Healthy Animals, Healthy Canada

The Expert Panel on Approaches to Animal Health Risk Assessment

Council of Canadian Academies
Conseil des académies canadiennes

Science Advice in the Public Interest

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The Expert Panel on Approaches to Animal Health Risk Assessment

THE COUNCIL OF CANADIAN ACADEMIES
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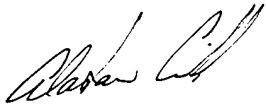
During the course of its deliberations, the Panel sought assistance from many people and organizations that provided valuable information and advice. A full list of the invited speakers is provided in Appendix A. The Panel would like to thank these speakers; the respondents to the Animal Health Risk Assessment Researchers, Surveillance Organizations, and Training Trends surveys; and the risk assessors, risk managers, and other CFIA staff who met with the Panel at the outset of the assessment to inform the deliberative process. We would also like to thank Nancy Rheault (CFIA) for her support in coordinating the Panel's meetings with CFIA staff.



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Report Review

This report was reviewed in draft form by the individuals listed below — a group of reviewers selected by the Council of Canadian Academies for their diverse perspectives; areas of expertise; and broad representation of academic, industrial, policy, and non-governmental organizations.

The reviewers assessed the objectivity and quality of the report. Their submissions, which will remain confidential, were considered fully by the Panel, and many of their suggestions were incorporated into the report. They were not asked to endorse the conclusions nor did they see the final draft of the report before its release. Responsibility for the final content of this report rests entirely with the authoring Panel and the Council.

The Council wishes to thank the following individuals for their review of this report:

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report reviewers. The Board of the Council authorizes public release of an expert panel report only after the report review monitor confirms that the Council's report review requirements have been satisfied. The Council thanks Dr. Bergeron for his diligent contribution as review monitor.

Elizabeth Dowdeswell, President and CEO
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Executive Summary

Animals are integral to Canadian culture and society, to our economic well-being, and, in many ways, to our health. The direct and indirect links between animal health and human health have become more apparent over the last decade with a greater appreciation of emerging and re-emerging diseases. The pandemic H1N1 influenza virus in 2009 provides one recent example. Identifying, assessing, and managing risks to the health of our animal populations serves to protect not only the economic benefits derived from animals, but also the health of individuals, populations, our society, our domestic and wild animals, and our ecosystems.

Risk assessment is employed by all levels of government, by industry organizations, and informally by individuals, to solve problems and aid in decision-making. Formal risk assessment is a structured, systematic process to determine the likelihood of the occurrence of an event and the likely magnitude of the consequences following exposure to a hazard. Because animal health risk assessment occurs within the context of international agreements, stakeholder expectations, and/or complex socio-political considerations, a structured, systematic approach is needed to help ensure it contributes to decision-making in a meaningful way.

The context and demands of, and for, animal health risk assessment are changing. Emerging disease and food safety are a greater part of the public consciousness. We are in an era of rapid travel and communication. The impact of globalization and urban expansion on animal and human health is only now beginning to be understood. Climate change is affecting disease spread and disease range. Societal expectations and our knowledge base are changing. Therefore, the Minister of Agriculture and Agri-Food, on behalf of the Canadian Food Inspection Agency (CFIA), asked the Council of Canadian Academies to assemble a panel of experts to address the following question:

> *What is the state and comprehensiveness of risk assessment techniques in animal health science, specifically pertaining to risks which may impact human health?*

The Expert Panel on Approaches to Animal Health Risk Assessment (the Panel) examined the practices of Canadian agencies and institutions engaged in risk assessment in animal health and other areas, and of Canada's major international trading partners. The Panel also reviewed the available literature on risk assessment and the views of experts in the area, and conducted its own surveys and reviews on the state of animal health risk assessment in Canada.

The Panel recognized that the drivers of animal health risk assessments range from relatively routine animal import requests to requests for assessments to help establish overarching policy directions. The context and constraints (e.g., the need to comply with international agreements) for risk assessments may vary; however, there are some useful general approaches that can and are being applied to animal health risk assessments conducted for this range of purposes.

THE FINDINGS

The Panel's major finding was that an integrated, multidimensional approach that considers the appropriate range of potential animal, human, and environmental consequences, as well as risk management outcomes, in the risk assessment process would contribute to assessments that provide increased value to risk managers, decision-makers, and stakeholders. Further, risk-based decision-making and subsequent risk communication and management could benefit from a greater engagement of stakeholders in establishing risk assessment questions, scope, and consequences, and from improved access to expertise and knowledge among risk assessment practitioners. Because risk assessment is part of a broader risk analysis process that comprises hazard identification, risk assessment, risk communication, and risk management, all four phases need to be effectively carried out to maximize the benefits of the risk assessment component.

Animal health risk assessment in Canada is built on a solid foundation of knowledge and expertise. Although other organizations are involved, the CFIA plays a major role in carrying out animal health risk assessments in Canada. The CFIA conducts systematic risk assessments within a structured risk analysis framework that is consistent with international guidelines. Many of these risk assessments are carried out for the purposes of international trade, most often related to importation requests. The majority of risk assessments conducted are qualitative and, while they may consider a range of consequences, the major focus is on the economic and trade consequences of introducing animal disease into Canada. In reviewing risk assessments from other countries, the Panel observed that several countries were taking a broader view of the consequences of animal health events.

The Panel noted a number of gaps in the knowledge required to conduct specific risk assessments, but these deficits in knowledge and/or data were generally specific to the hazard or importation in question. A coordinated approach to address animal-human health risk research to support such risk assessment does

not exist in Canada. Enhanced training and research are required to support animal health risk assessments. The Panel observed that dedicated funding sources and organizations were being utilized in other jurisdictions to address this issue.

The Panel further concluded that integrating human health and environmental consequences into animal health risk assessments would improve their applicability and utility in risk analysis and risk-based decision-making. While the Panel recognized that not all risk assessments need be comprehensive in their consideration of consequences, the integration of consequences into a comprehensive risk assessment, as opposed to the completion of independent risk assessments for animal and human health, would be most valuable. Additionally, the Panel identified differences in terminology describing the risk assessment process, as well as differences in the cultures of the animal and human health risk assessment communities in Canada, as significant impediments to achieving integration. Therefore, the Panel proposed a standardized use of language and definitions to facilitate communication and shared activities.

The Panel identified several contributions to achieving an integrated, multidimensional approach in animal health risk assessment:

1. Integration: increase the breadth and depth of consequences considered in risk assessments; and address consequences for animals, humans, and the environment.

Many risks to animal health have economic, ecological, and social implications beyond those directly affecting domestic animal health. Consequence identification and selection should be a formal element of animal health risk assessment. A full range of potential consequences (increased breadth) should be identified early in the risk assessment process using input from risk managers, risk assessors, and relevant stakeholders.

Further, secondary or subsequent consequences should be considered (increased depth) as well as immediate, direct consequences. The Panel felt that exploring this breadth and depth of consequences within a single, integrated risk assessment would be more effective than considering different consequences independently. Methodologies and perspectives from more disciplines should be integrated (*interdisciplinarity*, as opposed to multidisciplinarity, is the goal) to ensure adequate consideration is given to the consequences.

The Panel is not suggesting that all consequences should be explored in all risk assessments, but rather that there is a conscious consideration of the full breadth and depth of consequences. This should be accompanied by a transparent selection process for determining which consequences to include. This approach would ultimately facilitate risk communication and risk management, and the acceptance of decisions by stakeholders.

2. Multidimensional approach: include evaluation of consequences of various management options in the assessment.

Risk assessment is most commonly viewed as a two-dimensional process: the first dimension is the likelihood of a risk occurring, and the second is the severity of the consequences. The Panel considered that the value of risk assessment would be increased by including a third dimension that considers not only the consequences of the hazard or risk, but also the consequences of the risk management or mitigation measures. For example, the consequences of management options, such as vaccination or quarantine, should be analyzed against the impact on animals, humans, and the environment. The element of time should also be included, in that risk estimation may change with time; thus consequences might not be immediate. The Panel felt that it would be valuable to formalize this process as a systematic step in risk assessment. One promising method for achieving this goal is multiple criteria decision analysis, as described in Appendix D. The specific method, however, would be less important than the overarching goal of including multiple interventions and their associated consequences.

3. Ensure transparency: use risk managers and stakeholders strategically in the risk assessment process, have a structured prioritization process, document decisions, and maximize risk communication.

Transparency adds value to the risk assessment process and facilitates subsequent risk communication and management. Transparency can be facilitated by recognizing and using the strategic role of risk managers, by having a clear process for *engaging stakeholders* in the risk assessment process, by having a structured prioritization process, and by effective risk communication. Where possible, completed animal health risk assessments should be publicly available. Risk communication is an ongoing activity throughout the risk assessment process. Areas of uncertainty and assumptions should be clearly identified in the risk assessment, particularly so that it is understood when and what assumptions or estimations have been made. Transparency and communication are important throughout the risk assessment and, indeed, the whole risk analysis process.

It may be acceptable to employ a quantitative, qualitative, or a mixed approach to risk assessment, depending on the available supporting data and the goal of the assessment. Quantitative risk assessment may assist with transparency in some cases.

Adoption of an integrated, multidimensional approach is not inconsistent with Canada's obligations to international agreements and guidelines related to animal health risk assessment. The Panel noted that some of our major trading partners or peers (including New Zealand and the European Union) are adopting aspects of this approach. Further, a number of international trading partners have a more transparent process, including public availability of completed risk assessments.

The Panel also viewed the following points to be important for achieving an integrated, multidimensional approach to risk assessment, maximizing the utility of the assessment in risk-based decision-making, and ensuring that the appropriate risk assessments are completed in a timely fashion:

- Risk assessment organizations across the animal-human-environment health spectrum should work to *align and integrate processes*, where appropriate, to ensure efficiency, transparency, communication, integration, and continuity. The conditions for effective, integrated animal-human health risk assessment will be affected by a range of factors such as institutional arrangements and resource constraints.
- A *structured and transparent prioritization system* helps to ensure that routine risk assessments, as well as those required for policy decisions and strategic planning, are completed in a timely fashion.
- Canada's research and training in animal health risk assessment should be enhanced to *strengthen its knowledge capacity* for protecting animal health, human health, and the environment. Canada's current research funding structure does not facilitate integrated animal-human health research.

The Panel recognized that expanding the range of consequences and adopting an integrated, multidimensional approach might require increased, or at least realigned, resources. This could be minimized by ensuring there is not only a structured process for prioritizing the conduct of the risk assessment itself, but also a process for prioritizing the range of consequences and management options considered within a risk assessment. The precise details of these processes are less important than the fact that both should be structured and transparent. It is also important to conduct risk assessments that address future or unknown risks and inform public policy decisions. These risk assessments should be identified as a priority to ensure that resources are directed to them. A variety of strategic

planning processes or foresight analyses can be applied to the prioritization process. Again, the exact process is less important than the fact that a structured process would be considered and conducted.

CONCLUSION

Animal health risk assessment in Canada currently appears to be meeting the majority of our needs with regard to importation and international trade obligations. A more integrated, multidimensional approach, however, like that adopted by some of our peer trading partners, may better serve the broader goals of animal health risk assessment and better support the risk-based decision-making process. Adopting an integrated, multidimensional approach and conducting strategic risk assessments could be resource intensive if not managed properly. Therefore, a systematic, transparent prioritization process, for both the extent and range of risk assessments, needs to be in place. Risk assessment organizations in Canada (e.g., the CFIA, the Public Health Agency of Canada) should work to align and integrate processes to ensure efficiency, transparency, communication, integration, and continuity. A robust and effective risk assessment process to support risk-based decision-making will help to ensure the health of Canada's animal populations and help to protect human health.

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List of Abbreviations

AAFC	Agriculture and Agri-Food Canada
AHRA	Animal Health Risk Assessment
AHEM	Animal Health Emergency Management
AVSN	Alberta Veterinary Surveillance Network
BfR	Federal Institute of Risk Assessment (Germany)
BSE	Bovine Spongiform Encephalopathy
CAC	Codex Alimentarius Commission
CAHSN	Canadian Animal Health Surveillance Network
CanNAISS	Canadian Notifiable Avian Influenza Surveillance System
CBRNE	Chemical, Biological, Radiological-Nuclear, and Explosives
CCIA	Canadian Cattle Identification Agency
CCWHC	Canadian Cooperative Wildlife Health Centre
CFIA	Canadian Food Inspection Agency
CIDPC	Centre for Infectious Disease Prevention and Control
CIHR	Canadian Institutes of Health Research
CRTI	Research and Technologies Initiative
CSIP	Canadian Sheep Identification Program
CVMA	Canadian Veterinary Medical Association
DALYs	disability-adjusted life years
Defra	Department for Environment, Food and Rural Affairs (U.K.)
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency (U.S.)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FAWC	Farm Animal Welfare Council (U.K.)
FDA	Food and Drug Administration (U.S.)
FMD	foot-and-mouth disease
Fore-CAN	Foresight for Canadian Animal Health
GDP	gross domestic product
GIS	Geographic Information Systems
HAIRS	Human Animal Infections and Risk Surveillance group
HALYs	health-adjusted life years
HHCAHE	human health consequences of animal health events

IMDA	integrated, multidimensional approach
MAVT	multi-attribute value theory
MCDA	multiple criteria decision analysis
NML	National Microbiology Laboratory
NRC	National Research Council
NSERC	Natural Sciences and Engineering Research Council
OIE	World Organisation for Animal Health
PHAC	Public Health Agency of Canada
QALYs	quality-adjusted life years
SARS	severe acute respiratory syndrome
WHO	World Health Organization
WTO	World Trade Organization

1

Introduction

1 Introduction

Animals are integral to Canadian culture and society. From the early days of the fur trade and fishing to our current agricultural and companion animal industries, the health of our animal populations has been central to our well-being. Many facets of our economy, our food supply, our cultural identification, and our social activities remain linked to healthy animal populations: fishing and aquaculture on the coasts, farm animals in the agricultural heartlands, equestrian sports across Canada, wildlife in our parklands, and companion animals in our homes. The nature of our interactions with animals varies considerably across geographic, socio-economic, and cultural dimensions, but the health of our animal populations influences virtually all of us in some way.

The interactions between animals and humans are still evolving. The impact of globalization and urban expansion on animal and human health is only now beginning to be understood. We do not yet know the full effects of climate change on animal populations and on the animal-human-environment interface. The direct and indirect links between animal health and human health, however, have become more apparent over the last decade with a greater appreciation of emerging and re-emerging diseases. Identifying and managing risks to the health of our animal populations serve to protect not only the economic benefits derived from them, but also the health of individuals, populations, our society, and our environment.

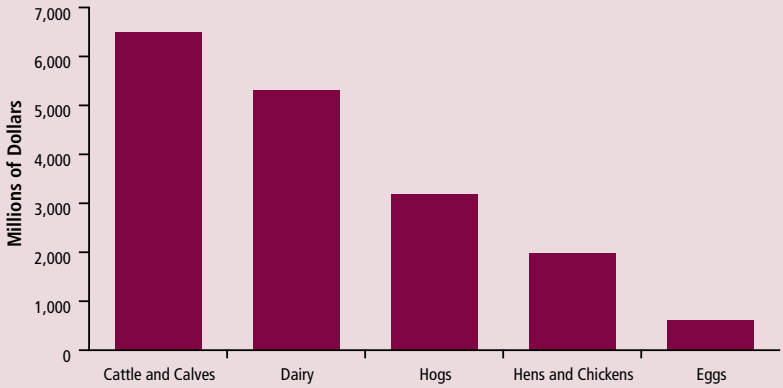
The benefits provided by animal industries and healthy animals are many and varied. Livestock production accounts for $18.7 billion in Canadian farm income and is directly responsible for close to $3.2 billion in exports (Statistics Canada, 2009; Industry Canada, 2009) (see Box 1.1). Additional economic contributions come from related activities such as animal food manufacturing, animal processing, and associated activities in transportation, finance, and other sectors connected to animal production.

Horses serve as companion animals for thousands of people and remain working animals in agriculture and tourism. In many regions horse industries are important economic drivers. For example, the Ontario horse racing and breeding industry supports approximately 37,000 permanent, full-time positions and 25,000 part-time positions, generating $1.3 billion in wages and salaries (ORC, 2004; Econometric Research Limited, 2005).

Box 1.1

The Economic Value of Livestock Industries in Canada

Primary production of livestock accounted for 41 per cent of all farm cash receipts in Canada in 2008, totalling $18.7 billion. The five largest categories of livestock and livestock products include cattle and calves, dairy products, hogs, hens and chickens, and eggs (Statistics Canada, 2009).



(Data Source: Statistics Canada, 2009)

Figure 1.1

Farm Cash Receipts of the Top Five Livestock Products in Canada, 2008

Companion animals have become an increasingly important part of Canadian society with growing recognition of their public health benefits (Friedmann & Son, 2009; Cutt *et al.*, 2007; Headey, 2003). The close relationship between people and companion animals not only provides positive health benefits, but also facilitates the transmission and spread of certain diseases from animals to humans.

Looking beyond the farm and home, protection of wildlife is generally viewed as a societal responsibility. In Canada, wildlife and fish populations continue to serve as important sources of food and income for many First Nations peoples. Healthy wildlife populations are draws for tourists in many parts of the country.

The economic impact of wildlife- and fish-related activities in Canada has been estimated to be $7.2 billion a year (Environment Canada, 2000). The encroachment of urban Canada on wildlife habitats and the continuing development in rural areas increase the interactions between humans, domestic animals, and wildlife. These pressures may threaten our wild populations and increase the spread of infectious disease to domestic animals and humans.

Zoonotic diseases are infectious diseases that can be transmitted and shared between animals and humans.[1] Their impact on human health can range from mild to severe for individuals and populations. When zoonotic diseases change such that there is direct spread among humans, the impact of a disease on human health can change dramatically. Severe acute respiratory syndrome (SARS), human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), and the H1N1 virus are all examples of pandemics with at least partial origins in animal populations (NAS, 2009). According to one estimate, the majority of emerging diseases in humans (approximately 75 per cent) originate in the animal kingdom (Taylor *et al.*, 2001). This finding has led to a greater sensitivity to the importance of animal health events for human health.

Despite depending on animals as sources of food and embracing them as sources of entertainment and companionship, people do not regularly consider the broader benefits of positive animal health. Attention is only drawn to animal health when a significant disease event occurs (see Box 1.2). Regardless of whether a disease infects humans or is limited to animal populations, the impact can go beyond the direct effects on human or animal health. The SARS outbreak in 2003 is estimated to have cost the Toronto economy nearly $1 billion in reduced travel, tourism, and entertainment spending (The Conference Board of Canada, 2003), while the "mad cow disease" (BSE) scare of that same year is said to have cost the Canadian economy close to $6 billion, devastating the cattle industry and the communities that depend on it (Mitura & Di Piétro, 2004), despite a relatively low risk to consumers. The large-scale animal culling that may accompany outbreaks of infectious disease in animals and the subsequent economic burden can lead to psychological strains on farm families and other agricultural industry workers (Mitra *et al.*, 2009). In addition, potential environmental consequences can range from threats to indigenous animal populations to the spread of invasive species (Government of Manitoba, 2010; George, 2004; Dickenson, 2010).

[1] Although zoonotic diseases are often defined as diseases that pass from animals to humans (Porta, 2008; OIE, 2010c), for this report the Panel has used the broader sense of the term to also refer to diseases that are "common to both animals and humans." (Martin *et al.*, 1987; PAHO, 2003).

Box 1.2
Animal Health in the News

Beef farmers with BSE loans struggling to repay province: "It will take some cattle farmers another decade to pay off government loans they took out during the BSE crisis… Today, 1,184 loans worth $32.9 million remain on the books of the Manitoba Agricultural Services Corp." (*Winnipeg Free Press,* 10 May 2010)

Quebec expands the fight against the Nile virus: Quebec expanded its efforts to fight the West Nile Virus "because the surveillance data of the 17 human cases in 2003, coupled with the survey of dead bird carcasses, showed the emergence of new zones at risk in those regions… In 2002, 20 human cases of infections and 3 deaths due to the West Nile virus have been reported in Quebec. And in 2003, no deaths were reported amongst the 17 identified infection cases." (*Le Devoir,* 1 June 2004)

B.C. inspectors stay vigilant for foot-and-mouth: "British Columbia is facing the same illegal smuggling that Britain suspects may be responsible for its foot-and-mouth disaster, which cost the country more than $20 billion. Inspectors for the Canadian Food Inspection Agency routinely intercept cured pork, beef, and other meats from Asian countries where the disease is endemic. The slightest morsel can carry foot-and-mouth disease. While not harmful to humans, it devastates livestock." (*Edmonton Journal,* 2 April 2001)

Deadly virus discovered in N.S. salmon: "Infectious salmon anaemia was detected in three of seven Nova Scotia salmon farms in routine testing… More than 1.5 million salmon had to be destroyed in New Brunswick last year and the year before after the disease spread through stocks kept in cages in the Bay of Fundy. That province ended up paying salmon companies $25 million to destroy the infected fish." (*Toronto Star,* 27 April 1999)

Pet turtles may make owners sick: "In British Columbia, an 8-year-old, her father, 26, and 5-month-old twins developed salmonella after visiting a grandmother who kept two pet turtles. Both Agriculture Canada and the U.S. Food and Drug Administration banned the importation of turtles in 1975, but the ban did not extend to eggs. A man imported eggs to Canada and shipped the hatched turtles across the country to pet shops." (*Toronto Star,* 24 August 1985)

Canadians also rarely appreciate how effective risk assessment and management contribute to maintaining healthy populations. Governments have a responsibility to ensure healthy animal populations for the benefit of society and to protect human and animal health. There are considerable societal expectations and values that influence the nature and extent of the government response in these areas. One of the tools to support operational and policy decisions in animal health events is risk assessment, the formal process of identifying and characterizing risk as part of an overall risk analysis process (see Key Definitions, Box 1.3).

The needs and context for animal health risk assessments have changed over the last two decades. The world has transformed in ways that significantly affect the occurrence and impact of animal health events. Globalization, rapid transport, demographic shifts, increasing urbanization, and environmental changes all appear to be contributing to changes in animal health events and health events at the animal-human-environment interface. The continuing emergence and re-emergence of diseases affecting animal and human health suggest the need for a broader context for risk assessments. Social networking, electronic communications, and ready access to large volumes of information are also changing societal expectations and perceptions of risk and management of risk (Scherer & Cho, 2003; Slovic, 1993). Complex, and sometimes conflicting, stakeholder interests create challenges within the risk assessment process and influence how risk assessment feeds into the decision-making processes of all levels of government, industries, and individuals.

1.1 CHARGE TO THE PANEL

In recognition of the changing global context, the Minister of Agriculture and Agri-Food, on behalf of the Sponsor, the Canadian Food Inspection Agency (CFIA), requested that the Council of Canadian Academies (the Council) assemble a panel of experts, the Expert Panel on Approaches to Animal Health Risk Assessment (the Panel), to address the following question:

> *What is the state and comprehensiveness of risk assessment techniques in animal health science, specifically pertaining to risks which may impact human health?*

Further to the main question, the following sub-questions were posed:

- On what basis are risks prioritized and selected for assessment?
- Are risks to animal health that also impact human health (e.g., zoonoses) assessed using the same techniques employed for those impacting only animal health?

- Does animal health risk assessment contribute to prioritization, planning and coordination of integrated animal-human health research in Canada?
- What, if any, gaps exist with regard to integrated animal-human health research that may have an impact on human health?
- How do risk assessment techniques employed in Canada compare to those used by Canada's major trading partners?
- How could strategic foresight be applied to animal health risk assessment in Canada?

1.2 COUNCIL PROCESS AND RESEARCH METHODOLOGY

To address the scope of the above topics, the Council assembled a multidisciplinary group of Canadian and international experts with backgrounds in animal health, epidemiology, risk assessment, economic analysis, the agricultural industry, and other fields. The Panel's initial deliberations took place from July 2009 to October 2010, during which time it gathered and analyzed evidence through:

- expert testimony by representatives from federal and provincial government agencies engaged in risk assessment or related activities for animal, human, and environmental health (Appendix A);
- expert testimony by academic and industry experts and researchers in risk assessment (Appendix A);
- review of publicly available risk assessments conducted in Canada and around the globe;
- review of confidential risk assessments conducted by the CFIA and the Public Health Agency of Canada (PHAC);
- collection of documentation from Canada's major trading partners on their approaches to animal health risk assessment, particularly as they relate to human health risks;
- surveys of animal health researchers and risk practitioners in public and non-profit organizations;
- review of national and international literature relating to risk analysis, animal health risk assessment, and the integration of animal and human health risk assessment; and
- debate and discussion among Panel members on the interpretation of the data available.

The preliminary report produced as a result of this work was peer reviewed by academic, industry, and government experts in human health, veterinary medicine, risk assessment, and other disciplines. This final report, incorporating the feedback of reviewers, was then completed in early 2011. All content remains the responsibility of the Panel and the Council.

1.3 SCOPE OF THE ASSESSMENT

To assist in understanding the main issues of interest to the Sponsor, the Panel held several teleconferences and meetings with representatives of the CFIA to clarify the question at the outset of the assessment process. The Sponsor specified the scope of this report as pertaining to *animal health events* — as opposed to *animal product risks* — as the specific hazard of interest. For example, foodborne *listeriosis* arising from practices within processing plants was not considered to be within the scope of this assessment.[2]

In essence, the central issue put before the Panel was to assess whether the risk assessment process currently in place for animal health issues was addressing the correct risks and consequences. In other words, was animal health risk assessment in Canada employing the most effective approach for the issues facing Canada? Particular emphasis was to be placed on the assessment of animal health events (infectious, chemical, or other) and how these may affect human health, directly or indirectly. The focus was to be on risk assessment in the context of the overall risk analysis process. The sub-questions were provided for further guidance to the Panel, but were not intended to limit the scope when considering the primary question.

Although the primary question refers to risk assessment techniques, the Sponsor was not seeking, nor does this report intend to provide, a how-to guide for conducting risk assessments. Rather, the focus is on approaches (or a framework) for animal health risk assessment, particularly for animal health events that may have impacts on human health. To provide an overall analysis of the best techniques for animal health risk assessment would require a much broader and more in-depth consideration of specific techniques than is possible in this report. The Panel therefore considered the issue of quantitative and qualitative risk assessment within a broader framework, but did not address specific components within each of those broad techniques in this assessment.

[2] The Panel notes that there have been at least two recent comprehensive considerations of risk assessments for food-borne diseases (IOM, 2003; WHO, 2009a).

1.4 CHALLENGES IN CONSIDERING THE STATE AND COMPREHENSIVENESS OF ANIMAL HEALTH RISK ASSESSMENT

The Panel recognized the significant difference between the approach and nature of risk assessments routinely performed for imports (or other animal movements) that must comply with international requirements (and which lead to specific operational decisions), and of risk assessments that are conducted to help make policy decisions.

A policy decision, for example, might say that animals with a more than negligible risk of introducing disease X into Canada cannot be imported. An operational decision would say that this group of animals cannot be imported into Canada because it has a greater than negligible risk of introducing disease X into Canada. Both decisions would be expected to employ risk assessment in the decision-making process, but the requirements, constraints, implications, and stakeholder expectations would be appreciably different.

This report does not intend to provide an evaluation of the CFIA or of any other agencies providing animal health or other risk assessments. Such an evaluation would require a different set of data and a different approach than was undertaken in this report. What the Panel sought to do was to understand "the state and comprehensiveness of risk assessment techniques in animal health science, specifically pertaining to risks which may impact human health." Although the Panel reviewed the CFIA's approach to animal health risk assessment, it did not evaluate the agency's activities; the Panel also did not limit itself to a review of the CFIA's approach.

Animal health risk assessments are often conducted for the purpose of meeting international trade and import considerations. The trade environment within which Canada operates is shared to a large extent with the United States, Australia, and New Zealand (the Quadrilateral Group). Therefore, the Panel focused its comparisons on this group and the European Union, also an important trading partner and peer group member.

As the Panel deliberated, it became clear that it would be critical to put risk assessment within the fuller context of risk analysis, and, more specifically, of risk-based decision-making. The Panel first reviewed approaches to animal health risk assessment without the constraints of specific international agreements or guidelines. It then considered how such frameworks could be employed within the context of regulated risk assessments. The Panel's role did not include commenting on specific policy decisions of Canadian or international agencies.

Most stakeholders and decision-makers understand that the risk communication and risk management steps of risk analysis are value-laden. Yet the association of risk assessment with science may lead some to assume that it is objective and free of value judgments. The risk assessment process itself, however, is infused with value judgments (Brunk *et al.*, 1991). Understanding the wider social and political contexts within which risk assessments are conducted, and the impact that these contexts have on the process and the outcomes of risk analysis, is important when considering approaches to risk assessment.

Another challenge that affected the scope of the Panel's work was the obstacle of assessing the quality of risk assessments by looking at outcomes. The purpose of risk assessments is primarily to produce the information necessary to establish appropriate mitigation measures; the goal of mitigation measures is to reduce or eliminate the risk. However, the vast majority of animal health risk assessments in Canada are confidential, making it impossible to systematically compare the assessments to the outcomes. There is also little opportunity to conduct a systematic assessment of the accuracy of risk assessments, their impact on policy and operational decisions, and the impact of risk management options. Even when a risk assessment is public the ultimate outcome is influenced by the mitigation measures chosen and how effectively they were implemented. Moreover, the effectiveness and appropriateness of a risk management strategy can be measured against any number of societal expectations, many of which may not be directly related to the risk assessment that underpins the decisions. Therefore, the Panel had to look for indirect measures of the effectiveness of risk assessment processes and to apply professional, expert judgment in its considerations.

