cases where there are large discrepancies between perceptions and scientific assessments of risk. Special care must be taken care when communicating with groups whose first language is neither English nor French, to ensure that their concerns are understood and that risk messages are communicated in an understandable manner.

Use a Broad Perspective.

To the extent possible, take into account a variety of information when identifying, assessing, and managing risks, while maintaining a focus on health and safety. A sufficiently broad understanding of the issue and its context are key to focusing risk assessment efforts, identifying risk management goals, selecting efficient and effective strategies, and appropriately allocating resources.

Risk assessment must be sufficiently broad to ensure adequate understanding of the risk and to identify effective risk management options. Where possible, assessments must take into account both data from “scientific” studies, and information on determinants of health (e.g. social, cultural, ethical considerations,

economic status), where these determinants are demonstrated to have an effect on the level of risk for specific populations. Where possible and appropriate, assessments must also consider interactions between agents rather than individual agents in isolation.

Risk management decisions must consider a variety of information in order to ensure that the best risk management strategy is selected and that it is implemented in an effective manner. The expected effectiveness of potential risk management options, and legislative, international trade, or other requirements and limitations are obviously key considerations. Taking a broad perspective means also taking into account factors such as risks vs. benefits, potential social, cultural, ethical, political, environmental, legal, economic, and other impacts, and the perspectives of interested and affected parties.

While it is important to strive for a broad perspective, it should be noted that the extent to which this is possible may be limited by existing legislation, which obviously, takes precedence.

Taking a Population Health Approach

Determinants of health is the collective label given to factors and conditions that are thought to have an influence on health. These include things such as income and social status, social support networks, education, employment and working conditions, social and physical environments, personal health practices, and coping skills. Some determinants play a more prominent role than others for given health issues, and interact in complex ways to affect population health.

Taking a population health approach involves focusing on the health of the population as a whole, and of subgroups within the population, by addressing factors that contribute to health and their complex interactions. The approach addresses not only the physiological, psychological and behavioural components of health, but also the entire range of factors that contribute to our physical, mental and social well-being. The overall goal of a population health approach is to maintain and improve the health status of the entire population while reducing inequalities in health status among population sub-groups.

Use a Collaborative and Integrated Approach.

Use a collaborative and integrated approach for identifying issues, and assessing and managing risks. The volume and complexity of information, and the cross-cutting nature of many risk issues (e.g. contaminants in air, water, and food), make it impossible for a single individual or group to maintain the necessary expertise to deal with most health risks of concern to the Department. Working together can increase efficiency, effectiveness, and consistency of decisions, reduce duplication of effort, and identify gaps in science and policy.

Maintain sufficient in-house expertise to support policy making, to implement regulations, to set standards and regulations, and to respond to emerging health issues. To supplement this, take advantage of the expertise that exists within other national and international organizations, including those involved in health

protection, academia and industry. Don't duplicate existing efforts where they meet the level of scientific and health protection standards of the Department, taking current jurisdictional constraints into account.

Make Effective Use of Sound Science Advice

Success in maintaining and improving our health requires an evidence based approach to decision making. This can only be achieved by making effective use of sound science advice. Such an approach helps to address public confidence that decision makers are using science in the best interests of Canadians, that science advice is credible, and that decision makers are confident that this advice is based on a rigorous and objective assessment of all available information. In order to achieve these goals, the decision making process must include measures to ensure the quality, integrity and objectivity of science advice (Council of Science and Technology Advisors, 1999, Industry Canada, 2000).

Use a Precautionary Approach.

A key feature of managing health risks is that decisions are often made in the presence of considerable scientific uncertainty. A precautionary approach to decision making emphasizes the need to take timely and appropriately preventative action, even in the absence of a full scientific demonstration of cause and effect. This emphasis in decision making is reflected in the final report of the Krever Commission of Inquiry. It concludes that a lack of full scientific certainty should not be used as a reason not to take preventive measures when reasonable evidence indicates that a situation could cause some significant adverse health effect.

This general concept has been expressed in a variety of contexts, especially in the area of environmental protection. The most widely quoted is Principle 15 of the ***Declaration of the Rio Conference on Environment and Development (1992)***. In the Canadian context, the ***Canadian Environmental Protection Act (1999)*** provides that "... the government of Canada is committed to implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

There is considerable debate, both nationally and internationally, over the use of the phrases "precautionary approach" and "precautionary principle". No definition is universally accepted. The Health Canada Decision Making Framework treats the concept of precaution as pervasive. As such it does not require extremes in the actions taken. Instead, risk management strategies reflect the context and nature of the issue, including the urgency, scope and level of action required.

Tailor the Process to the Issue and its Context.

Maintain flexibility throughout the risk management decision-making process. Using a flexible approach can lead to more effective and more acceptable risk management decisions. While recognizing there are urgent situations that require quick action, the emphasis on timeliness and flexibility should never be at the cost of thorough and thoughtful, even if rapid, consideration of all the steps and considerations identified

in the framework.

Using a flexible approach includes: undertaking the process in a way that is best suited to different agents and situations; limiting the depth and breadth of the process to take into account the requirement for a timely response; revisiting previous steps when new findings provide important insights related to earlier deliberations and decisions; incorporating significant new information that may emerge throughout the process or following evaluation; using a variety of risk management options and levels of response as needed to provide a given level of health protection; and revisiting decisions periodically to determine whether a revised risk management approach or strategy is needed.

Using a flexible approach may also involve implementing a “two-track” process in certain situations. Such a process could include a reactive and timely response, involving an interim risk management strategy, and the pro-active, systematic development of longer term strategy, which enhances the Department’s capacity to anticipate, prevent and respond to the new instances of the risk issue. Using a two-track approach allows the decision-making process to move forward without having to delay necessary action until more comprehensive work is done.

Clearly Define Roles, Responsibilities, and Accountabilities.

Clearly define the roles, responsibilities, and accountabilities of all parties who participate in the risk management decision-making process, as well as Health Canada’s relationship with each of them. This includes identifying who is responsible for undertaking comprehensive risk assessments in cases where precautionary action has been implemented. Clearly delineating roles, responsibilities, and accountabilities helps to ensure that participants and other interested and affected parties know what is expected and what commitments have been made, and thereby can lead to more efficient and effective risk management strategies. It also helps in the allocation of resources.

The responsibility for improving and maintaining health is one shared by individuals, communities, industry, and all levels of government. Health Canada has a primary role in protecting the health and safety of Canadians at the national level; however it is but one component of a complex system of health protection, which includes, among others, various levels of government, government agencies, the health care and medical professions, the academic and health sciences research and development communities, manufacturers and importers, consumer groups, and individual Canadians. This makes it important to identify potential conflicts (e.g. conflicting regulations and overlapping jurisdictions of governments and related agencies), to eliminate gaps, and to ensure that health protection programs are delivered seamlessly across the country. It is also important to be specific about accountabilities, especially when there is shared responsibility, and to avoid giving the impression that Health Canada is accountable for matters outside the Department’s mandate or jurisdiction.

In addition to specifying the roles of various organizations, it is necessary to differentiate between the roles of scientists and policy makers. While both teams may contribute to issue identification, their primary roles are to undertake risk assessment and risk management, respectively. The role of scientists is to assess risk

based on the science (both biophysical data and information on risk factors), and to identify potential risk management options that are related to the level of risk. The role of policymakers is to consider the results of risk assessments, together with a broad range of other considerations, and use this information to make risk management decisions.

Strive to Make the Process Transparent.

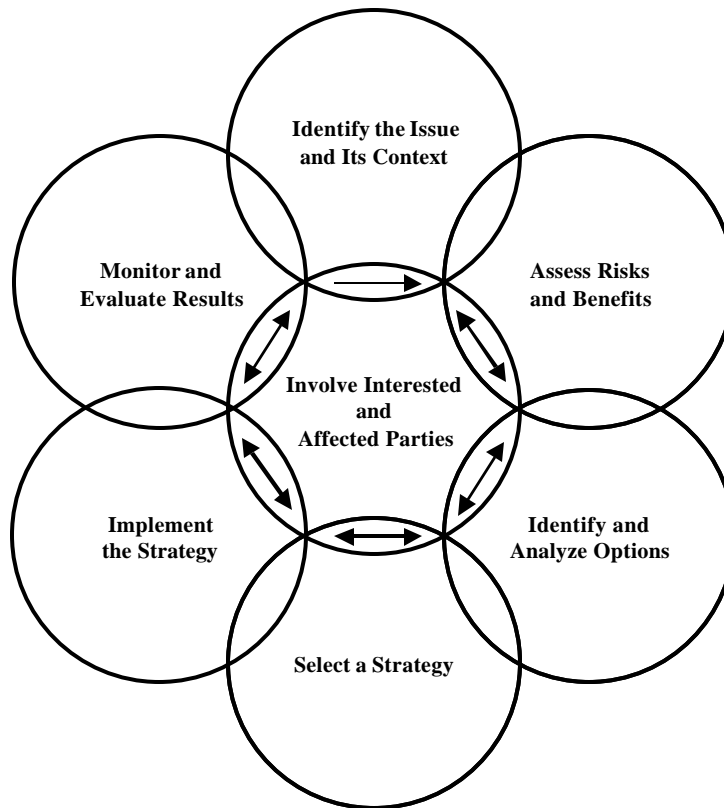
Clearly document all activities, considerations, assumptions, uncertainties, and decisions, to ensure that all aspects of the risk management decision-making process are clear and easily understandable. Bearing in mind any requirement for confidentiality, make this information accessible to interested and affected parties. Individuals who review the documentation should be able to understand how and why things were done, what decision-making processes were used, and who is accountable and responsible for various activities and decisions. Although it is important to maintain clear and comprehensive documentation, the extent of documentation needs to be balanced by resources and priorities, especially when the timeliness of the response is critical.

1.4 Overview of the Framework

The proposed risk management decision-making framework is depicted in Figure 1 and consists of a series of inter-connected and inter-related steps, which may be grouped into three phases: issue identification (identify the issue and put it into context); risk assessment (assess risks and benefits); and risk management (identify and analyze options; select a strategy; implement the strategy; and monitor and evaluate the results). The framework reflects the involvement of interested and affected parties throughout the process, including partners, the public, and other stakeholders.

Generally speaking, the process begins at the top of the diagram, and proceeds clockwise through the other steps; although the steps are depicted as a series of circles, there is a general linear progression. Each step involves a decision point, as to whether to proceed to the next step, revisit a previous step, or end the process. The process is flexible in that one may move back and forth between steps or revisit steps based on available information. For example, a previous step may be revisited when there is a need to improve the accuracy and completeness of information, or when new information becomes available and needs to be considered.

Figure 1: Decision-Making Framework



Interested and affected parties, including partners, the public and other stakeholders can play a key role in issue identification, risk assessment and risk management. They can provide valuable information, knowledge, expertise, and insights throughout the process, and should be involved as early as possible. The roles, responsibilities, and accountabilities of all parties who participate in the process must be clearly defined for each issue being addressed.

The effective communication of risk-related information (i.e. *risk communication*) is an integral part of the process, because both the substance and the process of risk management decisions must be acceptable to a broad range of interested and affected parties. Effective risk communication assists in the exchange of information, and facilitates informed decision-making. The goal of effective risk communication is to ensure that there is an adequate understanding of the process by all interested and affected parties.

Documentation is also a key aspect of the process. Two types of documentation are needed for each step: first, a description of how the step should be undertaken, including data requirements, assumptions,

considerations, and how decisions should be arrived at; and second, a summary of how the step was actually undertaken, the assumptions used, the uncertainties that exist, and how decisions were made, with an explanation given of any changes from the original plan. The requirement for detailed documentation may vary depending the issue being addressed and its context, with consideration being given to factors such as the importance of the decisions to be made, the level of concern, the resources available, and the need for timeliness. Consideration must also be given to the need and/or legal obligation to keep certain information confidential. Reasonable efforts should be made to document the process without generating excessive paperwork

While implementation of the framework will help to ensure that risks are addressed in a consistent and comprehensive manner, its application is not intended to be rigid or prescriptive. The manner in which the framework is applied to specific situations or specific risks may vary. Similarly, the relative importance of the steps, the extent to which they are carried out or revisited, and the tools, data, and specific considerations involved, can vary depending on the issue being addressed and its context. For example: the framework need not be invoked in a detailed way, for risk situations that are routinely and expeditiously managed (e.g. voluntary product recalls); in dealing with crises situations, steps may be undertaken rapidly or implicitly due to the need to act quickly; a more detailed risk assessment may be undertaken later, following the implementation of a risk management strategy.

The selection of a circle diagram as opposed to a linear one, reflects an emphasis on an integrated decision process, its component steps, and their interrelationships, and is similar to that proposed by the U.S. Presidential/Congressional Commission on Risk Assessment and Risk Management in 1997. It is recognized that certain programs within Health Canada and certain external organizations use different diagrams to depict the risk assessment and risk management process, and that the choice of diagram reflects an emphasis on different aspects of the same process. This includes for example: the roles, responsibilities, objectives, and functional autonomy of participants (e.g. Codex Alimentarius Commission; Health Canada's Food Program; the Canadian Food Inspection Agency); tasks and work flow (e.g. 1993 Health Canada Framework; Canadian Standards Association Q850 Framework); and a decision making process with continuous improvement (e.g. Health Canada's Therapeutic Products Program). It is important to note that the decision making processes noted above are consistent in approach despite being represented by different images or diagrams (i.e. they reflect similar tools, ideas, and goals).

Detailed descriptions of each of the steps in the decision-making framework are provided in section 2 below. With the exception of the first step (which is new), all steps are generally similar to those in the 1993 framework. The key differences lie in the integration of the underlying principles (described earlier) within the various steps. Of particular note are the emphasis on: providing opportunities for the involvement of interested and affected parties; communicating risk-related information; clearly documenting all aspects of the decision-making process; using a precautionary approach when warranted; taking a broader, population health perspective; and measuring the effectiveness of risk management strategies.

As noted earlier in the *Underlying Principles* section, these changes have already begun to take place in

practice, over the last several years. Explicitly defining the steps (and the inherent principles) in the revised framework, can help to ensure a common understanding among individuals who participate in, are interested in, or affected by, the risk management decision-making process, and that the steps (and principles) are implemented in a more consistent manner across all health protection programs.

Taking Population Health Approach

Taking a “population health” approach to risk management decision-making means:

- ! making greater effort to identify subpopulations for which a health issue is of particular concern;
- ! incorporating information on social, cultural, economic, and other health determinants into risk assessments, when these factors are demonstrated to have an impact on the level of risk for specific populations;
- ! considering a greater variety of potential risk management options, particularly non-regulatory ones where they offer an acceptable level of health protection;
- ! paying greater attention to the unintended impacts of potential risk management options, particularly on social, cultural, and other factors that affect health;
- ! making greater use of multi-faceted risk management strategies, where possible, to improve effectiveness with different populations;
- ! involving a variety of partners in implementing strategies, and implementing these strategies on several levels, in several sectors, and using several methods, where possible, to improve effectiveness; and
- ! considering the effectiveness of risk management strategies, both in terms of traditional measures, and in terms of their impact on a variety of health determinants.

This approach has been evolving in practice over the past several years. Its integration within the decision-making framework will help to ensure that it is applied routinely and consistently across all health protection issues (unless limited by legislative or other requirements or commitments).