1.5 THE NEED FOR CLARITY: DEFINITIONS IN RISK ASSESSMENT

The Panel grappled early on with the comparison of the approaches applied by the animal and human health risk assessment communities. Discussions within the Panel and with invited experts were often a challenge in that there was not a commonly shared set of definitions for basic risk assessment activities. Several of the expert witnesses testified to the barriers associated with working across animal and human health risk assessment organizations at the provincial and federal levels because of communication challenges. Failure to collaborate was directly attributed to lack of a shared language (and disciplinary or organizational culture) in specific instances. Even within the Panel itself, the use of different terminology led to communication challenges. Commonly used terms, such as *risk assessment*, *risk analysis*, *surveillance*, and *consequences*, had multiple definitions, and similar steps had multiple names across different organizations (e.g., Food and Agriculture Organization of the United Nations (FAO); World Health Organization (WHO); CFIA; PHAC). The ability to determine the best approaches to animal health risk assessment, to compare animal and human health risk assessment approaches and ultimately, to have an effective integrated approach to animal-human risk assessment (when appropriate) requires the use of a common terminology. The Panel recognized that the terminology used by participants in the animal and human health risk assessment process related to a combination of historical usage, different perspectives on why risk assessments are being conducted, and the language used by the legislation or international agreements that guide their work. The challenges of different language usage and definitions are very real.

The Panel therefore established agreed-upon definitions of the most important terms that would guide discussions (see Box 1.3). Appendix B contains a more detailed explanation of the rationale for the Panel's definitions, the sources employed in helping to develop the definitions, and the current usage by some of the major international and national organizations involved with animal and human health risk assessment.

At an animal-human health symposium on H1N1 in Calgary in September 2009 it also became clear that asking the same question was as essential as speaking the same language. An apparently straightforward question on the effectiveness and appropriateness of using respirators in pig barns was soon submerged in the murky area of who was being protected — the people or the pigs.[3] Therefore, while a common language appears to be requisite for effective collaborations it is not sufficient, in and of itself.

[3] University of Calgary (Faculty of Veterinary Medicine) (2009, September 1–2). Animal and Public Health Challenges of Interspecies in Influenza Transmission: The H1N1 Experience (Symposium). Some Panel members were participants at this event.

Box 1.3
Key Definitions of Risk Assessment Terms in the Context of Animal Health[4]

Consequences: the direct and indirect, or primary and secondary, effects of animal health events and the management options selected, including effects on animal health, human health, the environment, the economy, industries, international trade, and other relevant areas.

Hazard: a risk agent (e.g., chemical, physical, or biological) or event (e.g., an animal importation) that may change the health status of an animal, human, or plant. An animal health hazard is a hazard that alters the health status of individual animals or populations of animals.[5] An animal health event is considered to have occurred when there is a change in the health status of animals, or when an event occurs that creates a high risk of a change in status. While many animal health hazards are infectious in nature, they are not exclusively infectious (e.g., lead poisoning in cattle); see also *Signal*.

Hazard identification: the process of identifying hazards (i.e., agents, events). Hazard identification is typically part of the decision process for engaging in a risk assessment within the field of animal health risk assessment.

Management options: the range of strategies and policies that risk managers and policy-makers may implement to control or mitigate risks (e.g., disallowing certain imports, requiring vaccinations, imposing temporary quarantines), as well as their outcomes. The potential consequences associated with a specific management option should be considered when completing a risk assessment.

Risk: the likelihood of the occurrence of an event and the likely magnitude of the consequences (e.g., animal, human, environmental, economic) to the system of concern following exposure to a hazard.

Risk analysis: the comprehensive process comprising hazard identification, risk assessment, risk management, and risk communication.

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4 The Panel has related these definitions to animal health events, but feels that they are generalizable across all related risk assessment areas and could form the basis for a common dialogue.

5 For the purposes of this report, and in accordance with the Sponsor's directives, the Panel considered only hazards with a direct or indirect impact on the health of animals. These include zoonotic and non-zoonotic infectious disease and toxicants such as lead or dioxins.

Risk assessment: a structured, systematic process to determine the likelihood of the occurrence of an event and the likely magnitude of the consequences following exposure to a hazard. (Note: although risk assessment employs scientific data, it is not strictly a scientific process.)

Risk characterization or estimation: the process within risk assessment where the qualitative and/or quantitative estimation, including uncertainties, of the probability of occurrence and the severity of known or potential effects (consequences) is determined.

Risk communication: the continuing, open exchange of information and opinion between risk assessors and managers, policy-makers or decision-makers, and stakeholders (including the public), at all stages of the risk analysis process.

Risk management: a systematic approach to setting the best course of action based on a risk assessment, and subsequently monitoring and evaluating the consequences of the management strategy.

Risk mitigation: steps taken to reduce the likelihood and/or magnitude of the adverse outcomes following exposure to a hazard.

Risk-based decision-making: a systematic approach to making risk management decisions based not only on consideration of the primary risk through risk assessment, but also of the consequences of risk management options. Risk-based decision-making requires risk analysis, with inclusion of likelihood, consequences, and risk management outcomes within the risk assessment.

Signal: any information that may indicate the possibility of an animal health event occurring or lead to hazard identification. For example, any of the following could be considered a signal: a decision or request to import an animal, an unusual increase in the incidence of sick animals, the occurrence of an undefined animal health event, or the diagnosis of a foreign animal disease in Canada or elsewhere. A signal leads to the suspicion or identification of a hazard.

Surveillance: the process of collecting, analyzing, and interpreting data relating to animal health hazards.

1.6 ORGANIZATION OF THE REPORT

The Panel chose to organize the report according to the major issues identified in the assessment, rather than aligning the report with the individual questions posed in the charge. The Panel recognized that a shift in perspective was required in both the overall approach to animal health risk assessment and in the relationship between risk assessment and the other components of the risk analysis process. To appreciate why necessitates an understanding of the background of risk assessment and, specifically, animal and human health risk assessment in Canada and internationally. Chapter 2 therefore outlines the history and context of animal health risk assessment, while Chapter 3 provides an overview of the current practice or state of animal health risk assessment in Canada.

The remainder of the report examines the most effective approach to animal health risk assessment in risk-based decision-making. Chapter 4, which focuses on risk-based decision-making, explains the Panel's overall consideration of the comprehensiveness of animal health risk assessment in Canada. Chapter 5 examines the identification and selection of consequences in animal health risk assessments. Chapter 6 identifies gaps in knowledge and capacity requirements in animal-human health risk assessment in Canada. Chapter 7 explores challenges in prioritization and integration of animal and human health risk assessments. Chapter 8 outlines the Panel's responses to the main question and sub-questions of the charge, based on the evidence presented in the preceding chapters.

The following bullets summarize the relationship between the sub-questions and the structure of the report:

- On what basis are risks prioritized and selected for assessment?
  - This is addressed in Chapter 7.
- Are risks to animal health that also impact human health (e.g., zoonoses) assessed using the same techniques employed for those impacting only animal health?
  - The Panel determined that similar techniques are employed, but the largest differences relate to the overall approach to risk analysis and the value context within which risk assessments are conducted and risk management decisions made. The relevant material is most fully addressed in Chapters 3 and 4.

- Does animal health risk assessment contribute to prioritization, planning and coordination of integrated animal-human health research in Canada?
  - The Panel concluded that there is no coordinated approach to integrated animal-human health research in Canada. Therefore, the Panel focused on identifying the current status of related research, as described in Chapter 6.
- What, if any, gaps exist with regard to integrated animal-human health research that may have an impact on human health?
  - The Panel identified that the gaps in animal-human health knowledge were extensive, and specific to individual risk assessments, and therefore a comprehensive cataloguing of these gaps was determined to be neither useful nor possible. Gaps that became apparent during the work of the Panel are noted in the body of the report. Chapter 6 also addresses gaps in research capacity and expertise in animal health risk assessment as an indicator of knowledge gaps.
- How do risk assessment techniques employed in Canada compare to those used by Canada's major trading partners?
  - This sub-question is addressed throughout the report.
- How could strategic foresight be applied to animal health risk assessment in Canada?
  - Strategic foresight can be a general term to describe futures planning of any description and the taking of specific strategic decisions to prepare for the future. It can be also a very specific approach to futures planning that incorporates scenario planning and the identification of specific strategic decisions to prepare an organization for multiple futures (i.e., it does not try to predict one scenario). To compare different futures processes was beyond the scope and expertise of the Panel. The Panel did, however, look at the importance of conducting risk assessments to inform policy decisions that would protect animal and human health against future threats, and not just respond to specific events. These issues are addressed in Chapters 4 and 7.

2

History and Context of Animal Health Risk Assessment

2 History and Context of Animal Health Risk Assessment

Key Message

Animal health risk assessment occurs within the context of international agreements, stakeholder expectations, and complex socio-political considerations. A structured, systematic approach ensures the appropriate consideration of risk.

Risk assessment is a structured, systematic approach to determine the likelihood of the occurrence of an event and the likely magnitude of the consequences following exposure to a hazard. Risk assessment is conducted for the purpose of making risk management and communication decisions. It is based on scientific information and employs science-based tools, but is not in itself a strictly scientific process. The context within which animal health risk assessment in Canada is carried out includes complex societal context and expectations, as well as the structured requirements of international organizations and agreements that manage international trade and risk. The state and comprehensiveness of risk assessment techniques and approaches cannot be determined without consideration of this complex environment.

People have long sought to evaluate and manage risks. The first concepts of risk assessment were developed in the 14th century by insurers looking to spread the risk of shipping goods long distance by sea among a pool of investors (Mazur, 1980). To charge the appropriate premiums, shippers needed an accurate understanding of the real risks of shipping losses. Setting premiums too high could mean an overpriced product rendering their businesses uncompetitive, while setting premiums too low could be equally ruinous because the insurance pool would be too small to cover payouts on a profitable basis. By examining historical data on shipping losses, insurers could reach reasonably accurate predictions about the scope and distribution of the losses expected on a particular shipping route.

From these early beginnings, risk assessment has matured through further applications in business, engineering, economic, and military affairs. In the 20th century, the tools and methods of risk assessment became increasingly

sophisticated. The increased use of risk assessment, which expanded during the 1960s and 1970s, has been driven largely by four factors:

1. the development of better tools, methods, and data for risk assessment (Nacht, 2001; Omenn, 2003);
2. growing public demands for a better assessment and management of the risks faced by individuals in modern society (Mazur, 1980; Rosa & Freudenburg, 2001);
3. business desires for an objective and consistent regulatory regime (Merrill, 2003); and
4. government desires for a scientific basis for formulating a regulatory regime that balances immediate public concerns with the long-term social good (Merrill, 2003; Omenn, 2003).

The development and application of risk assessment, the same as for other decision-making tools, has been challenged by three misconceptions:

1. The process will give the "right" answer.
2. It will provide an "objective" analysis that separates it from any emotional or subjective input.
3. It will take the pain out of decision-making by providing a single approach.

(Belton & Stewart, 2002)

The Panel took both the drivers and challenges noted above into account during its deliberations.

2.1 THE RED BOOK FRAMEWORK FOR RISK ASSESSMENT

The increased demands for knowledge of risks and policies to manage them appropriately prompted extensive consideration of risk assessment and management in Canada, the United States, and many other countries. The 1983 publication of the U.S. National Research Council (NRC), *Risk Assessment in the Federal Government: Managing the Process*, remains one of the seminal publications of the risk assessment process. The "Red Book," as it came to be known due to its bright red cover, was sponsored by the U.S. Food and Drug Administration (FDA). The purpose of this study was to:

- consider the feasibility of developing uniform risk assessment guidelines for use by all regulatory agencies;
- consider the feasibility of designating a single organization to do risk assessments for all regulatory agencies; and
- assess the merits of separating the analytic functions of developing risk assessments from the regulatory functions of making policy decisions (NRC, 1983; Omenn, 2003).

The NRC expert panel recommended the establishment of common guidelines for the conduct of risk assessments. It identified the steps to be followed in determining hazards, the types of evidence to be considered, and the ways in which the evidence could be explained and integrated into a "coherent, quantitative assessment of risk" (NRC, 1983; Merrill, 2003). The NRC panel also outlined a four-step framework for risk assessments: hazard identification, dose-response assessment, exposure assessment, and risk characterization (see Box 2.1). While the main focus of the Red Book was on environmental contaminants, its proposed framework, or some variation thereof, has been widely incorporated into risk assessment approaches across a wide spectrum of areas.

Box 2.1

The Four Steps of the Red Book Framework for Risk Assessment

1. Hazard identification

- Can the agent cause an adverse affect?
- What is the nature and strength of the link to causation?

2. Dose-response assessment

- What is the relationship between the dose and the incidence and severity of adverse events in humans and animals?
- What factors might affect susceptibility and severity?

3. Exposure assessment

- What is the intensity, frequency, and duration of the exposures currently experienced or anticipated under various circumstances?
- What is the magnitude and property of the emissions that result in exposures?

4. Risk characterization

- What is the estimated incidence, nature, and severity of the adverse effects of exposure in a particular population or sub-population?

Sources: Adapted from NRC, 1983, 1994; Omenn & Faustman, 2002, as reproduced in Omenn, 2003.

The NRC panel further endorsed the "intellectual premise" of separating the formal process of risk assessment from the decision-making process of risk management, including the policy choices regarding which risk should be mitigated and how (NRC, 1983; Merrill, 2003). Risk analysis is a comprehensive process, of which risk assessment is only one step. The rationale for the relative isolation of the risk assessment step was that protecting the objective *technical process* of risk assessment, as performed by expert analysts from risk management, would prevent the assessment from being unduly influenced by the *policy process* of formulating management responses that reflected social values and administrative concerns, as interpreted by government policy-makers. The NRC panel did not, however, go so far as to advocate the full "institutional separation" of risk assessment from risk management, nor did it recommend the centralization of all risk assessment activities into a single "centralized body." According to Richard Merrill, a NRC panel member, the panel thought this might "disrupt critical lines of communication, interfere with planning and management, and likely slow decision-making" (Merrill, 2003).

The Red Book risk assessment framework has been used for the last three decades. While this framework was developed primarily for addressing the risks associated with chemical exposures, and not for infectious or biological agents, most risk assessment paradigms follow some variation of this general theme. For example, the recent WHO/FAO (World Health Organization/Food and Agriculture Organization of the United Nations) document, *Risk Characterization of Microbiological Hazards in Food Guidelines* (WHO, 2009a), describes four similar steps; however, "dose-response assessment" is replaced with "hazard characterization." The World Organisation for Animal Health (OIE) steps are shown in Box 2.2. The ubiquitous use of this paradigm (or its variations) demonstrates the robustness of employing a systematic approach to risk assessment. It remains the reference point for the majority of considerations of risk assessment approaches and techniques.

2.2 CHEMICAL VERSUS BIOLOGICAL RISK ASSESSMENT

Risk assessment of animal health hazards may entail significantly different challenges than those considered in the Red Book. While chemical exposures (e.g., lead exposures and dioxin exposures from animal consumption) (Waldner *et al.*, 2002; Knowles *et al.*, 2007) can be important components of animal health risk assessments that pertain to human health, many animal health events deal with biological risk from exposure to infectious agents, and the possible transmission to other animals and humans. There are considerable differences between biological and chemical risk assessment. Using experimental models and other quantitative

systems, it is generally possible in the case of chemicals to generate dose-response information, assess quantitative exposure, and describe consequences through experimental exposure studies. There are challenges, however, when the dose-response paradigm is used as the basis for risk assessment of other types of exposures. A publication from the Institute of Medicine, *Scientific Criteria to Ensure Safe Food*, summarized the key distinctions between chemical and biological risk assessment in its chapter on "Food Safety Tools" (IOM, 2003). Some key elements include the following:[6]

1. **Hazard identification:** Hazard identification for chemical risk assessment primarily involves determining if the chemical causes adverse effects that can then be investigated in experimental systems. Hazard characterization for biological agents involves identifying the causative agents and factors, identifying exposure pathways, and considering other aspects of disease ecology. While experimental data are an important part of the process (i.e., experimental evidence is required to identify a hazard), it often relies on epidemiological or outbreak data to identify cause and infection pathways that are relevant in the real world. With chemical exposures, we are often able to identify the hazard and ask the questions before exposure actually occurs — that is, we have created a new chemical entity for use and we are now asking questions regarding its use. In contrast, infectious agents are naturally occurring and are often identified after exposure to a population has occurred (e.g., the 2009 pandemic of H1N1) and before studies have been conducted to establish exposure pathways and other aspects of disease ecology. Risk assessment (and the extent of available data) of known infectious agents will differ from risk assessment of animal health events where infectious agents are suspected but have not yet been identified.
2. **Dose-response assessment:** Dose-response curves can, in general, be established for chemical exposures. For chemicals, it may be possible to establish exposures at which no effects are observed.[7] Dose-response curves, particularly for animal-to-human transmission and secondary or indirect human health effects, are often difficult to generate because of the lack of human data and major species differences. When based on naturally occurring exposures, determining actual exposure, and thereby predicting a dose-response effect, is very difficult.

[6] These have been modified from the original reference.

[7] The principle of no observable effect levels is being challenged as we become more concerned with cumulative and synergistic effects. Moreover, it is well recognized that there are significant species differences with chemical exposures as well. An extensive discussion of this area is beyond the scope of this report.

3. **Exposure assessment:** Assessing human or animal exposure to chemicals can be complex, but it is possible to measure concentrations in the environment, determine exposure routes, assess disposition in animal models or in humans, and predict the exposure through different routes. For biological risks, predicting exposure is difficult and the results of exposures can be different. Movement of animals and humans, or movement of microbiological agents, makes locating and measuring exposures extremely difficult.
4. **Risk characterization:** This involves estimating the incidence, nature, and severity of the adverse effects of exposure in a particular population or sub-population. While there is no doubt that risk characterization for chemicals presents many challenges, in general it can be standardized more easily than for biological hazards. Dose-response relationships change as biological agents mutate, as exposure conditions vary, and because immunological host responses differ. In short, a consideration of the disease ecology, for which information is often lacking, is required. Some exposure almost always poses some risk for infectious diseases.

Animal health risk assessment paradigms have generally been modified, presumably to account for these differences. The four steps of risk assessment within the OIE *Terrestrial Animal Health Code* (OIE, 2010c), which governs animal import risk assessment, are shown in Box 2.2. *Hazard identification* could be equivalent to *release assessment*, which considers whether a particular hazard will be released into the environment. This can be either qualitative or quantitative, but is based essentially on whether a hazard exists or will exist as a result of release *(hazard identification)*. *Dose-response assessment* (the adverse effects that will occur at any given dose) has been replaced by *consequences*, which describes the consequences that occur following a defined exposure to the agent (note that this definition varies from the definition of *consequences* employed throughout this report). *Exposure assessment* specifies a consideration of the biological pathways. Within the Codex Alimentarius Commission definitions (Codex Alimentarius Commission, 2008), *hazard characterization* replaces *consequences* and *dose-response assessment*. The intent of the steps identified within each of these paradigms of — or approaches to — risk assessment is generally similar.

Box 2.2
The Four Steps to Risk Assessment Defined in the OIE *Terrestrial Animal Health Code*

Article 2.1.4 of the OIE *Terrestrial Animal Health Code* defines the four steps in risk assessment:

1. **Release assessment:** The process of describing the biological pathway(s) necessary for an importation activity to "release" (i.e., introduce) pathogenic agents into a particular environment, and estimating the probability, either qualitatively or quantitatively, of that complete process occurring.
2. **Exposure assessment:** The process of describing the biological pathway(s) necessary for exposure of animal and humans in the importing country to the hazards (in this case, the pathogenic agents) released from a given source, and estimating the probability of the exposure(s) occurring, either qualitatively or quantitatively.
3. **Consequence assessment:** The process of describing the relationship between specified exposures to a biological agent and the consequences of those exposures.
4. **Risk estimation:** The process of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset.

(OIE, 2010c)

2.3 THE CONTEXT FOR ANIMAL HEALTH RISK ASSESSMENT IN CANADA

Canada, like all its major trading partners, conducts animal health risk assessments for three main purposes: (1) to ensure that trade and commerce obligations are met in such a way that the economy is sustained; (2) to respond to urgent policy and risk management decisions; and (3) to ensure adequate preparation for future and emerging threats (review of risk assessments; interviews with experts). Most routine risk assessments are *import risk analyses*, aimed at preventing the

importation of diseased animals or infected animal products, and meeting trade obligations. The majority of risk assessments take place within a defined legislative and policy framework, designed primarily to protect and support Canadian import and export trade, and also within the context of other international agreements and organizations (Box 2.3).

The Panel spent a significant amount of time deliberating on these broad categories of risk assessment. Recognizing that import and export risk assessments are generally carried out within defined regulations (Box 2.3), the Panel then chose to focus its efforts on broader policy-oriented risk assessment. The Panel, believes, however, that the considerations discussed for policy-oriented risk assessments can also be applied in the context of import risk assessments.

As will be discussed in Chapter 7, a priority framework is required to ensure appropriate distribution of effort and to avoid unnecessarily complicated risk assessments that consider consequences that are not relevant to the assessment at hand or are not required to make the necessary operational decision. In reviewing approaches taken across the globe, it is clear that many countries are working to balance their specific needs (i.e., international trade and protecting against specific risks) with their risk assessment needs which address broader issues that help to protect animal and human health.

Box 2.3
The International Context of Animal Health Regulations

The World Health Organization (WHO) was created in 1948 to direct and coordinate health for the United Nations (UN), and is currently composed of 193 countries and two associate members (WHO, 2007). According to the WHO constitution, its primary objective is the attainment "of the highest possible level of health" for all peoples (WHO, 2010a). In order to meet this objective, the WHO conducts activities such as:

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. Shaping the research agenda and stimulating the generation, translation, and dissemination of valuable knowledge;
3. Setting norms and standards, and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalyzing change, and building sustainable institutional capacity; and
6. Monitoring the health situation and assessing health trends.

(WHO, 2006)

The WHO serves as the UN's main health authority, and is the leading agency dealing with international health issues and providing standardized regulations and protocols (WHO, 2005).

The World Organisation for Animal Health (OIE)[8] was created in 1924 by 28 countries to share information on methods to fight animal diseases and allow collaborative work to fight epizootic events, which are temporary but widespread diseases among animals (OIE, 2011a). The OIE is currently composed of 178 member countries and territories (OIE, 2011b). Its mission involves:

- ensuring the transparency of animal disease status worldwide;
- collecting, analyzing, and disseminating veterinary scientific information, and supporting international solidarity for the control of animal diseases;

[8] The acronym stands for the organization's former name, *Office international des épizooties*.

- publishing health standards for international trade in animals and animal products;
- developing the legal framework and resources of national veterinary services; and
- offering better guarantees of animal food products and supporting animal welfare based on scientific approaches (OIE, 2010b).

The OIE is recognized as the reference organization for animal health by the body that regulates international trade, the World Trade Organization (WTO). Standards developed by the OIE are intended to "harmonize sanitary and phytosanitary measures" taken by WTO members in order to facilitate trade between affiliated members (WTO, 2010a).

The Food and Agriculture Organization of the United Nations (FAO) was established in 1945 for the purpose of leading international efforts to defeat hunger. Its four main areas of activity include:

- creating and disseminating knowledge to aid development;
- sharing expertise to assist countries in promoting rural development and alleviating hunger;
- providing a neutral forum where policy-makers and experts from around the world can collaborate, share information, and form agreements; and
- mobilizing funding and managing field projects (FAO, 2010).

The FAO also collaborates with the WHO in jointly funding the **Codex Alimentarius Commission** (CAC), which governs the **Codex Alimentarius** (the "food code"). The CAC was founded in 1963 and has 180 member governments. Decisions regarding Codex regulations are made by member delegations, with input from consumer organizations, industry associations, and other stakeholders (FAO/WHO, 2010). The purpose of the Codex is to "protect the health of consumers and ensure fair trade practices." Although Codex regulations are not binding, the Codex serves as a "benchmark" for national food legislation and regulations, and is often used as a "reference text" in trade disputes at the WTO (FAO/WHO, 2010).

The World Trade Organization (WTO) was founded on 1 January 1995 but developed out of the pre-existing General Agreement on Trade and Tariffs (GATT), which had been in place since 1948 (WTO, 2010b). Currently there are 153 member countries that work together to break down trade barriers and negotiate between competing interests. Although GATT dealt primarily with exchange of goods, the WTO is expanded to also include trade in services, inventions, creations, and designs (intellectual property).

The WTO maintains an agreement on **sanitary and phytosanitary (SPS)** measures (known as the "SPS Agreement") to ensure that a country does not block trade under the guise of health protection of its citizens. The WTO SPS Agreement permits nations to set their own standards for health and safety, but those measures must be based on science. Regulations may be developed to protect human, plant, and animal life, but cannot "arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail" (WTO, 2010c).

The OIE *Terrestrial Animal Health Code*

The standard, accepted process for animal import risk analysis is set out in Chapter 2.1 of the OIE *Terrestrial Animal Health Code* (OIE, 2010c). All member nations of the OIE are advised to follow these general guidelines when conducting an animal import risk analysis. The OIE's risk analysis framework consists of four main elements: hazard identification, risk assessment, risk management, and risk communication.[9] Risk assessment (see Box 2.2), which the OIE defines as "the evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a hazard within the territory of an importing country" (OIE, 2010c), is the main topic discussed in this report (see Chapter 1 for scope of the question). The broader risk analysis process is crucial for protecting the human and animal health of the importing country, as well as its domestic industries and economy. Formalizing the process is intended to provide OIE member countries with some assurances that decisions surrounding imports are being driven by standardized assessments of risk rather than trade considerations and internal political pressures.

While the OIE sets the broad framework, each country develops its own specific approaches within this overarching structure. Individual member countries thus have some scope to establish their own domestic standards and policies, according to their needs and the requirements of other international trade agreements to which they may be a party.

[9] The OIE definition of these elements can be found in the comparative terminology table in Appendix B.

The WTO *Agreement on the Application of Sanitary and Phytosanitary Measures*

Any country that is a member of the WTO is expected to comply with WTO agreements when that country is a signatory party of such agreements. The WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* (otherwise known as the "SPS Agreement") is one such agreement.[10] It outlines the manner in which countries may establish and employ sanitary and phytosanitary measures in order to protect human, animal, or plant life. The measures must meet the following criteria:

- Measures are only applied to the extent necessary.
- Measures must be based on scientific principles.
- Measures can be maintained only while justified by science.

The SPS Agreement sets parameters within which measures may be established. Although there is latitude in which risks and the extent to which consequences are considered, there must be evidence to support any justifications of economic impact or risks to human, animal, or plant life. An example of the breadth of risk assessment that can be conducted is contained in the report of the potential economic damage caused by an incursion of *Didymosphenia geminate* as part of a risk assessment by New Zealand, which takes into account direct and indirect economic loss, and effects on native species (NZIER, 2006) (see Section 4.4).

2.4 THE EVOLVING CONTEXT OF ANIMAL HEALTH RISK ASSESSMENT

Changes around the globe are leading to reappraisal of approaches to animal health risk assessment and the organizational structures to support it. There have been many demographic and environmental changes over the last 50 years that have affected the incidence of animal health events, their impact on human and animal health, and the nature of the animal-human-environment health interface (Bowi, 2009; Veterinary Public Health, 2010; Reed *et al.*, 2003). Humans and animals are living in higher integrated population densities due to increased urbanization and shrinking wildlife habitats. The scale of agricultural operations in many areas has grown; while these larger units tend to have improved biosecurity, a larger number of animals are affected when a disease does penetrate the operation. The greater ease, frequency, and rapidity of travel for humans and animals contribute to a quicker and more extensive spread of infectious disease.

[10] The SPS Agreement has been reprinted with permission as Appendix F in this report.

Larger volume and wider variety of trade in animals and animal products, and changes in the habitats and migration patterns of animal populations, further contribute to changing risks. Climate change adds another complicating factor, as it may change the normal life cycle of animals and their pathogens, change distribution of wildlife, or cause additional stress that changes susceptibility.

Public perceptions and expectations are also changing. The internet, 24-hour-news channels, and social networking have led to rapid exchange of information. This, in turn, has not only intensified the level of public scrutiny but also has increased the ease with which misinformation can spread (Slovic, 1993; Scherer & Cho, 2003). Public officials, industry representatives, and other stakeholders in animal-human health thus need to establish the appropriate policies, keep people well informed, and make transparent decisions.

As population growth, accelerating technological progress, and increasing international trade and travel continue to "flatten" the world (Friedman, 2005), it is becoming easier for infectious diseases to spread rapidly around the globe (Wolfe *et al.*, 2007). The transmission of disease from animals to humans is influenced not only by epidemiological and human/animal health factors, but also by environmental, economic, social, cultural, and political forces.

Protecting public and animal health requires a deeper understanding of the interconnected relationship between human health, animal health, and the environment. According to one estimate, the majority of emerging diseases (75 per cent) are animal in origin (Taylor *et al.*, 2001). Consideration of chemical exposures to humans that originate in animals requires not only an understanding of the chemicals in animals, but also of the role of the environment in determining exposure to the animals and subsequently to humans if the chemicals are excreted into the environment or passed on in the food chain. The greater appreciation of species and individual differences in susceptibility to toxins and infectious agents is changing our understanding of risks, exposure-response assessments, and their impacts. Individual susceptibility can be driven by environmental and genetic factors.