2. Steps in the Decision-Making Framework

This section describes the major tasks and considerations that comprise the various steps in the risk management decision-making framework. The section is purposefully general in nature; the specific tasks and considerations, and the extent to which they are undertaken or taken into account, respectively, depends upon the specific risk issue and situation that is being addressed. Judgement and expertise must be used to determine how to apply the information provided below in practice.

2.1 Identify the Issue and Its Context

Clearly define and describe the issue and its context. This is key to focusing risk assessment efforts, identifying risk management goals, selecting efficient and effective strategies, and appropriately allocating resources.

This step involves determining the nature of the risk management issue, and establishing the administrative basis and operating procedures needed to proceed. Clarification of the issue and its context is critical, because it provides direction and focus both for risk assessment and risk management. The “context” of an issue refers to its contribution to a specific health concern (e.g. respiratory disease), as well its importance relative to other issues that must be addressed. The nature and scope of an issue’s context may vary with given situations.

A critical question that needs to be asked at the outset is whether the issue falls within Health Canada’s mandate, either in terms of a specific program, or the Departmental mandate of maintaining and improving the health of Canadians. Another important question is whether the issue needs to be addressed quickly (for example, in the case of a serious communicable disease), or whether there is time to move through the process in a more detailed and formal way.

Identify the Issue and Its Context - General Tasks

Content-Related Tasks:

- ! Identify the Issue.
- ! Begin to Characterize the Risk.
- ! Put the Issue into an Appropriate Context.
- ! Identify the Risk Management Goal(s).
- ! Identify Issues Relevant to Risk Assessment and Risk Management.

Process-Related Tasks:

- ! Allocate Resources for Issue Identification, Risk Assessment, and Risk Management.
- ! Establish the Risk Assessment and Risk Management Teams.
- ! Identify Roles, Responsibilities, and Accountabilities.
- ! Prepare an Action Plan.
- ! Establish the Documentation Process.
- ! Identify Interested and Affected Parties.
- ! Initiate Risk Communication Efforts.

Both the sequence of these tasks, and whether they are performed sequentially or simultaneously, may vary depending on the specific issue and context involved. Many of the tasks may be revisited throughout the decision-making process, as additional information becomes available.

Content-Related Tasks

Identify the Issue

Issues may be identified proactively (for example, through the review of premarket submissions for prescription drugs) or reactively (for example, in response to concerns related to contaminant levels in imported foods), and may have varying levels of urgency and importance. Issues may change throughout the decision-making process, as more information becomes available. New issues may arise, issues may disappear, or priorities may change.

Issues may be identified using a number of different sources. Examples include:

- ! toxicology studies (e.g. on laboratory animals, cultured cells, or tissues);
- ! epidemiology studies (e.g. of occupationally exposed workers);
- ! environmental monitoring (e.g. levels of chemical contaminants in air);
- ! biological monitoring (e.g. lead levels in blood);
- ! product surveillance (e.g. adverse reactions to specific therapeutic products);
- ! disease surveillance (e.g. distribution of cases of a disease over time);
- ! investigations of disease outbreaks (in Canada and elsewhere);
- ! targeted risk assessment programs;
- ! targeted public health research;
- ! information supplied by industry as required by legislation;
- ! lack of compliance with legislative requirements;
- ! consultation with experts (e.g. advisory committees);
- ! literature review;
- ! monitoring of the news media;
- ! communications from interested and affected parties (e.g. health care professionals, consumers, industry);
- ! focus groups; and
- ! examination of public perceptions and concerns.

The nature and importance of these sources varies with the specific issue involved; where possible, a multi-disciplinary approach should be used to ensure that as many aspects of the issue are identified as possible.

Some Issues Addressed by Health Canada

Health Canada addresses a variety of different types of health risks including those related to: specific diseases, such as HIV/AIDS, cancer, or cardiovascular disease; the quality, safety and effectiveness of drugs, medical devices, other therapeutic products, and pesticides; the safety of consumer products and workplace substances; the safety and nutritional quality of food; and the quality of air and water.

Begin to Characterize the Risk

Preliminary risk characterization involves collecting sufficient information to begin the process of identifying and characterizing the hazard(s), and assessing exposure(s); more in-depth information is obtained during *Risk Assessment*. In general terms, this involves collecting and synthesizing basic information on: the agent(s) underlying the issue; the adverse health consequences associated with the agent(s); susceptible populations; exposure to the agent(s); and the scientific uncertainties that exist. It also involves considering public perceptions of the issue. Preliminary risk characterization is an iterative process, and may require several attempts at refinement as new information is gathered. It is important to determine the underlying or root cause(s) of the issue, rather than the symptoms, in order to ensure that risk assessment and risk management efforts are appropriately focused.

Preliminary hazard identification involves determining: what type(s) of adverse health effects might be expected as a result of exposure to the agent(s); and how quickly these effects might be experienced. Preliminary hazard characterization involves: determining who (what human populations) might be exposed to the agent(s); whether certain subpopulations might be susceptible to greater exposure or be more susceptible to the effects of the agent (s) (i.e. as a result of social, cultural, economic, or other risk factors); and evaluating the adverse health effect(s) that they may experience under expected levels of exposure to the agent(s).

Preliminary exposure identification involves determining: the relevant sources of exposure; the contribution of each source to the problem situation; the differential exposures experienced by various subpopulations; whether exposures are likely to be short term or long term; and how frequently exposures might occur (e.g. seasonal variations). Since exposure can change over time, it may be useful to proactively address an issue where exposure to the agent is currently low, to prevent increased exposure in the future.

Put the Issue into an Appropriate Context

Considering issues in a broad context can be time- and resource-intensive, so it is important to clearly determine when this should be done and what the scope should be. A broad perspective may be useful when developing a risk management policy for a disease having many potential sources or routes of exposure (e.g. Hepatitis B), for example. A narrow context may be used for example, when investigating a localized outbreak of food poisoning.

Using a Broad Context: Some Health Canada Examples

A number of types of issues are typically considered in a broad context. For example, the relative risk of disease transmission and infection, are routinely considered for infectious diseases. In the case of chemicals on CEPA Priority Substances Lists, relative risk is sometimes considered in a group of chemicals, depending of the nature of the group and the mechanisms of action. For therapeutic products, the context may be a product made by one of several manufacturers (e.g. a GMP [good manufacturing process] issue), one of several formulations or routes of administration of a drug (e.g. fast release nifedipine), all forms and manufacturers of a product (e.g. laxatives containing phenolphthalein), or a whole class of products (e.g. calcium channel blockers).

A number of factors can be considered when determining the context of an issue; their nature and relative importance varies with the situation being addressed. Examples include:

- ! similar sources of the same agent (e.g. pesticide residues in different types of food);
- ! other routes of exposure for the same agent (e.g. lead in food versus lead in air);
- ! other agents from the same source (e.g. different air pollutants in automobile exhaust);
- ! the collective impact of exposure to similar agents (e.g. multiple air pollutants and their effect on respiratory illness);
- ! the effects of the agent in combination with other agents (e.g. synergistic effects, promoter effects);
- ! the magnitude of the risk compared to other risks (e.g. air pollution and cardiorespiratory disease versus mercury contamination of fish and neurological impairment);
- ! how quickly the issue must be addressed, including the consequences of delaying action;
- ! the availability of resources and technology needed to examine the issue;
- ! current, short term and long term impacts of the issue (demonstrated and potential);
- ! ethical concerns;
- ! the scope of the issue (e.g. national, international); and
- ! international processes, agreements or obligations.

Once an issue has been put into context, and the context information combined with that from preliminary risk characterization, a decision can be made about how to proceed. Possibilities include whether to: take action to address the issue immediately (e.g. there is a crisis); undertake a more detailed analysis before taking any action (i.e. to proceed to the risk assessment/benefit assessment step); proceed using a two-track approach (i.e. immediate action combined with longer term investigation); or discontinue the process, as the issue is not an important concern.

Identify the Risk Management Goal(s)

Risk management goals should be used to guide risk assessments.

One or more risk management goals can be established once the issue has been identified in an appropriate

context. In doing so, consideration should be given to the needs, issues, and concerns of interested and affected parties, the nature of the decisions that have to be made, and any assumptions and constraints governing the decision. Regardless of the situation, the primary goal of any risk management strategy must be to ensure an appropriate level of health protection.

Risk management goals may be risk-related (e.g. reduce the incidence of adverse health effects), may involve public values (e.g. protect the most sensitive subpopulation), may consider economic impacts (e.g. achieve an acceptable level of health protection without causing loss of jobs), or be determined by legislative requirements, policy, or national or international obligations. They also may be influenced by priorities that have previously been established, or by priorities dictated by limited resources. Goals may be revised as new information is obtained and considered, either later in this step or in subsequent steps of the decision-making process.

Identify Issues Relevant to Risk Assessment and Risk Management

Information obtained through the previous tasks can be used to flag key issues for consideration during the risk assessment and risk management processes. For example, preliminary risk characterization may reveal that further research in a specific discipline is required before risks can be more accurately assessed. Early consideration of risk perceptions may help to flag risk management options that would be unacceptable to affected parties.

Process-Related Tasks

Allocate Resources for Issue Identification, Risk Assessment, and Risk Management

A key aspect of being able to address any risk is identifying and obtaining the human, monetary, and other resources required. Preliminary resources may be identified to initiate the issue identification process, with more substantive resources being flagged once there is a better sense of the extent of work to be undertaken. Typically, an action plan must be developed to justify the resource requirements. The nature and complexity of the plan, and the route and level of approval may vary depending on the situation involved.

Establish the Risk Assessment and Risk Management Teams

The *risk assessment and risk management teams*, as the names suggest, are responsible for undertaking the activities related to risk assessment and risk management, respectively. While both teams should play a role in issue identification, and need to exchange information throughout the entire decision-making process, their roles are distinct. The role of the risk assessment team is to assess risk based on the science (both biophysical data and information on risk factors), and to identify potential risk management options that are related to the level of risk. The role of the risk management team is to consider the results of risk assessments, together with a broad range of other factors, and use this information to make risk management decisions.

While the specific nature and composition of each team may vary depending on the situation being addressed, it is critical for each team to have a leader who not only provides direction but maintains a linkage with the other team. In addition there needs to be an overall risk manager responsible for guiding and integrating the work of the two teams, moving the process forward, and dealing with various process-related issues. In cases where there is shared responsibility for decision-making, as in federal/provincial/territorial matters, it may be necessary for more than one risk manager to be identified.

While the composition of the teams may change as the risk assessment and risk management process progresses, there should be core teams in place to maintain continuity. If it is discovered that an important contributor is missing, the teams can be expanded later. Careful documentation of actions and decisions is important for maintaining continuity as team membership changes. In any case, early identification of the teams is important.

Identify Roles, Responsibilities, and Accountabilities

Along with the establishment of teams goes the assignment of roles, responsibilities and accountabilities. This is critical to ensure that both the teams and others, including interested and affected parties, know what is expected and required. The assignment of roles, responsibilities and accountabilities should be done early in the process, and can be captured through the development of “terms of reference”. In order for the teams to function effectively, it is important that they have access to the necessary information, the authority to act, and the resources required to accomplish their objectives.

Other individuals may also be involved in the risk management decision-making process. These include communication specialists, individuals responsible for implementing, monitoring, and evaluating risk management strategies, individuals providing resources, and representatives of interested and affected parties who have specific knowledge and experience of the issue at hand. The roles, responsibilities and accountabilities of these individuals also needs to be specified.

Prepare an Action Plan

The action plan is one of the most important documents produced within the entire issue risk decision-making process. It describes how and when various steps in the process will be undertaken, key definitions that will be used, and the roles, responsibilities, and accountabilities of participants (including those of the person or person(s) with the authority to ensure that the plan is implemented). The action plan provides a basis for obtaining “up-front” understanding and agreement from the risk assessment and risk management teams, and helps to ensure that the process is clear. The action plan must be approved by an appropriate level of management before the process proceeds further. The plan may be revised as new information becomes available throughout the process.

Establish the Documentation Process

A *risk information library* should be established to serve as a repository for all of the information that is documented during the decision-making process. Proper documentation can: help to make the process clear and understandable; provide a record of considerations, assumptions, decisions, and actions taken; identify the roles, responsibilities, and accountabilities of the parties involved; help to ensure that decisions are evidence-based; assist in evaluating the process; and provide a reference for future processes, to facilitate training and continuous improvement.

In general, the risk information library should contain the following:

- ! the roles, responsibilities, and accountabilities of team members and other participants;
- ! an outline of the process used for issue identification, risk assessment and risk management;
- ! the action plan (for implementing the process);
- ! the implementation plan (for the risk management strategy);
- ! the evaluation plan (for the risk management strategy);
- ! the risk communication plan;
- ! the consultation plan (i.e. with interested and affected parties);
- ! activities undertaken in accordance with each plan, and an explanation of any deviations;
- ! information collected during each step of the process;
- ! details of all qualitative and quantitative analyses undertaken, including uncertainties, assumptions, and judgements associated with the results and their impact;
- ! decisions made, and the basis for the decisions;
- ! the level of resources to be dedicated to the process;
- ! feedback arising from consultations with interested and affected parties; and
- ! results and recommendations arising from evaluations.

Specific details as well as additional information will be added to the library as the decision-making process progresses. In establishing the documentation process, it should be recognized that some information may be confidential, and that appropriate measures must be taken to ensure that confidentiality is maintained. Other important points to consider include: why specific information is confidential; what information can be released; to whom the information can be released; whether the confidential nature of the information will adversely affect certain parties (and if so, what if anything, can be done); and who is responsible for ensuring confidentiality.

Identify Interested and Affected Parties

Early in the process, it is important to identify those parties who may be interested in, affected by, involved in, risk management decisions. This includes identifying concerns, and perceptions, as well as any roles, responsibilities, and accountabilities that they may have. Depending on the situation, representatives of some interested and affected parties may be part of the risk assessment or risk management teams. In any case, it is important to specify the role that interested and affected parties might play, and when and how they

would be involved in the process.

Examples of Interested and Affected Parties

Health Canada interacts with a wide range of parties during the decision-making process, including: other federal government departments, provincial and territorial governments, municipal governments, provincial health systems, non-governmental organizations, health professionals, public health agencies, health associations, environmental associations, industry, the academic community, consumer groups, community groups, international governments, international agencies, other agencies, regional representatives, representatives of different cultural, economic, or ethnic groups, and the general public.

The early and ongoing involvement of interested and affected parties is important for several reasons:

- ! it provides a source of valuable information, values, perceptions, concerns, knowledge, expertise, and insights for characterizing issues and identifying viable solutions;
- ! it helps to identify better, more generally acceptable decisions, and strategies that are often easier to implement, more effective, more timely, and in some cases less costly;
- ! it helps in resolving the often conflicting interpretations about the nature and significance of risks;
- ! it provides opportunities to bridge gaps in understanding, language, values, and perceptions;
- ! it facilitates exchange of information and ideas essential for enabling all parties to make informed decisions about reducing risks;
- ! it helps to ensure that risk management decision-making is as equitable, participatory, open and transparent as possible; and
- ! it responds to the desire of individuals to be involved in decisions that affect them, especially when it comes to their health and to the growing support for the use of flexible approaches for dealing with health risk issues.

In order to determine who should or may want to be involved, it is useful to answer the following questions:

- ! Who might be affected by the risk management decision?
- ! Who may have contributed to, or will be responsible for resolving, the issue?
- ! Who has information and expertise that might be helpful?
- ! Who has been involved in similar risk situations before?
- ! Who has expressed interest in being involved in similar decisions before?
- ! Who else might be interested in the decision?
- ! How was the issue identified?