The concept and understanding of our need to focus on the full range of animal-human-environment interactions, and to bring together an appropriate range of expertise, have garnered more attention in recent years. Changes in perspective on the risks of animal health events and associated risk factors have

led Canada and other countries to re-examine how to approach risk assessment for animal health events, especially those with a possible impact on human health. For example, the European Food Safety Authority (EFSA) — established to provide, on request from the European Commission, European Parliament, or European Union (EU) member states, independent scientific evidence on existing and emerging risks associated with the food chain — collects and analyzes EU-wide data on zoonotic disease (EFSA, 2010). The EFSA's Zoonoses Unit, in collaboration with the European Centre for Disease Prevention and Control (ECDC and EU member states), provides information for both risk assessors and risk managers, and actively seeks open consultation with stakeholders across animal health, human health, and the environment (Deluyker, 2011). The EFSA also undertakes risk assessments and other scientific works independent of any request — so-called self-tasks — in areas of emerging multidimensional health risks where scientific knowledge and methodologies are advancing (e.g., biosafety of antibiotic resistant marker genes) (EFSA, n.d.).

In a similar vein, Germany's Federal Institute of Risk Assessment (BfR), in its scientific assessments of potential risks from food, consumer products, and chemicals, offers advice to three different departments: Federal Ministry of Food, Agriculture and Consumer Protection; Federal Ministry for the Environment, Nature Conservation and Nuclear Safety; and Federal Ministry of Transport, Building and Urban Affairs (BfR, 2010). The current state in Canada with regard to the range of cooperation required to fully address these important interrelationships is discussed in Chapters 3 and 7.

2.5 RECENT CONSIDERATIONS OF THE RISK ASSESSMENT PROCESS

The general concept that we need to take a broader perspective in risk assessment and other global health questions has stimulated or been accompanied by other changes in risk assessment. Since the publication of the Red Book, decision-makers in North America and elsewhere have continued to struggle with the question of how best to balance the desire for objectivity with the values-based decisions inherent in risk analysis.

Periodic reviews of the practices around the world have taken place within the context of evolving scientific and political perspectives over the past three decades.

As an example of changing perspectives around the world, it is instructive to look at the evolution that has occurred in the United States, which is Canada's largest trading partner (see Figure 2.1). These examples are mostly drawn from the perspective of environmental protection (including chemical exposures) which falls under the responsibility of the U.S. Environmental Protection Agency (EPA) (EPA, 2011). The basic tenets, however, are applicable across a range of risk assessment areas. The Panel observes that three major trends are evident: a movement from qualitative to more quantitative risk analysis; a movement from no stakeholder involvement to integral stakeholder involvement; and an ongoing consideration of the relationship between risk assessment and risk management (see Figure 2.1 for a broad timeline).[11] Influenced by these themes, the evolution toward greater transparency in the risk assessment process runs from the initial work of the Red Book (NRC, 1983) through to the most recent *Science and Decisions* report (NRC, 2009).

The NRC *Science and Decisions* report (2009) recommends the engagement of all relevant stakeholders, including risk managers, prior to formally undergoing Phase 1 of risk assessment (defined as problem formulation and scoping). It suggests that the objectives and values of decision-makers and stakeholders should be clearly articulated and incorporated at the onset. This means that risk assessment effectively becomes a process that begins and ends with risk management. Unlike the Red Book, which proposed a *conceptual* — and, in many ways, a *practical* — distinction between the two, *Science and Decisions* integrates the practices of risk assessment and risk management into the paradigm of risk-based decision-making. This framework advocates that risk assessments produce readily communicable management options that "capture and accurately describe what various research findings [suggest]… but only *after* the risk-management questions that risk assessment should address have been clearly posed" (NRC, 2009). The primary driver for this integration of management and assessment was to shorten the timeline between the launch of a risk assessment, production of a final risk assessment, and appropriate management or mitigation steps. However, it also has some additional advantages in the context of a broader integrated, multidimensional approach. This concept is explored and expanded further in Chapter 4, within the context of animal health risk assessment.

[11] Readers are also directed to the May 2010 issue of *Risk Analysis* which contains a range of articles addressing similar issues. The most recent International Organization for Standardization (ISO) standards for risk assessment and risk management provide an internationally accepted methodology that specifies uniform terminology, performance criteria, and a common process for identifying, analyzing, evaluating, and treating risks (ISO, 2009a, 2009b; Purdy, 2010). These and other works cited in Figure 2.1 illustrate the evolving trends in the recent history of risk assessment and risk management.

1980s

1983
National Research Council's (NRC) ***Risk Assessments in the Federal Government: Managing the Process*** (1983), also known as the "Red Book," urges a "conceptual separation" of risk assessment and risk management. Also defines "four steps of risk assessment practice," and recommends "uniform inference guidelines" be adopted by federal regulatory agencies involved in risk assessment (Johnson & Reisa, 2003).

1994
NRC's ***Science and Judgment in Risk Assessment*** (1994) recommends that the use of "conservative default options" in risk assessments conducted by the Environmental Protection Agency (EPA) continue in areas where there is "an absence of convincing scientific knowledge," but with an "iterative approach" to risk assessment. It further advises that the reporting of risk assessments should include "the sources and magnitudes of uncertainty" associated with estimates. Such an approach, it says, would lead to a more "appropriate blending" of risk assessment and risk management, and assist in improving the scientific foundations of risk management policy decisions over time (NRC, 1994).

1990s

1996
NRC's ***Understanding Risk: Informing Decisions in a Democratic Society*** (1996) cautions policy-makers to "resist the temptation" of using risk assessments as "substitutes for informed and appropriately broad-based deliberation in weighing conflicting values." It further contends that increasing stakeholder involvement not only improves policy, but also makes for "better science" (Stern, 1998; NRC, 1996).

1997
Presidential/Congressional Commission on Risk Assessment and Risk Management delivers its ***Final Report*** (1997), embodying "two crucial concepts:" (1) that each "environmental problem or issue" should be placed into its "public health and/or ecological context;" and (2) that the "relevant stakeholders, especially affected or potentially affected community groups," should be "proactively engaged" throughout the risk assessment and risk management processes (Omenn, 2003).

2000s

2002
NRC's ***Estimating the Public Health Benefits of Proposed Air Pollution Regulations*** (2002) advocates that risk-reduction health benefits analyses conducted by the EPA present "a realistic range of options" for decision-makers, examine foreseeable and reasonably significant "unintended secondary effects," and communicate findings in ways that are clear, concise, and place quantitative findings into a qualitative context (NRC, 2002, 2009).

2009
NRC's ***Science and Decisions: Advancing Risk Assessment*** (2009) establishes a three-phase "framework for risk-based decision-making." It calls for a more robust approach to "problem formulation and scoping" (Phase I), so as to ensure that the "level and complexity of risk assessment" (conducted in Phase II) are aligned with "the goals of decision-making" (or "risk management") in Phase III. Its framework further provides "a formal process for stakeholder involvement throughout all stages," while recognizing "time constraints" should be embedded to keep the process moving and that the "conceptual distinction" between risk assessment and risk management should be maintained to ensure the integrity of the process. Moreover, the report notes the importance of "making uncertainties and choices more transparent" in the interests of fostering better decisions (NRC, 2009).

(Council of Canadian Academies)

Figure 2.1
U.S. Policy Reviews Relating to Risk Assessment Over the Last 30 Years

2.6 MANAGEMENT OF ANIMAL AND HUMAN HEALTH RISK ASSESSMENT IN CANADA

In Canada risk assessment of animal, human, and environmental health events can occur at the federal, provincial, and municipal levels of government. The Panel consulted with a variety of representatives from the provincial and federal governments, from multiple agencies and departments (see Appendix A). Surveillance and risk assessment of animal and human health occurs across a range of levels of governments and departments, agencies, and institutions; these groups have disparate and, in some cases, specific mandates. While it was apparent that all levels and many different groups within governments may engage in risk assessments, the Panel was only able to uncover a few examples of close coordination among the various levels in conducting risk assessments. A clearly defined responsibility to conduct risk assessments seemed to exist only at the federal government level. Because risk assessments at other levels tended to be sporadic, the Panel concluded that a systematic assessment of these activities was neither feasible nor would it provide insight into the "state and comprehensiveness of risk assessment" in Canada.

At the federal level, three main agencies are involved in animal and human health risk assessment: the Canadian Food Inspection Agency (CFIA), the Public Health Agency of Canada (PHAC), and Health Canada. Fisheries and Oceans Canada, Department of National Defence Canada, Natural Resources Canada, and some other agencies also conduct specific risk assessments (interviews with experts). Representatives and documents from these other agencies were consulted and broadly informed the Panel's understanding of risk assessment conducted by federal and provincial organizations in Canada.

The role of Health Canada has become very limited with respect to animal health risk assessment since the formation of the CFIA and the PHAC. Health Canada focuses on health products and drugs (Health Canada, 2007), which are not within the scope of this assessment. Therefore, to assess the current state and comprehensiveness of animal health risk assessment in Canada, and its relationship to human health, the Panel focused its attention primarily on the PHAC and the CFIA. In its discussions with these two organizations, an important philosophical difference in their approaches to risk assessment was identified. The CFIA undertakes risk assessments most commonly to support operational decisions (interviews with CFIA staff), while the PHAC may undertake risk assessments to identify gaps in knowledge or appropriate practice (interviews with expert witnesses).

Canadian Food Inspection Agency

Although the CFIA has only been in existence since 1997, the basic functions and responsibilities that fall within its mandate have been exercised within the federal government for more than a hundred years, beginning with the *Contagious Diseases in Animals Act* of 1869. Historically, the surveillance, inspection, and quarantine programs related to food safety, and animal and plant health were the shared responsibility of Health Canada, Agriculture and Agri-Food Canada, Industry Canada, and Fisheries and Oceans Canada (Evans, *et al.*, 2003). As of 27 March 1997, these responsibilities were consolidated and delegated to the newly minted CFIA (Evans, *et al.*, 2003).

Specifically, in carrying out its mandate, the CFIA strives to:

- protect Canadians from preventable health risks;
- protect consumers through a fair and effective food, animal, and plant regulatory regime that supports competitive domestic and international markets;
- sustain the plant and animal resource base;
- contribute to the security of Canada's food supply and agricultural resource base; and
- provide sound agency management.

(CFIA, 2010a)

The CFIA's activity generally focuses on areas such as: food safety, biotechnology regulation, export certification and import controls, domestic plants and animal surveillance,[12] and disease response strategies (CFIA, 2010a). In terms of animal health, the CFIA is concerned with areas such as conducting disease surveillance, maintaining import standards and controls for animals and animal products, verifying that exports meet foreign requirements, and developing biosecurity standards with industry organizations, provincial/territorial governments, and academia (CFIA, 2010a). The CFIA is the central authority for the surveillance, prevention, control, and eradication of foreign *reportable* animal diseases in Canada (CFIA, 2010a). These activities support or require risk assessment. Within the CFIA, there are several branches that share responsibility for these and other areas (CFIA, 2010b; see Appendix C).

The CFIA also works formally and informally with a variety of partners to achieve its mandate. For example, Box 2.4 summarizes the other government departments and organizations that contribute to surveillance activities in Canada. This illustrates that even though the CFIA is the primary organization carrying out animal health risk assessment in Canada, it depends on a variety of formal and informal partners in carrying out its mandate.

[12] The identification of risks associated with outbreaks in wildlife and the overall health of wildlife are the collaborative responsibility of the CFIA, Environment Canada, the Canadian Cooperative Wildlife Health Centre, and the relevant provincial/territorial departments and agencies (CFIA, 2010a; CCWHC, 2011).

Box 2.4
Animal Disease Surveillance in Canada

The **Canadian Food Inspection Agency** (CFIA) is the main federal agency responsible for gathering information on animal disease. Under the terms of the *Health of Animals Act* (Minister of Justice, 1990) and associated regulations (Minister of Justice, 2009), veterinarians, laboratories, and animal owners are required to immediately report certain diseases to the CFIA. These diseases, classified as *reportable diseases*, have been identified by federal authorities as being of significant importance for the protection of human health, animal health, or the Canadian economy. These include both exotic and indigenous diseases (CFIA, 2010c).

In addition to reportable diseases, other diseases of importance are classified into two groups:

1) *Immediately notifiable* diseases are "diseases that are exotic to Canada [and] for which there are no control or eradication programs."
2) *Annually notifiable* diseases are "diseases for which Canada must submit an annual report to the World Organisation for Animal Health (OIE)."

(CFIA, 2010c)

The information gathered assists the CFIA in taking appropriate measures in disease containment and eradication. It also supports Canada in meeting its obligations toward the international community, especially regarding requirements of the OIE (CFIA, 2010c).

Disease specific surveillance programs that involve the CFIA and other stakeholders are also in place. The Canadian Notifiable Avian Influenza Surveillance System (CanNAISS), which monitors H5 and H7 sub-types of avian influenza in Canadian poultry, is one example that includes participation from both industry and farmers (CFIA, 2010d). Another example is the bovine spongiform encephalopathy (BSE) enhanced surveillance program, which takes samples from the Canadian cattle herd in order to detect infected animals (CFIA, 2011a).

Industry-run animal identification programs such as the Canadian Cattle Identification Agency (CCIA) (CCIA, 2009) and the Canadian Sheep Identification Program (CSIP) (CSF, n.d.) further support animal disease surveillance. Both the CCIA and the CSIP are industry-led, non-profit organizations that develop trace-back systems to help in containing and eradicating cattle and sheep diseases.

Networks and centres with specific mandates are further contributors to animal health surveillance at the federal level. Examples include the following:

- The **Canadian Animal Health Surveillance Network** (CAHSN), led by the CFIA's Director of the National Centre for Foreign Animal Disease, is a partnership between federal, provincial, and university laboratories. The CAHSN serves as a network of collaborating laboratories whose main objective is to develop the capacity to detect emergent animal diseases that are of particular threat to human health. The information gathered is shared with both human and animal health agencies (CFIA, 2009a).
- The **Canadian Cooperative Wildlife Health Centre** (CCWHC) is a partnership encompassing Canada's five veterinary colleges, as well as numerous federal agencies, provincial and territorial governments, and non-government organizations. The CCWHC is dedicated to wildlife conservation, management, and disease surveillance. Its integrated disease surveillance system is composed of four distinct, but closely related, activities: detection of diseases, identification of diseases (diagnosis), disease information management, and communication (CCWHC, 2010).

Provincial and territorial governments have a major role in animal health surveillance as well. Each provincial/territorial government has an Office of the Chief Provincial Veterinarian (or equivalent) responsible for areas such as animal health disease surveillance, food safety, and animal welfare (Government of Alberta, 2011; Government of Manitoba, n.d.). In addition to collaborating with national organizations and programs involved in animal health surveillance, several provinces and territories have provincial surveillance organizations and programs (e.g., Alberta Veterinary Surveillance Network; Ontario Animal Health Surveillance Network).

Municipal governments contribute to animal health surveillance through their surveillance role for diseases in wildlife and companion animals. Many municipal governments maintain a department responsible for animal care and control (e.g., the City of Edmonton Animal Care and Control Centre and the City of Ottawa Animal Care and Control). Such departments typically operate in conjunction with local community organizations and other levels of government to promote animal health and welfare, as well as to collaborate on disease surveillance.

Community-based animal disease surveillance is developing in Canada. Rural communities participate in the design of programs they require for local health and economies, and also participate in the sampling, analysis, and use of the resulting information. Examples include surveillance for Trichinella in country foods carried out through the Nunavik Research Centre, Quebec (Makivik Corporation, 2011), and a more general wildlife health surveillance program established by the Sahtu Nation, Northwest Territories, in collaboration with the CCWHC at the University of Calgary (Sahtu Monitoring Project, 2010).

The Policy and Programs Branch of the CFIA contributes to guiding policies and risk management options, and the Science Branch provides research and advice for senior management (interviews with experts). As part of the Science Branch, the Animal Health Risk Assessment (AHRA) unit conducts risk assessments, predominantly relating to imports but also including issues relating to animal-human health (e.g., BSE and H1N1 risk assessments) (CFIA, 2011b).

The responsibilities of these and other branches of the CFIA enable Canada to meet its obligations to international authorities such as the WHO and the OIE (see Section 2.2 and Box 2.3). These international trade obligations largely determine the work in which the CFIA engages. Although the CFIA has some responsibilities related to public health, it does not have the primary responsibility to directly assess the human health outcomes of animal health events (interviews with CFIA staff). The Panel observed that this leads to variable consideration of human health consequences (see Chapters 3 and 5).

Public Health Agency of Canada

The delivery of health care and public health services was identified as a provincial responsibility in the 1867 *British North America Act*, now part of the Constitution of Canada, while the provision of safe food and the prevention of the importation of communicable diseases were deemed federal responsibilities (Tiedemann, 2006). The federal government, through Health Canada, is also "responsible for protecting Canadians against risks to health and the spread of diseases," and should assist in a crisis such as infectious disease outbreak (Tiedemann, 2006). The complexity of these interwoven responsibilities was reflected in the 2008 *Report of the Auditor General of Canada*, which emphasized the need to both coordinate federal, provincial, and territorial approaches to public health issues, and to clarify these roles and responsibilities, in particular with respect to health surveillance (Auditor General of Canada, 2008).

The challenges that emerged during the response to the 2003 outbreak of severe acute respiratory syndrome (SARS) underscored the need to improve coordination among public health organizations in Canada (Tiedemann, 2006). Several reports that examined the efficacy of the public health response to SARS, most notably the National Advisory Committee on SARS and Public Health (commonly referred to as the "Naylor Report") (Health Canada, 2003),[13] recommended the establishment of a pan-Canadian public health agency. In September 2004 the PHAC was created by order-in-council, and subsequently by legislation in December 2006 via the *Public Health Agency of Canada Act* (PHAC, 2006a). As the main federal agency responsible for public health, the PHAC supports approximately 2,400 researchers and staff, as well as a wide variety of programs and services offered by both the federal government and non-government agencies across Canada (PHAC, 2008a).

The PHAC's primary goal is "to strengthen Canada's capacity to protect and improve the health of Canadians, and to help reduce pressures on the health care system." This is accomplished by a five-pillar approach:

- promote health;
- prevent and control chronic diseases and injuries;
- prevent and control infectious diseases;
- prepare for and respond to public health emergencies; and
- promote public health capacity.

(PHAC, 2008b)

The risk assessment process at the PHAC is largely focused on direct human health outcomes with less emphasis on the economic or socio-cultural impacts (interviews with experts). Moreover, the PHAC is only concerned with animal health insofar as it contributes to general public health (interviews with experts). The Panel's discussions with the PHAC representatives and its review of public documents indicated that the PHAC does not yet have a clearly defined, systematic risk assessment process (CPHO, 2010), and it has conducted very few risk assessments relevant to animal-human health risk assessment. Although the Panel did review some risk assessments related to the 2009 H1N1 pandemic, it did not conduct a wider systematic review due to limited availability of assessments.

[13] Also see, Ontario SARS Commission, *SARS and Public Health in Ontario* (Toronto: Ministry of Health and Long-Term Care, 2004); and Ontario Expert Panel on SARS and Infectious Disease Control, Initial Report (Toronto: Ministry of Health and Long-Term Care, December 2003).

CFIA/PHAC Collaborations

It is not always clear how responsibilities in the risk assessment arena, where there are human-animal health interactions, are delineated between the CFIA and the PHAC. Although certain responsibilities may overlap, the overarching mandates of the two organizations that elicit these responsibilities are distinct. The CFIA undertakes surveillance to help ensure that animal diseases transmissible to humans are controlled within animal populations (CFIA, 2011c), whereas the PHAC performs surveillance only in the context of public health (PHAC, 2011a).

In the context of a zoonotic disease outbreak, two sub-agencies of the PHAC play crucial roles in linking federal and provincial/territorial efforts, and in seeking to integrate animal and human health. First, the Centre for Infectious Disease Prevention and Control (CIDPC) is responsible for the international reporting of the Canadian situation, expert and international consultation, and human resources to support outbreak response (PHAC, 2006b). The CIDPC liaises with the involved provinces and territories to ensure that technical advice provided to the CFIA and Workplace Health and Public Safety Programme (WHPSP) is consistent with recommendations being provided by the provinces and territories and local public health authorities (PHAC, 2006b). Second, the National Microbiology Laboratory (NML) consults with the CIDPC and provincial and territorial public health authorities on recommendations for the collection, transportation, and reporting of human laboratory specimens and tests, and on facilitating appropriate and timely management of outbreak specimens (PHAC, 2006b). In addition, the NML then conducts laboratory testing, including virus isolation and characterization, and provides reagents and diagnostic testing kits (PHAC, 2006b).

The 2008 *Report of the Auditor General of Canada* noted that the CFIA and the PHAC have not "determined jointly which of the animal diseases that could affect people are the highest priorities for surveillance, and which of the two agencies will carry out surveillance of what diseases." Specifically, the report recommended that "to improve their ability to anticipate and control zoonotic diseases, the Public Health Agency of Canada and the Canadian Food Inspection Agency should jointly assess the possible risks to human and animal health, clarify how the responsibilities will be divided, and act on joint surveillance objectives and priorities" (Auditor General of Canada, 2008).

Similar concerns were echoed in the 2010 *Audit Report on Emergency Preparedness and Response* of the Chief Public Health Officer, which called upon the PHAC to "develop a long-term comprehensive risk and threat assessment process," and to improve the sharing of surveillance information among its various partners and stakeholders (including the CFIA) (CPHO, 2010). The 2010 *Report of the Auditor General of Canada* also further urged the CFIA to "set priorities based on risk, for completing hazard-specific plans and procedures for dealing with higher risk diseases" (Auditor General of Canada, 2010).

In response to these recommendations, the CFIA and the PHAC have recently worked toward increasing collaboration, and have organized several joint conferences aimed at both increasing the degree of interaction and minimizing duplication in surveillance and assessment efforts.[14] From discussions with CFIA and PHAC officials, the Panel noted that although there is a commitment to integrating animal and human health, the best mechanisms remain unclear. There are, for example, a number of different approaches that can be taken to "jointly assess" risks, and such approaches are among the considerations in this report (see Chapter 7).

[14] Note the collaboration on the H1N1 risk assessment, and the conferences and events listed at http://forecan-precan.ca/ and http://www.phac-aspc.gc.ca/publicat/2009/er-rc/index-eng.php

Review of Key Findings

- The general approach to risk assessment comprises four related steps, the description of which varies among organizations (see Appendix B). Some examples include:
  - hazard identification/release assessment
  - dose-response/consequence assessment
  - exposure assessment
  - risk characterization/estimation
- The CFIA conducts animal health risk assessments primarily to meet international trade obligations and to support immediate operational decisions that protect animal and human health. Risk assessments are also conducted to support policy decision-making that protects against current and future threats to animal and human health.
- The context in which animal health risk assessments are conducted is evolving as demographic, economic, societal, and environmental (climate) changes occur globally.
- Historically, risk assessment and risk management were separated. Currently, there is a shift to increased interactions between risk assessors and risk managers, and greater stakeholder input during the risk assessment process in order to improve efficiency and to ensure that the full range of management options and their consequences are considered.
- There is growing recognition of the need to consider the full range of consequences of animal health risk assessments (see Chapter 5).
- In Canada the CFIA is the main federal agency with responsibility for conducting animal health risk assessment. The PHAC is the main federal agency responsible for conducting human health risk assessment. The two agencies are seeking to improve collaboration in order to employ collective resources with maximum efficiency and effectiveness to address animal-human health interactions.

3

Current Practice in Animal Health Risk Assessment in Canada

3 Current Practice in Animal Health Risk Assessment in Canada

Key Message

Animal health risk assessment in Canada is built on a solid foundation of knowledge and expertise. The CFIA conducts systematic risk assessments within a structured risk analysis framework that is consistent with international guidelines. The majority of risk assessments are qualitative, import risk assessments.

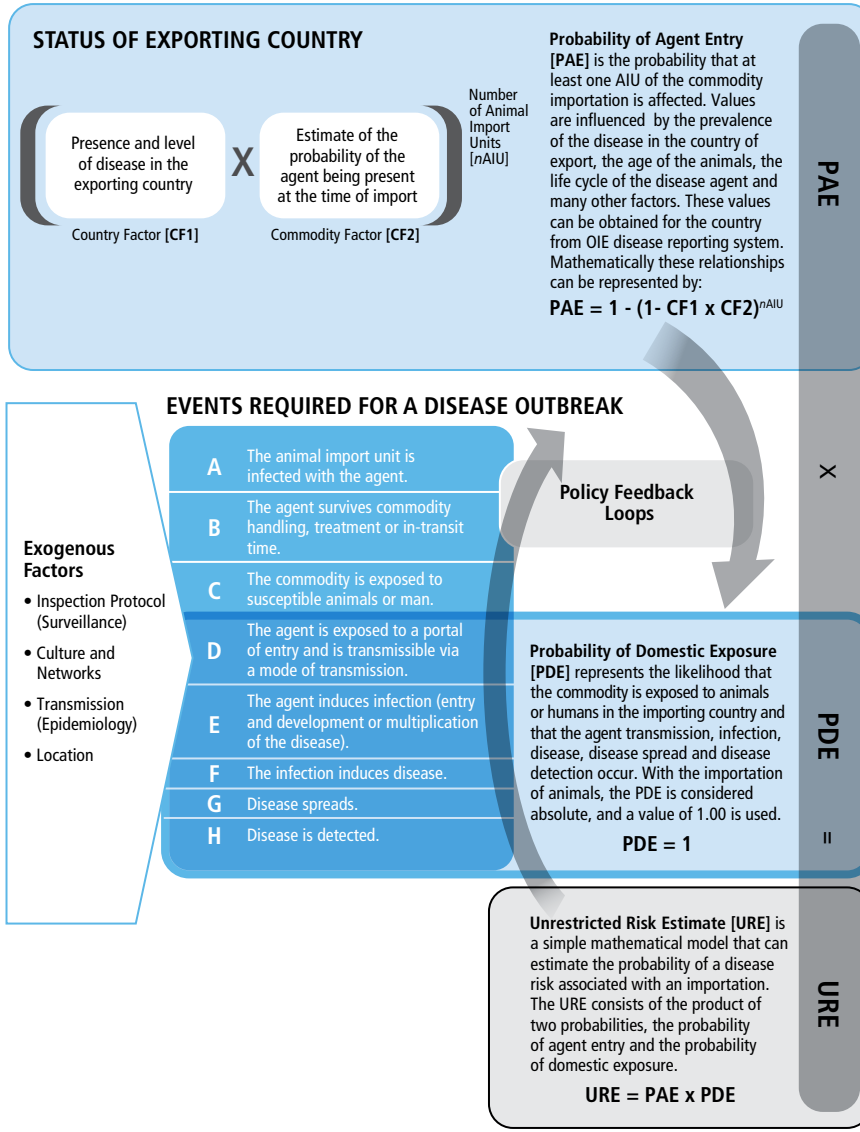
The Canadian Food Inspection Agency (CFIA) is the main federal institution responsible for animal health import risk assessment (CFIA, 2010a). Other organizations (e.g., government, industry, academic) also contribute to the risk assessment process at the CFIA, and conduct or sponsor independent risk assessments. Nevertheless, given its important role, a review of CFIA's activities remains essential background to understanding animal health risk assessment in Canada. The Panel reviewed public CFIA documents pertaining to its risk assessment practices, reviewed available literature describing risk assessments and risk assessment techniques employed by the CFIA, met in person and by teleconference with CFIA representatives, and reviewed in depth 30 randomly selected animal health risk assessments conducted by the CFIA between 2007 and 2009. The Panel recognizes that even during the period of this assessment, the CFIA was continuing to evolve its approach and its practices.

3.1 THE FOUNDATIONS FOR IMPORT RISK ASSESSMENT IN CANADA

From the early 1990s to the early 2000s, the foundations for an objective, structured, and transparent approach to risk assessment were outlined in two papers published in the OIE's *Revue scientifique et technique*. Randy S. Morley, at that time with the CFIA's predecessor organization, the Animal and Plant Health Directorate of Agriculture Canada, presented a mathematical model to assess the risk of the occurrence of disease associated with animal or animal product importation (Morley, 1993). Starting from the premise that the total risk of disease to an importing country actually consists of a series of intermediate events leading to a risk, Morley constructed a probabilistic model that incorporated the animal

health conditions of exporting countries; the epidemiological characteristics of disease agents; the potential for domestic exposure and susceptibility; and the role played by surveillance, inspection, and control policies (see Figure 3.1 and Box 3.1). This framework provides the unrestricted risk estimate (URE). More precisely, URE estimates "the risk associated with the importation of a commodity in the usual commercial form" (Morley, 1993). URE is the product of two probabilities: the probability of agent entry (PAE) and the probability of domestic exposure (PDE).

Subsequently, Morley *et al.* (2003) gave an overview of the World Organisation for Animal Health (OIE) risk factors to determine the bovine spongiform encephalopathy (BSE) status of countries, and demonstrated the application of the OIE's BSE guidelines using a risk assessment. This assessment included a specific set of events (or criteria) recommended by the OIE, and incorporated the mathematical model of the previous paper into the steps of a full risk assessment (hazard identification, release assessment, exposure assessment, consequence assessment, and risk estimation). This paper also demonstrated that the risk estimate, which included the release, exposure, and consequence assessment, indicated that the probability of BSE introduction and establishment as an epidemic in Canada was negligible, and would support limited risk management intervention. The consequence assessment, of direct and indirect consequences, however, demonstrated that the economic consequences would be extreme.



(Council of Canadian Academies)

Figure 3.1

Representation of Morley's Model for the Assessment of Disease Risks Associated with the Importation of Animals

Box 3.1
Technical Description of Morley's Model for Import Risk Assessment

The probability of agent entry (PAE) is the probability that at least one unit of the imported animal or animal product (commodity) is infected with a disease agent. This probability is a function of three factors: disease prevalence in exporting country (CF1), likelihood of disease agent survival as of time of import (CF2), and the number of animal import units (*n*AIU). The first factor, CF1, is determined by country-specific factors such as demography, climate, culture, poverty levels, and disease-relevant policies. This factor is calculated according to the recorded OIE data on outbreak occurrences, herd sizes, and epidemiological characteristics within the exporting country. The second factor, CF2, is an estimate of the probability of the agent being present at the time of import and is calculated based on the epidemiology of the disease agent, the transportation time, animal characteristics, and, for animal products, the production process. The final factor, *n*AIU, is a count of the quantity of animals or animal products that are imported; as this quantity increases, the likelihood of agent entry (PAE) increases.