These questions and others can be answered by conducting a *stakeholder analysis* [see the box that follows for additional information]. This type of analysis can help decision-makers to better address the needs, issues, and concerns of interested and affected parties. It is also critical for risk communication, as it forms the basis upon which communication processes, messages, and tools are determined. The stakeholder analysis can be refined and additional information added as required, throughout the decision-making process.

Throughout the process, the mix of interested and affected parties may change, depending, for example, on the capacities of the representatives. New parties may wish to be included, while others may drop out of the process. The level of interest may also change throughout the process, in response to new information, either because a party's needs or concerns have been addressed, or because the new information has given rise to new needs or concerns. Both possibilities should be considered in advance and factored into the risk communication strategy [see the section *Initiate Risk Communication Efforts* that follows]. It should be noted however, that changes in membership, especially late in the process, may disrupt continuity and compromise the effectiveness of the group.

Stakeholder Analysis

A stakeholder analysis captures the following type of information:

- ! names, affiliations, phone and fax numbers, and email and mailing addresses of representatives;
- ! background, culture, values, knowledge, interests, objectives, and responsibilities of the representative and group (i.e. those things that might underlie their needs, issues, and concerns, or affect their decisions);
- ! whether the stakeholders are actually at risk as a result of issue or potential decision(s);
- ! whether stakeholders perceive themselves to be at risk;
- ! any significant knowledge gaps and/or misconceptions stakeholders might have;
- ! who stakeholders trust to provide them with information about the issue;
- ! types of communication processes stakeholders prefer and trust; and
- ! other relevant information that may aid in discussions.

Source: Adapted from the Canadian Standards Association. *CAN/CSA-Q850-97 Risk Management: Guideline for Decision-Makers*. Rexdale (Toronto). 1997.

There are a number of different ways to involve interested and affected parties, ranging from the provision of information to joint decision-making [see the table that follows for some examples]. Determining how to involve individuals depends on many factors including: the nature and context of the issue; the complexity, uncertainty, impact and level of controversy associated with the decision to be made; the urgency with which the issue needs to be addressed (i.e. the need for timeliness); the manner in which the parties would like to be involved; the extent to which they can be involved and have a genuine influence on decisions (given legislative or other considerations); the extent to which they are required to be involved; the extent to which they may have contributed to the issue; and resources available to facilitate involvement. While it is not necessary to involve all parties in every aspect of the decision-making process, the greater the impact of a decision, and the level of concern, the greater their involvement should be.

Range of Involvement Activities and Relationships	
One-Way Communication	Information out, designed to increase knowledge or understanding.
Two-Way Communication	A timely response to questions or concerns, designed to raise general awareness and understanding.
Advisory Bodies	A short-term body with a mandate to gather expert opinion on an issue or bring together different types of expertise (scientific, economic, community, traditional).
Consultation/Dialogue	A facilitated process for fostering dialogue and gathering public input. Interested and affected parties can contribute to process design and implementation. Information-sharing and learning are involved.
Partnerships	A participatory process, in which two or more parties accept joint responsibility for implementing various aspects of the decision-making process.
Joint Decision-Making	An approach in which two or more parties make decisions about a policy, program and/or process, and share responsibility and accountability for the outcome.
Source: Working Group for Public Involvement, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. <i>Draft Core Framework for Public Involvement</i> . 1998.	

There may be times when there is a conflict between the role that some parties would like to play and the role that others would like them to play, or that they can play given legislative or other restrictions. Such situations make it difficult to clearly define and come to agreement upon respective roles and responsibilities. Consultations can help to improve understanding of different perspectives and can help to identify solutions that are acceptable to a majority of participants.

Regardless of the form of involvement that is selected, members of the risk assessment and risk management teams must have the necessary resources, skills, tools and information to allow them to interact effectively with interested and affected parties. Among the things that may be required are: lead time to prepare for consultations; conceptual tools for dealing with different parties and to conceptualize issues from different viewpoints; and training on various methods of communication, particularly communication of risk-related information.

There may be instances where incentives are required to interest a range of interested and affected parties to become involved in the process. Examples of incentives include: funds to cover expenses for involvement (e.g. travel); payment for the services of experts/professionals; acknowledgment of participation (e.g. having

names on documents, press releases, etc.); an opportunity for potential conflict resolution between groups; an opportunity for a “safe environment” where everyone has a chance to speak and be heard; an opportunity to network with other concerned parties who are involved; and equal access to meaningful and timely information.

Some Considerations

- ! Involve interested and affected parties early in the decision-making process.
- ! The nature, extent, and complexity of involvement should be appropriate to the scope and impact of the decision, the potential of the decision to generate controversy, and how quickly action must be taken.
- ! Attempt to engage representatives of all potentially interested and affected parties to solicit a diversity of perspectives.
- ! Be clear about the extent that parties can be involved and the goals of involvement; identify considerations and limitations that exist so that the scope and nature of involvement are clear.
- ! All participants, including those from Health Canada, must be willing to negotiate and be flexible (unless there are legislative or other limitations that preclude this). They must be prepared to listen to and learn from diverse viewpoints.
- ! Give participants credit for their roles in decisions, and explain how their input was used. If suggestions were not used, explain why.
- ! Allow for formal inclusion of minority views or dissenting opinions, where appropriate.
- ! Recognize that broad participation is a learning process.

Further information on involving interested and affected parties may be found in the draft *Guidance Document on Public Involvement*.

Initiate Risk Communication Efforts

Risk communication is an integral part of the decision-making process, because risk management decisions must be acceptable to a broad range of interested and affected parties.

Risk communication refers to any exchange of information concerning the existence, nature, form, severity or acceptability of health or environmental risks. Effective risk communication involves determining the types of information that interested and affected parties need and want, and presenting this information to them in a useful and meaningful way.

The goal of effective risk communication is to ensure that there is an adequate understanding of the component elements of the risk management decision-making process by all participants. Effective risk communication facilitates the exchange of information, and helps interested and affected parties make more informed decisions. Well-informed individuals can make better decisions about factors that can affect their

health, both positively and negatively. Effective communication can improve understanding of the many different dimensions of the decision-making process, and thereby enhance confidence in government decisions and recommendations. Effective risk communication can also provide critical information to the risk assessment and risk management teams on the perceptions, values, and concerns of interested and affected parties, and as a result can play an important role in decision-making.

In order for risk communication to be effective and open it must be both reciprocal and be tailored to the context and to the participants. In order to account for differences and to integrate differing forms of knowledge, cultural complexities and perceptual variability, risk communication must be flexible and adaptable. The form of risk communication that is chosen must reach the audience and allow for a two-way dialogue. An understanding of the cultural background, types of knowledge, differences and similarities of participants in the communication process is necessary for adapting risk messages to meet the needs of the audience.

Mistrust among parties represents the single most daunting challenge in the practice of effective risk communication. If the information source is not trusted, then the information itself will not be trusted regardless of its quality. Credibility of a source is a combination of expertise and trust as perceived by those who receive a message. The most important factors affecting the perceived credibility of a source and its messages relate to previous experience with the source (including actual experience and that which is obtained through others), the accuracy of the messages and the legitimacy of the process by which the contents are determined.

Communicating Risk-Related Information to the Public

- ! Provide Information That Your Audience Wants and Needs
- ! Incorporate the Audience's Perspective
- ! Respect the Audience and its Concerns
- ! Empathize with Your Audience
- ! Ensure You Are the Correct Person to Respond to an Inquiry or Provide Information
- ! Show You Are a Trustworthy and Credible Source of Information
- ! Provide a Clear Message
- ! Deal with Uncertainty
- ! Use Risk Comparisons with Caution
- ! Ensure That Only Appropriate Information Is Released
- ! Ensure the Appropriate Message Was Delivered

Adapted from: Health Protection Branch, Health Canada. *Health Risk Communication Handbook: Report of the Risk Communication Working Group*. Ottawa, 1996.

A risk communication plan must be developed early in the decision-making process. As a minimum, the plan should include the following:

- ! the goals and objectives of the planning exercise;
- ! the messages that the Department would like to convey, including the sequence in which the messages should be delivered;
- ! who the messages are intended for and when they should be delivered;
- ! who is responsible for undertaking the communications (e.g. the risk manager);
- ! the communication vehicle(s) (e.g. newspaper) that will be used for delivering the messages;
- ! the communication vehicle(s) that will be used to collect information (e.g. focus groups);
- ! who will be responsible for collecting the information (e.g. a consultant);
- ! how the information will be collated (e.g. in a detailed report as well as a summary report);
- ! the expected results of the communication (e.g. to correct a specific misunderstanding); and
- ! the expected use of any information resulting from the communications (e.g. in defining new legislation).

Considering Risk Perceptions

Risk perception refers to the way that individuals intuitively see and judge risks. Risk perception is influenced by many factors including age, gender, level of education, region of residence, values, social, cultural, and ethical factors, and previous exposure to information on the hazard. Key influences include the degree to which people understand or experience the hazard through their senses; the degree to which the hazard elicits feelings of dread, including fatalities; and the size and type of the population at risk, especially if children are affected. Also important is whether people voluntarily assume a risk or whether it is imposed upon them. Perceptions can change over time, as new information becomes available or as social norms change.

In order to adequately examine risk perceptions, it is necessary to ensure that the views of a range of interested and affected parties are considered. Risk perception information may be collected in a number of ways, including through surveys, analysis of news media reports, and by inferring perceptions based on other factors, such as past responses to similar risk situations.

For additional information on risk communication, see the draft *Guidance Document on Risk Communication*.

2.2 Assess Risks and Benefits

Assess risks using biological, chemical, and physical data from scientific studies; integrate information related to risk factors (e.g. social, cultural, ethical considerations, economic status), and risk perceptions, where this information is demonstrated to have an impact on the level of risk. Assess benefits in a similar manner.

This step involves assessing the health risks (both known and potential) that may result from exposure to a specific agent.. Where appropriate, such as in the evaluation of a therapeutic agent, the step also involves assessing the health benefits (known and potential) related to the agent, and examination of risks relative to benefits. Where possible, both risk and benefit assessment should be undertaken in a multi-disciplinary fashion, taking into account all available, scientifically credible information.

2.2.1 Assess Risks

Risk assessment must be conducted distinctly from other activities. Appropriate mechanisms must be in place to ensure that there is no interference with the scientific assessment of risk.

Taking a Broad Approach

Risk assessment involves determining the likelihood that a specific adverse health effect will occur in an individual or population, following exposure to a hazardous agent. This is typically accomplished by examining physical, chemical, and biological data obtained from scientific investigations, such as those conducted in laboratories (e.g. toxicology or microbiology studies), and those involving human populations when available (e.g. epidemiological investigations, clinical trials). Risk assessment involves recognizing that a hazard exists (*hazard identification* - is it harmful?), defining its characteristics (*hazard characterization* - how harmful is it?), considering the extent of exposure to the hazard (*exposure assessment* - what levels are humans exposed to?), and comparing current or predicted levels of exposure to a measure of the potential of the agent to induce adverse health effects (*risk characterization*, a summary and integration of the scientific analyses from the preceding tasks).

It is important to include all relevant scientific data in the assessment of health risks. Failure to evaluate all relevant data may limit the ability of the management team to identify and analyze an appropriate range of potential risk management options, and to select the strategy that will be most effective, have the least unintended negative effects, and be undertaken at a reasonable cost.

The value of using a broad approach to risk assessment stems from the recognition that a variety of different factors or determinants may influence our health, in addition to the “physical” environment, both natural (air, water, food, soil) and human-built, and that health effects (known and potential) should be examined both directly and indirectly. It also involves considering the outcomes for specific populations in addition to risks

to whole populations, including maximally exposed individuals. It further involves considering the perspectives and knowledge of a range of interested and affected parties to the extent possible and appropriate for a given risk situation.

Thus risk assessment involves examining and integrating information on risk factors (such as gender, age, ethnic origin, social situation, economic conditions, education, culture or personal convictions), when following critical examination, there is a demonstrated influence on the level and/or likelihood of risk for specific populations. Such an approach may be used for example, when determining different levels of exposure to food contaminants, which may result from different consumption patterns that occur due to social/cultural practices or economic status. It is important for Health Canada to acknowledge the influence of various risk factors on health, even if it is ultimately decided that they are best addressed by other departments. In order to bring together all the relevant information, the risk assessment team may need to include experts from a variety of disciplines, the nature of which may vary from risk to risk. The extent to which a broad approach can be taken during risk assessment, may be limited by existing legislation.

The Link With Risk Management

Risk assessment is a key part of the decision-making process, not only because it provides an estimate of the level of risk, but because it can help to identify possible options for risk management. For example, examining information on a range of exposures and how changing the exposures would affect the level of risk, helps to identify and analyze potential risk management options and thereby contributes to policy development. While risk assessment must be conducted separately from risk management, in order to maintain scientific integrity, the two processes must be linked: risk management goals are used to focus risk assessments, while the results of risk assessment provide critical information for risk management.

Assess Risks - General Tasks

- ! Identify Hazards.
- ! Characterize Hazards.
- ! Assess Exposures.
- ! Characterize Risks.

Identify Hazards

Although hazards are identified in a preliminary way during issue identification, this is undertaken in more detail during risk assessment. Typical activities in the identification of hazards includes:

- ! identifying the agent(s) causing the adverse health effect(s);
- ! collecting relevant scientific data;
- ! determining the relative weight of studies having different results;
- ! determining the relative weight of different types of studies (e.g. epidemiology, toxicology);

- ! examination of the scientific data for evidence of a relationship between the agent(s) and the adverse health effect(s);
- ! identifying the mode and mechanism of action of the agent(s);
- ! identifying those dose levels that are, and are not, associated with adverse health effects (e.g. for toxicology studies, No Observed Adverse Effect Levels [NOAELs] or Lowest Observed Adverse Effect Levels [LOAELs]);
- ! determining the critical effects associated with exposure to the agent;
- ! determining the significance of a positive finding in studies having different routes of exposure compared to the population(s) at risk;
- ! deciding if the studies have any data limitations that might affect their interpretation or invalidate their results;
- ! for nonhuman studies, ensuring that adequate protocols, a sufficient number of animals, and appropriate dose levels have been used, and determine how different metabolic pathways or rates should be considered;
- ! considering sources of uncertainty and other limitations, and how may these impact upon the hazard identification;
- ! deciding the overall weight of evidence taking into account the quality of the data; and
- ! identifying the hazard(s) of concern.

Characterize Hazards

Hazard characterization is a process that involves qualitatively and/or quantitatively evaluating the adverse health effect(s) that humans may experience under expected levels of exposure to the agent(s) under study. Traditionally, hazard characterizations have focused on physical health effects, and have relied on data from toxicology and epidemiology studies and in some cases, from surveillance; more recently, emotional and mental health effects are starting to be explored. As scientific data are often incomplete or not available, estimations must often be supplemented with more qualitative approximations. Since most exposures tend to be at low, chronic, levels, hazard characterization often requires extrapolation of data from studies involving high level of exposure (i.e. exposure in occupational settings or in laboratory studies).