For a disease outbreak to happen, a series of events needs to occur. Although each disease and importation has a specific series of events, a generic list can be established (see Figure 3.1, A-H). Those events, in turn, can be influenced by several factors (e.g., infectivity of agent, virulence of the disease). The probability of domestic exposure (PDE) "represents the likelihood that the imported commodity is exposed to animals or humans in the importing country and that agent transmission, infection, disease, disease spread and disease detection occur" (D-H on the figure). When importing animals, the value of PDE is considered absolute and is given the value of 1.00.

The unrestricted risk estimate (URE), the product of PAE and PDE, evaluates the risks associated with the importation of an animal or animal product. The "word 'unrestricted' represents the risk before selecting and applying any risk reduction options" (i.e., the risk that exists prior to any risk management interventions). The usefulness of this probabilistic model resides in its use of best available data, which can then be used in a quantitative risk assessment.

(Morley, 1993)

3.2 ANIMAL HEALTH RISK ANALYSIS PROCESS AT THE CFIA[15]

Animal health risk analysis at the CFIA is described in the *Protocol of the Animal Health and Production Division and Animal Health Risk Analysis, Science Advice, and Biohazards Division* (CFIA, 2005). Risk analysis is the comprehensive approach that includes hazard identification, risk assessment, risk communication, and risk management (see Figure 3.2). It is important to understand how risk assessment fits into this process.

The first steps in the risk analysis process are undertaken to determine if a formal risk assessment is required. As shown in Figure 3.2, the risk manager is involved early in the process to determine if a risk assessment is indeed required. The following are considered.

Request for Importation

Every request for import must go through the risk assessment process if no import policies exist, or if no risk assessment has been done for this particular commodity or activity (CFIA, 2005; interviews with CFIA staff).

Process Initiation (Risk Assessment Request)

If a risk assessment is required, an Operations Officer will inform the importer and gather the necessary information to begin the process (e.g., rationale and background for the request; description of the commodity to be assessed; volume, quantity, and frequency of import; and timeframe associated with request). The importer must provide this information and pay a fee for the risk assessment to be completed. Once these steps have been completed, the National Manager of the Animal Health Risk Assessment (AHRA) unit determines the priority of the risk assessment and the resources that will be applied to conducting it.

Hazard Identification

This phase of the risk analysis process involves identification of "biological agents that could be introduced with a commodity or activity, and for which pathways exist for exposure of the agents to susceptible animals and humans" (CFIA, 2005). Inputs for this process include:

- information gathered from the internal knowledge and expertise of CFIA staff; and

[15] The following section is based on *Protocol of the Animal Health and Production Division and Animal Health Risk Analysis, Science Advice, and Biohazards Division* and interviews with CFIA staff.

- a *Disease Status Evaluation of the Country/Region/Zone*, in which the disease status of the origin of the import is assessed, including:
  - an *Evaluation of Veterinary Services*, in which the veterinary infrastructure of the origin of the import is assessed; and
  - an *Evaluation of Surveillance and Monitoring of Animal Health*, in which the surveillance infrastructure of the origin of the import is assessed.

Based on the above, a priority is established and a decision to complete a formal risk assessment is taken (CFIA, 2005; interviews with CFIA staff).

Risk Assessment

The request for import then enters the formal risk assessment process, as defined by the OIE. All risk assessments include an extensive literature review about the commodity or activity in question, in addition to the other steps of the risk assessment framework (i.e., release assessment, exposure assessment, consequence assessment, and risk estimation) (see Figure 3.2). This process is guided by several principles, which are shown in Box 3.2.

Review Process

All risk assessments are internally reviewed by a risk manager. Managers may also decide to request external consultations or reviews if they are unsure of the final results or information contained in the risk assessment (CFIA, 2005; interviews with CFIA staff).

Risk Communication

Risk communication is defined by the CFIA as "the continuing, open exchange of information and opinion between risk assessors and managers, policy-makers or decision-makers, and stakeholders (including the public), at all stages of the risk analysis process" (CFIA, 2005). Elements of risk communication include stakeholder involvement, risk manager involvement, and other internal and external consultations. It is important to note that risk communication occurs throughout the risk assessment process as well as on completion.

Stakeholder Involvement

For most of the risk assessments completed by the AHRA unit, the clients (or stakeholders) do not have direct contact with the risk assessors. Clients deal with the Operations Officers, who are responsible for preparing the risk assessment request. If risk assessors require further information about the request, they make contact with the Operations Officer who in turn contacts the client (stakeholder) directly. This indirect method of communication is meant to insulate risk assessors from conflict, bias, or pressure in the risk assessment process from the stakeholder. Once a draft version of the risk assessment is completed, the client has another opportunity to provide feedback.

Risk Manager Involvement

Risk managers typically provide input to risk assessors throughout the risk assessment process, usually in the form of verifying the accuracy and scope of information contained in the risk assessment, providing comments on the work to date, or requesting further information within the risk assessment.

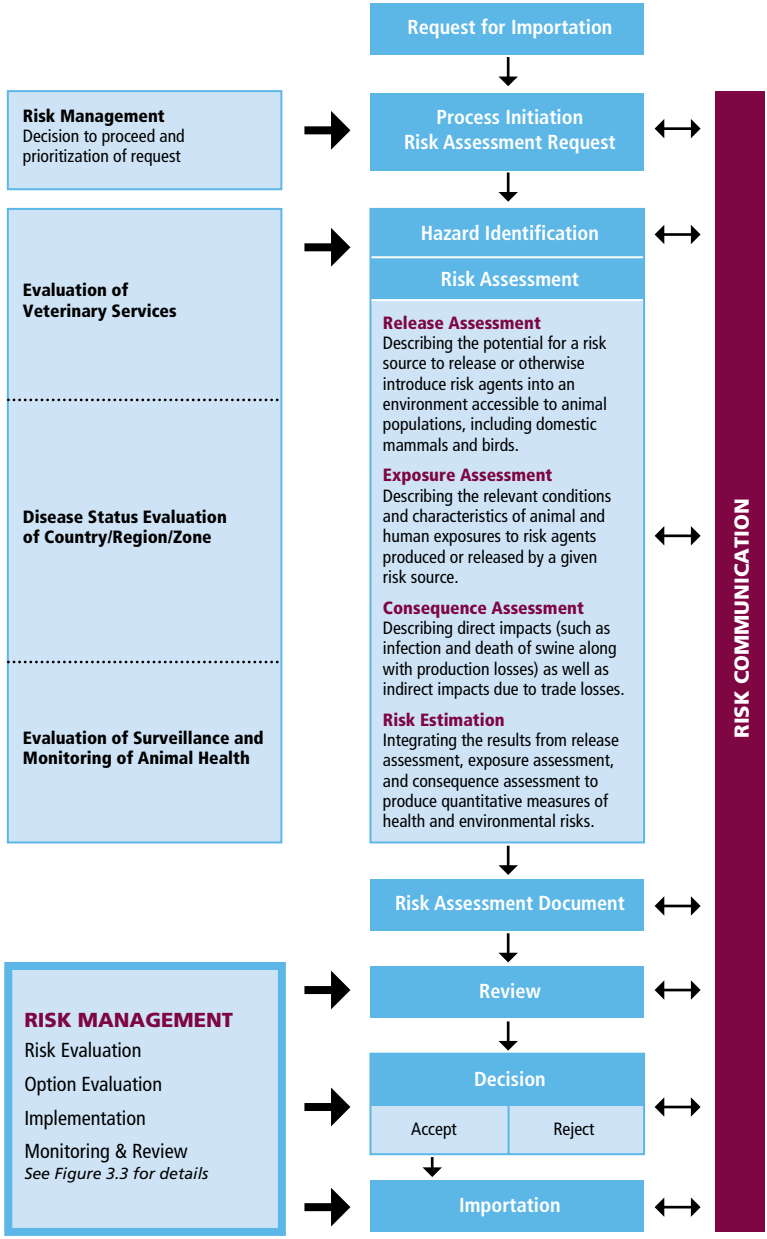
Other Internal and External Consultations

These include consultations with experts internal to the CFIA (but external to the AHRA unit), as well as outside experts or organizations, to either verify data, gather new data, or review the analysis.

Even after the risk assessment is completed, risk communication and risk management continue.

Decision

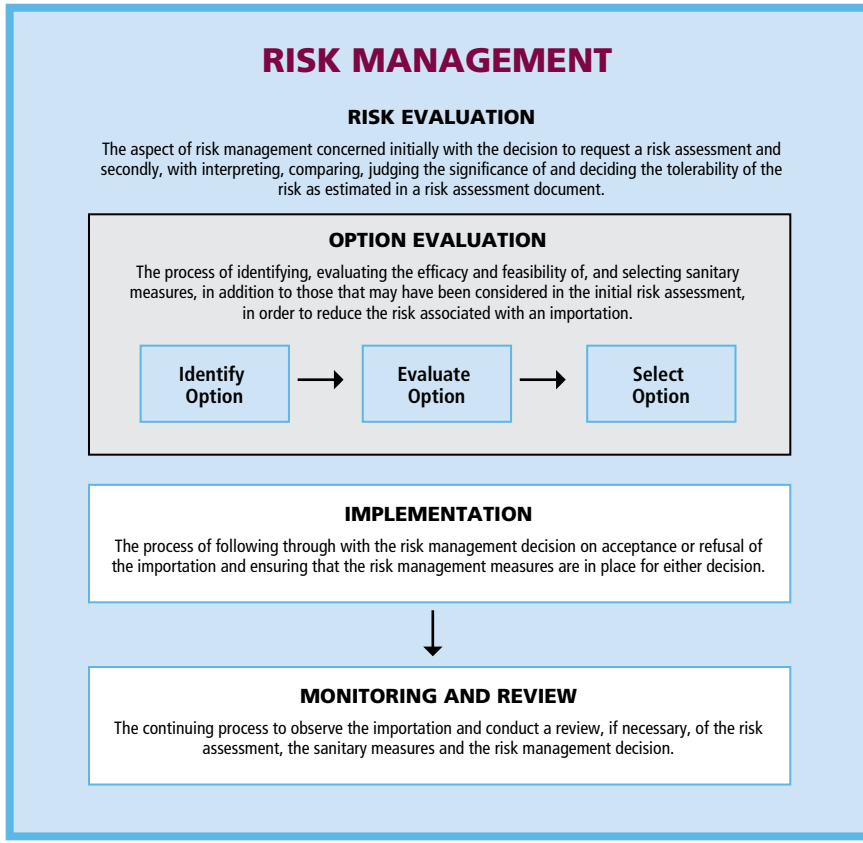
Upon completion of the review process, the draft document is finalized and a decision is made on whether to accept or reject the import. This decision takes into account the possibilities considered in the risk management phase, including option identification, evaluation, and selection (see Figure 3.3). The decision is then implemented, monitored, and reviewed.



(Adapted from: CFIA, 2005)*

Figure 3.2

Import Risk Analysis Process for Animals and Animal Products at the CFIA



(Adapted from: CFIA, 2005)*

Figure 3.3

The Elements of Risk Management

Box 3.2
CFIA Principles for Risk Assessment

1. Risk assessment should be flexible to deal with the complexity of real-life situations.
2. Both qualitative and quantitative risk assessments have merit.
3. An organizational arrangement that separates risk assessment from risk management decision-making is encouraged to ensure that the risk assessments are not influenced to fit prior regulatory conclusions.
4. The risk assessment should be based on the best available information that is in accord with current scientific thinking.
5. Consistency and transparency in risk assessments should be encouraged in order to ensure fairness and rationality, comparison of risks, and ease of understanding by all the interested parties.
6. Risk assessments should illustrate the uncertainty in the risk estimation output.
7. Generally the estimates of risk increase with increasing volume or quantity of commodity imported.
8. The risk assessment should be amenable to updating when additional information becomes available.

(CFIA, 2005)

3.3 THE CURRENT PRACTICE OF ANIMAL HEALTH RISK ASSESSMENT AT THE CFIA

In early 2010 the Panel reviewed a sample of 30 risk assessments conducted by the CFIA's AHRA unit between 2007 and 2009. This review was not undertaken to evaluate either individual risk assessments or the overall work of the AHRA unit, but rather to gain a better understanding of the actual practice of animal health risk assessment at the federal level in Canada. The Panel examined the reasons for the risk assessments, whether they were qualitative or quantitative, the range of consequences considered, and other relevant data.

Overall Available Data

Between 2007 and 2009, the AHRA unit produced 46 risk assessments, 37 scientific advices and similar documents, and numerous other products (e.g., country evaluations, training sessions, and conference presentations) (see Box 3.3). Of these activities, the Panel reviewed 30 randomly selected risk assessments.

Box 3.3
Key Products of the AHRA Unit

Risk assessments include scientific risk assessments that follow the full framework and procedures established in the formal protocols of the CFIA (i.e., release assessment, exposure assessment, consequence assessment, and risk estimation) (CFIA, 2005). Most of the risk assessments conducted by risk assessors in the AHRA unit consist of import assessments initiated by private stakeholders, although some deal with other subjects such as regulatory assessments initiated by the CFIA. Much of this work is conducted employing a qualitative methodology.

Scientific advices, scientific opinions, and similar documents provide decision-makers with information on a particular subject outside of the formal risk assessment process. These reviews are undertaken as a result of specific questions that do not require a full risk assessment. Examples include reviews undertaken to determine whether a risk assessment is necessary, or those conducted in cases where a full risk assessment already has been done but managers determine that an update or check should be conducted. A scientific advice mainly consists of a literature review, usually combined with consultations conducted with experts (internal and/or external).

Disease status evaluations of a country/region/zone are performed to comply with World Trade Organization (WTO) requirements. Such evaluations are designed to be a scientific, transparent, and consistent process to evaluate the disease status of countries/regions/zones (CFIA, 2005). The evaluation includes visit evaluations, surveillance program evaluation, presence of disease, veterinary structure, etc. These evaluations do not represent a complete risk assessment but rather a risk-based evaluation of the country/region/zone status.

(Based on interviews with CFIA staff)

Types of Risk Assessments Reviewed

Of the 30 risk assessments that the Panel examined, 24 were import risk assessments and 6 dealt with other subjects (e.g., regulatory or emerging zoonosis assessments). Seventeen risk assessments were initiated by private stakeholders, seven by the CFIA, and six by other countries (e.g., disease status evaluations). The Panel noted the flexibility in the response of the CFIA, both in the extent of the risk assessment produced and in the ability to use other approaches to address questions of risk that did not entail a formal risk assessment.

Consequences Assessed in Risk Assessment Sample

According to the CFIA framework for risk assessment, "consequence assessment consists of describing and quantifying the relationship between specified exposures to a biological agent and the economic consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences. The consequence assessment typically includes a specification of the impact on health in the animal and human populations sustained under given exposure scenarios" (CFIA, 2005). Within this context, the way in which *consequence* is used is consistent with the definition adopted by the Panel (see Box 1.3). The Panel noted the emphasis on economic consequences, and the clear directive for consideration of effects on human populations.

The CFIA indicates that it considers a range of potential consequences, both direct and indirect, in its risk assessments (see Box 3.4). Direct consequences may include disease introduction, cost of clinical outbreaks, and production losses. Indirect consequences may include loss of export markets, trade restrictions, public health concerns, and financial compensation (CFIA, 2005). Whether a consequence is considered to be direct or indirect depends on the nature of the hazards and risks.

The consequences examined in the sample of 30 risk assessments reviewed by the Panel are summarized in Figure 3.4. As anticipated based on the CFIA's mandate, economic and animal health consequences were considered in over 80 per cent of its assessment documents. Direct human health, psycho-social, and environmental consequences were considered in roughly 30 per cent of assessments. This summary demonstrates that the CFIA considers a range of consequences, going beyond the list shown in Box 3.4, in its risk assessments. Due to the nature of this review, the Panel's intent was not to determine if the CFIA took into account the appropriate consequences in each assessment but simply to understand the range considered.

Box 3.4

Potential Consequences Considered in CFIA Risk Assessments

Examples of consequences that may be considered in CFIA risk assessments include:

- animal losses from deaths and removal with slaughter/destruction;
- production losses including abortions and infertility;
- loss of gene pool;
- losses from trade embargoes;
- losses from domestic animal movement restrictions;
- losses in domestic marketability;
- control and eradication costs;
- monitoring, surveillance, laboratory testing, and trace-back costs;
- quarantine and isolation costs;
- compensation costs;
- cleaning and disinfection costs;
- treatment costs;
- vaccination costs;
- human illness and deaths;
- treatment and hospitalization costs for human illness; and
- adverse consequences to the environment.

(CFIA, 2005)

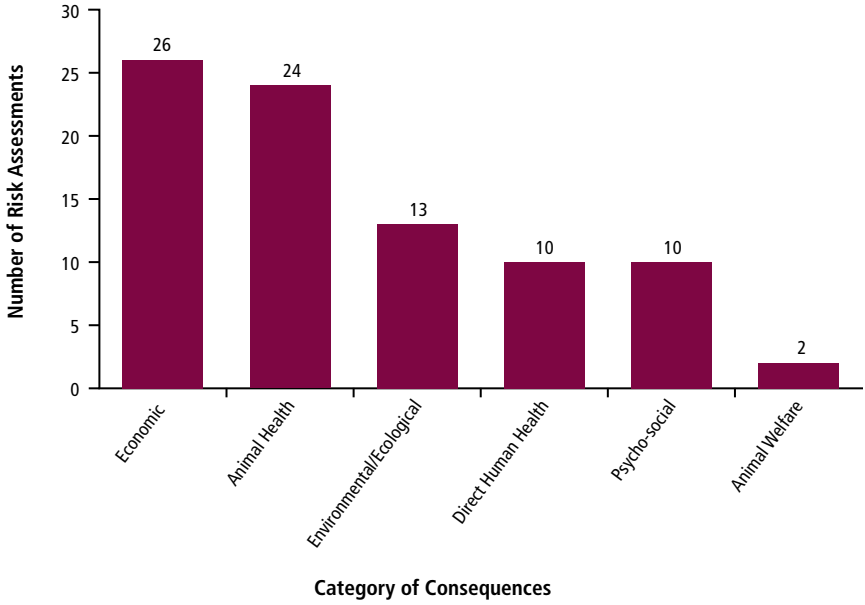


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Figure 3.4
Categories of Consequences Examined in Sample CFIA Risk Assessments

Use of Qualitative/Quantitative Methodologies

The CFIA's "Principles for Risk Assessment" recognize that both quantitative and qualitative methods have merit (see Box 3.2) (CFIA, 2005). Most of the risk assessments reviewed by the Panel were qualitative in nature (29 out of 30) (i.e., did not contain extensive, original quantitative calculations). Nevertheless, the majority of these qualitative assessments had some quantitative basis. For example, likelihoods in risk assessments were based on the probability ranges shown in Table 3.1.

It also is important to note that many qualitative assessments were based on quantitative assessments that were conducted by the CFIA at an earlier date, and/or on information gathered from quantitative work conducted by other jurisdictions, organizations, or experts.

Table 3.1

Likelihood Definitions and Probability from the CFIA Handbook

Likelihood definitions		Probability range		
Negligible	The event would be virtually unlikely to occur	10^{-7}	–	10^{-6}
Extremely low	The event would be extremely unlikely to occur	10^{-6}	–	10^{-5}
Very low	The event would be very unlikely to occur	10^{-5}	–	10^{-4}
Low	The event would be unlikely to occur	10^{-4}	–	10^{-3}
Small	The event would be minimally likely to occur	10^{-3}	–	10^{-2}
Moderate	The event would be fairly likely to occur	10^{-2}	–	10^{-1}
High	The event would be likely to occur	10^{-1}	–	1

(Reproduced with permission from CFIA, 2005)*

Extent of Risk Assessments

Of the 30 risk assessments examined, 24 included all the steps (i.e., release assessment, exposure assessment, consequence assessment, and risk estimation), while 6 stopped after the release assessment. According to the OIE, if the release assessment demonstrates that the risk is negligible, every other step of the risk assessment, and therefore the entire risk assessment, will be negligible. If the release assessment is negligible, the risk assessment can stop at this point (OIE, 2010c). This saves time and resources.

Review Process

All 30 of the risk assessments examined had been reviewed internally, and 2 of them had been sent for external review.[16]

Stakeholder and Advisory Input

According to CFIA protocol, clients have the opportunity to provide input at the beginning and end of each risk assessment. Of the 30 risk assessments reviewed, 12 assessments also involved consultations with experts *external* to the AHRA unit (but not necessarily external to the CFIA or the Government of Canada).

[16] Internal review consists of review by risk managers, other risk analyst in the AHRA unit, or other experts internal to the CFIA; external review consists of review from experts outside of the CFIA.

Gaps in Data

Gaps in the data required to complete the assessment existed in 15 of the 30 cases. In each case, the nature of the gaps was explicitly stated in the assessment. Examples included "uncertainties with regard to species susceptibility, prevalence, pathogenesis;" "uncertainties with respect to routes of transmission in other species;" and "lack of available data on risks."

Gaps in data and other forms of uncertainty are inherent in the risk assessment process, as certain information may be unavailable or difficult to obtain. A lack of data can increase costs and lengthen timelines as attempts are made to obtain the data, and it also can contribute to the challenges involved in efforts to quantify risks and consequences.

Resources and Timelines

Most of the 30 risk assessments were completed by one or two risk assessors within three to seven months. Time for completion varied from 1 to 13 months, depending on the priority, information required, and competing demands in the AHRA unit. Time horizons for which the risk assessment informed decision-making also varied, ranging from immediate to long term, depending on the nature of the assessment and other factors, such as new animal health events.

Review of Key Findings

- The process for conducting importation risk assessments at the CFIA is consistent with international regulations governing animal health risk assessment.
- The majority of risk assessments conducted at the CFIA are for import risk analyses, though some risk assessments address other topics (e.g., regulations or emerging zoonoses).
- Most risk assessments at the CFIA employ a qualitative methodology, and focus on assessing economic and animal health consequences. Other consequences are also considered.
- Clients of the CFIA have the opportunity to provide input at the beginning and end of the risk assessment process. The CFIA conducts consultations with external experts (including peer reviewers) as deemed appropriate by risk managers.

4

Risk Assessment in Risk-Based Decision-Making

4 Risk Assessment in Risk-Based Decision-Making

Key Message

Animal health risk assessment can be most effective as a tool for decision-making when undertaken in the context of an integrated, multidimensional approach. Consideration of animal health, human health, and the environment in risk assessment is required for a comprehensive and relevant risk estimation. Transparency adds value to the risk assessment process and facilitates subsequent risk communication and management.

Animal health risk assessments are conducted to support operational or policy decisions that protect animal and human health, maintain the economic viability of our animal industries, protect our indigenous animal and plant populations, and maintain our trade partners (interviews with experts and review of risk assessments). To support the necessary decisions, the objectives of risk assessments are to:

- identify the probability of a given consequence, event, or effect;
- understand how and when such consequences may occur;
- estimate the impact of the various consequences; and
- evaluate the potential outcomes or consequences of selected management options.

(interviews with experts and review of risk assessments)

Once assessed, risks can be managed by implementing actions to mitigate or control them. Diversification strategies can be developed to protect business assets, engineering solutions can help reduce potential damages from natural disasters, while disease prevention and pandemic planning can help prevent or mitigate the potential impact of adverse health events. Risk assessment, therefore, is a tool to inform risk managers and policy-makers about risk management (i.e., risk-based decision-making) (NRC, 2009; CFIA, 2005).

To be effective as a decision-making tool, risk assessments must be timely, broadly based, and well informed, founded on the most reliable and relevant data, accurate in the interpretation of data, and transparent in the communication of results to interested parties (NRC, 2009; ISO, 2009a; Morgan *et al.*, 1990). They also must be conducted with consideration and recognition of the socio-political context in which such activities and decisions are undertaken.

The Panel believes that animal health risk assessment can best meet these criteria by adopting an integrated, multidimensional approach (IMDA). As discussed in the following sections, this approach means incorporating the consequences for animals, humans, and the environment in a broad and robust way, as well as integrating key information from the wider perspective of *risk analysis* (particularly, hazard identification and risk management options) into the process of *risk assessment* (i.e., release assessment, exposure assessment, consequence assessment, and risk estimation). It is important to recognize that the risk environment is not static; it changes with time, context, and decisions, creating a multidimensional system in which to assess risk.

In the Panel's view, the integrated, multidimensional approach includes the following aspects:

- recognizing and using the strategic role of risk managers (Section 4.2.1);
- increasing the breadth and depth of consequence assessment, including integrating potential consequences for animals, humans, and the environment (Sections 4.1 and 4.2.2, and Chapter 5);
- ensuring that the dimension of management options and its outcomes or consequences are embedded in the risk assessment process (Sections 4.1 and 4.2.1);
- expanding stakeholder and advisory engagement (Section 4.2.3 and Appendix D);
- incorporating appropriate methodologies (Section 4.2.4);
- obtaining the appropriate disciplinary perspectives required to address the hazards and consequences (Section 4.2.5 and Appendix E);
- improving access to expertise, training, and research resources (Section 4.2.6 and Chapter 6);
- balancing immediate and long-term needs with a structured approach to prioritization of risk assessments (Section 4.2.7 and Chapter 7); and
- ensuring transparency in the risk assessment and risk analysis process (Section 4.2.8).

4.1 AN INTEGRATED, MULTIDIMENSIONAL APPROACH TO ANIMAL HEALTH RISK ASSESSMENT

Risk-based decisions concerning animal health, human health, and the environment are made daily by governments, businesses, and individuals. In all risk-based decisions, the Panel contends that decision-makers and stakeholders must be aware of the potential interactions among these components, as well as the outcomes of risk management options themselves. A consequence or change in any one of these three components potentially affects the others (see Figure 4.1).

The concept of interfaces or interrelationships between domestic and wild animal health, human health, and the environment has been well established (Figure 4.1). It has been considered under the terms *ecohealth*, *ecosystem health*, *One Health*, and others.[17] The potential for disease transmission both among and between animals and humans will be influenced by the environment in which they exist. Similarly, attempts to mitigate risk by environmental manipulation — for example, a risk management decision to restrict movement of domestic animals by construction of fences — may also affect other animal habitats and behaviour, thereby further affecting other animals, the environment, and ultimately humans. The impact of a mass cull of animal populations on humans from a psycho-social perspective can be quite different from implementation of a mass vaccination protocol. Assessing the impact of the introduction of a new animal species only on domestic animals without considering the possible impacts on indigenous wild populations may underestimate the extent of consequences. When considering both direct and indirect consequences, it is important to recognize that the consequences of the primary risk (hazard) and the consequences of the management options chosen can both be influenced by the interrelationships between these three components.

The Panel maintains that these examples underscore the need to understand how decisions about risks and risk management may affect animals, humans, and the environment. How the outcomes of risk management strategies may affect the level of risk, or perhaps even create new risks, needs to be considered in the risk assessment process itself. Risk managers and stakeholders need to be aware that considering a broader perspective can have a significant impact on the perception of risk not only by immediate stakeholders but also by society at large. Understanding these complex dynamics begins with understanding the connections among the key components themselves. Mapping or adding clarity to this interaction of the components is part of the challenge. Consciously adopting an integrated, multidimensional approach can aid in addressing this challenge.

[17] As a starting point for more detailed information on this concept of ecohealth (or ecosystem approaches to health management), the reader is referred to: (1) http://www.idrc.ca/in_focus_health/; and (2) "HEALTH An Ecosystem Approach" by Jean Lebel and available at http://www.idrc.ca/in_focus_health/ev-29393-201-1-DO_TOPIC.html. Inter-professional cooperation between physicians, veterinarians, and other health-related professionals, and inclusion of other disciplines (e.g., social scientists), are increasingly seen as a valuable approach in addressing and identifying many health issues (OHI, 2010; PHAC, 2009a).

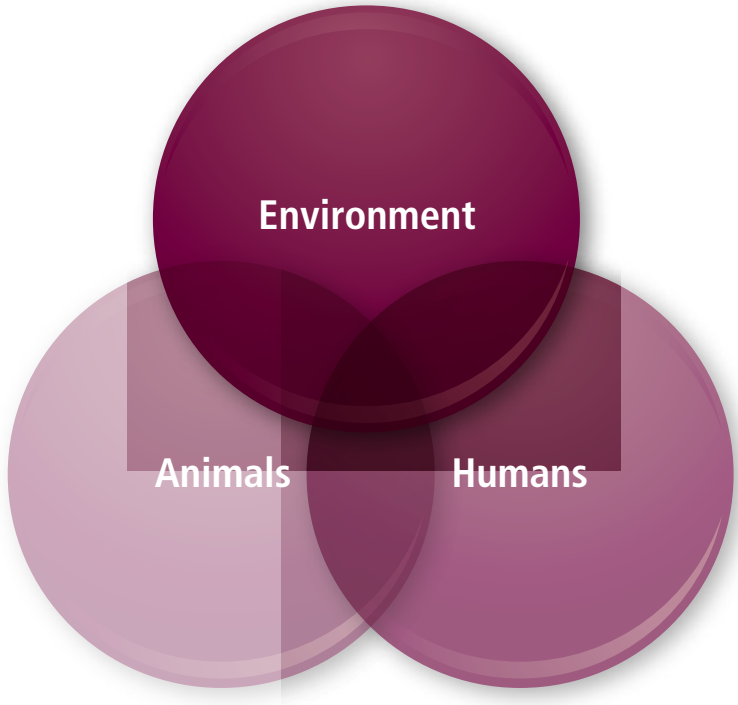

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Figure 4.1

Animals, Humans, and the Environment

The health of animals (domestic and wild), humans, and the environment are interrelated and need to be considered in an integrated fashion.

The Panel observes that there are two facets to this animal-human-environment interface and the consequences of risks. The first facet is the *breadth* of consequences, which is addressed in Section 4.2.2 and in Chapter 5. The second facet is the *depth* of consequences, which involves the incorporation of indirect or secondary consequences. This includes not only the direct consequences associated with a specific hazard (or signal; see Box 1.3), but also the secondary or indirect consequences from both the hazard and the management option chosen.

This consideration of an expanded *depth* of consequences is illustrated conceptually in Figure 4.2, which converts risk assessment from a two-dimensional consideration of the likelihood of occurrence and the likely magnitude of consequences to a three-dimensional consideration of the signal/hazard, the management option, and the combined consequences. There are two areas that feed into the potential consequences: those that are related to the signal itself and those that occur from the management options chosen. The first is not something that can be controlled (although it can be influenced), but the management options can be controlled. When making a risk management decision, whether it be an operational or policy decision, both areas need to be considered in assessing the impact.

Figure 4.2 uses the broader terms *signals*[18] or *hazards* to denote the X-axis. A signal could be a specific hazard if it is known (for example, lead contamination in cattle following lead consumption); it could be a possible range of hazards if the signal is importation of an animal (each disease that could be imported with that animal would have its own set of consequences); or it could be an unidentified signal (that is, increased deaths in a herd). The X-axis could therefore be viewed as representing different specific risks (i.e., a bar graph) or as representing increasing exposures or increasing likelihood of exposure. Regardless of the specific configuration, the signal or hazard itself will have a set of associated consequences even if no management decisions are taken.

To complete the risk assessment, it is essential that management options and their consequences (or outcomes) are also considered (the Z-axis). This could be viewed as a bar graph with different choices, or as increasingly restrictive or consequential management options. Take for example a mass vaccination response versus a mass cull in response to invasion of a foreign animal disease. A mass vaccination would have direct costs associated with the vaccination itself and could have indirect costs associated with international trade restrictions. This approach would have few negative psycho-social consequences, but as it also would not result in disease eradication, the disease could potentially infect wild populations that could not be vaccinated. Alternatively, a mass cull could potentially eliminate the disease threat, protect our trade position, and protect domestic and indigenous populations. It would, however, have extensive psycho-social consequences, create major animal welfare issues, and have a different public perception. Choosing to quarantine a relatively rapidly reproducing and growing species of animals such as pigs or poultry is considerably different from quarantining a zoo, a cattle herd, or a horse operation.

[18] For definitions of *signal*, *consequences*, and risk *management options*, see Box 1.3.

For any given situation, the ultimate consequences for society (considering the three components of animals, humans, and the environment) are the product of the consequences of the signal or hazard and the consequences of the management option. A particular management option may reduce the likelihood of a hazard occurring or it may reduce the severity of the consequences. In any particular situation, risk assessors, risk managers, and policy-makers should gather information from various signals, consider a range of consequences, and develop and evaluate a number of management options.

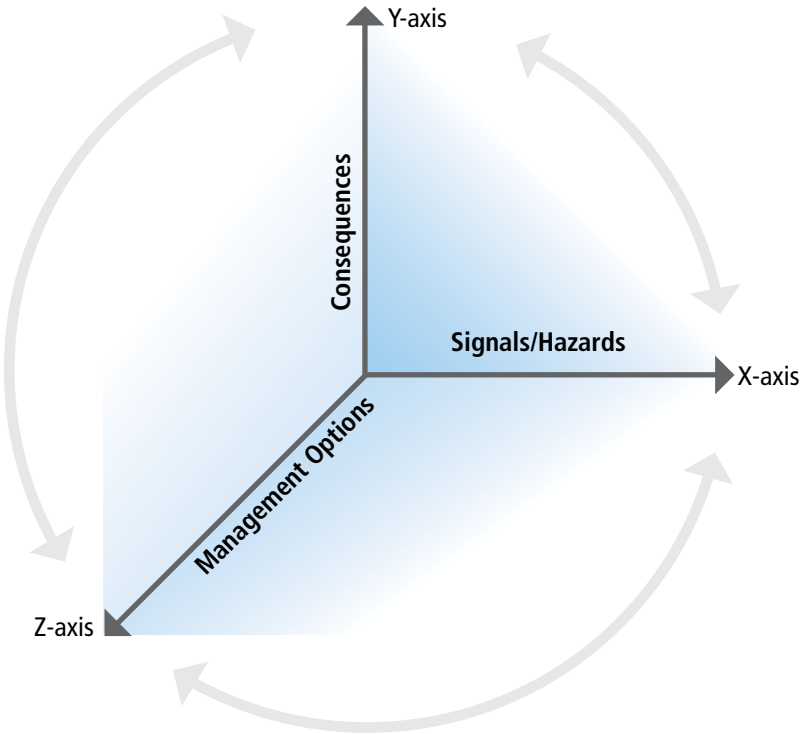

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Figure 4.2

A Multidimensional Perspective on Animal Health Risk Assessment

This figure is meant to represent the concepts discussed; it is not intended to be a mathematical rendering of how one determines the risk. Determination of risk for a specific event or hazard remains a two-dimensional consideration. The risk assessment and risk management, however, are not two-dimensional considerations.

If, for instance, a government or industry is not aware of a particular signal or hazard (owing to lack of knowledge, absence of surveillance data – i.e., lack of signal, or another reason), it may not consider a possible set of consequences and thus fail to implement management options that could have contained or minimized the risk. The way a management option (which essentially can act as a signal or hazard itself) is implemented could have its own set of consequences, which is much more likely to be recognized and included in the decision-making process if it is identified and considered in the risk assessment process itself. The key is to ensure that the range of signals and their consequences and the range of options and their consequences are considered. It is also important to recognize that these three axes interact and influence each other, as illustrated in Figure 4.2.

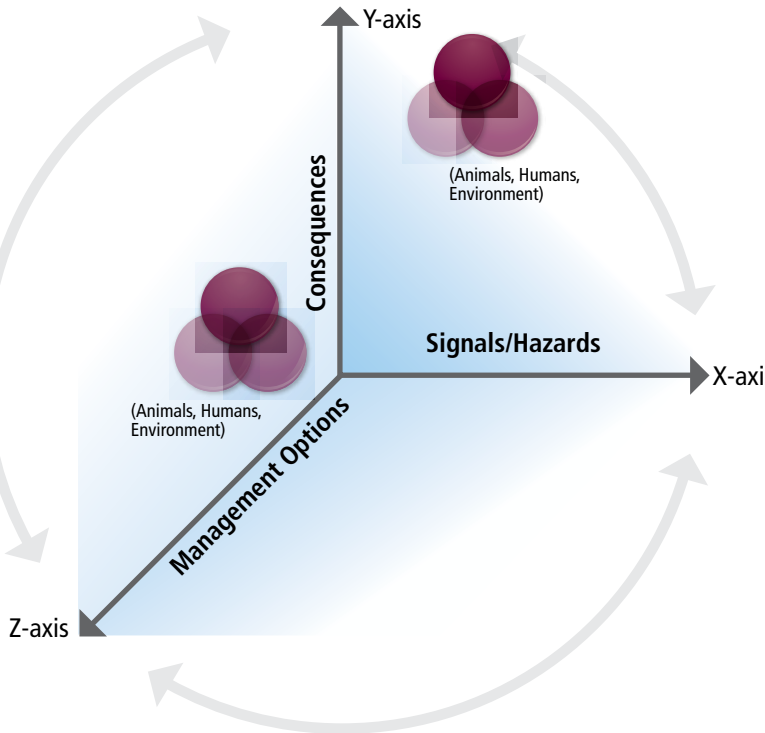
Ensuring that this broader view is incorporated into animal health risk assessment, particularly as it pertains to human health, is the goal of adopting an integrated, multidimensional approach. Although there is considerable effort internationally and within Canada to incorporate similar strategies, the Panel identified the need to establish a structured, systematic approach to ensure the goal is achieved.

Consequence assessment (Y-axis) should consider not only the relationship with the signal or hazard (X-axis), but also the consequences of the management options (Z-axis) and the impact of these management options on the consequences of the hazard. A signal (or, once identified, a hazard) will come with a probability of occurrence and a set of consequences. This will be of high or low consequence. This could be viewed as either an increasing likelihood of occurrence as one moves down the X-axis, or as a range of possible signals or hazards, each with a different set of consequences. The management options (Z-axis) then represent a range of choices, each of which will have its own set of consequences (economic, psycho-social, international trade, disease transmission). The combined consequences from both the signal/hazard and the management options need to be considered in risk management decisions.

Incorporation of the three components of animals, humans, and the environment is illustrated in Figure 4.3. When considering the consequences of any particular signal/hazard or management option, impacts on the three components and their interrelationships also need to be taken into account. Together, these three components comprise healthy ecosystems (Lebel, 2003). In this representation,

the three components are shown for two different combinations of management options and signals. Risk assessors, risk managers, and stakeholders can use this conceptual approach in the risk assessment process and integrate it into risk-based decision-making. This provides a more comprehensive picture of the magnitude of risk and the outcomes of risk management options.

As illustrated in Figure 4.3, the consequences of both the primary hazard/signal and the management options chosen should be addressed and considered in an integrated concept of animal health, human health, and the environment. The economic and other consequences then flow from this construct.



(Council of Canadian Academies)

Figure 4.3
The Integrated, Multidimensional Approach to Animal Health Risk Assessment

4.2 MOVING TOWARD AN INTEGRATED, MULTIDIMENSIONAL APPROACH

Implementing an integrated, multidimensional approach (IMDA) calls for action across several areas. Although there are different approaches that could be used to achieve this goal, there are several common characteristics that can be adopted to advance the IMDA framework in animal health risk assessment. In describing these characteristics below, it is important to note that while the various characteristics would need to be incorporated within the organization, the extent of incorporation into each individual risk assessment depends on the context (for example, a routine import risk assessment versus a risk assessment to support a new policy development).

4.2.1 Recognize and Use the Strategic Role of Risk Managers

Risk managers can be an essential link throughout the entire risk analysis process: gathering input from multiple stakeholders, defining the scope and boundaries of risk assessments, ensuring that a range of management options are considered in the risk assessment, allocating resources and establishing timelines, and selecting and implementing management options. The recent National Research Council (NRC) report, *Science and Decisions* (2009), opines that risk assessments (at least in the United States) have become "bogged down" largely owing to insufficient input from risk managers and other stakeholders. This lengthens the risk assessment process and limits the usefulness of its results because the appropriate range of options is not considered early in the process.

Risk assessment organizations benefit when risk managers can use their role in a strategic way. Strategic risk management begins with asking the right questions, and scoping or boundary critiquing. Some questions that risk managers might ask include:

- Which consequences should and should not be considered?
- Which stakeholders need to be involved and when?
- Which signals should be examined?
- What are the scope and/or boundaries of the assessment?
- What is the time range of possible consequences to consider?
- Which management options are to be considered and which are not?
- What is the timeframe for completion of the assessment?
- What resources are needed to meet the objectives?

To answer these questions effectively, risk managers need the right tools and information. They need to have the right approaches and methods for selecting the consequences and populations of concern, involving the right experts and stakeholders at the right times, and identifying and implementing the best management options. Failure to answer these questions at the start of the assessment may result in an analysis that does not provide all the information that managers and stakeholders need to complete the decision-making process.

At the most general level, the process of "boundary critique" is one way to approach setting up the boundaries. Boundary critique offers a systematic method for incorporating a broad range of input — data, interpretation, and value-based judgments — and defining the limits of a particular analysis (Foote *et al.*, 2007; Yolles, 2001). Its objective is to ensure the analysis is sufficiently broad to gather all relevant input, while being succinct enough to remain workable (i.e., timely, cost-effective, and informative) as a tool for decision-making (For examples see Foote *et al.*, 2007; Ulrich, 1983; Midgley, 1992, 2003; Midgley *et al.*, 1998).

Once the boundaries have been defined, risk managers then need a process for combining the input in a way that supports decision-making. It is not easy to address a large quantity of (often conflicting) input from a wide range of sources, assess and incorporate this input, and undertake decisions that can affect large numbers of stakeholders. But it is the reality faced by risk managers. According to the latest trends in risk analysis and decisions science, the solution to this complexity is not to be found in building an artificial wall between risk assessment and risk management. Instead, it is to be found in embracing and leveraging the inseparable connection between risk assessment and risk management (see Section 2.5 and Figure 2.1). In practice, this means there needs to be a systematic way for not only defining the boundaries, but also for integrating the relevant input from the relevant experts and stakeholders in an effective way.

When defining potential management options, risk managers need to consider the primary and secondary outcomes (consequences) of those options in a broad way as part of the risk assessment process (e.g., by using the approach illustrated in Figure 4.3). For example, what impact will the options of vaccination, quarantine, and other management options have not only upon the risks to be managed, but also on the stakeholders and the environment? What signals may trigger consideration — or reconsideration — of risks, risk management options, and risk management outcomes? All these questions need to be addressed in some detail: in the process of defining the boundaries for risk assessments, in gathering the information and conducting the analysis, and in undertaking and implementing risk management decisions.

It is equally important that the monitoring and review of such decisions are captured and fed back into the risk assessment process. Scenario analysis is one tool that can help risk assessors and managers answer such questions (Ahl, 1996; Etter *et al.*, 2006). A structured, systematic approach such as multiple criteria decision analysis offers another tool that can help capture and integrate the information gathered through such exercises and practical experience. Later in this chapter, and in Appendix D, the Panel offers examples of how these tools may be applied at the Canadian Food Inspection Agency (CFIA) and other organizations involved in conducting animal health risk assessments.

It is also essential for risk managers and policy-makers to recognize that risk communication is a multidirectional and iterative process. The sooner stakeholders are involved in the process through the strategic role of risk managers, the more likely that an optimal, workable decision can be achieved. Many mitigation measures and other management options developed by risk managers are ultimately implemented by stakeholders in the field. Moreover, stakeholders often have information and insights that are of value to risk managers. Early and frequent stakeholder engagement is likely to lead to better risk-based decisions and higher levels of compliance. Yet this can only happen when decision-makers are open to stakeholder input and delivering transparent, evidence-based decisions. Consultation merely for the sake of appearance will be quickly spotted and may actually worsen relations with stakeholders, thereby impeding effective decision-making and implementation. Risk communication is most effective when stakeholders and managers together address the above questions before the assessment process begins.

4.2.2 Increase the Breadth and Depth of Consequence Assessment

The need to increase the breadth and depth of consequence assessment has been addressed previously in this chapter and receives extensive treatment in Chapter 5. The majority of risk assessments at the CFIA currently focus on economic and animal health consequences (see Chapter 3). This approach aligns with the main activities of the agency's Animal Health Risk Assessment (AHRA) unit: conducting import risk analysis to meet Canada's obligations under international trading agreements[19] (refer also to Section 2.3, Box 2.3, and Chapter 3) while protecting Canada's industries, ecosystems, and communities from the importation of animal diseases. While risks relating to ecosystem, human health, and psycho-social consequences are sometimes included in the risk assessments conducted at the CFIA as well, such risks are typically mentioned rather than quantified or assessed in detail (review of

[19] For example, see the World Trade Organization *Agreement on Application of Sanitary and Phytosanitary Measures* (SPS Agreement) included in Appendix F.

risk assessments and interviews with CFIA staff). For example, in terms of human health considerations, the CFIA sometimes identifies the possibility of a zoonotic disease being transferred to humans. It does not assess, however, the consequences beyond identifying that the risk exists (review of risk assessments and interviews with CFIA staff). A comprehensive animal health risk assessment needs to give consideration to the greater depth of consequences. Various approaches to how this can be achieved are addressed in Chapter 5 and Section 7.2.

In recent years, other countries have been adopting a broader perspective on the consequences of animal health events. This trend has come out of the growing recognition that many risks related to animal health have wider economic, ecological, and social implications. Humans and animals are linked not only through animal industries and companion relationships, but also because they share the same ecosystems. The question, therefore, is not so much whether the wider consequences should be assessed, but rather which of the risks should be assessed in each particular case and how far the assessment of the risks should go in each instance. Evidence and suggestions as to how this can be approached are outlined in Chapter 5.

4.2.3 Expand Stakeholder and Advisory Engagement

As other groups have reviewed the state of risk analysis, the trend has been to increase stakeholder input into the risk analysis process rather than to decrease it. For example, the NRC *Science and Decisions* report underscores the need for expanded stakeholder involvement and input (see NRC, 2009 and Appendix D). The Panel also believes that enabling stakeholder input throughout the process of risk assessment is a valuable approach, in particular as it enhances transparency.

Although stakeholders have an opportunity for input at the beginning and end of the risk assessment process at the CFIA, they are not able to contribute to informing the assessment as the work unfolds and evolves (CFIA, 2005; interviews with CFIA staff). The rationale for excluding stakeholders during the risk assessment process is to insulate the scientific work of risk assessors from the "political world" of stakeholders (interviews with CFIA staff). As a result, opportunities for gathering data and input from stakeholders may be missed. Risk managers should take the lead in involving stakeholders while addressing the required boundary critique and management option questions. Although this process might create some political controversy before a risk assessment is even implemented, it would result in a more informative analysis, feasible management decision, and acceptable solution. This is not to say that constant stakeholder involvement is desired or necessary; rather, specific identified stages at which relevant stakeholder input is sought could be established.

Other countries and organizations have begun to look at ways that stakeholder engagement can be effectively integrated throughout the process, without jeopardizing the scientific rigour, objectivity, and independence of the risk assessors. One working example where there is frequent interaction of stakeholders to assess and address potential pathogens of concern is the U.K. Human Animal Infections and Risk Surveillance (HAIRS) group. This "horizon-scanning" group, formed in late 2004, meets monthly to "[act] as a forum to identify and assess infections with potential for interspecies transfer" (i.e., identify signals) (HAIRS, 2008). In such an arrangement, many stakeholders are represented within the group including various governmental and industry trade groups. The *Science and Decisions* report is explicit in its recommendations that "good design of a risk assessment involves bringing risk managers, risk assessors, and various stakeholders together early in the process to determine the major factors to be considered, the decision-making context, and the timeline and depth needed to ensure that the right questions are being asked in the context of the assessment" (NRC, 2009). Finally, the Alberta Veterinary Surveillance Network is an example of a comprehensive, integrated surveillance program that includes input from a range of stakeholders including private-sector veterinarians and other health experts as well as indirect input from producers via these experts (Alberta Agriculture and Rural Development, 2010; personal communication). These three examples are further evidence of the trend toward expanded stakeholder engagement throughout the risk analysis continuum, and its perceived value.

One further option is an advisory panel to provide regular input into assessments, with potential representation from external government agencies, universities and other research institutions, industry, non-government organizations, and other key groups of stakeholders. Using such an advisory panel would expand opportunities for gathering external data and expertise. As suggested by the NRC report (2009), an advisory panel could provide input into the problem (assessment) structuring, the scope, and the evaluation of management options for consideration. The expansion of stakeholder input would likely increase the transparency of the resulting risk assessment as well as make the management decisions more acceptable and palatable among stakeholders. The Panel concludes that consideration for expanding stakeholder and advisory input into the risk assessment process is warranted, provided that it is structured.

4.2.4 Incorporate Appropriate Methodologies

Having established the broad boundaries of what is to be considered and who is to be involved, risk managers then need to figure out the most appropriate methods for gathering and analyzing the data contributing to a risk assessment. Part of this will be determined by the nature of the data that have been identified as being

important and the consequences to be considered, through the consultations with risk managers and other stakeholders. Economic indicators will feed into economic analysis, physical symptoms will help to inform medical opinions, social trends will lend insight for community studies, and so on. But part of the selection of methods will be determined by the decisions of risk managers. Within the range of available options, what type of analysis should be conducted — quantitative or qualitative? What disciplinary perspectives should be involved in the assessment, and what insights might they offer for a given assessment? As outlined in the next two sub-sections below, the answers to these questions will be determined by the details of the case in question.

The Arguments for a Quantitative versus Qualitative Approach

It is not uncommon in applied science for researchers to call for a more quantitative approach to analysis, implying a more detailed, repeatable, numerical approach complete with theoretical validity, computer simulation, and statistical testing. In contrast, qualitative analysis might be considered less structured; some might describe it as a general discussion during which the researcher might generate an impression of the health of the participants rather than methodically measuring blood pressures and body weights to obtain a quantitative measure of health. Neither characterization is a reasonable summary of the attributes of each approach. What is more important — and often overlooked — is the set of guiding principles and process structure to which the risk assessment should adhere and the degree to which resources can be invested to obtain results.

While precise definitions may vary, quantitative approaches tend to rely more on numbers and statistics, while qualitative approaches, which are no less valuable to decision-making when properly employed, tend to be based more on the categorical evaluation of many types of information (some of which might be numerical). Clearly there will be occasions when one approach will be more appropriate than the other. In those circumstances, the analysis, whether quantitative or qualitative, may be perfectly rigorous and repeatable, with testing of results based on sound procedures.

In current risk assessments conducted by the AHRA unit at the CFIA, consequences are often ranked qualitatively as low, medium, or high, and probabilities are described as negligible to high (see Chapter 3 and Table 3.1). The consequence descriptors used are similar to the "risk descriptors" that have been applied in other countries, such as New Zealand (Biosecurity New Zealand, 2006), and in other organizations involved in risk assessment (Sumner *et al.*, 2004; Negus, 2010; Chevreau, 2010). Such terms are easily understandable and have value for

communicating levels of risk to wide groups of stakeholders (Negus, 2010). The potential problem, however, lies in the degree of subjectivity that may be inherent in such rankings when these terms are not precisely defined for each specific type of risk in each risk assessment. What constitutes a "low-medium" level of risk for one analyst, risk manager, or policy-maker may mean something entirely different for another stakeholder (Sumner *et al.*, 2004; Chevreau, 2010; NRC, 1983). The Panel asserts that adding a quantitative measurement in cases where it makes sense to do so — given the availability of data, resources, and the perceived need — can help add transparency to a risk assessment, as well as enhance scientific controls and the reliability of outputs.

The following criteria are examples of what may be considered in weighing the benefits of one approach over another when planning and conducting a risk assessment:

- purpose of the risk assessment (i.e., question being asked);
- nature, quality, and quantity of the data available for analysis;
- demands for consistency, repeatability, validity, fairness, and rigour of process;
- demands for specificity and detail of results;
- resources available for the assessment, particularly labour and funding;
- urgency of the assessment and/or timeline for the assessment; and
- predicted extent of outcomes from potential management decisions.

None of the above criteria by necessity call for a strictly quantitative or qualitative approach. There may be additional criteria depending on the specific circumstances. The most important consideration is the rigour applied to either the qualitative or quantitative approach, as well as transparency with regard to what is known and what is estimated.

4.2.5 Obtain the Appropriate Disciplinary Perspective

Risk assessment organizations can also benefit from adopting a multidisciplinary approach. Animal health risk assessment can rely heavily on the disciplines of epidemiology and statistics; this is implicit in the nature of conducting an animal health risk assessment. But, in general, the more that risk assessment is driven by a well-defined, narrowly deviating process, the more likely it is to lose its flexibility and utility for a broad range of stakeholders. For example, an animal health importation risk assessment heavily driven by a process that examines the

likelihood of hazard importation and escape (e.g., foot-and-mouth virus) may well consider the health impact on the livestock sub-sector of that particular area, but it is unlikely to consider the impact on small businesses, wildlife, tourism, or the social concerns of local inhabitants. Stakeholders with such interests would be disappointed to find that the approach and findings of the assessment do not address their concerns. Furthermore, if the assessment is to be an accurate measure of the outcomes of the escape of such a hazard, most stakeholders would claim it falls considerably short of the mark, possibly addressing only the concerns of a single category of stakeholder. While the Panel is not suggesting an exhaustive approach to every risk assessment, integration of a wider range of disciplinary perspectives into risk assessment would increase the robustness of these estimates and their significance to a wider group of stakeholders.

Examples of some disciplines that could contribute to animal health risk assessment are outlined in Table 4.1. The table includes brief descriptions of the potential contributions of the disciplines, examples of tools or methodologies, and brief examples of data requirements and indicators generated by including the various disciplines in the assessment. As an example, in-depth economic analysis is rarely included as part of an animal health risk assessment, nor is wildlife biology. But if a particularly virulent strain of foot-and-mouth virus should escape as the result of an animal importation, the economic consequences to Canadian agriculture and rural livelihoods could be devastating. Furthermore, the survival of young ruminants including deer, elk, and moose would be at risk, possibly jeopardizing the stability of ecozones where such species play a significant role.

The decision about which disciplines to include will depend upon the answers that risk managers arrive at for the original scoping or boundary critique questions. While no risk assessment can be all-inclusive and address the complete concerns of every stakeholder, the Panel believes that including well-established, mainstream multidisciplinary interests of clear relevance to the assessment will bring value, increase confidence, and improve transparency. Where a risk assessment is intended to support broader policy decisions, the inclusion of a wider disciplinary perspective is more important. Multidisciplinary contributions to animal health risk assessment are explored in Appendix E.

Table 4.1

Examples of Disciplinary Contributions to Animal Health Risk Analysis*

Discipline	Contributions**	Tools/ Methods***	Statistics/Indicators/ Sources of Information***
Bioethics/ Philosophy	Understanding of the ethical context of animal health risk assessment and risk management decisions	Ethical theory Literature reviews	Surveys of current practices Discussions of ethical principles and evolving social norms
Economics	Estimation of impact of various risk events, consequences, and risk management options and outcomes across different groups of stakeholders	Cost-benefit analysis (CBA) Econometrics	Industry data (e.g., production statistics, inventories) Market trends (e.g., commodity prices, retail sales) Labour force information (e.g., employment, wages) Macroeconomic indicators (e.g., GDP growth, exports)
Ecology/ Environmental Science	Understanding of the interconnections among animals, humans, and the environment	Population models	Wildlife population statistics Environmental impact studies Veterinary surveillance data (e.g., information on disease outbreaks)
Engineering	Management of complex systems under conditions of uncertainty	Systems science Multiple criteria decision analysis (MCDA) Probability theory	State vector data (see Appendix D) System performance metrics (i.e., results of risk management options and outcomes) Stakeholder input
Epidemiology	Understanding of disease pathways, transmission, and prevalence	Associative models Simulation models	Public health data (e.g., incidence counts, mortality) Veterinary surveillance data Disease information (e.g., knowledge of disease characteristics, transmission mechanisms)
Geography	Mapping of disease prevalence, location, and socio-economic impact	Geographic Information Systems (GIS)	Public health data, veterinary surveillance data Economic indicators, industry data, market trends Other health and socio-economic metrics

continued on next page

Table 4.1 *(continued)*

Examples of Disciplinary Contributions to Animal Health Risk Analysis*

Discipline	Contributions**	Tools/ Methods***	Statistics/Indicators/ Sources of Information***
Health Sciences	Understanding of health and well-being of human and animal populations Knowledge of disease susceptibility among population subsets	Sampling techniques Simulation models	Community health indicators (e.g., vaccination rate, health care access, primary care providers) Public health data (e.g., HALYs, QALYs) (see Appendix E) Veterinary surveillance data
Law	Recognition of the international, federal, and provincial-level regulatory environment	Legal theory and research	Legal regulations, decisions, and precedents
Social Sciences	Knowledge of psycho-social consequences of adverse animal health events	Social theory Community studies Psychological case studies	Community impact data (e.g., income, health, and well-being of local population centres)
Statistics	Tools for predicting potential outcomes of various risks, consequences, and risk management options and outcomes	Sampling techniques Probability theory	Public health data, veterinary surveillance data Economic indicators, industry data, market trends Other health and socio-economic metrics
Wildlife Biology	Understanding of animal behaviour and transmission of disease among wildlife	Biological sciences Animal psychology Biostatistics	Veterinary surveillance data Wildlife population statistics

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* This table is not intended to be all-encompassing or exhaustive.

** Defined as the contribution to various stages of risk analysis.

*** Sample tools/methods and statistics/indicators are shown for each discipline. It is assumed that all disciplines can, and should, integrate insights from across disciplinary boundaries, as appropriate for each analysis.

4.2.6 Improve Access to Expertise, Training, and Research Resources

The capacity to adopt an integrated, multidimensional approach with multidisciplinary perspectives can be enhanced by increased access to expertise, training, and research resources. Based on its review of CFIA expertise, animal health risk assessment, and surveillance research, training trends in Canadian and international veterinary colleges, and research funding models, the Panel proposes three developments that could be beneficial in this regard:

1. increased opportunities for access to formal training among CFIA personnel;
2. expanded animal health risk assessment course offerings at Canadian veterinary colleges; and
3. more targeted mechanisms for mobilizing research in areas supporting integrated animal-human health risk assessment.

The evidence supporting these proposals is detailed in Chapter 6.

4.2.7 Integrate Strategic Planning in the Framework for Prioritizing Risk Assessments

Resources for conducting risk assessments are bound to be limited. There are too many potential risks to be assessed and only so much time, money, people, and other resources to go around. As such, risk assessment organizations must prioritize which risk assessments will get done and in what order. In these circumstances, risk managers and assessors naturally focus on the most pressing and immediate issues (i.e., those with the shortest timeframes) (interviews with experts). This often leaves longer-term strategic assessment for later, which, in practice, can mean that such issues are seldom addressed, if at all.