In order to characterize hazards it may be necessary to determine a number of factors, including:

- ! which critical health effects are associated with exposure to the agent;
- ! for which of these effects data are adequate to characterize exposure-response;
- ! what dose-response models should be used to extrapolate from observed to relevant doses (i.e. when the potency of the agent to induce effects does not fall within or near an observable range);
- ! how the dose-response relationship should be extrapolated (e.g. using best estimates or upper confidence limits);
- ! whether traditional data analysis should be used or whether an alternative approach should be used;
- ! whether there is a need to take into account interactions between agents, and if so how to do this;
- ! whether certain human populations are likely to be more sensitive to exposure than others (susceptible populations);

- ! how to deal with differences in exposures between study populations and the population for which risk estimates are required;
- ! how to deal with differences in physiological characteristics between study populations and the population for which risk estimates are required;
- ! for nonhuman studies, what mathematical models and assumptions to use to extrapolate results to humans;
- ! sources of uncertainty and other limitations, and how these may impact upon the hazard characterization;

- ! a threshold of exposure for the induction of the critical effect by the agent, taking into account the quality of the data; and
- ! the nature, severity, and reversibility of the known or potential adverse effects in humans at expected levels of exposure.

Assess Exposures

Exposure assessment is a process used to develop a qualitative and/or quantitative estimate of the magnitude, frequency, duration, route and extent of human exposure to an agent. In other words, the purpose of an exposure assessment is to calculate the dose of a hazardous agent to which one or more populations or subpopulations are exposed. This activity is key to the risk assessment process because without exposure there is no risk. Exposure assessment may include a number of the following steps.

- ! characterize the exposure pathway to the extent possible [see the *Characterizing the Exposure Pathway* section that follows];
- ! determine whether exposures are source-specific (e.g. for radiation), or medium-specific (e.g. for consumer products), from point or disperse sources, or whether a combination of sources and media are relevant;
- ! consider the physical and chemical properties of the agent;
- ! identify the location(s), point(s) of contact, and pattern(s) (e.g. seasonal) of exposure;
- ! determine how to estimate the size and nature of the populations likely to be exposed;
- ! determine whether certain segments of the population are exposed to the agent at higher levels than others;
- ! determine what method should be used to assess exposures (e.g. deterministic, probabilistic, scenarios; refer the Box that follows);
- ! examine exposure data when available (e.g. through monitoring);
- ! in cases where exposure data are not available, predict exposure based on data for related agents as well as on exposure simulations;
- ! determine how to extrapolate exposure measurements from the study population to the population(s) of interest;
- ! determine how to take into account various factors that may affect exposure, including the time and duration of exposure;
- ! if there is a need to consider interactions between agents, examine exposure for each of these agents;
- ! document sources of uncertainty and other limitations, and how may these impact upon the exposure

assessment;

- ! determine the overall weight of evidence taking into account the quality of the data;
- ! estimate the likelihood of exposure; and
- ! estimate exposure levels.

Characterizing the Exposure Pathway

Before exposure can be assessed, it is necessary to characterize the exposure pathway, which describes how a hazardous agent reaches an individual or population. This involves obtaining information on: the source from which the agent originates; environmental media which carry the agent to individuals or populations of humans (e.g. food, air, water, soil, consumer products); the location, which is the point where contact between the agent and humans occurs (e.g. the home, workplace, recreational sites); the target population(s) or subpopulation(s), the people who are exposed to the agent (e.g. a swimmer who bathes in a contaminated river); and one or more route(s) of exposure, which are the means of entry into the human body. Examples of routes of exposure include: ingestion, which includes swallowing food, water, soil, and other substances; inhalation, which includes breathing in a gas, vapour or airborne particles; skin contact, which may involve corrosion caused by skin irritants or skin penetration by agents such as ionizing and non-ionizing radiation; through the intravenous, intramuscular, intraperitoneal, subcutaneous, or intradermal routes, as in the case of drugs.

The Use of Modeling

For some agents, particularly those involving voluntary exposure, such as prescription drugs, exposure assessment is relatively straightforward. But for other agents, such as environmental or food contaminants, an exposure assessment is usually based on considerable uncertainties. It is often not possible to measure exposures directly; rather they must frequently be predicted, for example by using monitoring data and mathematical modelling and reconstructing historical exposure patterns.

There are two broad types of mathematical models used in exposure assessment: those that predict exposure to the agent, and those that predict the concentration of the agent. Exposure models can be used to estimate the exposures of populations based on small numbers of representative measurements. Models that predict concentration can be combined with information on human time-activity patterns to estimate exposures. Modeling may be done on long-term and short-term exposures, both of which have limitations. For example, in long-term exposure modeling, changes may occur in natural levels of exposure over time and in activity patterns of exposed persons; in short-term modeling, there are difficulties in modeling concentrations that vary widely over time.

As with modeling, extrapolation of results can lead to uncertainties in exposure assessments. Sometimes exposures of particular groups of individuals, such as occupational workers, are used to estimate exposures in other populations. Uncertainties may result from the extrapolation of data from high to low doses, because adverse effects observed at high doses may not be seen at lower ones. An important aspect of

exposure assessment is to determine which groups in a population may be exposed, as well as which groups may be especially sensitive. Another concern is how to deal with the effects of exposure to multiple agents, which may have similar adverse health effects.

Examining Information on Risk Factors

A variety of risk factors can influence the level of exposure experienced by specific subpopulations. Where appropriate, information on social, cultural, ethical, economic, and other risk factors, as well as risk perceptions, must be collected and analyzed to determine how exposure may be affected. Information that meets an acceptable level of scientific rigor is then integrated with other exposure-related information to develop more comprehensive exposure estimates.

Characterize Risks

A sound risk management decision is based on a careful analysis of the weight of scientific evidence that supports conclusions about the risks of an agent to human health.

When characterizing risks, investigators determine whether exposure to a hazardous agent poses a significant risk to human health, by comparing information obtained through hazard characterization and exposure assessment. Risks are usually characterized in terms of their potency (for chemicals or radiation, in terms of a dose-response relationship), pathways of exposure, and reasons for variation in response among exposed populations. Risk characterization often involves no additional scientific information, but requires judgement, for example, when interpreting data related to population groups with varied sensitivity and different exposures.

To be truly useful, risk characterization must be accurate, balanced, and informative. This requires “getting the science right and getting the right science”[National Research Council, 1996]. It involves the use of reliable technical and scientific input from a range of disciplines, including biological, chemical, physical, economic, social, and behavioural sciences; sound scientific analyses; and providing opportunities for discussion and deliberation, recognizing that this needs to be much more extensive in some situations than in others [National Research Council, 1996].

The success of risk characterization depends on conducting a systematic analysis that is appropriate to the issue, that carefully considers scientific uncertainties, related assumptions, and potential impacts on decision-making, and that responds to the health-related needs of interested and affected parties. Success also depends on discussions or deliberations that formulate the risk issue, guide analyses, seek the meaning of analytical findings and uncertainties, and improve the ability of interested and affected parties to understand and participate effectively in the decision-making process.

Requirements of Risk Characterization [U.S. NRC]

- ! **Get the science right:** Ensure that the underlying analysis meets high scientific standards in terms of measurement, analytic methods, databases used, plausibility of assumptions, and consideration of both the magnitude and the nature of uncertainty, taking into account limitations that may result from the level of effort expended on the analysis.
- ! **Get the right science:** Ensure that the analysis addresses the significant risk-related concerns of public officials and the spectrum of interested and affected parties. Set priorities for assessment so as to emphasize the issues most relevant to the decision.
- ! **Get the right participation:** Ensure that there is sufficiently broad participation so that important, decision-relevant information enters the process, that all important perspectives are considered, and that legitimate concerns about inclusiveness and openness are addressed.
- ! **Get the participation right:** Ensure that the process used for risk characterization satisfies both decision makers and interested and affected parties, and is responsive to their needs, to the extent possible. Ensure that the information, viewpoints, and concerns of all parties are adequately represented and taken into account, that parties are adequately consulted, and that their participation can potentially affect the way risk issues are defined and understood.
- ! **Integrate information in accurate, balanced, way:** Ensure that the risk characterization presents the state of knowledge, uncertainty, and disagreement about the risk situation, and reflects the range of relevant knowledge and perspectives. The risk characterization should strive to satisfy interested and affected parties that they have been adequately informed within the limits of available knowledge. It should also consider and reflect the limitations of scientific knowledge (e.g. various kinds of uncertainty).

[Source: Adapted from - National Research Council (1996). *Understanding Risk: Informing Decisions in a Democratic Society*. National Academy Press, Washington, D.C.]

Involving Other Technical Specialists, Policy Makers, and Interested and Affected Parties

Although scientists play the lead role in risk characterization, policy makers, other technical specialists, and interested and affected parties should also have opportunities for involvement. Risk characterizations provide a key source of information for risk management decision-making, and consequently play an important role in ensuring that risk management goals are met. Policy makers and interested and affected parties can help to ensure that the characterizations have focused on the correct risk issue and have answered the health-related questions of primary concern. Other technical specialists, particularly economists, can help to ensure that the characterizations provide the type of information that they need to perform further analyses (e.g. comparison of risks and benefits). The manner and extent of involvement will depend on many factors as noted in the *Identify the Issue and Its Context* section above [National Research Council, 1996].

A summary of some of the tasks involved in risk characterization follows.

Review the Hazard and Exposure Information

This involves examining, summarizing and integrating information obtained through hazard identification, hazard characterization, and exposure assessment. Among the factors to consider are the quality, completeness, and relevance of the information, and the nature and impact of uncertainties and other limitations related to the information and any analyses that are conducted.

Generate a Quantitative Estimate of the Risk

In order to produce a risk estimate, quantitative information on exposure (and if available, dose), from the exposure assessment, is combined with information on the dose-response relationship obtained through hazard characterization. The process of developing a quantitative risk estimate will differ, depending on the type of risks being considered - carcinogens and “noncarcinogens” (agents that do not cause cancer or for which there are insufficient data on carcinogenic potency), microbial pathogens, etc.

Consider Statistical and Biological Uncertainties and Their Impacts

Risk estimates often contain a some level of uncertainty. Uncertainties may result from: the limited availability of scientific data, on for example, exposure or intake rates; long time delays between exposure and effect; the need to extrapolate data to predict the health consequences of human exposures; difficulties in determining appropriate mathematical models for extrapolation; simultaneous exposures to a variety of different agents (making it difficult to determine the effects of a single agent); and judgements made at each step of the process.

It is important to consider the nature, sources, and levels of uncertainties related to the risk estimates, and how these may impact upon the risk assessment, and to document this information. It is also important to determine whether the uncertainties are “acceptable”, or whether analyses need to be repeated using better data or better techniques in an attempt to reduce the uncertainties. Both uncertainty analyses and individuals’ interpretations of what uncertainties mean, can be strongly affected by the social, cultural and institutional context of a decision.

Uncertainties that result from the incompleteness and unavailability of scientific data frequently require scientists to make inferences, assumptions, and judgements in order to characterize a risk. Making judgements about risk based on scientific information is called *evaluating the weight of the evidence*. Risk characterizations based on scientific data, should include not only plausible conclusions about the characteristics of the risk (based on available information), but also evaluations of the weight of evidence that support the conclusions, descriptions of major sources of uncertainty, and alternative views.

Uncertainties related to potential health effects, dose-response relationships, and exposure, have increasingly

led to the use of a range or distribution of risk estimates rather than a single value. Single numerical estimates of risk can give the misimpression of precision, be easily misinterpreted and be misused in the absence of information which puts them into context. Using a distribution indicates the likely maximum and minimum risks for different individuals and the relative likelihood of intermediate risks between these extremes.

Generate a Qualitative Description of Uncertainty

This involves preparing a summary of the uncertainties that have been noted throughout the risk assessment process, and explaining the potential impacts of the uncertainties on the risk estimates in a nontechnical manner, which is understandable to the risk management team and to interested and affected parties. Among the general uncertainty issues to be addressed are the following:

- ! For what purpose was the assessment conducted and what are the potential implications of the results of the assessment?
- ! How much is known about the capacity of the agent to cause adverse health effects in laboratory animals (if relevant) and humans?
- ! How much is known about the biological mechanisms and dose-response relationships underlying any effects that are observed in the laboratory and/or in epidemiological studies?
- ! How much is known about the pathways, sources, patterns, and magnitudes of human exposure and number of persons likely to be exposed?
- ! How much is known about susceptible subgroups and their likelihood of exposure?
- ! What do other risk assessors, decision-makers, and interested and affected parties need to know about the primary conclusions and assumptions and about the balance between confidence and uncertainty in the assessment? What are the strengths and limitations of the assessment?

Dealing with Uncertainty - Some Health Canada Examples

The method for dealing with uncertainty depends on number of factors, including the nature of the agent being examined:

- ! For diseases, public health decisions are often based on the best available information, in consultation with appropriate stakeholders. Where possible, statistical inferences are used to assess uncertainty/confidence levels. In some cases, statistical re-sampling methods through simulation are used. In extremely difficult cases, scenario analysis combined with qualitative information may be used.
- ! For radiation, if the risk is significant, then the uncertainty provides a range for the estimated number of deaths/injuries due to the radiation exposure. In some cases, standard dose-response relationships are based on the mean value and ignore the uncertainty in the data. For practical purposes, advice is often based on the mean value of the risk, as long as the risk is significant.
- ! For Priority Substances (under the Canadian Environmental Protection Act), confidence and/or uncertainty in a data set are reflected in the manner in which or the extent to which the data are used. Qualitative statements concerning uncertainty are always included; where data permit, uncertainty and variability are characterized quantitatively.
- ! For food additives, uncertainty/confidence level in data are considered through the use of appropriate safety factors or mathematical models. Equally important is the nutritional value of the food.

Identify Which Population Group(s) Should Be the Primary Target of Risk Management Efforts

This involves determining which population or populations are at greatest risk (known or potential) and thus which should be the focus of risk management efforts.

Perform a Risk Comparison

Risk characterizations often include some form of *risk comparison*, which is a way to combine frequency estimations with some estimates of the significance (or severity) of the health effects. Two increasingly common methods used to compare risks are *risk ranking* and *risk prioritization*. Risk ranking is useful for comparing hazards that cause a similar effect in a single medium, such as carcinogens found in drinking water. Risk prioritization involves using specific criteria, such as the exposure levels compared to the potency to induce cancer, to determine the priority for action.

Examine the Weight of Evidence

This involves determining and examining the weight of the scientific evidence, in a qualitative way, order to determine whether there is support for the conclusions about risk. It may also involve: determining whether other agents might cause the same type of effects; examining the contribution that a particular agent makes, relative to those having similar types of effects in the affected population(s), or subpopulation(s); determining

how the risk is distributed in relation to other risks to which the affected population(s), or subpopulation(s) are exposed; and examining the effects of risk interactions (combined exposure to two or more agents or conditions, such as immune status, genetic risk factors).

Determine Whether Additional Data Must Be Collected

If the data and methods used for analysis are not adequate based, for example, on scientific standards, or if no evidence exists (e.g. there is no statistical significance), it may be necessary to conduct additional studies or repeat the analysis using different methods or data. Results of the analysis may reveal that additional information must be collected to properly address the issue (this does not however, preclude use of a precautionary approach, involving implementation of an interim risk management strategy while further data are collected). If peer review is required, it is necessary to identify the reviewers, and then to obtain and consider their comments. In cases where there are legislated timeframes for completion of assessments, as for Priority Substances under CEPA, it is often not possible to collect additional data or repeat analyses; in such cases it is usually indicated that better data might help to reduce uncertainty.

Present the Risk Assessment to the Risk Management Team

Risk assessments may be presented using a variety of methods; the choice of method may be a function of the legislative mandate. It may be useful to provide a table indicating the estimated level of risk for the exposed population by route of exposure, as well as a full characterization of the risk, including a discussion of uncertainties, a discussion of the comparability and consistency of similar but different risks (e.g. for the average individual versus the most exposed individual), and the extent to which professional judgements have been used to deal with sources of uncertainty and their potential impacts. Risk assessment should also be made available to interested and affected parties, taking into account the need to keep some information confidential (e.g. drug formularies).

2.2.2 Assess Benefits

The inclusion of *benefit assessment* (and consequently the comparison of risks and benefits) as part of the decision-making framework, is not intended to imply that benefits (known or potential) must be assessed in every situation, but rather that it should be undertaken in a consistent and systematic manner in situations where it is appropriate to do so.

In general, benefit assessment should be attempted when it is difficult or impossible for consumers to judge the benefits associated with exposure to an agent and to compare them with the associated risks. For example, it is often necessary to evaluate the benefits of a specific product (e.g. a drug or medical device), when a claim is made that a product improves health, in order to put the risk associated with that product into the proper context of overall health. There are however, instances where benefit assessment is not necessary or possible, such as where the level of risk is deemed to be minimal or “de minimus”, where it is not ethical to consider benefits because it might imply that a product is being endorsed, or where legislative

mandate does not allow benefits to be assessed.

In cases where it is appropriate to compare risks and benefits, the comparison should be done using a societal perspective, unless dealing with a situation in which only an individual is affected (e.g. special release of an unapproved drug). A population or sub-population should not be placed at risk for the benefit of others.

Technical specialists (in this case, economists) play the lead role in benefit assessment and in making risk/benefit comparisons. However, there is a role for other participants to play, including scientists responsible for the risk assessment, policy makers, and interested and affected parties. Like risk assessments, benefit assessments and risk/benefit comparisons provide a key source of information for risk management decision-making, and consequently play an important role in ensuring that risk management goals are met. Policy makers and interested and affected parties can help to ensure that assessments are focused on the benefits of most relevance, and that appropriate consideration is given to specific populations and equity issues. Other technical specialists, particularly scientists, can provide guidance in the use of risk assessment results in risk/benefit comparisons, and can flag additional risk information needs. The manner and extent of involvement will depend on many factors as noted in the *Identify the Issue and Its Context* section above.

Assess Benefits - General Tasks

- ! Collect and Assess Information on Benefits.
- ! Prepare a Risk/Benefit Comparison.

Brief descriptions of these tasks as well as some related considerations are provided below. Further information related to benefit assessment may be found in the draft *Guidance Document on Socioeconomic Analysis*.

Collect and Assess Information on Benefits

In order to assess benefits (known or potential), specialists:

- ! identify the type(s) of benefits to be examined;
- ! identify the measures to be used;
- ! collect and analyze the benefit information;
- ! determine how to deal with uncertainty; and
- ! summarize the benefit information.

Identify the Type(s) of Benefits to be Examined

The first task involved in benefit assessment is to determine what types of benefits are to be examined.

These may include direct health benefits (e.g. relief of disease symptoms), or indirect health benefits (e.g. economic, social, or cultural impacts). An important part of this determination is identifying the perspective to be used for the analysis (e.g. specific interested and affected parties), and the nature and size of the population(s) that would benefit.

Identify the Measures to Be Used

Once the type(s) of benefits have been determined, it is necessary to identify the measures for the benefit assessment, and for reporting of the results (e.g. effectiveness, efficiency, quality of life, dollar values). Like risks, benefits may be assessed qualitatively or quantitatively, depending on the nature of the information available. The extent to which benefits are assessed, as well as the specific considerations taken into account, vary depend upon factors such as the issue being addressed, the context in which it is being considered, and the nature and amount of information that is available. Once measures have been identified, it is necessary to select the methodology to be used (e.g cost-benefit analysis), as well as any modeling techniques to be used.

Collect and Analyze the Benefit Information

This task involves collecting and analysing the benefit-related information. Information may be collected through various means, for example through socioeconomic analysis, or for therapeutic products, through the results of clinical trials. One of the first things to examine once the information has been collected and analyzed, is the adequacy of the data and methods used for the analyses, as well as whether the analyses have addressed the appropriate concerns. If the data or methods are not of high quality or are not relevant, it may be necessary to conduct other studies or reanalyze the data. Another item for consideration is whether any analyses should be reviewed by third-party experts, and if so, who the third parties should be.

Determine How to Deal with Uncertainty

As with risk assessments, benefit assessments are frequently subject to uncertainty. Given this, it is important to identify the nature, sources and level of uncertainty, both in terms of the benefit data themselves and in terms of the analyses that are conducted. As well, it is important to determine the potential impacts that the uncertainty will have on the benefit assessment. If the level of uncertainty is not acceptable, it may be necessary to repeat the analyses using better data or better techniques.

Summarize the Benefit Information

The final task in benefit assessment involves summarizing and integrating the information in a fair and balanced manner, similar to what is undertaken during risk characterization. The resulting benefit assessment summary should include any assumptions, uncertainties, and judgements, and should be written in a nontechnical format, suitable not only for risk managers, but for interested and affected parties.

Prepare a Risk/Benefit Comparison

In order to complete the risk/benefit assessment, specialists:

- ! examine risk and benefit data; and
- ! present the risk/benefit comparison to risk managers.

Examine Risk and Benefit Data

This involves integrating, analysing, and comparing the results of the risk and benefit assessments. Risks, benefits, and any associated costs must be evaluated in terms of the needs, issues, and concerns of interested and affected parties. In the case of therapeutic products, such as drugs, the risk-benefit profile of the agent may be compared with that of alternative therapeutic agents.

When comparing risks, benefits, and costs, consideration can be given to individual versus collective risk and benefits, who benefits relative to who bears the risk (as different parties may be involved), and freedom of choice versus risks and benefits to society as a whole. As with risk assessments, benefit assessments can benefit from peer review, especially when they are complex.

Present the Risk/Benefit Comparison to Risk Managers

Risk/benefit comparisons may be presented using a variety of methods, depending on the type of analytical techniques used. It is useful to summarize technical results in an easily understandable manner, to explain the methodology and criteria used, to discuss uncertainties, assumptions, and their potential impact on analyses and on decision-making. Risk/benefit comparisons should also be made available to interested and affected parties, taking into account the need to keep some information confidential (e.g. drug formularies).

2.3 Identify and Analyze Options

Consider a range of risk management options whenever possible. Take into account a variety of considerations when analyzing options, including the perspectives of interested and affected parties.

This step involves identifying and analysing potential options to prevent or reduce the risk of concern, and making recommendations regarding the preferred option(s).

Identify and Analyze Options - General Tasks

- ! Identify Potential Risk Management Options.
- ! Analyze Potential Risk Management Options.

Identify Potential Risk Management Options

A variety of options are available for risk management. *Regulatory options* generally rely on the government's authority to enforce compliance with legislation, and may include direct regulation, self-regulation and the issuing of permits or approvals. *Non-regulatory options* include the use of advisory, economic, and technological measures, and can include taking no action when none is required to maintain the current level of health protection. For further information, see the table that follows.

Options for Risk Management	
Regulation	Direct regulation involves the enforcement of requirements stated in legislation. Self-regulation involves allowing parties that produce the risk (<i>risk producers</i>) to create mechanisms to ensure that regulated processes or products conform to legislated requirements. The use of permits and approvals require risk producers to obtain written permission from government before undertaking a specific risk-producing activity.
National Guidelines	National guidelines include voluntary standards and codes of practice that provide approaches for dealing with specific risk-related issues or undertaking specific risk-related activities.
Education/Advice	Education/advice includes the provision of information that helps risk producers reduce risk, or that help interested or affected parties make more informed decisions.
Voluntary Compliance	Voluntary compliance involves encouraging risk producers to take action that reduces risk. This is a good example of risk management through collaboration.
Economic	Economic approaches are typically directed at risk producers, and use financial incentives or disincentives to limit risk; examples include providing financial assistance to developers of risk-reducing technologies and imposing penalties on polluters.
Technological	Technological approaches involve the development of new risk-reducing methods or the application of existing methods by risk producers.
Taking No Action When None is Required	This option involves maintaining the current level of health protection. It may be used for example, when the current level of risk is considered to be <i>negligible</i> , when the risk management strategy that is already in place is considered sufficient, or when there are no feasible, effective risk management options to implement.

A number of factors may be considered when identifying potential risk management options, including legislative authority, policies, and commitments, and how quickly the risk must be addressed. A wide range of potential options should be identified unless the nature of the risk issue or situation makes it unwise, unnecessary, or impossible to do so (e.g. there is a crisis situation which requires a quick response; the only option based on legislative requirements is direct regulation).

To the extent possible and appropriate for the given situation, options should be identified in consultation with a range of interested and affected parties. This is especially important in cases of where the responsibility for managing the risk is shared, or where various parties may participate in implementation of the selected strategy. The breadth and depth of consultation should reflect factors such as the nature of the issue, who the issue affects, the urgency required to resolve the issue, and the resources available.

Options Used by Health Canada: Some Examples

Health Canada uses a combination of regulatory and non-regulatory approaches for risk management. Regulatory options are most frequently used, with the most common being direct regulation. The most commonly used non-regulatory options are national guidelines, advice/education, and voluntary compliance (an example of the latter is the 1996 removal of lead-containing miniblinds from Canadian stores, in response to a health advisory issued in the United States). Technological approaches are also sometimes used, in conjunction with legislation (e.g. the development of childproof cigarette lighters, which fall under the *Hazardous Products Act*).

Analyze Potential Risk Management Options

A number of factors may be considered when analysing potential risk management options. The expected effectiveness of potential options (especially for different populations), and legislative, international trade, or other requirements, obligations, and limitations are key considerations, as is the feasibility of the option (in terms of technological, legal, economic, and other factors). Other considerations may include:

- ! how quickly the risk must be addressed;
- ! risks vs. benefits;
- ! expected costs (of implementing the option);
- ! risk, cost, and benefit ratios (efficiency);
- ! distribution of risks, costs, and benefits (fairness);
- ! available resources;
- ! unintended consequences (e.g. creation of a new risk, or unwanted social, cultural, ethical, environmental and other indirect health impacts);
- ! residual risk (level of risk that remains after the option is implemented);
- ! the perceptions, concerns, and values of interested and affected parties;
- ! acceptability of the risk, the option, and the residual risk to interested and affected parties; and
- ! other criteria used for option analysis in similar situations.

The nature and relative importance of the criteria used for option analysis will vary depending on the situation being addressed, and may be influenced by existing legislation. Some options may be eliminated quickly for various reasons. A shorter list of potential options can then be produced, and a more detailed analysis performed on this list. In general, preferred risk management options are those that provide an “acceptable” level of health protection, are most effective in reducing or preventing the risk, cost the least, create the fewest adverse unintended consequences, and are acceptable to a wide range of interested and affected parties.

In some cases, options analysis can serve to refine the goal of the risk management process. This may occur once risk managers and other interested and affected parties gain some appreciation for what is feasible, what the costs and benefits are, and what contribution reducing exposures and risks can make toward improving human health.

Involving Interested and Affected Parties

Interested and affected parties can play an important role in option analysis by helping to identify criteria to be used for analysis, collecting or providing required information, participating in analyses, providing a range of perspectives on the acceptability of the criteria and the results of the analysis, and helping to redefine risk management goals as required.

Some Key Considerations

One key consideration when analysing options is that the same measures can affect different populations in different ways depending on a range of risk factors such as gender, age, ethnic origin, social situation, economic conditions, education, culture or personal convictions. It may be necessary to tailor options to meet the needs of specific groups or to use different options for different groups. For example: advisory information could be provided at different reading levels, through different types of news media, and in different languages; recommended daily intakes of specific chemical contaminants in food could be different for general and sensitive populations.

A second consideration is Health Canada’s difficult but necessary responsibility to balance the rights of individuals and groups with the needs and interests of society. Related to this is the importance of ensuring that societal and group rights do not unnecessarily override the rights of the individual. In principle, when the rights of an individual and society are in conflict, precedence should be given to the latter; in practice this may be a challenge to achieve.

A third consideration is the difficulty in determining what constitutes an “acceptable” level of risk. An *acceptable* risk is one that is so small, whose consequences are so slight or whose associated benefits (perceived or real) are so great, that persons or groups in society are willing to take or be subjected to that risk. The acceptability of risk, from both an individual and social perspective, is influenced by risk perception, values, judgments and other factors, such as the trade-offs people make between potential risks

and benefits. The level of trust in the person or agency responsible for managing the risk is also a factor.

Although individuals may hold opinions about what is acceptable, there are often no objective measures for determining acceptability. What is acceptable to one group or individual may be unacceptable to another. Given this, attempts need to be made to determine acceptability from the perspectives of a range of interested and affected parties (e.g. women, cultural minorities, seniors, children and other groups).

2.4 Select a Strategy

Maintaining and improving health is the primary objective. This must take precedence over all other considerations.

This step involves reviewing the results of the option analysis and making a decision about the strategy to be used to address the risk of concern.

Select a Strategy - General Tasks

- ! Review the Results of Option Analysis.
- ! Select One or More Options for Risk Management.

Review the Results of Option Analysis

In order to determine the best approach for risk management, the risk management team must examine the results of the analyses that were conducted in the previous step, together with any related recommendations. These documents are key to the risk management process because they represent a summary and synthesis of all available information that has been considered to date. Together, they provide the foundation for selecting the risk management strategy.

Select One or More Options for Risk Management

Depending on the situation, the risk management strategy may consist of a simple approach involving a single risk management option, a multi-faceted approach in which a number of different options are implemented to varying degrees, or something in-between. The selection of a specific strategy frequently depends on a number of considerations, including the scope of the decision, related events or decisions occurring within the same timeframe, and other new information that becomes available. The nature and relative importance of these considerations varies depending on the situation involved. As noted earlier, the extent to which a broad approach can be taken may be limited by existing legislation.

Where choices are not limited by legislation or other factors, a combination of options is often most effective

for managing risks. Use of a flexible approach can improve the efficiency and effectiveness of risk management, result in solutions that are more generally accepted and easier to implement, and may reduce the cost of implementation. It may also encourage further research, which could provide useful information that can be used to improve the risk management process. Regulatory options still need to be implemented in certain instances (and may be the only or primary part of the risk management strategy), in order to maintain current levels of health protection. However, where the cost of implementation is very high relative to the impact on health, alternatives should be considered to the extent possible.

Using Socioeconomic Analyses in Risk Management

Among the most controversial types of criteria considered during risk management decision-making are the results of socioeconomic analyses. Three common concerns are that:

- ! socioeconomic analysis places too much emphasis on assigning dollar values to aspects of health that are difficult, if not impossible, to quantify in monetary terms;
- ! risk management decisions might be based strictly on whether the estimated benefits, quantified in monetary terms, outweigh the estimated quantifiable costs; and
- ! the results of socioeconomic analysis are often conveyed in a manner that ignores assumptions and uncertainties, giving the impression of far greater precision than is generally possible or appropriate.

Socioeconomic analysis should never be the sole or over-riding factor in making risk management decisions. The primary objective of risk management is maintaining and improving health; any socioeconomic impacts should be one of many considerations. Economists are responsible for providing decision-makers with the best technical information available or reasonably attained, including evaluations of the weight of the evidence that supports different assumptions and conclusions. Information about costs and benefits that cannot be assigned monetary values also must be explicitly considered, along with information about risks, and social, cultural, ethical and other concerns. Peer review should play a critical role in evaluating the quality of economic analyses and the technical information underlying them.

[Source: Presidential/Congressional Commission on Risk Assessment and Risk Management. *Framework for Environmental Health Risk Management - Final Report Volume 1*, 1997.]