In animal health risk assessment, the most pressing and immediate assessments tend to be those conducted to meet international trade and commerce obligations, and those undertaken to address urgent policy and risk management decisions (interviews with CFIA staff). The import risk assessments conducted by the AHRA unit are examples of the former, while the H1N1 assessment jointly conducted by the CFIA and the Public Health Agency of Canada (PHAC) is an example of the latter. But there are also risk assessments that should be conducted to examine emerging threats, in support of future policy and risk management decisions. Assessments of the risks associated with avian influenza conducted by Switzerland's Federal Veterinary Office are one such example (FVO, 2006, 2008, 2010). Future scenario planning projects, forums, and exercises conducted by the CFIA, the Association of American Veterinary Colleges, the U.K. Department for Business Innovation and Skills, and others can contribute to this process (see Fore-CAN, n.d.; Willis *et al.*, 2007; Brownlie *et al.*, 2006; Meagher, 2005; BIS, n.d.).

The challenge is that strategic scenario planning assessments and projects often compete for the limited pool of resources used to meet short-term obligations and needs. This means that there needs to be a process in place for getting emerging threats on the agenda, and for allocating the resources necessary for such risk assessments. These areas are further explored in Chapter 7.

4.2.8 Ensure Transparency of Risk Analysis/Assessment Process

Transparency is important to the risk analysis/assessment process not only because it may improve the risk assessment itself, but also because it improves risk communication and therefore ultimately influences the acceptance of risk management strategies (Schreider *et al.*, 2009). Although the previously described engagement of stakeholders and expansion of disciplinary perspectives will assist in transparency, it is not sufficient. These steps help to ensure transparency of the process, but they do not necessarily bring transparency to the risk assessment itself.

Transparency is particularly important when assumptions or estimates are made. Risk assessments, as discussed in Chapter 2, are structured and systematic to try and reduce bias and value judgments; but this is not always successful. Comprehensive risk assessments will bring together information from multiple sources and, as risk assessors and managers expand to an integrated, multidimensional approach, the areas where specific supporting scientific data are not available will increase.

Risk assessors are often called on to make judgments, relying on, for example, the weight-of-evidence approach to integrate available information. This process often involves professional judgment and/or use of limited quantitative methods (Linkov *et al.*, 2009). This practice in risk assessment often lacks transparency, resulting in a lack of "quantified uncertainty" (Linkov *et al.*, 2009) so that the decision-makers and stakeholders do not fully understand the extent or impact of such judgments on the risk estimate (Brunk *et al.*, 1991).

The Panel proposes three essential requirements if conclusions are to be reached in a clear, transparent and convincing manner: outlining the presenting evidence, detailing a clear methodology for analysis of the evidence, and explaining the rules on which to base conclusions. Drawing on evidence from multiple sources and incorporating the use of an integrated, multidimensional approach make this process all the more challenging. The added complexity increases the need for clarity of presentation.

To be considered a transparent process, risk assessment should incorporate these six characteristics:

1. Elements of the risk assessment process are identified, documented, and available for review by other parties, particularly the theoretical basis, methods, model specification, and choice of methodology.
2. Prioritization and stakeholder input follow defined processes that are communicated to stakeholders.
3. Assumptions and value judgments are clearly stated.
4. Criteria for decisions in the risk assessment process are detailed.
5. Outcomes whose probabilities are not measurable (i.e., uncertainties) are identified; values assumed for uncertain variables are declared.
6. Methods, results, and conclusions are clearly documented and available for review by other parties.

(Morgan *et al.*, 1990; ISO, 2009a; NRC, 2009)

The characteristics identified here are fully supported by the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (Article 2.1.7) (OIE, 2010c).

Where the privacy and economic concerns of clients are at stake (e.g., first-entrant advantage in the pursuit of a newly opened market), not all these criteria can necessarily be met on a case-by-case basis. The Panel maintains that an institution engaged in risk assessment should always meet at least the first five. Without this as a minimum the process cannot be clearly understood or replicated. Failing to publicly disclose data and analysis, where it is feasible, as well as a lack of clarity, are what lead to concerns over lack of transparency.

Transparency, along with following a structured, systematic approach in the risk assessment process, is the best protection against bias, mistrust, and lack of stakeholder acceptance of a risk assessment (Schreider *et al.*, 2010; NRC, 2009). It is particularly vital where risk assessments are expected to inform policy formulation. Stakeholders will understandably demand full disclosure of information sources, methodologies, decision criteria, and so forth before accepting the conclusions of a risk assessment. Where policies are controversial, transparency is especially important in order for policy-makers to be in a position to justify the development of policies and their subsequent impact. Without this critical element, even if policy is formulated it is unlikely to be effective because of the lack of buy-in from stakeholders.

Transparency is obviously improved and reinforced through timely and continued risk communication, starting with consideration of stakeholder needs and preferences, and continuing with frequent consultation and sharing of concerns. Risk managers have the responsibility to maintain continual risk communication throughout the risk assessment process.

4.3 MULTIPLE CRITERIA DECISION ANALYSIS: AN EXAMPLE OF A FRAMEWORK FOR AN INTEGRATED, MULTIDIMENSIONAL APPROACH TO ANIMAL HEALTH RISK ASSESSMENT

Integrated, multidimensional approach (IMDA) is a methodological framework that can offer several benefits for animal health risk assessments. Animal health risk assessment can require the analysis of complex issues to support decision-making under conditions that may also involve high degrees of uncertainty and significant consequences for multiple stakeholders. Adopting an integrated, multidimensional approach can make the risk assessment process even more complex by broadening the range of consequences and stakeholder perspectives to be considered. It provides a means for facilitating participation by all stakeholders in the risk analysis process. The approach may also necessitate dealing with higher levels of uncertainty, as risk managers and risk assessors seek to include broader sources of information and stakeholder perspectives. Added to this complexity is the need to incorporate a wider range of disciplines to analyze and interpret these data. The end result of such efforts can be a better informed risk assessment.

One key challenge is how to combine all these criteria into a risk assessment in a timely, cost-effective, and transparent way. Risk assessment is an applied practice aimed at supporting decision-making in a real-world environment. Human and financial resources are limited. Information may be incomplete or imperfect. Stakeholder interests and perspectives may be conflicting. Contributions from different disciplines may be difficult to coordinate, compare, and communicate. These factors make it all the more important to have a structured, systematic procedure for defining the boundaries of risk assessment, selecting the right tools for the analysis, and capturing the lessons learned from the implementation and monitoring of both risk assessments and risk management decisions.

In its consideration of various approaches to animal health risk assessment, the Panel reviewed the OIE standards (OIE, 2004, 2010c) as well as several internationally recognized risk assessment frameworks (ISO, 2009a; HAIRS, 2008; Biosecurity New Zealand, 2006; CFIA, 2005; Animal Health Australia, 2005) and risk assessments (Cohen *et al.*, 2001).[20] There were valuable aspects to these frameworks and risk assessments and each had used different approaches, although there were some similarities in tools and methods such as the use of Monte Carlo simulation, sensitivity, and scenario analysis. The consensus view of the Panel, however, was that incorporating an integrated, multidimensional

[20] The Panel also reviewed other confidential risk assessments as part of the research for Chapters 3 and 5.

approach in a structured, systematic framework was the best option for animal health risk assessment. To achieve this, it is essential that the framework:

- ensures integration of animal health, human health, and the environment in the consideration of risk;
- adopts a multidimensional approach that considers management options and their outcomes in the risk assessment;
- engages risk managers and stakeholders in the boundary setting and question formulation;
- utilizes appropriate methodology and disciplinary perspectives; and
- assures stakeholders and decision-makers of transparency.

The challenge is to find a framework that enables assessors, managers, and stakeholders to collaborate effectively, document the process, and analyze management options. One such framework is multiple criteria decision analysis (MCDA), which has been used in several decision-making venues and facilitates decision-making in a complex environment (see Appendix D).

The value of MCDA rests on providing a systematic structure allowing decision-makers to efficiently and effectively use large volumes of information from an array of sources, including both stakeholders and disciplines. As one set of practitioners put it, "The very nature of multiple criteria problems is that there is much information of a complex and conflicting nature, often reflecting differing viewpoints and often changing with time" (Belton & Stewart, 2002). MCDA can "help decision-makers organize and synthesize information in a way that leads them to feel comfortable and confident about making a decision, minimising the potential for post-decision regret by being satisfied that all criteria or factors have been properly taken into account" (Belton & Stewart, 2002). In a way, MCDA provides a scaffolding of sorts into which analysts and decision-makers can build their decision tool set to address risk questions. In addition, MCDA helps to improve risk communication by making the areas of subjective decisions explicit and the reasoning behind decisions transparent. It accomplishes all of this by providing a systematic framework for gathering information from diverse perspectives; weighting, comparing, and integrating such input into a coherent analysis; and clearly describing the factors involved in the decision-making process (Belton & Stewart, 2002; Kiker *et al.*, 2005; Roy, 2005). For more information on the MCDA framework, readers are directed to Appendix D.

4.4 APPLICATION OF AN IMDA IN THE INTERNATIONAL CONTEXT OF ANIMAL HEALTH RISK ASSESSMENT

The adoption of an integrated, multidimensional approach (IMDA) to animal health risk assessment does not face unusual restrictions, but one of the issues is the application of such an approach within the context of international agreements. The Panel considered this carefully and felt that IMDA was consistent with the requirements of such agreements. Moreover, as in all risk assessment processes, the extent to which an IMDA is applied (i.e., the full range and integration of consequences) is dependent on the specific context of the risk assessment.

By way of an example, one may consider the World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) (WTO, 2010c). Any country that is a WTO member is expected to comply with WTO agreements when that country is a signatory party of such agreements. The SPS Agreement outlines the manner in which countries may establish and employ sanitary and phytosanitary measures in order to protect human, animal, or plant life (see Appendix F). According to Article 2 of the Agreement, the measures must meet the following criteria:

- Measures are only applied to the extent necessary.
- Measures must be based on scientific principles.
- Measures can be maintained only while justified by science.

As such, the question arises on occasion as to whether a country has a right to develop its own SPS guidelines. The answer is yes, provided it meets the above criteria. Similarly, it is perfectly allowable to estimate the negative economic impact of an importation on post-harvest losses when importation poses a risk to human, animal, or plant health. It would not be allowable to use those losses (e.g., effect on local industry) in the absence of risk to human, animal, or plant health to disallow entry of an item. Thus, such estimation could be based on new techniques or methodologies included in an IMDA.

An illustration of this comes from New Zealand. The New Zealand economic model estimates economic damage beyond initial exposed organism/food of concern (Biosecurity New Zealand, 2006). This is packaged into the term *post-harvest costs*. How liberally that is interpreted may be up for debate, but there is no question that this is being conducted without challenge by the risk assessment unit of a country that is a respected WTO member. Also, the effect on both domestic

and export market prices could include (and should at least consider) price erosion due to environmental damage; damage to the tourist trade, which will put a dent in some regional agricultural markets; and similar effects.

The report on the potential economic damage caused by an incursion of *Didymosphenia geminate*, as part of a New Zealand risk assessment, provides an example:

> This assessment estimates potential present value impacts of didymo on New Zealand's commercial eel fisheries, municipal, industrial and agricultural water intakes, community, municipal and domestic drinking water, local recreation values, international and domestic tourism expenditure, local and national existence values and existence values associated with extinction of native species, over the eight years 2004/05 to 2011/12, to total:
> • $57.798 million under the low impact scenario;
> • $167.233 million under the medium impact scenario; and
> • $285.132 million under the high impact scenario.[21]
>
> (NZIER, 2006)

Further reference to this approach can be found in the *Outline of New Zealand's Use of Risk Assessment Procedures in Determining SPS Measures* (WTO, 1995):

> 13. New Zealand has also developed a generic computer model for economic impact assessments. Using standard economic techniques such as partial budgeting, scientists and economists can calculate the direct economic impact of pest introductions. The variables considered in this model include such factors as yield loss, additional pest control costs, additional post-harvest costs and effect on both domestic and export market prices. Such economic impact assessments are currently being undertaken for a number of fruit fly species using the model.
>
> 14. The data from biological assessments and economic impact assessments will be used to develop or review phytosanitary measures so that risk management options used are consistent with the level of risk identified and are technically justifiable and transparent.

Furthermore, the SPS Agreement, Article 5, states (WTO, 2010c):

> 1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

[21] Note that costs are listed in NZ$.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; ***relevant ecological and environmental conditions***; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, ***Members shall take into account as relevant economic factors***: the potential damage in terms of loss of production or sales in the event of the entry, ***establishment or spread of a pest or disease***; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.[22]

These examples demonstrate not only the applicability of an IMDA, but also the application of a broader interpretation of consequences within the SPS Agreement.

Review of Key Findings

- An integrated, multidimensional approach offers an effective way for supporting risk-based decisions in the context of animal health risk assessment.
- This approach involves integrating consideration of animals, humans, and the environment into risk assessment, with consideration of consequences of the signal/hazard and of the management options.
- Avenues for moving toward the integrated, multidimensional approach in Canada include:
  - recognizing and using the strategic role of risk managers;
  - increasing the breadth and depth of consequence assessment;
  - expanding stakeholder and advisory input;
  - incorporating appropriate methodologies;
  - obtaining appropriate disciplinary perspectives;
  - deepening the available pool of expertise and knowledge;
  - integrating foresight in the prioritization of risk assessments; and
  - ensuring transparency in the risk assessment/risk analysis process.

[22] Emphasis added.

5

Consequences in Animal Health Risk Assessments

5 Consequences in Animal Health Risk Assessments

Key Message

Animal health risk assessments should consider the full range of potential animal, human, and environmental consequences, and the reasons for selecting which consequences to include should be fully and transparently explained.

Concern about consequences that may occur is the reason risk assessments are undertaken. The selection of which consequences are to be considered in a risk assessment determines the content, scale, and usefulness of the assessment. Several widely used frameworks and protocols for animal health risk assessment place consequence assessment toward the end of the assessment process (CFIA, 2005; OIE, 2010c). As discussed in the previous chapter, the Panel believes that an earlier and broader consideration of consequences in animal health risk assessment is needed. Further, the reasons for selecting which consequences to include should be fully and transparently explained.

A wide range of consequences can result from events related to animal health. Risk assessments usually focus on a sub-set of potential consequences, rather than attempting to consider all consequences (review of risk assessments). Selecting which consequences, or which categories of consequences, to consider is one of the most important decisions in risk assessment, and involves not only evaluating evidence of linkages between cause and effect but also recognizing the values and tolerances of the affected human societies. This decision determines many key parameters of the risk assessment, and defines the range of policies and decisions that may be affected by the outcome of the assessment. This is a significant determinant of its usefulness and its ability to meet the purpose for which it was conducted. The selection of the consequences to be considered in a risk assessment can be subject to bias and social inequity. Many policy-driven risk assessments are launched because certain potential consequences are of concern to a particular segment of society or government (review of risk assessments and interviews with experts). There may be other potential consequences, however, not of interest to those particular segments, which nonetheless could threaten other groups in society. Equity demands that the process of deciding which potential consequences to include in a risk assessment must encompass an evaluation of bias and of completeness in identifying and addressing the full range of potential consequences and legitimate concerns.

What is an Animal Health Hazard?

The term *animal health hazard* designates the actions, occurrences, or events involving animal health and disease for which a risk assessment might be undertaken.[23] Animal health hazards include a wide and diverse spectrum of actions or events, including:

- the transport of animals and animal products;
- policy decisions regarding farm animal management;
- an animal disease outbreak;
- tax legislation affecting animal industries;
- an outbreak of a zoonotic disease in people;
- municipal bylaws affecting pet licences;
- food inspection practices;
- animal or human disease response plans;
- land use policies and practices;
- border service policies and practices;
- drug and chemical policies and practices;
- wildlife management policies and practices;
- disaster and other emergency management plans; and
- many other similar events, actions, and occurrences.

The common feature is that each relates to health and disease of animals to some extent, and could be subject to a risk assessment of this animal health component.

5.1 CATEGORIES OF CONSEQUENCES ASSOCIATED WITH ANIMAL HEALTH HAZARDS

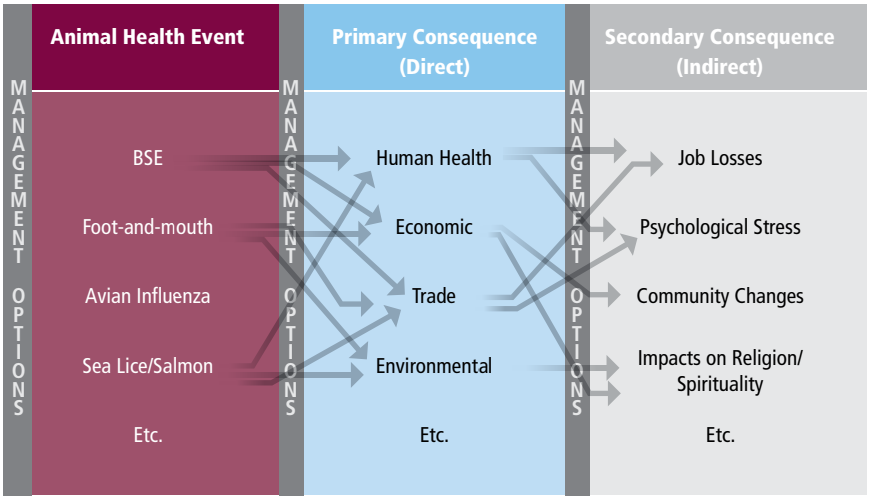
The admittedly wide spectrum of potential consequences from an animal health hazard can be sorted into eight broad categories (Figure 5.1). For any particular animal health hazard, some consequences may seem obvious as potential direct or indirect consequences, while others may appear to have a weak and unimportant association with the hazard (see Figure 5.2 and Box 5.1). Some consequences, if they occur, would bring immediate effects while others might be delayed. In practice, potential direct and immediate consequences would likely be viewed as legitimate concerns, while most people would be more skeptical about the legitimacy of potential consequences only indirectly associated with the animal health hazard or delayed in time. Yet the effects of indirect or delayed consequences

[23] See "Key Definitions" in Chapter 1, Box 1.3.

are nonetheless real. Thus it is important for risk managers, risk assessors, and other stakeholders to review all of these categories of potential consequences in the light of scientific evidence that each could potentially and plausibly be a true consequence of an animal health hazard.

(Council of Canadian Academies)

Figure 5.1
Categories of Consequences Associated with Animal Health Hazards



(Council of Canadian Academies)

Figure 5.2

Examples of Links Among Direct and Indirect Consequences and the Influence of Management Options

This figure illustrates examples of links between animal events, primary consequences, and secondary consequences and the opportunities that management options have to influence the extent of consequences in each of these different steps.

Box 5.1
Direct and Indirect Consequences

Direct consequences may include trade embargoes, a culling of animals with major economic consqeuences, human health effects, and so on.

Indirect consequences may include job losses, associated individual and community (psycho-social) impacts, and so on.

Whether a consequence is direct or indirect will depend on the nature of the animal health event.

Animal Health Consequences

Often the consequences of most concern in assessments of animal health hazards are the secondary effects of the infection or disease in the animals, and not the health of the animals per se. For example, some national and international guidelines for animal health risk assessment focus almost entirely on secondary economic effects (Animal Health Australia, 2005; CFIA, 2005; OIE, 2004). Others also include the welfare of the animals themselves as a consequence of concern (CaribVET Epigroup, 2007; Biosecurity New Zealand, 2006; EU, 2008). So while the probability of occurrence of disease in animals is often the event of paramount concern in animal health risk assessments, the consequences of concern are usually wider in nature (review of risk assessments). Animal health risk assessments may also include some susceptible animal populations and exclude others, explicitly or implicitly. When the health of the animals themselves is included as a consequence of concern, it is as a part of the cluster of consequences described below under animal welfare.

Animal Welfare Consequences

The concept of animal welfare often is expressed in the form of *five freedoms* that all animals should experience, as spelled out by the Farm Animal Welfare Council of the United Kingdom (FAWC, 2010), and acknowledged as appropriate operational guidance by the World Organisation for Animal Health (OIE, 2010c) (see Box 5.2). Included is freedom from disease, achieved by prevention or by rapid diagnosis and treatment. So, in the context of animal welfare, animal suffering because of disease is a potential consequence of animal health hazards that is of legitimate concern.

Box 5.2

Animal Welfare as Defined by the U.K. Farm Animal Welfare Council

The Five Freedoms

1. *Freedom from thirst and hunger* by ready access to fresh water and a diet to maintain full health and vigour.
2. *Freedom from discomfort* by providing an appropriate environment including shelter and a comfortable resting area.
3. *Freedom from pain, injury, and disease* by prevention or rapid diagnosis and treatment.
4. *Freedom to express normal behaviour* by providing sufficient space, proper facilities and company of the animal's own kind.
5. *Freedom from fear and distress* by ensuring conditions and treatment which avoid mental suffering.

(FAWC, 2010)

Other potential consequences for animal welfare can flow from animal health hazards. Many are indirect and linked to the handling of animals in response to an animal health hazard. In the 2001 outbreak of foot-and-mouth disease in the United Kingdom, for example, movement of animals off farms to market or slaughter was halted (Schley *et al.*, 2009; Crispin *et al.*, 2002). In some cases, not enough feed was available on the farms, and animals suffered from hunger (Schley *et al.*, 2009; Crispin *et al.*, 2002). Especially in swine herds, animals continued to be born into the same limited living space, resulting in crowding, stress, injury, and breakdown of sanitation (Laurence, 2002). Urgent on-farm destruction of animals made strict adherence to animal welfare standards for humane slaughter difficult to achieve (EFSA, 2008). Many aspects of animal welfare also are inherent in the transportation of live animals, as outlined in Section 7 of the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code* (OIE, 2010c). And such transportation is part of numerous activities for which animal health risk assessments may be undertaken.

The same animal welfare principles potentially apply to wild animals captured, handled, or manipulated for various reasons, including harvest and translocation for trade or other purposes. Such handling of wild animals may be part of animal health hazard events for which risk assessments are undertaken, thus making animal welfare issues legitimate consequences for inclusion within such risk assessments (Cattet *et al.*, 2008; CCWHC, 2010).

Human Health Consequences

Human health is usually ranked as a potential consequence of animal health hazards because of pathogens that can be transmitted to people from animals or animal products. Thus, zoonotic diseases and foodborne illnesses often are included as consequences of concern in animal health risk assessments (Morley *et al.*, 2003).

Other aspects of human health can also be considered consequences of animal health hazards. These consequences will vary considerably with the societal and cultural context of a country. General human nutrition may be affected by the loss of draft animals to disease and the loss of animal manure for fertilizer or for cooking fuel (Ravindran *et al.*, 1994; Wilkinson, 1979; Winterhalder *et al.*, 1974). Protein nutrition, in particular, may be affected by diseases that kill animals critical to protein supply or that trigger their depopulation through regulated culls (Jutzi & Domenech, 2006). The security of human food supply is cited as a potential consequence of animal health hazards by both the European Union and Caribbean nations (EU, 2008; CaribVET Epigroup, 2007). In Canada zoonotic and foodborne diseases are potential consequences for all segments of society. By contrast, threats to food security and sufficiency — and to protein nutrition — from animal health hazards jeopardize mainly the animal-dependent food supplies of remote and aboriginal communities (Davidson *et al.*, 2011).

Social Organization and Psychological (Psycho-Social) Consequences

Outbreaks of diseases in animals can exact a devastating toll on the well-being of the people and communities affected by an outbreak — increased levels of individual and community stress, heightened anxiety, depression and other mental disorders, and the fragmentation of family and community accord (Booth & Lloyd, 2000; Kelly *et al.*, 1995). These impacts arise from both the direct consequences of the animal disease — such as loss of animals and their associated economic and other values to the owners — and from the indirect effects of society's

response to the disease outbreak. Often taking the form of government-imposed disease eradication programs involving mass slaughter, quarantines, movement restrictions, and related actions, such reactions can badly disrupt the routines and practices of normal living.

Hood and Seedsman (2004) assessed the impact of a campaign to stamp out Johne's disease in sheep in Australia. The affected sheep farmers experienced trauma, shame, guilt, and social stigma, with outcomes including grief, anxiety, and depression. Some communities and families disintegrated. Government intervention was perceived as inflexible, heartless, authoritarian, and lacking scientific credibility. Mort *et al.* (2005) made a similar study of an outbreak of foot-and-mouth disease in the United Kingdom in 2001, and found similar effects. Mitra *et al.* (2009) assessed the social and psychological effects of the discovery of bovine spongiform encephalopathy (BSE) in Canada in 2003. Their observations line up with those previously cited while also placing the impact of BSE occurrence in the context of existing and subsequent additional stresses on farm families and their communities.

These studies amply demonstrate that many animal health hazards include potential human social and psychological consequences extending well beyond any economic consequences, direct and indirect. Nor are these social and psychological consequences spread evenly across everyone affected. For example, BSE and the government response in Canada affected smaller-scale producers more severely than larger-scale agribusiness enterprises or the slaughter and meat sales sectors (Mitra *et al.*, 2009).[24]

Environmental and Ecological Consequences

There is abundant evidence that the occurrence of various animal health hazards can have noteworthy environmental and ecological effects. The introduction of myxomatosis to control the European rabbit *(Oryctolagus cuniculus)* in England altered the vegetation patterns of southern England profoundly (Thomas, 1960). International spread of the chytrid fungus *(Batrachochytrium dendrobatidis)* has caused widespread decline and extinction of amphibian species in the tropical Central America and Australia (Berger *et al.*, 1998). Introduction of plague (infection with the bacterium Yersinia pestis) to native rodents in western North America at the beginning of the 20th century has been a key factor in the near extinction of the black-footed ferret *(Mustela nigripes)* and remains a significant

[24] Also see the papers in a special issue of the *International Journal of Risk Assessment and Management* (Volume 14 – Issue 3/4 – 2010) dedicated to risk management associated with BSE.

threat to its recovery (Biggins & Godbey, 2003). The rising prevalence of chronic wasting disease among wild ungulates in the western United States is beginning to affect mule deer *(Odocoileus hemionus)* populations, their interactions with mountain lions *(Puma concolor)*, a major predator, and human encounters with mountain lions in the band of land between suburbs and open countryside (Miller *et al.*, 2008). Importation of raccoons to West Virginia for hunting in 1977 initiated the current epidemic of raccoon-strain rabies in eastern North America, which threatened to invade Ontario, Quebec, and New Brunswick (Curtis, 1999; Torrence *et al.*, 1992).

Societal responses to animal health hazards also may have environmental and ecological effects. Large-scale slaughter, typical of responses to animal disease outbreaks aimed at pathogen eradication, requires disposal of a large mass of biological material, usually through burning or burial (Scudamore *et al.*, 2002). Contamination of air, water, soil, and compost necessarily accompanies such undertakings, and may have subsequent consequences for human, animal, and ecosystem health (Scudamore *et al.*, 2002). The successful elimination of the fox-strain of rabies virus from western Europe through oral vaccination of foxes has been accompanied by a substantial rise in fox populations with a high prevalence of infection with the zoonotic tapeworm *Echinococcus multilocularis* (Schweiger *et al.*, 2007).

Environmental and ecological consequences of animal health hazards often are complex and difficult to foresee. For example, the decision to permit importation to Canada of European wild boar for agricultural production may well have included consideration of pathogens that the imported animals might bring to Canada. It is unlikely, however, that it was foreseen that wild boar, escaped or released from farms on the Canadian prairies, would establish the current self-sustaining wild populations that have the potential to expand in size and range to overlap with wild pig populations in northern U.S. that carry pathogens such as pseudorabies virus and porcine brucellosis, currently not present in Canada (Government of Manitoba, 2010; George, 2004; Dickenson, 2010).

Economic Consequences

The potential economic consequences of animal health hazards are widely documented and understood, and usually are one of the primary focuses of animal health risk assessments (review of risk assessments). The first decade

of the 21st century furnishes plenty of examples. The discovery of BSE in Canada is estimated to have cost the Canadian economy more than $6 billion (Mitura & Di Piétro, 2004). An outbreak of highly pathogenic avian influenza in commercial poultry in British Columbia in 2004 was estimated to be $380 million (Bowes, 2007). Approximately 17 million birds were killed during control measures and an estimated 1,700 jobs vanished, food bank use rose sharply in the affected communities, and uncompensated costs to enterprises affected by loss of business were put at $156 million (Bowes, 2007). In an economic modelling study, Paarlberg *et al.* (2008) estimated that, on average, an incursion into the United States of an important foreign animal disease would cost U.S. livestock-related enterprises somewhere between US$2.7 billion and US$4.1 billion over a four-year-period.

Political Consequences

Animal health hazards can be challenging to manage. In open societies, large-scale disease outbreaks usually are dealt with under direct public scrutiny, and the public is predisposed to blame political leaders for any failure to minimize the magnitude and diversity of negative consequences. The cost may well be a drop in voter support. As already noted, responses to animal disease outbreaks can be highly divisive within communities. Political consequences — just like social and psychological ones — may be felt at a very local level of social leadership, as well as at regional, provincial, and national levels (see Gerodimos, 2004; Frewer & Salter, 2002; Weinburg *et al.*, 2002).

National Security Consequences

While not necessarily a separate category of potential consequences of animal health hazards, national security is included here to recognize that the potential consequences of some animal health hazards are so great that some nations have identified them explicitly as possible threats to national security. For example, the U.S. *Homeland Security Presidential Directive* 9 of 30 January 2004 identifies animal pathogens as potential risks to the national food system, and sets out policies to defend that system against the use of such pathogens by terrorists or others (Homeland Security, 2004). When national security is thought to be threatened by an animal health hazard, the actual consequences of concern are most likely to be from human health effects; human social impacts; and psychological, economic, and political consequences. The shared attribute is that the probability of occurrence of the hazard and the magnitude of its potential consequences are high enough that someone in authority declares that the hazard has the potential to destabilize a society.

One such example of a potential threat to national security from an animal health hazard is the highly pathogenic H5N1 strain of avian influenza virus, which evolved in domestic poultry in the late 1990s and spread dramatically to central Asia, Europe, and Africa in 2004 (WHO, 2011). It has never come under complete control or been eradicated (Capua & Alexander, 2010), and is responsible for much human hardship, anxiety, and fear. Through direct mortality from infection and culling to control the virus, H5N1 has caused the death of millions of domestic poultry worldwide, which represents an enormous loss of human dietary protein and large economic losses, particularly to small farms and rural communities (Otte *et al.*, 2008). It is a human pathogen with a very high case fatality rate (about 60 per cent), but with little, if any, human-to-human transmission (CDC, 2010). Yet it has the potential to rapidly acquire genetic changes and new phenotypic traits. Such new traits could include the capacity for rapid human-to-human transmission typical of other influenza viruses infectious for people. Attempts to achieve mass vaccination against the H1N1 influenza virus in 2009 were not always successful, emphasizing human vulnerability to an influenza — such as a mutated H5N1 — that is both highly pathogenic and highly contagious among people (Friscolanti, 2009; Fidler, 2009). Other examples of animal health hazards that could be viewed as threats to national security include the severe acute respiratory syndrome (SARS) coronavirus (Casadevall & Pirofski, 2004) and the pool of retroviruses in non-human primates from which the various strains of HIV-I and HIV-II (human immunodeficiency virus) have become established as devastating human pathogens, and which may yet produce further human pathogens of similar kinds (Hahn *et al.*, 2000).

5.2 SELECTION OF CONSEQUENCES IN ANIMAL HEALTH RISK ASSESSMENTS

Despite the wide range of potentially important consequences of animal health hazards, only rarely has there been systematic evaluation of which categories of consequences should be considered in animal health risk assessments. An explicit rationale for including some potential consequences, and not others, is seldom incorporated in templates or process guidelines for animal health risk assessment or in the risk assessments themselves. General statements are made in guidelines that health, environmental, and economic consequences should be taken into consideration, but no process is then described for how this can be done in a complete and transparent way. Deciding which potential consequences to consider in an animal health risk assessment is usually left to the discretion of the assessors, often with the implicit assumption that the outlook of the organization

undertaking the risk assessment — a national veterinary service, a commodity-based organization, or a public health service — will correctly determine which categories of consequences are appropriate to include in the assessment. This appears to be the most common practice.

For example, in its *Terrestrial Animal Health Code* (OIE, 2010c), *Aquatic Animal Health Code* (OIE, 2010d), and *Handbook on Import Risk Analysis for Animals and Animal Products* (OIE, 2004), the OIE does not explicitly include a process for selection of the consequences to be considered in the animal health risk assessment process. The *Terrestrial Animal Health Code* defines risk as "the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health" (OIE, 2010c). The categories of "biological and economic" consequences are vague and potentially quite limited. In the OIE documents, consequence assessment is explicitly included as a step in the risk assessment process following identification of potential animal health hazards and estimation of their probability. The *Terrestrial Animal Health Code* states, "Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences" (OIE, 2010c). The *Aquatic Animal Health Code* says much the same (OIE, 2010d). While not explicit, some consideration of the categories of consequences to be included in the risk assessment is embedded in *hazard identification*. In that step each potential health hazard is assessed according to some predefined criteria to determine whether each will be considered a health hazard and thus evaluated further in the risk assessment. The criteria used for hazard identification necessarily incorporate some notion of the categories of consequences of concern to the risk assessors. As in the *Terrestrial Animal Health Code*, however, consideration of the categories of consequences is a vague and undefined aspect of this hazard identification process.

Thus, at the stage of *consequence assessment* in the widely practiced formal risk assessment process espoused by the OIE, the animal health hazards to be assessed already have been selected and their probability of occurrence estimated. This is perhaps appropriate when the risk assessment process is applied to a very specific proposal, such as importation of a commodity, for which only one or a few animal health hazards (pathogens) can be identified. But, if the list of potential health hazards is long, as it sometimes is, some risk assessment procedures will include a step, usually in the *hazard identification* process, to reduce that long list to a small number of health hazards judged by the risk assessors or the risk managers to be the most likely to occur or to have the most important consequences (OMAFRA, 1996, 2001). A full risk assessment then is carried out only for this short list of health hazards.

To come up with these short lists, those making the selection must have a working idea of the categories of consequences of greatest concern, at least to themselves and the interests they represent. If there is no specified process for reviewing all the potential categories of consequences and deciding which categories to consider, however, this selection process may well be biased toward a small number of categories and fail to consider others. This triage of categories of consequences will typically occur before the formal step of consequence assessment (review of risk assessments). It thus has the potential to result in a biased assessment of risk in which there has been no formal and transparent review of the categories of consequences to be considered in the risk assessment.

The animal health risk assessment protocol of the Canadian Food Inspection Agency (CFIA) follows this OIE model. No formal process to define the categories of consequences to be considered in a risk assessment is explicitly included in the CFIA risk assessment process. Consideration of consequences takes place only after hazards have been identified and the probabilities of release and exposure determined (CFIA, 2005). The protocol document states:

> Consequence assessment consists of describing and quantifying the relationship between specified exposures to a biological agent and the economic consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences. The consequence assessment typically includes a specification of the impact on health in the animal and human populations sustained under given exposure scenarios (CFIA, 2005).

As in the OIE protocol, the categories of consequences to be considered are not explicitly decided early in the risk assessment process, and the guidelines for assessment of consequences at the end of the process are general and limited in scope.

The CFIA followed this framework for the consideration of consequences in the 30 animal health risk assessments that the Panel reviewed (see Section 3.3). There was no formal consideration of the categories of consequences to be included in each risk assessment. The categories of consequences considered in depth in the consequence assessment step tended to be focused upon animal health and the economic consequences for animal owners and regulatory agencies. Animal welfare issues and other consequences were sometimes included as well.

Several national and international guidelines for animal health risk assessment have taken a more inclusive approach when determining which categories of consequences should be considered in a particular risk assessment. For example, the Scientific Panel on Animal Health and Welfare of the European Food Safety Authority (EFSA) advocated that the risk manager should clarify to the risk assessor which categories of consequences are important to the risk question before them as an initial step in the risk assessment process (EFSA, 2007). It also advocated that the risk assessor should then develop a *risk profile*, which sets out the scope of the risk assessment to be undertaken, including identification of the consequences to be considered (EFSA, 2007). In a slightly different, but related, context, discussion papers from international workshops about criteria for assigning priority for response to, and management of, animal pathogens generally identify a wide range of categories of consequences as relevant to this form of animal disease risk evaluation. For example, the Working Party of Chief Veterinary Officers of the European Union (EU, 2008) included lists of consequences on human health and society and several categories of indirect economic consequences in addition to the usual concerns about immediate economic consequences to animal owners and trade. Similarly, the veterinary services of several Caribbean countries (CaribVET Epigroup, 2007) identified human health and a range of socio-cultural consequences as criteria for assigning priorities for control to animal pathogens in their region. While New Zealand's national guidelines for risk assessment (Biosecurity New Zealand, 2006) follow the general procedural outline used by the OIE, the guidelines nonetheless emphasize that a wide range of categories of potential consequences — virtually all of those listed in this chapter — must be taken into consideration in each risk assessment.

5.3 PROPOSED BEST PRACTICE FOR SELECTION OF CONSEQUENCES IN ANIMAL HEALTH RISK ASSESSMENTS

Rigorous processes and procedures for animal health risk assessment have been developed over the past few decades to ensure that animal health hazards are correctly identified and that the probability of their occurrence is correctly and transparently evaluated. Unfortunately, the evaluation of the potential consequences of animal health hazards has not received the same detailed and rigorous attention. Most animal health risk assessment frameworks, and the resulting risk assessments themselves, do not include formal processes for determining which categories of potential consequences are to be included in a given risk assessment and which are not. The Panel believes that this is an oversight, particularly in the current global context in which animal, human, and environmental health are ever more closely connected. It is the Panel's

view that the full range of potential consequences of each animal health hazard should be acknowledged, and that the categories of consequences to be included in any animal health risk assessment should be stated explicitly and explained. To achieve this goal, consequence identification and selection should be made a formal component of the animal health risk assessment process. Without this formal process, each assessment risks being limited and biased in terms of the consequences it takes into consideration.

The formal consideration of the categories of consequences to be included in a risk assessment should take place early on in the process. Recent reviews by the EFSA (2007) and the U.S. National Research Council (NRC, 2009) emphasize closer interaction between risk managers and risk assessors at the beginning of a risk assessment process to ensure that the assessment addresses the questions and issues most relevant to the needs of risk managers. A clear determination of the categories of consequences to be included in a risk assessment also belongs at the beginning of the process, perhaps as a risk profile developed collaboratively by the risk manager and risk assessor, as recommended by the EFSA Scientific Panel on Animal Health and Welfare (EFSA, 2007).

Review of Key Findings

- Consequence identification and selection should be a formal element of the animal health risk assessment.
- In order to produce a comprehensive risk assessment, a full range of potential consequences should be identified and, where appropriate, assessed in depth.
- Consideration of the categories of consequences should take place early in the process, and should involve input from risk managers, risk assessors, policy- and decision-makers, and other relevant stakeholders.
- For reasons of transparency, the consequences to be considered should be explicitly stated in the risk assessment, and the reasons for the selection explained.

6

Knowledge Capacity in Animal-Human Health Risk Assessment Science in Canada

6 Knowledge Capacity in Animal-Human Health Risk Assessment Science in Canada

Key Message

Animal health risk assessments rely on the training and work experience of risk assessors and risk managers, combined with the production of research by academics and other experts. Canada's current research funding structure could better facilitate integrated animal-human health research. Canada has opportunities to strengthen its knowledge capacity for protecting animal health, human health, and the environment.

Effective risk assessment requires knowledge and research. Knowledge in the form of expertise, experience, and established (or known) facts and procedures (Aune, 2008) provides the intellectual foundation for the practice of risk assessment. Research in the form of scientific observations and hypotheses provides the means for advancing that knowledge. Together these areas comprise Canada's *knowledge capacity* in animal health risk assessment. To understand the state and comprehensiveness of animal health risk assessment knowledge capacity in Canada, the Panel undertook a number of specific activities:

1. survey of the training experiences of the Canadian Food Inspection Agency (CFIA) personnel involved in animal health risk assessment (Section 6.1.1);
2. bibliometric analysis of animal health risk assessment science (AHRAS) and the human health consequences of animal health events (HHCAHE) (Section 6.1.2 and supplementary online material);[25]
3. survey of surveillance organizations across the federal and provincial levels of government, and in academia (Section 6.2.1);
4. survey of university researchers at Canadian veterinary colleges working in areas related to applied animal health research (AAHR) of potential relevance as input to animal health risk assessment (Section 6.2.2);
5. review of course descriptions and trends in the course offerings dealing with animal health risk assessment in veterinary schools in Canada and other countries (Sections 6.3.1 and 6.3.2); and
6. review of funding sources for research relating to animal health risk assessment in Canada and other countries (Sections 6.3.3 and 6.3.4).

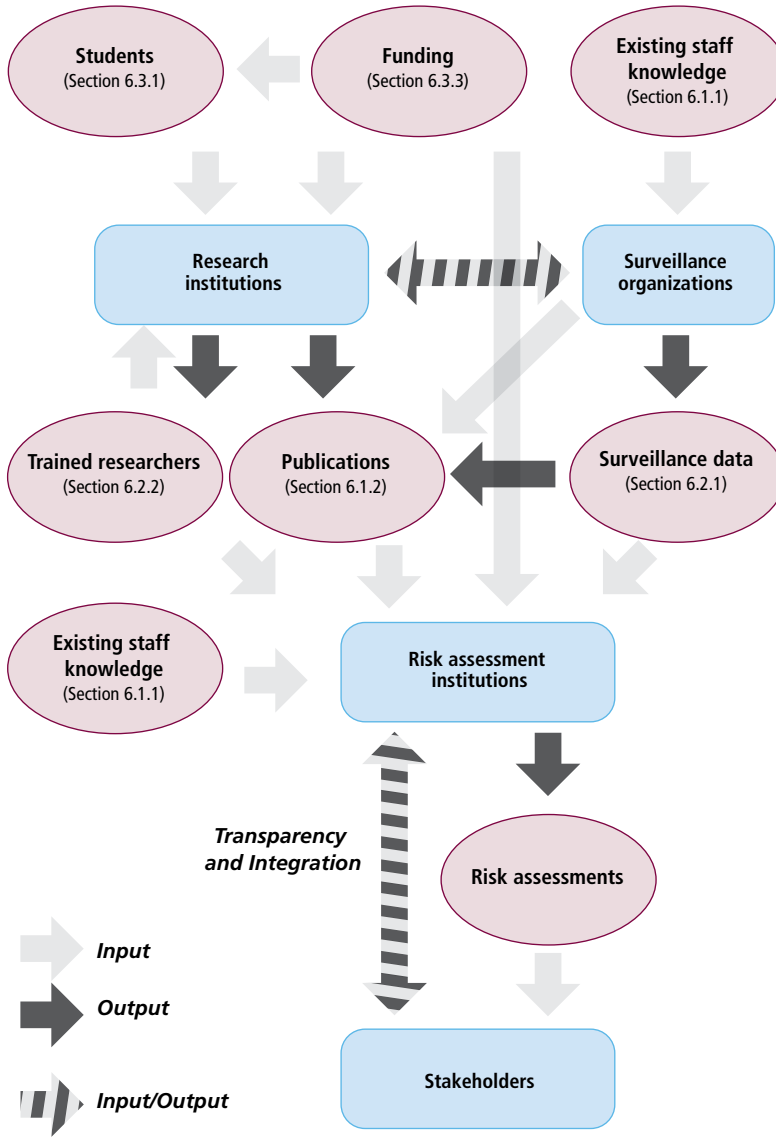
[25] Supplementary material can be found at www.scienceadvice.ca/en/animal-health.aspx

The production and exchange of knowledge can be viewed as an integrated system composed of the inputs and outputs from research institutions, surveillance organizations, research assessment institutions, and other stakeholders. Figure 6.1 provides a schematic overview of the relationships between surveillance and research *inputs* (including the knowledge and expertise of the current risk assessment practitioners; academic researchers, students, and publications; surveillance data; and funding sources), and the production of specific knowledge *outputs* (academic researchers and publications; surveillance data; and risk assessments). A weak link in the chain of knowledge production will affect the others.

The Canadian research community performs relatively well compared to its international peers in producing certain types of research contributing to integrated animal-human health risk assessment science. There remains significant opportunity, however, for Canada to enhance the research and practice of integrated animal-human health risk assessment. Considerations for building knowledge capacity in Canada, including opportunities and challenges identified by the Panel's research, are addressed in the final section of this chapter.

6.1 EXPERTISE IN ANIMAL HEALTH RISK ASSESSMENT SCIENCE IN CANADA

The state and comprehensiveness of knowledge in animal health risk assessment science can be measured along two axes: (1) the expertise and experience of those who apply knowledge (e.g., risk assessors and risk managers); and (2) the know-how generated by those who produce the knowledge required to support the practice of animal health risk assessment (e.g., surveillance data, animal and human health research). This section seeks to provide insight from both perspectives, first by looking at the expertise and experience of the CFIA personnel involved with animal health risk assessment and then by examining the knowledge generated by Canadian researchers at veterinary academic institutions and government laboratories. Although other groups and individuals in academia, industry, and government produce animal health risk assessments, the Panel's analysis of risk assessors and risk managers focuses on the CFIA, which is the central federal agency for animal health risk assessment in Canada.



(Council of Canadian Academies)

Figure 6.1

Knowledge Production and Exchange in Animal Health Risk Assessment

6.1.1 CFIA Training

Animal health risk assessment at the CFIA is carried out by risk assessors, with additional input from scientific advisors and risk managers. Risk assessors conduct the formal risk assessments; scientific advisors provide input and advice on risk assessments and policies; and risk managers oversee the process and are responsible for risk management decisions. Each of these groups thus forms an important part of the CFIA — and Canadian — expertise and experience in the practical application of risk assessment science. In addition to risk assessments, these individuals are involved in a broad range of activities that contribute to the promotion of animal and human health and welfare in Canada. Between 2007 and 2009, those working with the CFIA's Animal Health Risk Assessment (AHRA) unit produced 46 predominantly qualitative risk assessments; 37 scientific advices and similar documents; plus country evaluations, conference presentations, training sessions, and other products.[26]

The Panel asked risk assessors and others involved in animal health risk assessment within the CFIA to complete a survey describing their training and years of paid employment in various areas of risk assessment. Of the 25 individuals asked to complete the survey (representing most of the total potential survey respondents), responses were received from 12 individuals: 5 risk assessors and 7 others (e.g., risk managers and scientific advisors). This is a relatively small number, and the results must be interpreted in that light; nevertheless, the information does provide an indication of overall training and experience. The major results are discussed below, and further details are presented in Table 6.1 (risk assessors) and Table 6.2 (risk managers and scientific advisors).

Risk Assessors

One of the primary roles of a risk assessor is to conduct animal health risk assessments according to the protocols established by CFIA management. Risk assessors may be trained as part of a professional veterinary medicine program or as research scientists. CFIA policy states that those hired as veterinarians must be graduates of a school of veterinary medicine recognized by the Canadian Veterinary Medical Association (CVMA), or hold a Certificate of Qualifications granted by the National Examining Board of the CVMA (CFIA, 2010e). Those hired as research scientists must hold a graduate degree in science with an area of expertise and experience relevant to animal health risk assessment (interviews with CFIA staff).

[26] Based on interviews with CFIA staff.

Academic Training

Four of the five risk assessor respondents held a Doctor of Veterinary Medicine (DVM)[27] and the other held a Medical Doctorate (MD). Three also held a Doctor of Philosophy (PhD), with specializations in epidemiology, infectious diseases, or veterinary science. All five also held a Master of Science (M.Sc.), with specializations in epidemiology (three), population medicine (one), and veterinary science (one).

Employment Experience

The level of employment experience varied from 20 years to less than a month. Four of the five respondents had more than three years of experience. Similarly, the number of years at their current position varied from less than a month to 16 years. Four of the five respondents had held their current position for three years or more.

Type of Risk Assessments Performed

Of the five respondents, four reported experience with performing qualitative risk assessments, three with semi-quantitative (data not shown on table), and three with quantitative.

Key Topics by Sources of Training

Respondents reported that most of the key topics (except economics) identified by the Panel were covered in graduate courses and/or by formal and informal on-the-job training (see Table 6.1).

Risk Managers and Scientific Advisors

Risk managers involved in animal health risk assessment at the CFIA help establish the parameters and need for risk assessments, review draft documents for risk assessments to provide comments, request further information, and determine whether an external review is necessary (CFIA, 2005; interviews with CFIA staff). Scientific advisors may be involved in helping to produce scientific advices, which may include scientific opinions, policy reviews, or other similar work (interviews with CFIA staff).

Academic Training

All seven of the risk manager and scientific advisor respondents held a DVM. Two also held a M.Sc., with one reporting a specialization in epidemiology.

[27] Note: The acronym for Doctor of Veterinary Medicine is DVM in English and DMV in French. For the purposes of this document, DVM is used.

Table 6.1

Training Experience of CFIA Risk Assessors

Topics	Potential sources of training									
	Covered in course(s) during graduate program	**Graduate-level course(s) taken outside of graduate program**	**Specific short course(s)**	**Web-based training**	**Learned on own**	**Formal workplace training program** (e.g., in-house training course)	**Informal mentoring on the job** (e.g.,training by manager or colleague)	**Other**	**I have not received training in this particular area**	**This area is not relevant to my specific position**
Qualitative risk analysis	1		1		2	2	4			
Quantitative risk analysis	2	1	3		1	1	1		1	
EPIDEMIOLOGY i. measures of disease frequency	5		2		1	2	3	1		
ii. measures of association	5		1		1		1	1		
iii. disease surveillance	5		1		1	2	2	1		
iv. disease modelling (e.g., use of NAADSM)	4		1		1	1		1		
Principles of disease transmission	5	1			1	1	2	1		
Dose-response modelling (e.g., food safety)	1	1			1			1	2	
Animal health	4	1	1		1	2	2	1		

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Table 6.1 *(continued)*

Training Experience of CFIA Risk Assessors

Topics	Potential sources of training									
	Covered in course(s) during graduate program	**Graduate-level course(s) taken outside of graduate program**	**Specific short course(s)**	**Web-based training**	**Learned on own**	**Formal workplace training program** (e.g., in-house training course)	**Informal mentoring on the job** (e.g.,training by manager or colleague)	**Other**	**I have not received training in this particular area**	**This area is not relevant to my specific position**
Critical appraisal of scientific literature	4	2	1		1	1	1	1		
Systematic reviews	3	1	1		1	3		1	1	
Meta-analysis			1		1	2			1	
Use of @risk or similar software			1	2	3	3	2			
Diagnostic test evaluation	3	1			1	1		1		
Communications/knowledge transfer/technical writing	3		1		2	3	3	1		
Economics (e.g., cost-benefit analysis)					1	1	1	1		

(Council of Canadian Academies)

This table represents the training of risk assessors at CFIA (n = 5). For example, 5 respondents received "epidemiology: measures of disease frequency" training during their graduate program.

Table 6.2

Training Experience of CFIA Risk Managers and Scientific Advisors

Topics	Potential sources of training									
	Covered in course(s) during graduate program	**Graduate-level course(s) taken outside of graduate program**	**Specific short course(s)**	**Web-based training**	**Learned on own**	**Formal workplace training program** (e.g., in-house training course)	**Informal mentoring on the job** (e.g., training by manager or colleague)	**Other**	**I have not received training in this particular area**	**This area is not relevant to my specific position**
Qualitative risk analysis		2	1	1	2	2	4			
Quantitative risk analysis		2	3	1	1	1	4		1	
EPIDEMIOLOGY i. measures of disease frequency	4	2		1	2		1	1		
EPIDEMIOLOGY ii. measures of association	4	2	1	1	2		1	1		
EPIDEMIOLOGY iii. disease surveillance	4	2	1	1	2	1	1	1		
EPIDEMIOLOGY iv. disease modelling (e.g., use of NAADSM)	1		2		1		2	2	2	
Principles of disease transmission	5	2			2	2	1	1		
Dose-response modelling (e.g., food safety)			1		1			2	4	1
Animal health	5	2		1	2	2	2			

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Table 6.2 *(continued)*

Training Experience of CFIA Risk Managers and Scientific Advisors

Topics	Potential sources of training									
	Covered in course(s) during graduate program	**Graduate-level course(s) taken outside of graduate program**	**Specific short course(s)**	**Web-based training**	**Learned on own**	**Formal workplace training program** (e.g., in-house training course)	**Informal mentoring on the job** (e.g.,training by manager or colleague)	**Other**	**I have not received training in this particular area**	**This area is not relevant to my specific position**
Critical appraisal of scientific literature	4	2		1	2		1	1		
Systematic reviews	2	2		1	1				1	2
Meta-analysis	1	1		1	1				2	2
Diagnostic test evaluation	1				1		1	1	2	1
Communications/knowledge transfer/technical writing	2	1		2	2	2	4	1		
Economics (e.g., cost-benefit analysis)		1	1	1	1		2	1		1

(Council of Canadian Academies)

This table represents the training of risk managers and scientific advisors employed at CFIA (n = 7). For example, 4 respondents received "epidemiology: measures of disease frequency" training during their graduate program.

Employment Experience

Several of the respondents had previous experience as risk assessors within the CFIA. Paid experience in the field ranged from 16 years to less than a month. Five of the seven respondents, had more than three years of experience. The number of years at their current position varied from less than a month to six years among the five out of seven respondents who answered this question.

Key Topics by Sources of Training

Respondents reported that most of the key topics identified by the Panel were covered in graduate courses and/or by formal and informal on-the-job training (see Table 6.2).

6.1.2 Bibliometric Analysis

Academic publications — an output of research institutions — are a crucial input into the risk assessments conducted at the CFIA (see Figure 6.1) and reflect Canadian expertise in relevant areas. By way of surveying specific expertise, the Panel chose to evaluate relevant Canadian research outputs as a reflection of expertise in a bibliometric analysis. Research outputs in key areas are also further explored in Section 6.2, which looks at the applied animal health research produced by surveillance organizations and university researchers.

For the bibliometric analysis, the Council commissioned Science-Metrix to examine the quantity, impact, and intensity (i.e., degree of specialization) of Canadian research in the areas of animal health risk assessment science (AHRAS) and the human health consequences of animal health events (HHCAHE), both over time and among countries. The findings showed that the quantity of research relating to animal-human health risk assessment produced in Canada compares reasonably well with that of other major agricultural producers. Overall, Canada's research production ranks above the Organisation for Economic Co-operation and Development (OECD) average (particularly when compared against total livestock production), and falls in the mid-range of major agricultural producers in terms of impact and specialization. Details of the methods and results of this analysis are available online as supplementary material (see www.scienceadvice.ca/en/animal-health.aspx).

6.2 THE PRODUCTION OF NEW APPLIED ANIMAL HEALTH RESEARCH

Knowledge required to support applied animal health research (AAHR) activities can be broken down into two general areas: surveillance data (knowledge about disease prevalence and incidence in populations of interest), and applied animal health research (knowledge about various disease aspects of concern such as methods of transmission, validity of detection tests, etc.). Surveillance activities are primarily carried out by federal and provincial government organizations, as well as in academic and private laboratories, often working with industry. Applied animal health research is primarily conducted by academic institutions, again often working with industry.

To better understand the state of knowledge generation to provide data inputs to risk assessment, the Panel surveyed the two main groups most directly involved: Canadian surveillance organizations and researchers at Canadian veterinary colleges. The next two sections outline the results of these surveys with material presented in the sequence described in Box 6.1. Some key elements of the methodology are outlined in Box 6.2.

Box 6.1
Survey Sections

Methodology and respondent profile
Describes the methodology and respondent profile in each survey.

Areas of activity
Explains the main areas of activity in each survey (see Table 6.3 and Table 6.5).

Contribution of knowledge to risk assessment
Asks respondents the extent to which their areas of activity contribute to animal health risk assessment.

Sources of funding
Looks at the sources of funding for supporting research among the survey respondents. Potential sources may include federal and provincial governments, national granting councils, and industry.

Methods of dissemination
Examines the methods respondents use for communicating results and knowledge transfer. Possibilities for dissemination may include peer-reviewed journals, public reports, in-house publications, industry publications, or other avenues.

Student involvement in research
Explores the quantity and categories of students (e.g., B.Sc., DVM, M.Sc., PhD) involved in surveillance and research activities. Student involvement is essential to the vitality of any scientific field, offering a means for training the next generation of scholars and technicians, supporting research activities, and incorporating new perspective.

Barriers to research
Identifies the main obstacles university researchers and surveillance organizations may face in carrying out their activities. Barriers may include "not in institution's mandate," "lack of time," "lack of expertise," "lack of funding," or "lack of student support," among other factors.

Box 6.2
Methodological Notes on Surveillance and Research Surveys

Each survey consisted of distinct research areas delineated by the Panel, with three areas in the surveillance activities survey (Table 6.3) and nine areas in the research activities survey (Table 6.5). In both surveys, respondents were asked if their activities (surveillance or research) related to each specific research area. If yes, respondents were then asked a series of questions regarding the activities conducted in that area (e.g., input into risk assessment, student involvement, dissemination methods, and funding). If no, respondents were asked which main barriers prevented them from engaging in such activities. This line of questioning was repeated for all the categories within each survey. Respondents could have activities contributing to more than one area so it is possible that the data contain some duplication.

For funding, dissemination, and barriers, the respondents were asked to rank the options presented from one to five (or from one to eight in some cases, according to the question) with one being classed as "most important." This data produced the "most important" category (based on the number of times the option was selected as "most important"). Respondents could not duplicate rankings

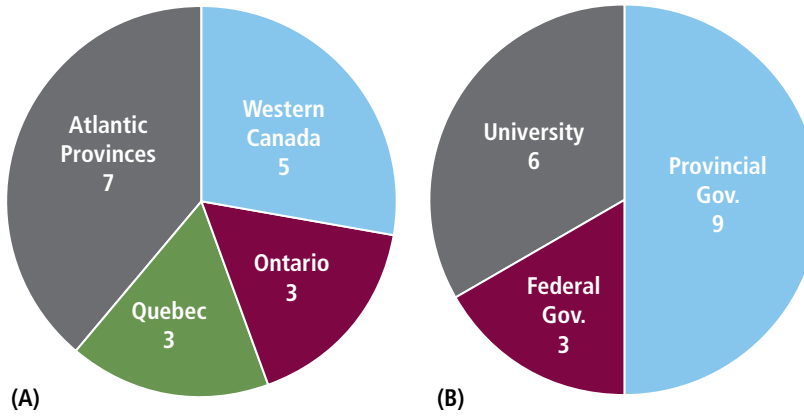
(list two options as number one, for example), but they could rank as many choices as they wished. In order to consider the total answers, the answers were pooled (regardless of ranking). This data provided the "frequency" category (number of times this answer was selected at any ranking). Since the respondents could choose more than one answer, the total number of answers may be greater than the number of respondents.

For further details, see the survey documents at www.scienceadvice.ca/en/animal-health.aspx

6.2.1 Survey of Surveillance Activities in Animal Health Risk Assessment

Methodology and Respondent Profile

The *Survey of Surveillance Activities in Animal Health Risk Assessment* was distributed to 30 individuals conducting surveillance activities in various organizations across Canada. A total of 19 responses were received. One incomplete response could not be analyzed, leaving 18 completed surveys. The respondents were distributed across Canada and represented different types of organizations (Figure 6.2).



(Council of Canadian Academies)

Figure 6.2
Distribution of Respondents by Region (A) and by Institution Type (B) — Surveillance Activities

Areas of Activity

The three areas of surveillance activities examined are identified in Table 6.3.