Making a Decision with Incomplete Information

An important concern in selecting a risk management strategy is how to make a decision when complete information is not available. In such cases, an attempt must be made to identify the missing information and determine its importance, and a decision made about whether to delay strategy selection until the missing information is obtained. A lack of important information does not necessarily mean a delay in taking action, as in cases where a decision is made to use a precautionary approach and to implement an interim strategy

until further data is gathered.

“Value-of-information” methods exist and can provide estimates both of the value of having better information and of collecting that information, usually in monetary terms. In many cases it may suffice to consider the value of additional information in a qualitative way. In any case, the efforts and benefits of obtaining further information should be weighed against factors such as the need to address the risk quickly, the magnitude of the risk and the level of effort to address it, and the expected time, cost, and benefit of obtaining further information. Where possible, it is useful for such decisions to be made by an expert committee of individuals who are knowledgeable about the issue and who can represent the views of key interested and affected parties.

Involving Interested and Affected Parties

Although responsibility for decision-making may rest with Health Canada, it is important to involve a range of interested and affected parties in the selection of a risk management strategy, where possible. Interested and affected parties can provide knowledge, experience, and information (such as feedback on the expected consequences of the decision) that can contribute to the development of an effective risk management strategy. The needs, perspectives and concerns of these parties must be identified and considered during the decision-making process, to the extent possible. Further, involving these parties can promote greater understanding and acceptance of decisions, and ultimately facilitate the successful implementation of the risk management strategy.

The extent to which interested and affected parties are involved in decision-making may vary from consultation to consensus, although the former is most often the case. Decisions made through consensus may be implemented differently from those not involving consensus, and often more effectively, as they allow interested and affected parties a sense of ownership in the decision. However, as consensus building may take more time and effort than traditional risk management approaches, it may not be feasible in certain situations, particularly emergencies.

Guidelines for Decision-Making
[U.S. Presidential/Congressional Commission]

- ! Maintaining and improving health is the key objective of risk management.
- ! Where possible, give priority to preventing risks rather than controlling them.
- ! Consider government, Departmental, Branch and program priorities when selecting risk management strategies.
- ! Consider the issue in context, to ensure that the strategy is comprehensive enough to achieve the desired risk management goal(s).
- ! Base the decision on the best available scientific, economic, and other technical information. Take note of the weight of evidence supporting conclusions, and uncertainties, assumptions, and their potential impacts.
- ! Select risk management options that are feasible, effective, and whose expected benefits are reasonable given the cost.
- ! Be sensitive to potential social, cultural, ethical, environmental, economic and other indirect health impacts. Considered these relative to the expected benefits.
- ! Where possible, use a flexible approach for risk management, rather than relying solely on regulation.

[Source: Adapted from Presidential/Congressional Commission on Risk Assessment and Risk Management. *Framework for Environmental Health Risk Management - Final Report Volume I*, 1997.]

2.5 Implement the Strategy

Strive to implement risk management strategies in an effective, expeditious, and flexible manner, and with the support of interested and affected parties.

This step involves developing and carrying out a plan to implement the selected risk management strategy. It also involves identifying criteria that can later be used to monitor and evaluate the effectiveness, impacts, and implementation of the strategy.

Implement the Strategy - General Tasks

- ! Prepare an Implementation Plan.
- ! Carry Out the Plan.

Prepare an Implementation Plan

The implementation plan is one of the most important documents prepared during the risk management process, as it is the basis for carrying out the selected strategy and monitoring and evaluating the results. As such, the plan and the way it is carried out have a major impact on the effectiveness of the strategy.

The implementation plan should include: specific tasks to be undertaken and timeframes involved; the roles, responsibilities, and accountabilities of participants; plans for communication, and for involvement of interested and affected parties; and the criteria that will be used for monitoring and evaluation.

The latter include: the activities that will be undertaken (the things done to carry out the risk management strategy; they typically require resources and generate products or services); the outputs that will result (tangible products or services that can be counted and that are produced or provided as a result of activities); who will be reached by these activities and outputs (those who are affected by, or interested in, outputs, including primary targets [generally clients or recipients of outputs], co-delivery agents, and other interested parties); what direct or short-term outcomes are intended (the impacts on those groups who are immediately affected by products or services, including service and behavioral influence outcomes); and what long-term outcomes are intended (changes in the original conditions that were the basis for developing and implementing the risk management strategy).

In order to prepare an implementation plan it is necessary to:

- ! review the goals of the risk management strategy;
- ! identify the roles and responsibilities of all parties who will play a role in implementation;
- ! review existing agreements or other considerations that may impact upon the way that the strategy is implemented, and incorporate these as required;
- ! identify the milestones required to achieve the goals of the strategy, the items required to achieve the milestones, the target dates for completion of the items, and the party responsible for carrying out each item;
- ! identify the criteria that will be used to monitor the effectiveness of the strategy in achieving the risk management goal(s) (e.g. reducing incidence of disease, or level of exposure);
- ! identify the criteria that will be used to monitor the effectiveness of the implementation process itself (i.e. for evaluation purposes);
- ! identify key decisions to be made;
- ! identify resource requirements;
- ! establish consultation/negotiation strategies;
- ! identify complaint resolution mechanisms;
- ! develop enforcement mechanisms, if necessary;
- ! develop training plans for individuals involved in implementing the strategy, if necessary;
- ! prepare communication plans; and
- ! obtain approval of the plan from the decision-maker(s).

Health-Based Outcome Measures

Health-based outcome measures are impacts, effects or changes in the health of a defined population resulting or related to a specific risk management strategy. These measures may be used as a basis for monitoring and evaluating risk management strategies.

Examples of health-based outcomes include: health status outcomes, which are often disease-focused, and reflect changes (or a lack of change) in the physical or mental status of a population; risk status (or intermediate) outcomes, which reflect changes (or a lack of change) in the risk that has been demonstrated or assumed to be associated with health status; social functioning outcomes, which reflect changes (or a lack of change) in the ability of individuals to function in society; and client satisfaction outcomes, which reflect the response of individuals to services received from a health provider, program or risk management strategy. Although it is desirable to measure different impacts, those related to physical health effects are often easier to measure than those related to non-physical health effects, such as stress. An important challenge in the use of health-based outcome measures involves dealing with situations where the impact of a risk management strategy is only seen in the long term, as in the case of reductions in environmental contaminants

Further information on health-based outcomes and development of a framework for identifying and measuring these outcomes can be found in the draft *Guidance Document on Developing Health-Based Outcome Measures*.

Carry Out the Plan

This involves implementing the plan noted above. Both the details of the implementation process and any changes to the plan must be noted.

Regional Involvement in Implementation

The implementation of risk management strategies by Health Canada may involve some or all of the regional offices. Regional involvement may vary depending on the nature and scope of the risk issue, the risk management strategy and the region's areas of expertise. If the level of the risk is high or if there are national implications, the issue will usually be handled at a national rather than regional level.

Involving Interested and Affected Parties

Interested and affected parties can play an important role in implementation by participating in the development or review of the implementation plan, implementing part or all of the risk management plan, and helping to develop criteria for monitoring (and evaluation). Interested and affected parties may provide a wide range of perspectives, information, and expertise that can lead to the development of action plans that

are more acceptable, more effective, less expensive, and easier to implement.

2.6 Monitor and Evaluate Results

Monitor and evaluate the risk management strategy to determine whether it has been effective. Revisit previous steps of the decision-making process as needed if the strategy is found to be ineffective, or if significant new information becomes available.

This step involves monitoring execution of the implementation plan, evaluating the effectiveness of the risk management strategy, and making recommendations for any changes that are required.

Monitor and Evaluate Results - General Tasks

- ! Monitor the Action Plan.
- ! Evaluate the Effectiveness of the Risk Management Strategy.
- ! Make Recommendations Regarding Changes Required.

A summary of these tasks is provided below. Further information can be found in the draft *Guidance Document on Developing Health-Based Outcome Measures*.

Monitor the Action Plan

Monitoring is often conducted to help identify whether changes need to be made to a risk management strategy or the way it is implemented. Monitoring has four primary functions:

- ! to detect a change in the context of the issue (including the nature of the risk, the acceptability of the risk, the identity of interested and affected parties, and other factors considered when first establishing the context);
- ! to determine whether the plan is achieving the expected results (this involves identifying criteria to be used to measure effectiveness, establishing standards of what constitutes an acceptable level of effectiveness, and collecting data that can be used to compare or evaluate the actual effectiveness against established standards or benchmarks);
- ! to ensure proper implementation of the plan (to improve effectiveness and reduce costs associated with improper implementation); and
- ! to determine the correctness of assumptions used in various analyses (if assumptions prove correct, this lends strength to the decisions made; if not analyses may have to be redone, which provides for continuous improvement) [Canadian Standards Association, 1997].

The criteria that were established as part of the implementation plan typically serve as the basis for monitoring.

Evaluate the Effectiveness of the Risk Management Strategy

Determine When to Conduct an Evaluation

Evaluation is critical to accountability and ensuring the wise use of limited resources. Through evaluation, the actual impacts, benefits, and costs of a risk management strategy can be compared with estimates made earlier in the risk management process. In doing so, evaluation can provide important information about whether or not:

- ! the intended risk management goals were achieved (i.e. whether the strategy was effective);
- ! any additional or revised actions should be taken, or in other words, whether any previous step of the decision-making process should be revisited (e.g. further risk assessment, selection of a different option);
- ! the options analysis was accurate;
- ! the implementation plan needs to be revised;
- ! any critical information gaps affected the outcome; and
- ! changes should be made when dealing with similar risks in the future.

As a general principle, the effectiveness of risk management strategies involving significant health risks or the investment of significant public resources should always be evaluated. As a general principle, an evaluation should not begin until enough time has elapsed that one can reasonably expect to measure actual changes (this assumes that baseline measurements are done prior to implementation of the strategy in order to allow changes to be detected). All risk management strategies should be reviewed periodically to determine whether they need to be continued. This ensures that ineffective or unnecessary actions are not continued indefinitely. In addition, the effectiveness of the decision-making process itself should also be evaluated, to determine whether it has been carried out effectively. This facilitates continuous improvement, and creates efficiencies for future efforts. It is useful to periodically review all evaluations to determine if there are common recommendations, as this can also facilitate continuous improvement.

Determine What Type of Evaluation to Conduct

There are two different but related ways to evaluate risk management strategies. The first involves examining the information that is collected during ongoing monitoring. This type of evaluation is often done by risk managers and can help to identify changes to strategies or the way they are implemented. The second involves periodic evaluation of the longer-term outcomes of risk management strategies, which can take several years to be measurable (this type of evaluation also takes into account the results of ongoing monitoring). Periodic evaluation is typically undertaken independently of the risk managers and other participants in the decision-making process, and is designed to meet formal accountability requirements, such as those required by Treasury Board for federal government departments.

Prepare an Evaluation Plan

An evaluation plan must be developed prior to undertaking either type of evaluation described above. The

plan should specify:

- ! why the evaluation is being conducted;
- ! what type of evaluation is being conducted;
- ! whether all or only part of the risk management strategy needs to be evaluated;
- ! how extensive the evaluation needs to be;
- ! what data must be collected, as well as when and how often;
- ! how to deal with missing data; who will conduct the evaluation (e.g. will it be conducted internally, or by an external party, or will a combination be used);
- ! when the evaluation will be conducted;
- ! how long the evaluation will take;
- ! what resources are required;
- ! who will be receiving the recommendations that result and what they will do with them; and
- ! whether to consult with interested and affected parties, and if so, how.

The time and resources devoted to the evaluation should be appropriate to the magnitude of the risk and scope of the risk management strategy.

Conduct the Evaluation

At this point, the evaluation is conducted. This is usually a four step process involving collection of data, analysis of data, preparation of conclusions and recommendations, and documenting and reporting of the evaluation. While the evaluator takes the lead role in these tasks, the preparation of conclusions and recommendations may be done in consultation with the manager responsible for implementing the risk management strategy.

Although evaluation is an important part of risk management, the effectiveness of risk management strategies may be difficult to measure for several reasons. For example: the impact may not be visible for many years, because of the time delay between exposure and effect; the impact may not be noticeable unless there are sizable changes in the effect, for example in disease incidence or in environmental concentrations of pollutants; there may be confounding factors that make it difficult to separate the effect of the strategy from other changes; and one outcome measure may relate to a number of risk management strategies, so that evaluating the impact of a single strategy is difficult. Further, there may be instances when it is difficult to obtain the data required for evaluation. In these cases it can be useful to extract data from known sources; to improve the tools and methods for getting data; and to select other evaluation criteria to be used.

Make Recommendations Regarding Changes Required

Recommendations should be feasible and be put into context; for example, if a risk management strategy is currently effective (based on previously identified criteria), then it may be appropriate to state that no changes are required at this time, but that a review should be conducted in five years. Justifications should also be provided to substantiate recommendations made. Recommendations should be made to managers

who have the authority to implement them. Managers in turn should review recommendations, determine the feasibility of implementing them, and proceed with implementation. Explanations must be provided if any recommendations are not implemented. It is also important to have a mechanism in place for both internal and external parties to appeal decisions that are made.

Involving Interested and Affected Parties

Interested and affected parties can play an important role in this step by helping to: monitor the implementation plan; identify criteria for evaluation (including the definition of “success”); assure the credibility of the evaluation and the evaluators; identify information gaps; determine whether a strategy was successful; and identify what lessons can be learned.

3. Overview of Guidance Documents

3.1 Environmental Risk Assessment

Health Canada is jointly responsible for implementing a number of Acts that require manufacturers to conduct *environmental risk assessments* on new products that they market in Canada, and/or on existing substances in the environment. These include the Canadian Environmental Protection Act (CEPA), the Pest Control Products Act (PCPA) and, where new projects are initiated in Canada, the Canadian Environmental Assessment Act (CEAA). Under certain circumstances, the Acts also require a responsible federal agency to conduct environmental risk assessments.

At present, Environment Canada is responsible for conducting environmental risk assessments for new chemicals, polymers and products of biotechnology that are regulated under CEPA, based on information or data submitted by manufacturers. These include any product new to Canada, for which an environmental assessment is not conducted under any other Act of Parliament. At present in Health Canada, these include foods, drugs, cosmetics and medical devices. Health Canada is responsible for conducting human health risk assessments for these agents under the Food and Drugs Act; one of the ways that Health Canada implements the Act is to conduct premarket reviews of certain types of these agents.

Health Canada has the legislative authority to conduct environmental assessments of foods, drugs and cosmetics but the necessary regulations are not yet in place. Environmental Assessment Regulations under the Food and Drugs Act have been drafted and are at the consultation stage (i.e. Canada Gazette I). There is no analogous legislative authority with respect to medical devices or the manufacturing source of foods, drugs or cosmetics (e.g. cell lines or transgenic animals).

Amendments to the Food and Drugs Act have been proposed, that will provide Health Canada with the legislative mandate to conduct environmental risk assessments for medical devices and manufacturing sources. In the meantime, a Memorandum of Understanding is in place between Environment Canada and Health Canada permitting Health Canada to evaluate environmental risk assessments for all these products.

Once the first set of Environmental Assessment Regulations are enacted, the Memorandum of Understanding will automatically terminate and only environmental risk assessments for medical devices and manufacturing sources will continue to fall under CEPA. The amendments to the Food and Drugs Act that will provide authority are consequential, tied to passing of "Renewed CEPA" (Bill C-32); once passed, new regulations addressing these areas will be required. A new Memorandum of Understanding with Environment Canada will be required covering the time between the enacting of the two sets of new regulations in order that a single regulatory window is maintained for medical devices and manufacturing sources.

The draft *Guidance Document on Environmental Risk Assessment* describes a proposed framework for undertaking environmental risk assessments, to assist Health Canada in undertaking its responsibilities.

3.2 Socioeconomic Analysis

In its broadest sense, *socioeconomic analysis* is a method of gathering information to support decisions related to the allocation of limited resources among alternative uses of those resources. While socioeconomic analyses may sometimes be construed as being driven by cost considerations alone, it is fundamentally about weighing the positive and negative impacts of decisions (i.e. benefits as well as costs). While socioeconomic analysis is a tool that can lead to more informed decision-making, it should not be viewed as the singular determinant of decisions. The analyses do not replace judgement or consideration of other factors, including health protection, competing policy priorities, the availability of resources for implementation of an intervention, or overriding moral imperatives.

Socioeconomic analysis of major government decisions has been a Treasury Board of Canada requirement for a number of years, and are often conducted as part of Health Canada's risk management decision-making process. However, the methods used by analysts in different programs can vary significantly, for various reasons, including differences in the risks being addressed.

The draft *Guidance Document on Socioeconomic Analysis* describes and provides recommendations regarding the major methodological issues that must be dealt with in a socioeconomic analysis, with a view to dealing with these issues in a more consistent and comprehensive way. The document is intended to provide more specific guidance for dealing with health-related issues, than is available in the Treasury Board Guidelines. (Some general information is also included in the *Using Socioeconomic Analyses in Risk Management* box in the *Select a Strategy* section above).

3.3 Risk Communication

Effective risk communication is an important part of the risk management decision-making process. The draft *Guidance Document on Risk Communication* describes a number of concepts related to risk communication, and provides detailed suggestions to help ensure effective risk communication. (Some general information is also included in the *Initiate Risk Communication Efforts* subsection of the *Identify the Issue and Its Context* section above.)

3.4 Public Involvement

Another important part of the risk management decision-making process, is ensuring that there are adequate opportunities for the involvement of interested and affected parties, especially the general public. The draft *Guidance Document on Public Involvement* describes general underlying concepts and values related to public involvement, provides general guidance on involving the public in the risk management decision-making process, and provides an example illustrating the types of public involvement activities that might be undertaken when there are few time and resources limitations. While the focus of the document is on involving the general public, the information provided may be applicable to the involvement of a broad range of interested and affected parties. (Some general information on public involvement is also included in the *Identify Interested and Affected Parties* subsection of the *Identify the Issue and Its Context* section above.)

3.5 Integrating Population Health and Risk Management Decision-Making

A traditional approach to health care focuses on the health of individuals, on particular diseases, and on responding to illness through direct patient care. A *population health approach* goes beyond the traditional approach to address not only the physiological, psychological and behavioural components of health, but also the entire range of factors (or determinants) that contribute to our physical, mental and social well-being. The identification, assessment, and management of risks to health is an essential element of an integrated, comprehensive approach to population health. Risk assessment and risk management contribute to population health both in terms of the methods (e.g. analysis, planning, decision-making, evaluating), and strategies used (e.g. policies, programs, services). Integrating a population health approach into the risk management decision-making process, will enable Health Canada to analyse and respond to risks using a broader perspective, and to do so in a consistent and comprehensive manner.

The draft *Guidance Document on Incorporating a Population Health Approach into Risk Management Decision-Making* explains the general concepts of population and risk management, explains the linkage between the two, and provides an example illustrating how a population health approach may be integrated into the risk management decision-making process. (Some general information is also included in the *Taking a Population Health Approach* box in the *Assess Risks* section above).

3.6 Developing Health-Based Outcome Measures

An important way to improve the effectiveness of risk management efforts, is to clearly define risk management goals, and to evaluate related strategies, in terms of health outcome and health status measures. The draft *Guidance Document on Developing Health-Based Outcome Measures* describes how to develop measures to monitor and evaluate the effectiveness of risk management strategies, and provides general guidance on conducting evaluations. (Some general information is also included in the *Prepare an Implementation Plan* subsection of the *Implement the Strategy* section, and the *Monitor and Evaluate Results* section, above).

3.7 Priority Setting

Federal regulatory agencies are typically faced with a number of issues to deal with, but have limited time and resources for action. The use of a structured approach for priority-setting, including the development and application of relevant criteria, can help to determine priorities for action and consequently assist in resource allocation. An important part of the priority-setting process is the involvement of interested and affected parties, not only because of the perceptions, knowledge, and information that they can provide, but because this can enhance their understanding and acceptance of decisions.

The draft *Guidance Document on Priority Setting* describes an approach that can be used to help to identify and set priorities within the risk management decision-making process.

References

Canadian Standards Association. *CAN/CSA-Q634-91 Risk Analysis Requirements and Guidelines, Quality Management—A National Standard of Canada*. Rexdale (Toronto). 1991.

Canadian Standards Association. *CAN/CSA-Q850-97 Risk Management: Guideline for Decision-Makers*. Rexdale (Toronto). 1997.

Consumers' Association of Canada. *Report on Consumer Consultations on Legislative and Structural Reform of The Health Protection Branch*. Prepared under contract for the Health Protection Branch, Health Canada. November 1998.

Contributors Group on International, Trade, and Industry Considerations, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Considering International, Trade, and Industry Information within the Risk Management Decision-Making Process*, Draft, October 1999.

Contributors Group on Risk Perception and Social, Cultural, Political and Ethical Considerations, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Considering Risk Perception and Social, Cultural, Political and Ethical Information within the Risk Management Decision-Making Process*, Draft, October 1999.

Council of Science and Technology Advisors. *Science Advice for Government Effectiveness (SAGE)*, May 5, 1999.

Environment Health Program (EHP) Policy Development Sub-Committee, Environment Health Program. *Risk Management Process Implementation Guidelines*, Draft, December 1997.

Hattis, Dale. *Drawing the Line: Quantitative Criteria for Risk Management*. *Environment*, July/August 1996, Vol. 38, No. 6., pp. 11-15, 35-39.

Health Canada. *Health Risk Determination: The Challenge of Health Protection*. Health Protection Branch, Ottawa. 1993.

Health Canada. *Health and Environment, Partners for Life*, Minister of Public Works and Government Services, Canada, Ottawa. 1997.

Health Canada. *Health Protection for the 21st Century: Renewing the Federal Health Protection Program*. Minister of Public Works and Government Services Canada. Ottawa. 1998.

Health Canada. *National Consultations Summary Report: Renewal of the Federal Health Protection Legislation*. Minister of Public Works and Government Services Canada. Ottawa. 1999.

Health Protection Branch, Health Canada. *Health Risk Communication Handbook: Report of the Risk Communication Working Group*. Ottawa. 1996.

Hrudey, S.E. *Environmental Risk Management - What Have We Learned*, Eco-Research Chair, Environmental Risk Management Newsletter, University of Alberta, Vol. 5 No. 1, May 15, 1998.

Industry Canada. *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making*, 2000.

Laboratory Centre for Disease Control, Health Canada. *Perspectives on Epidemiological Surveillance in the 21st Century*. Chronic Diseases Canada, Vol. 4, Number 4, 1998.

Legislative Renewal Project Team, Health Protection Branch Transition, Health Canada. *Transcription of Flip Chart Notes, Internal Transition Workshop (February 10, 1999)*. February 1999.

Legislative Renewal Project Team, Health Protection Branch Transition, Health Canada. *Transcription of Participant's Flip Charts Notes, Employee Working Group Consultation (February 22-23, 1999)*. February 1999.

Legislative Renewal Project Team, Health Protection Branch Transition, Health Canada. *Transcription of Participant's Flip Charts Notes, Employee Working Group Consultation (March 2-3, 1999)*. March 1999.

Legislative Renewal Project Team, Health Protection Branch Transition, Health Canada. *Stakeholders' Tracking Database*. Fall 1997 - Present.

Light, A. and Hrudey, S.E. *Toward an Ideal World of Environmental Risk Management*. Eco-Research Chair, Environmental Risk Management Research Report, University of Alberta, RR 96-4, 1996.

National Health Surveillance Network Working Group Integration Design Team, Office of National Health Surveillance, Health Protection Branch, Health Canada. *Proposal for Development of a Health Surveillance Network in Canada*, May 5, 1999.

National Health Surveillance Network Working Group Integration Design Team, Office of National Health Surveillance, Health Protection Branch, Health Canada. *Summary: A Network for Health Surveillance in Canada*, May 5, 1999.

National Research Council. *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington, D.C., 1983.

National Research Council. *Science and Judgement in Risk Assessment*. National Academy Press,

Washington, D.C., 1994.

National Research Council. *Understanding Risk: Informing Decisions in a Democratic Society*. National Academy Press, Washington, D.C., 1996.

Presidential/Congressional Commission on Risk Assessment and Risk Management. *Framework for Environmental Health Risk Management - Final Report Volume 1*, 1997.

Presidential/Congressional Commission on Risk Assessment and Risk Management. *Risk Assessment and Risk Management in Regulatory Decision-Making - Final Report Volume 2*, 1997.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Risk Management for the 21st Century*. Draft, March 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Risk Management in Health Protection, Revised HPB Risk Management Framework, Phase II Report*, Draft, December 15, 1997.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 1, General Framework: Purpose, Scope, Objectives, Principles, Underlying Assumptions, and Model (March 11, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 2, Identifying Issues and Putting Them into Context (March 12, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 3, Assessing Risks/Assessing Benefits (March 13, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 4, Identifying and Analysing Options (March 17, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 5, Selecting a Risk Management Strategy (March 18, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 6, Implementing the Strategy (April 9, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 7, Evaluating Results (April 9, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Group 8, Partners/Stakeholders/Public Involvement (March 26, 1998)*. May 15, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, Health Canada. *Summary of Notes from Focus Groups with Environmental Health Directorate Managers, (June 11 and 18, 1998)*. July 22, 1998.

Risk Management Framework Project Team, Health Protection Branch Transition, and HPB Working Group for Public Involvement, Health Canada. *Guidance Document on Public Involvement*, Draft, October 1999.

Risk Management Framework Project Team, Health Protection Branch Transition, and HPB Working Group for Public Involvement, Health Canada. *Guidance Document on Risk Communication*, Draft, October 1999.

Therapeutic Products Programme, Health Canada. *Strategic Framework for the Therapeutic Products Programme 1997-2000*, Draft, Ottawa. 1997

Working Group for Public Involvement, Risk Management Framework Project, Health Protection Branch Transition, Health Canada, *Public Involvement Framework & Guidelines, Health Protection Branch-Draft*, March 31, 1999.

Working Group on Environmental Risk Assessment, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Guidance Document on Environmental Risk Assessment*, Draft, October 1999.

Working Group on Health-Based Outcome Measures, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Guidance Document on Developing Health-Based Outcome Measures*, Draft, October 1999.

Working Group on Population Health and Risk Management, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Guidance Document on Incorporating a Population Health Approach into Risk Management Decision-Making*, Draft, October 1999.

Working Group on Priority Setting, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Guidance Document on Priority Setting*, Draft, October 1999.

Working Group on Risk Assessment, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Risk Assessment in Health Canada*, Draft, December 1998.

Working Group on Socioeconomic Analysis, Risk Management Framework Project, Health Protection Branch Transition, Health Canada. *Guidance Document on Socioeconomic Analysis*, Draft, October 1999.

Glossary

Acceptable Daily Intake
(ADI)

See: Reference Dose.

Acceptable Risk

In general terms, a risk that is so small, whose consequences are so slight or whose associated benefits (perceived or real) are so great that persons or groups in society are willing to take or be subjected to that risk. In more technical terms, an arbitrary value denoting a very low probability of occurrence of a seriously adverse effect in persons exposed daily over a lifetime. The dose associated with this risk may be considered to have an insignificant impact on human health. *Synonyms: Tolerable Risk; Negligible Risk; Risk Level.*

Activities

The actions taken to carry out a risk management strategy. They typically require resources and generate products or services.

Adverse Health Effect

A change in morphology, physiology, growth, development or life span of an organism, which results in impairment of functional capacity or which increases susceptibility to the harmful effects of other environmental influences.

Affected Parties

Individuals, groups, or organizations that may experience benefits or adverse effects as a result of exposure to a hazard, or as a result of proposed risk management decisions or actions. They need not be aware of the possible benefits or harm to be considered affected. *Also see: Interested Parties, Partner, Public, Stakeholder.*

Agent	A biological, chemical or physical substance, process, product, or other entity. Exposure to an agent under specific conditions may causes adverse health effects to occur.
Analysis	The systematic application of specific theories and methods, including those from natural science, statistics, probability theory, social science, engineering, decision science, logic, mathematics, and law, for the purpose of collecting and interpreting data and drawing conclusions about phenomena.
Audit	A critical review conducted according to established standards in areas of significance or risk, to provide senior managers or other authoritative bodies (e.g. Central Agencies, Parliament) with independent and professional advice and assurances on the performance of the risk assessment and management process.
Benefits	Effects that promote physical, emotional or economic well-being.
Carcinogen	An agent that causes cancer.
Contaminant	Any agent that enters food, water, air or soil, and that is not normally a constituent of that environmental medium. Some contaminants are created through human activities, whereas others are the result of natural processes.
Context	The context of an issue refers to its contribution to a specific health concern, as well its importance relative to other issues that must be addressed. It also includes the notion of whether an issue falls within the mandate of a specific agency, and consideration of the affected population.
Cultural Considerations	Ways in which traditions, values, practices and other characteristics of groups within society may affect or be affected by health risks and approaches to risk management.

Decision-Making Framework	A structured process for making risk management decisions. The process consists of three phases: issue identification, risk assessment, and risk management (identification and analysis of options, selection of a strategy, implementation of the strategy, and monitoring and evaluation of the strategy). <i>Also see: Issue Identification, Risk Assessment, Risk Management.</i>
Deliberation	Any formal or informal process that involves communication, and is intended to facilitate the discussion of issues so that a decision can be made. The process is usually iterative and is intended to move discussions toward closure.
Determinants of Health	The collective label given to the factors and conditions that are thought to have an influence on health, including things such as income and social status, social support networks, education, employment and working conditions, social and physical environments, personal health practices, and coping skills. Some determinants play a more prominent role than others for given health issues, and interact in complex ways to affect population health. <i>Also see: Population Health Approach, Risk Factor.</i>
Dose-Response Assessment	A study in which the subjects are given a range of doses of an agent, and the resulting health effects are monitored over time. The intent is to estimate the relationship between dose and the incidence and/or severity of an effect. <i>Also see: Dose-Response Curve, Dose-Response Relationship, Hazard Characterization.</i>
Dose-Response Curve	A graphical presentation of the dose-response relationship. <i>Also see: Dose-Response Assessment, Dose-Response Relationship, Hazard Characterization.</i>
Dose-Response Relationship	The association between the administered or absorbed dose of an agent and the nature, severity, incidence and/or prevalence of specific toxicological effects in populations. <i>Also see: Dose-Response Assessment, Dose-Response Curve, Hazard Characterization.</i>

Effectiveness	The extent to which a specific strategy, intervention, procedure, regimen, or service, does what it is intended to do for a defined population.
Environment	Includes both living (e.g. animals, plants) and non-living (e.g. soils, waters) entities. <i>Also see: Environmental Risk Assessment.</i>
Environmental Risk Assessment	The process that evaluates the likelihood that adverse environmental effects may occur or are occurring as a result of exposure to one or more agents. <i>Also see: Environment.</i>
Epidemiology	The study of the distribution and determinants of health-related states or events in specified human populations, and the application of this study to the control of health problems. Epidemiology is concerned with both the frequencies and types of illnesses and deaths in particular groups of people and with the factors that influence their distribution.
Equity	Fairness in the allocation of resources, risks or benefits, among different individuals or groups.
Ethical Considerations	Factors related to the multiple values and principles that may be of concern in decisions regarding risks to health.
Evaluation	An empirically-based analysis of the results of risk management strategies or programs, that provide senior managers, other authoritative bodies (e.g. Central Agencies, Parliament), or the public with relevant, objective, timely and well-documented findings and recommendations. <i>Also see: Health-Based Outcome Measures.</i>
Exposure	A process by which an organism comes into contact with an agent for a given period of time, resulting in a dose (the amount of the agent either in the organism as a whole or in a target tissue). Exposure is determined by the concentration and form of an agent in the environment, coupled with the presence of the organism, . <i>Also see: Exposure Assessment, Exposure Pathway, Route of Exposure.</i>

Exposure Assessment	A process that involves producing a qualitative and/or quantitative estimate of the magnitude, frequency, duration, route and extent of human exposure to an agent. <i>Also see: Exposure, Exposure Pathway, Route of Exposure.</i>
Exposure Pathway	A description of the way in which a hazardous agent reaches an individual or population. It includes information on: the source, from which the agent originates; environmental media, which carry the agent to individuals or populations of humans; the location, which is the point where contact between the agent and humans occurs; the target population(s) or subpopulation(s), who are the people exposed to the agent; and the route(s) of exposure, which are the means of entry into the human body (e.g. ingestion). <i>Also see: Exposure, Exposure Assessment, Route of Exposure.</i>
Genotoxic Carcinogen	An agent, such as ionizing radiation and certain types of chemicals, that causes cancer by damaging DNA. <i>Also see: Non-Threshold Substance.</i>
Hazard	The intrinsic property of the agent, that makes it capable of causing adverse effects to occur in humans or the environment, under specific conditions of exposure. <i>Also see: Hazard Characterization, Hazard Identification.</i>
Hazard Characterization	A process that involves the qualitative and/or quantitative evaluation of the nature of the adverse effects that humans may experience under expected levels of exposure to an agent. <i>Also see: Hazard, Hazard Identification.</i>
Hazard Identification	The process of recognizing that an agent has an inherent capacity to cause an adverse health effect; may be based on informal information or studies conducted under specific conditions. <i>Also see: Hazard, Hazard Characterization.</i>

Health-Based Outcome Measures	Impacts, effects or changes in the health of a defined population resulting from or related to a specific risk management strategy. These measures may be used as a basis for monitoring and evaluating risk management strategies. Outcome measures can relate to short-term, intermediate, or long-term results. <i>Also see: Evaluation, Long-Term Outcomes, Monitoring, Short-Term Outcomes.</i>
Health Surveillance	The tracking and forecasting of any health event or health determinant through the continuous collection of high-quality data, the integration, analysis and interpretation of those data into surveillance products (for example reports, advisories, warnings to name a few), and the dissemination of those surveillance products to those who need to know. Surveillance products are produced for a specific public health purpose or policy objective. In order to be considered health surveillance all of the above activities must be carried out.
Incidence	The rate at which new cases of disease, injuries, or deaths occur in a population during a specified time. The numerator is the number of <u>new</u> events that occur in a defined period; the denominator is the population at risk of experiencing the event during this period, sometimes expressed as person-time.
Interested Parties	Individuals, groups, or organizations that have some concern regarding a specific risk or the risk assessment and risk management process, or would like to be involved in the process. Interested parties may or may not also be affected parties. <i>Also see: Affected Parties, Partner, Public, Stakeholder.</i>
Issue Identification	A process that involves determining the nature and context of a risk management issue, and establishing the administrative basis and operating procedures needed to proceed through the risk management decision-making framework. <i>Also see: Decision-Making Framework.</i>
Iterative Process	Replication of a series of actions to produce successively better results, or to accommodate new and different critical information or scientific inferences.

Long-Term Outcomes	Changes in the original conditions that resulted in the creation of the risk management strategy. <i>Also see: Health-Based Outcome Measures, Short-Term Outcomes.</i>
Lowest-Observed-Adverse-Effect Level (LOAEL)	The lowest dose or concentration of an agent that produces a significant observable adverse effect in an exposed group when compared with a non-exposed group. <i>Also see: Reference Dose, Safety Factor.</i>
Monitoring	The repetitive and continued observation, measurement and evaluation of an activity, output or outcome to detect changes in human health or the environment over a period of time. <i>Also see: Health-Based Outcome Measures.</i>
No-Observed-Adverse-Effect Level (NOAEL)	The level of exposure to an agent at which no adverse effects are observed in an exposed group when compared with a non-exposed group. <i>Also see: Reference Dose, Safety Factor.</i>
Non-Carcinogen	An agent that does not cause cancer. <i>Also see: Threshold Substance.</i>
Non-Genotoxic Carcinogen	An agent that causes cancer but does not damage DNA. <i>Also see: Threshold Substance.</i>
Non-Threshold Substance	An agent for which it is assumed that there is risk associated with any amount of exposure, no matter how small (in other words, it is assumed that there is no threshold for effects). Examples include genotoxic carcinogens, such as ionizing radiation and certain types of chemicals, which cause cancer by damaging DNA. <i>Also see: Threshold Substance.</i>
Output	Tangible products or services that can be counted and that are produced or provided as a result of activities. <i>Also see: Health-Based Outcome Measures.</i>

Partner	An individual, group, or organization who is responsible for implementing some aspect of the issue identification, risk assessment and risk management process. Health Canada's partners include: other federal government departments, provincial governments, provincial health systems, non-governmental organizations, health professionals, industry, the academic community, consumer groups, international governments, international agencies, other agencies, and the general public. The identity of these partners varies depending on the specific risk situation being addressed. <i>Also see: Affected Parties, Interested Parties, Public, Stakeholder.</i>
Population Health Approach	An approach that focuses on the health of the population as a whole, and of subgroups within the population, by addressing factors that contribute to health and their complex interactions. The approach addresses not only the physiological, psychological and behavioural components of health, but also the entire range of factors that contribute to our physical, mental and social well-being. The overall goal of a population health approach is to maintain and improve the health status of the entire population while reducing inequalities in health status among population sub-groups. <i>Also see: Determinants of Health.</i>
Precautionary Approach	An approach to risk management decision-making that is applied in circumstances of scientific uncertainty, reflecting the need to take action in the face of a potentially serious risk without awaiting the results of scientific research. Cost-effective action must be taken when there are threats of serious or irreversible damage to human health, even if some cause and effect relationships are not fully established scientifically.
Public	A term that refers to the range of parties that may be interested in or affected by risk management decisions. It includes the general public, consumers, and special interest groups such as environmental, health and consumer groups, industry, scientists and professional associations. <i>Also see: Affected Parties, Interested Parties, Partner, Public Involvement, Stakeholder.</i>

Public Involvement	A range of activities and relationships related to the interactions between the public and the decision-making body (e.g. Health Canada) in the risk assessment and risk management process. This includes two-way communications, public education, public consultation and dialogue, advisory boards, partnerships, and joint decision-making. <i>Also see: Public.</i>
Quantitative Structure Activity Relationships (QSARs)	An approach used to describe or predict possible toxic or carcinogenic effects of compounds based on their chemical structure.
Reference Dose (RfD)	An estimate of the intake of a chemical to which it is believed a person can be exposed daily over a lifetime, without experiencing adverse health effects. The estimate is calculated on a body weight basis (usually mg/kg bw/day). The RfD is derived from the NOAEL or the LOAEL by applying safety (uncertainty) factors. <i>Synonyms: Acceptable Daily Intake, Tolerable Daily Intake; also see: Lowest-Observed-Adverse-Effect Level (LOAEL), No-Observed-Adverse-Effect Level (NOAEL), Safety Factor.</i>
Relative Risk	The ratio of the incidence rate of an outcome in an exposed group to the incidence rate of the outcome in an unexposed group.
Residual Risk	The risk remaining after a risk management strategy has been implemented.
Resources	The type and amount of expenditure (e.g. time, money, expertise) used to undertake an activity (e.g. implement a risk management strategy).
Risk	A measure of both the harm to human health that results from being exposed to a hazardous agent, together with the likelihood that the harm will occur. In order for a health risk to exist, three things must be true: there must be exposure to a hazard; there must be a health effect; and there must be some likelihood that the health effect will occur. <i>Also see: Adverse Health Effect, Hazard, Exposure, Risk Assessment.</i>

Risk Assessment	A process that involves determining the likelihood that a specific adverse health effect will occur in an individual or population, following exposure to a hazardous agent. Risk assessment includes four tasks: hazard identification, hazard characterization, exposure assessment, and risk characterization (a summary and integration of the previous tasks). <i>Also see: Hazard Identification, Hazard Characterization, Exposure Assessment, Risk Characterization, Decision-Making Framework.</i>
Risk Characterization	A process involving the qualitative and/or quantitative estimation of the severity and probable occurrence of known or potential adverse effects in a given population, based on hazard identification, hazard characterization and exposure assessment. The estimate includes information from biophysical studies, and where appropriate, integrates information related to social, cultural, ethical, and economic contributors to the risk, with consideration also being given to risk perceptions. Risk characterization is the final step in risk assessment. <i>Also see: Hazard Characterization, Hazard Identification, Exposure Assessment, Risk Assessment, Weight of Evidence.</i>
Risk Communication	Any exchange of information concerning the existence, nature, form, severity or acceptability of health or environmental risks. Effective risk communication involves determining the types of information that interested and affected parties need and want, and presenting this information to them in a useful and meaningful way.
Risk Factor	Something that can increase the likelihood that adverse health effects will occur following exposure to an agent. Examples of risk factors include behaviours, such as smoking or physical inactivity, and genetic predisposition. <i>Also see Determinants of Health.</i>

Risk Management	A term used to collectively describe the activities and considerations involved in addressing, and communicating information about health risks. Risk management includes a number of inter-related activities: identifying and analysing options for addressing the risk, developing and implementing a strategy for managing the risk, monitoring and evaluating the effectiveness of the strategy, and communicating information both about the risk and about the decision-making process. <i>Also see: Decision-Making Framework.</i>
Risk Management Strategy	One or more courses of action (options), intended to prevent or reduce a specific risk. A variety of different types of strategies may be used, ranging from a simple approach involving a single risk management option, to a multi-faceted approach in which a number of different options are implemented to varying degrees.
Risk Perception	The way that individuals intuitively see and judge risks. Risk perception is influenced by many factors including age, gender, level of education, region of residence, values, social, cultural and ethical factors, and previous exposure to information on the hazard.
Risk Prioritization	A process that involves using specific criteria, such as the potential to cause cancer (carcinogenic potency), to determine which of many risks should be addressed first.
Risk Ranking	The ordering of health issues on some scale of importance that reflects their relative level of risk. Risk ranking is useful for comparing hazards that are present in the same environmental medium and that cause a similar adverse health affect (e.g. potential carcinogens found in drinking water).
Risk Scenarios	A sequence of events, each of which has an associated frequency and consequence.
Route of Exposure	The means by which agents enter the body, such as through eating, drinking, breathing or skin contact. <i>Also see: Exposure, Exposure Assessment, Exposure Pathway.</i>

Safety Factor	A value applied to a No-Observed-Adverse-Effect-Level (NOAEL) or Lowest-Observed-Adverse-Effect Level (LOAEL), to derive a Reference Dose (RfD); the NOAEL or LOAEL is divided by the safety factor to calculate the RfD. The value of the safety factor depends on the nature of the toxic effect, the size and type of population to be protected, and the quality of the toxicological information, and includes scientific judgements. <i>Synonym: Uncertainty Factor; also see: Lowest-Observed-Adverse-Effect Level (LOAEL), No-Observed-Adverse-Effect Level (NOAEL), Reference Dose.</i>
Short-Term Outcomes	The impacts on those groups who are immediately affected by risk management strategies, including changes in service levels and behavior. <i>Also see: Health-Based Outcome Measures, Long-Term Outcomes.</i>
Social Considerations	Ways in which the structure, values and functioning of society may affect or may be affected by health risks and approaches to risk management.
Socioeconomic Analysis	A methodology that is used to examine the monetary and social consequences related to a specific risk, or resulting from a set of potential risk management options that are being considered. The methodology involves examining both positive and negative consequences (respectively, the effects or benefits and costs), and recognizing the broad societal context (i.e. social, cultural, ethical and/or equity considerations) of decisions.
Source	An entity or action that releases chemical, physical, or biological agents to the environment.
Stakeholder	An individual, group, or organization who may be affected by or otherwise interested in a risk management decision. <i>Also see: Affected Parties, Interested Parties, Partner, Public.</i>

Sustainable Development	The combination of economic, social and environmental goals, taking into account their effects on human health. The concept reflects the fact that development is essential to satisfy human needs and to improve the quality of human life but must be based on the efficient and environmentally responsible use of all our scarce resources: natural, human and economic. The goal is to meet the needs of the present without compromising the ability of future generations to meet their own needs.
Threshold	The dose or exposure concentration below which a significant adverse effect is not expected to occur. <i>Also see: Threshold Effect, Threshold Substance.</i>
Threshold Effect	An effect that occurs above a generally accepted minimum dose (or threshold). <i>Also see: Threshold, Threshold Substance.</i>
Threshold Substance	An agent for which is it assumed that there is a threshold dose below which adverse effects are unlikely to occur. Examples include chemicals that cause cancer but do not damage DNA (non-genotoxic carcinogens) and chemicals that do not cause cancer or for which there is insufficient data on carcinogenic potency (sometimes called “non-carcinogens”). <i>Also see: Non-Threshold Substance, Threshold, Threshold Effect.</i>
Tolerable Daily Intake (TDI)	<i>See: Reference Dose.</i>
Toxicology	The <i>science of poisons</i> ; the study of the adverse effects of agents on living organisms, including humans. Toxicological studies may involve individuals or groups.
Uncertainty	A deficiency in knowledge concerning parameter values and the appropriate extrapolation of the significance of adverse health effects, to a situation involving different species and exposure conditions. Uncertainty can result from lack of knowledge, inherent variability (stochasticity), confounding effects, or imprecise measurements. <i>Also see: Safety Factor.</i>

Uncertainty Factor	<i>See: Safety Factor; also see: Uncertainty.</i>
Value-of-Information Methods	Techniques that provide estimates both of the value of having better information (usually in monetary terms) and of collecting that information.
Weight-of-Evidence	A qualitative measure that takes into account the nature and quality of scientific studies intended to examine the risk of an agent. Uncertainties that result from the incompleteness and unavailability of scientific data frequently require scientists to make inferences, assumptions, and judgements in order to characterize a risk. Making judgements about risk based on scientific information is called “evaluating the weight of evidence”. <i>Also see: Scientific Risk Characterization.</i>

Appendix A: Project Team

William Ross Director (as of September 1998)
Patty Birkwood Project Manager

Former Members:

Thomas Henter Project Coordinator (February - August 1999)
Daniel Krewski Director (July 1997 - June 1998)
Anna Marie Muise Project Assistant (September 1997 - October 1998)
Anji Nahas Project Coordinator (July 1997 - December 1998)