Table 6.3

Areas of Surveillance Activities

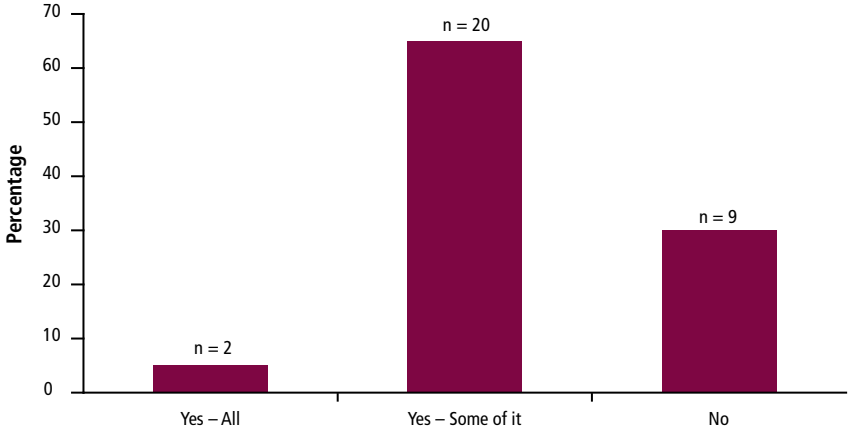
Area	Per cent
Disease frequency • Herd- and animal-level incidence and prevalence estimates	72
Evaluation of **surveillance systems** for the disease/pathogen	33
Other surveillance activities	66

(Council of Canadian Academies)

The column on the right of this table shows the percentage of respondents who indicated that their organization was involved in these types of surveillance activities and research.

Contribution of Knowledge to Risk Assessment

When asked if their surveillance activities were undertaken specifically to provide input to risk assessment, 71 per cent of the respondents answered that at least some of their work provided such input (Figure 6.3).



(Council of Canadian Academies)

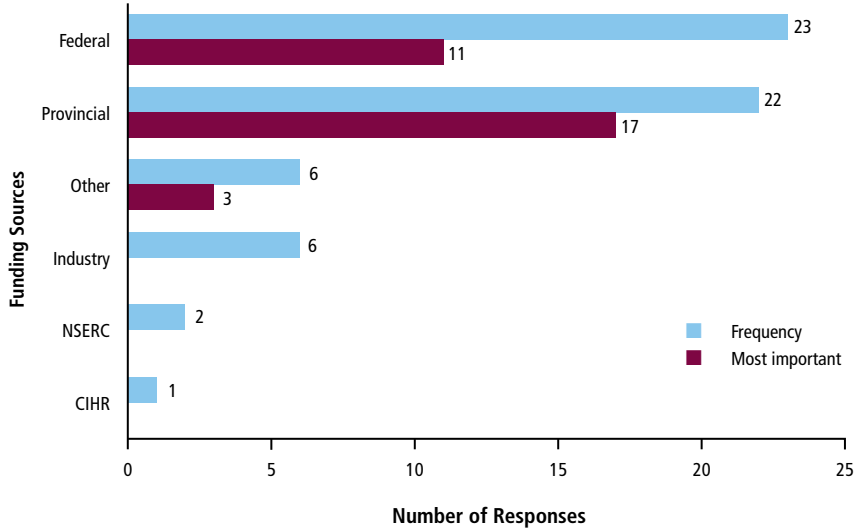
Figure 6.3

Percentage of Surveillance Activities Undertaken Specifically to Provide Input to Risk Assessment

This figure includes results from all three areas (Table 6.3) of the survey. Respondents could complete more than one area, explaining why the numbers add up to more than the total number of respondents. For example, 2 of 31 responses indicated that all their activities were undertaken specifically to provide input to risk assessment.

Sources of Funding

Surveillance activities are funded primarily by federal and provincial governments (Figure 6.4).



(Council of Canadian Academies)

Figure 6.4

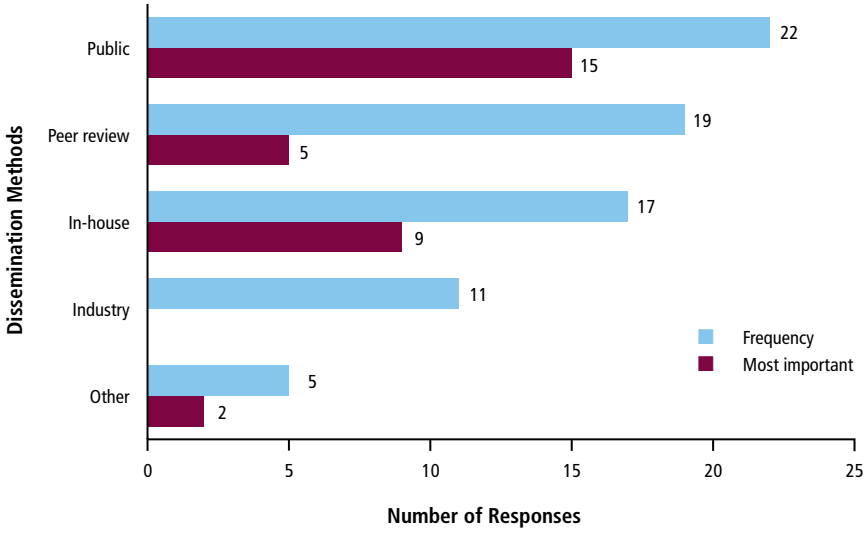
Frequency and Importance of Funding Sources — Surveillance Activities

In "disease frequency" and "surveillance systems," the federal government and provincial governments were both the most important and the most frequent sources of funding. In "other surveillance activities," provincial governments were the most important and frequent. Although industry was infrequently cited as a direct source of funding for surveillance activities, the Panel recognizes that industry players also have an important role in determining the priorities for surveillance, as industry organizations are often very involved as partners[28] in research or surveillance activities.

Methods of Dissemination

For surveillance activities, public reports were the most frequent and important method for the dissemination of results among surveillance organizations. Peer-reviewed publications followed closely in frequency but were less often cited as most important, while in-house reports came second in importance and third in frequency (see Figure 6.5).

[28] For example, see the surveillance programs at CFIA "Animal Disease Surveillance" and at OMAFRA "Animal Health Surveillance."



(Council of Canadian Academies)

Figure 6.5

Frequency and Importance of Dissemination Methods — Surveillance Activities

Table 6.4

Surveillance Organizations – Student Involvement

Area	Undergrad (per cent)	M.Sc. (per cent)	PhD (per cent)	Post-Doc (per cent)	DVM (per cent)	Other (per cent)	# of Students*
Disease frequency	26	24	10	0	38	2	79
Surveillance systems	0	100	0	0	0	0	1.5
Other surveillance activities	25	33	4	4	35	0	40.5

(Council of Canadian Academies)

* Students may be involved in more than one area. The number of students was provided via a range; this table provides the average value from the range, explaining why there can be 0.5 students.

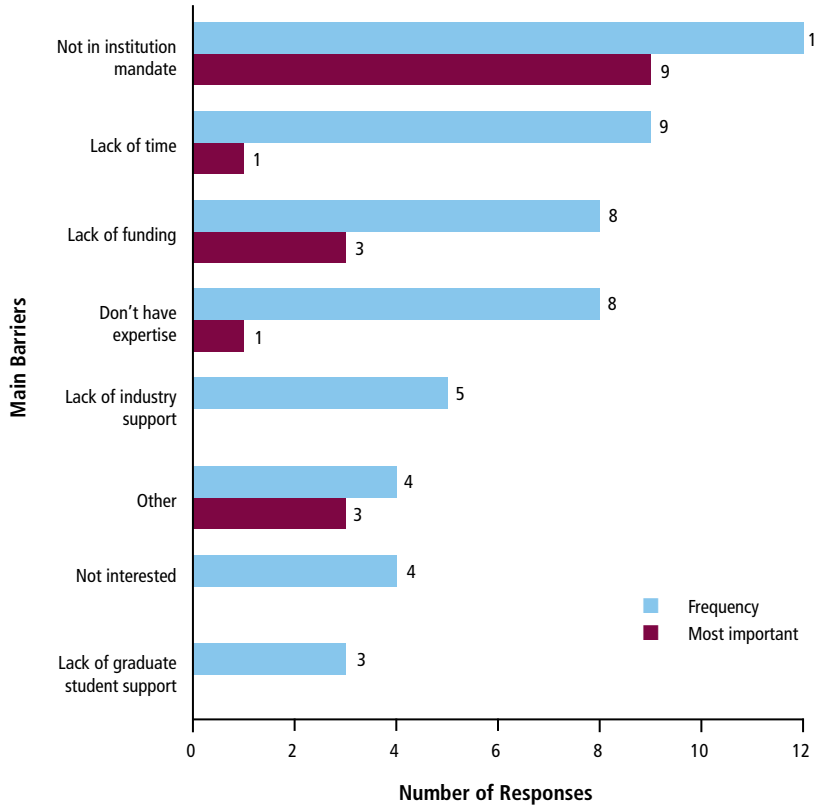
Student Involvement in Surveillance Activities

The Panel asked the surveillance organizations about the number and types of student involvement in the research projects they were conducting. A little more than half of the surveillance organizations involved students in their work

(Table 6.4). Overall DVMs and undergraduates were involved more often than graduate students (M.Sc. and PhD). DVMs were the students most often involved in "disease frequency" and "other surveillance activities" research, followed by undergraduate and M.Sc. students.

Barriers Faced

For surveillance organizations, the most frequent and important barrier to research cited was that an activity was "not in institution's mandate." "Lack of time," "lack of funding," and "don't have the expertise" followed closely in frequency, but were much lower in importance (see Figure 6.6).



(Council of Canadian Academies)

Figure 6.6

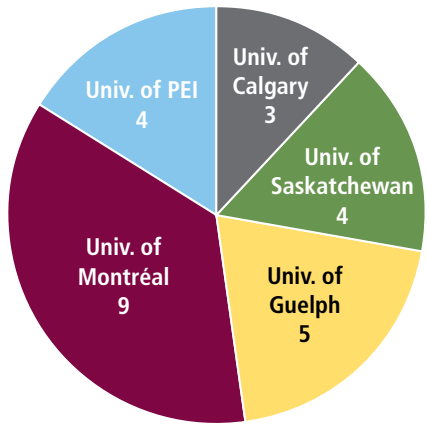
Frequency and Importance of Main Barriers — Surveillance Activities

6.2.2 Survey of Researchers in Animal Health Risk Assessment Science

The questions asked in this survey were identical to those in the *Survey of Surveillance Activities in Animal Health Risk Assessment* (see Box 6.1), but were applied to the nine areas of research identified in Table 6.5.

Methodology and Respondent Profile

The *Survey of Researchers in Animal Health Risk Assessment Science* was distributed to 38 individuals conducting research at the five veterinary schools in Canada (see Figure 6.7). A total of 27 responses were received. Two were removed from the final sample (one was incomplete and the other was out of scope), leaving 25 completed surveys. Most of these respondents were based at universities as either full or associate professors, and several were directors or chairs of research centres.



(Council of Canadian Academies)

Figure 6.7
Distribution of Respondents by Institution — Research Activities

Areas of Research Activity

The nine areas of research activities examined are described in Table 6.5.

Table 6.5

Areas of Research Activities

Area	Per cent
Disease frequency • Herd- and animal-level incidence and prevalence estimates	92
Evaluation of **surveillance systems** for the disease/pathogen	52
Diagnostic test evaluation	80
Epidemiology (natural history) of disease/pathogen • **Transmission mechanisms** and survival of pathogen in products	56
Epidemiology (natural history) of disease/pathogen • Effectiveness of **mitigation procedures**	76
Epidemiology (risk factors) of disease/pathogen • **Determination of risk factors**	80
Epidemiology (risk factors) of disease/pathogen • **Distribution of risk factors** in populations of interest	64
Economic models of consequences • The cost of **controlling the disease** in the animal	24
Economic models of consequences • The cost of **controlling an outbreak** in an animal population	12

(Council of Canadian Academies)

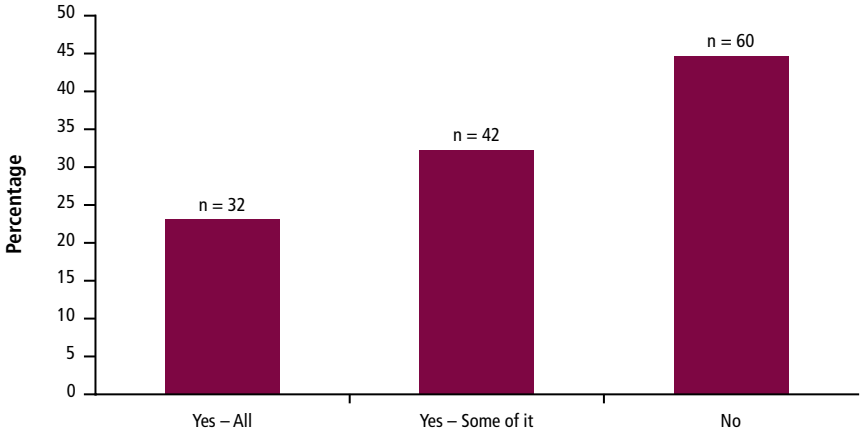
The column on the right of this table shows the percentage of respondents who indicated that they were involved in these types of research activities. Bolded text emphasizes short-hand descriptions used throughout Chapter 6.

Contribution of Knowledge to Risk Assessment

Fifty-four per cent of the respondents said that at least some of their work contributed to risk assessment (see Figure 6.8). "Disease frequency" was the area with the highest input (61 per cent); "mitigation procedures" was the area with the lowest input (42 per cent).

Source of Funding

When all the areas were combined, industry was identified as the major source of funding in terms of both importance and frequency among the survey respondents. Provincial and federal government funding followed, respectively, in overall importance and frequency (Figure 6.9).



(Council of Canadian Academies)

Figure 6.8

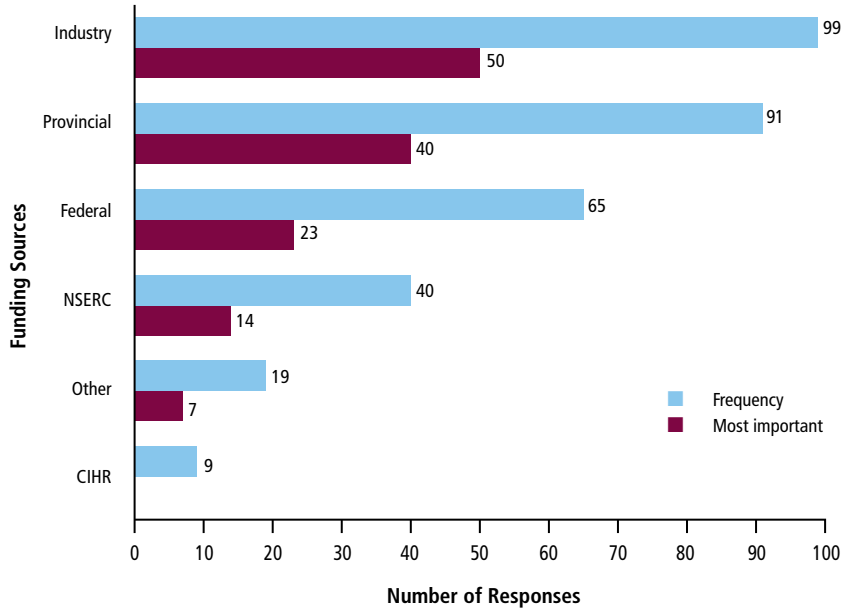
Percentage of Research Activities Contributing to Risk Assessment

The figure includes the results from all nine areas (Table 6.5) of the survey. Respondents could complete more than one area, explaining why the numbers add up to more than the total of respondents (25). For example, 32 of 131 responses indicated that all their activities were undertaken specifically to provide input to risk assessment.

In terms of specific research areas, industry funding was the most important source for "disease frequency," "transmission mechanisms," "mitigation procedures," and "determination of risk factors." Industry was also the most frequent source of funding for all areas except "diagnostic tests" and "economic models of disease control." Provincial funding was the most important source for "evaluation of surveillance" and "diagnostic tests." Federal funding from sources other than the granting councils (e.g., available as matching funds through regional development programs) contributed in many areas as well; however, federal granting councils (NSERC and CIHR) often trailed other sources in terms of importance in several of these specific areas.

Methods of Dissemination

In contrast to the surveillance organizations, peer-reviewed publications were by far the most important and frequent method for the dissemination of results for university researchers (see Figure 6.10). Industry reports were frequently used (probably reflecting industry's important role in funding this type of research),



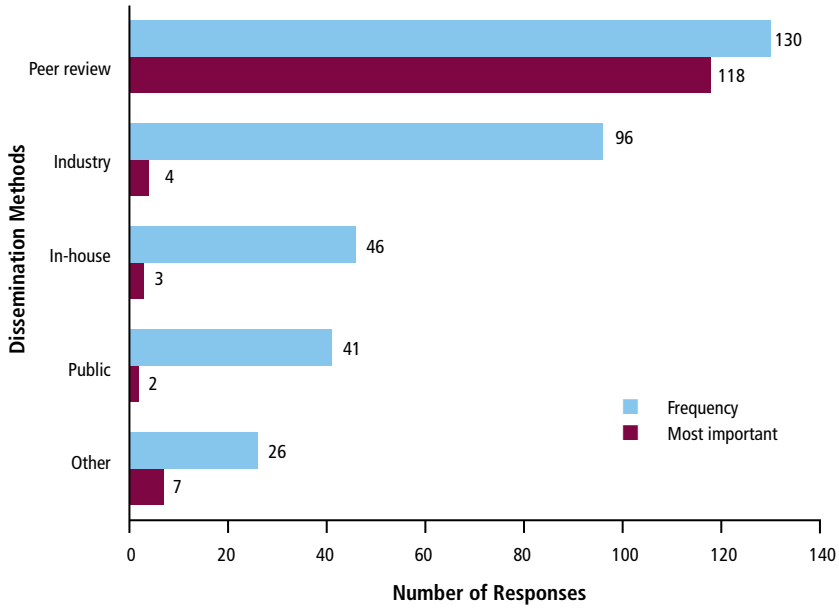
(Council of Canadian Academies)

Figure 6.9
Frequency and Importance of Funding Sources — Research Activities

although were not generally viewed as being of high importance by researchers. This ranking likely reflects the importance of publication in peer-reviewed journals in consideration for tenure and promotions in academia.

Student Involvement in Research Activities

The majority of the AAHR researchers surveyed involved students in their research (86.6 per cent). DVM and PhD candidates were the two categories of students most frequently involved (see Figure 6.11). Undergraduate students were most often involved in "disease frequency" (22 per cent) and "transmission mechanisms" (20 per cent) (see Table 6.6). All of the researchers in "disease frequency" involved students, and had the greatest number of students involved, with 211.



(Council of Canadian Academies)

Figure 6.10

Frequency and Importance of Dissemination Methods — Research Activities

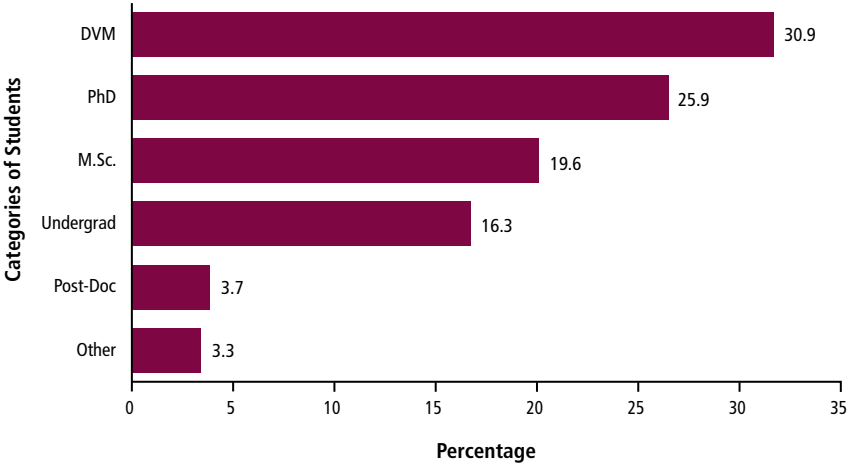


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Figure 6.11

Categories of Students Involved — Research Activities

This figure shows the percentage of students involved in all the areas; for example, 30.9 per cent of students involved across the research areas are DVMs.

Table 6.6

Researchers in AAHR – Student Involvement by Area

Area	Undergrad (per cent)	M.Sc. (per cent)	PhD (per cent)	Post-Doc (per cent)	DVM (per cent)	Other (per cent)	# of Students*
Disease frequency	21.8	23.9	19.7	2.1	30.1	2.4	**211**
Surveillance systems	18.4	21.8	22.4	6.1	27.2	4.1	**73.5**
Diagnostic tests	14.1	15.2	28.8	3.3	33.2	5.4	**92**
Transmission mechanisms	19.6	18.3	27.5	2.0	28.8	3.9	**76.5**
Mitigation procedures	14.7	18.7	29.3	8.0	27.3	2.0	**75**
Determination of risk factors	15.8	16.8	26.2	3.0	31.7	6.4	**101**
Distribution of risk factors	2.9	19.3	35.7	2.1	40.0	0.0	**70**
Economic models of disease control	7.1	14.3	38.1	7.1	33.3	0.0	**21**
Economic models of outbreak control	0.0	0.0	0.0	100.0	0.0	0.0	**1.5**

(Council of Canadian Academies)

* Students may be involved in more than one area. The number of students was provided via a range; this table provides the average value from the range, explaining why there can be 0.5 students.

Barriers to Research

The most frequent barriers for researchers in AAHR were "lack of time," "don't have the expertise," "lack of funding," and "lack of graduate student support" (Figure 6.12). This trend was consistent across most research areas. "Lack of time," "lack of funding," and "lack of graduate student support" were regarded as frequent and important resource barriers.

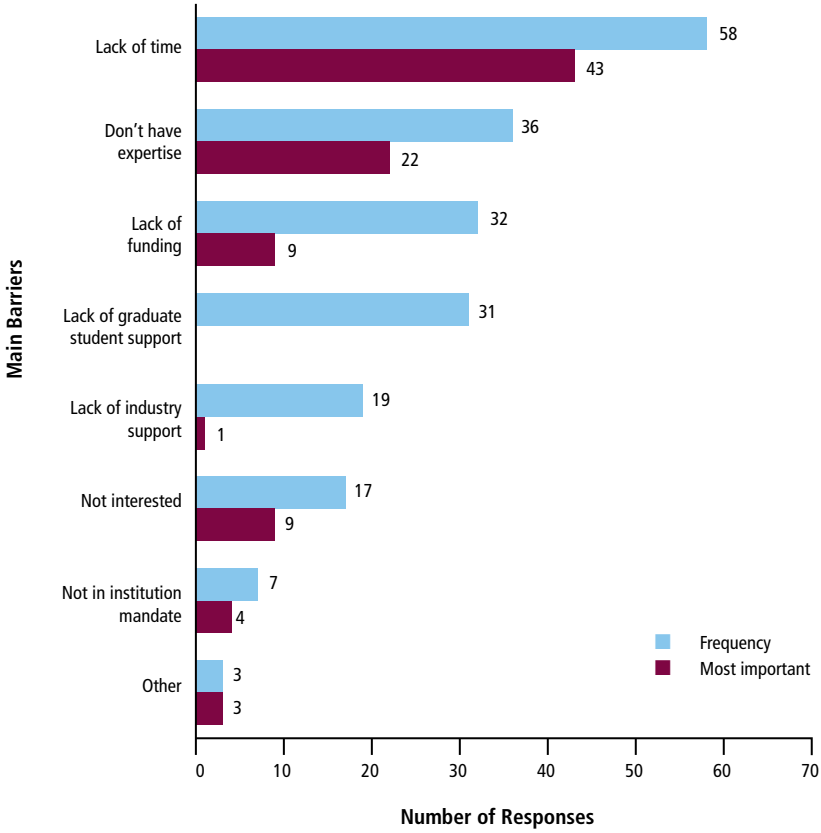

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Figure 6.12
Frequency and Importance of Main Barriers — Research Activities

6.3 COMPARISON OF CANADA'S TRAINING AND RESEARCH PROGRAMS WITH MAJOR TRADING PARTNERS

This section of the report compares Canada's efforts in university training and its systems for research funding in areas required for supporting animal health risk assessment with those of other major trading partners.[29]

[29] Comparison countries were selected based on similarities in markets and educational systems.

6.3.1 Training Trends in Animal Health Risk Assessment in Canadian Veterinary Colleges

Risk assessment plays an important role in protecting animal and human health. While the Panel acknowledges that other university programs may offer training in risk assessment, this report focuses on the curricula of select veterinary colleges in Canada and its major trading partners. Based on its survey of course offerings, the Panel believes that the importance of this subject is not fully reflected within the curricula of Canada's five veterinary schools.[30] Although most schools offer at least one course touching upon the subject of risk analysis or risk assessment, none offer a full course focusing solely on the study of risk assessment. Very few offer specialized courses dealing with risks pertaining to the interface between animal and human health. The Atlantic Veterinary College at the University of Prince Edward Island does offer short professional training courses available to animal health risk assessment professionals and scientists from Canada and other countries, and is in the planning phases of developing a full, graduate-level course on risk analysis. Moreover, other schools are in the process of developing master-level programs with a more extensive focus on risk assessment and the interface between animal and human health.

University of Calgary – Faculty of Veterinary Medicine

The University of Calgary's Faculty of Veterinary Medicine offers several mandatory DVM courses involving discussion of basic risk assessment concepts. Such courses include *Animals, Health and Society*, and *Public Health and Risk Analysis*. It offers one-week block courses in *Outbreak Investigation and Foreign Animal Disease*, which address risk assessment in scenarios. The Faculty of Veterinary Medicine is a new faculty and is currently expanding its graduate program. Future veterinary postgraduate courses will most likely focus on elements of public health and risk assessment. Additional relevant courses in risk assessment are available through other faculties at the University.

http://vet.ucalgary.ca/

Personal communication, April 2010.

University of Guelph – Ontario Veterinary College (OVC)

While the OVC's DVM program requires its students to participate in two courses covering general principles of health management, formal risk assessment does not feature prominently in either. Graduate students interested in risk assessment are encouraged to seek a graduate advisor with expertise in the subject, or to enrol in external, distance-based risk courses.

http://www.ovc.uoguelph.ca/

Personal communication, April 2010.

[30] This survey is based on a review of course offerings and interviews with faculty members.

Université de Montréal – Faculté de médecine vétérinaire

The Faculté de medicine vétérinaire at the Université de Montréal does not offer a course dedicated exclusively to risk assessment, but DVM students are exposed to the subject in one mandatory course, Veterinary Toxicology, and several elective courses, *Risk Management of Production Animals*, and *Veterinary Public Health*. Graduate students are given the option of participating in a course focusing solely on risk analysis. There are plans for a Master of Veterinary Public Health program, which would offer further courses in risk analysis and risk management.

http://www.medvet.umontreal.ca/index.html

Personal communication, April 2010.

University of Prince Edward Island – Atlantic Veterinary College (AVC)

The AVC offers several DVM courses that touch upon risk assessment. Examples include a course entitled *Veterinary Public Health*, and a specialized course that covers various topics in health management. At the graduate level, elements of quantitative and qualitative risk assessment are touched upon as selected topics within courses on biostatistics and epidemiology. In addition, the AVC has conducted risk assessment short courses for Canadian and international risk assessors and scientists, and in 2010 delivered on-site risk assessment courses in South America. Plans for a full graduate course in risk analysis are currently in preparation at the AVC.

http://www.upei.ca/avc/

Personal communication, April 2010.

University of Saskatchewan – Western College of Veterinary Medicine (WCVM)

WCVM offers several DVM and graduate courses that involve risk analysis/assessment. DVM students study risk in *Veterinary Public Health* and *Wildlife Health and Disease* courses, while graduate students are offered a course on *Zoonoses and Food Safety*. There are, however, no DVM or graduate courses that focus exclusively on animal health risk assessment.

http://www.usask.ca/wcvm/

Personal communication, April 2010.

6.3.2 Trends in Animal Health Risk Assessment in International Veterinary Colleges

International veterinary programs offer a benchmark against which to compare animal health risk assessment training in Canada. This section examines undergraduate and graduate training at select veterinary colleges in Australia, Ireland, New Zealand, the United Kingdom, and the United States. It is based on the Panel's review of course descriptions and interviews with faculty members. Results are presented in Table 6.7, and details of the information provided by each college are presented in the *Animal Health Risk Assessment Training Trends in Canada and International Veterinary Colleges* (available at www.scienceadvice.ca/en/animal-health.aspx).

Since risk assessment training varies enormously from one institution to another internationally, it is difficult to discern any trends by country. No colleges have specific undergraduate courses on risk assessment, though many touch on the subject in various courses (mainly epidemiology). A good example of training at the undergraduate level is the U.K. Royal Veterinary College, where students are not only exposed to the concept of risk assessment but also to the practical application of risk assessment.

The greatest disparity among institutions is at the graduate level. Some colleges offer no training at all. Other colleges offer short courses in collaboration with government institutions. Examples are Colorado State University and the University of Minnesota, both of which have short courses with some of the United States Department of Agriculture (USDA) agencies (Foreign Agricultural Service, FAS; Animal and Plant Health Inspection Service, APHIS) or the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). Another alternative is provided by institutions such as New Zealand's Massey University. It offers graduate students an opportunity to work on research contracts, with a risk assessment as a main component, enabling the students to gain practical experience. Still others have very specific Master of Public Health (MPH) programs, emphasizing risk assessment/risk analysis and the interface between human and animal health. Examples include Murdoch University and the University of Sydney in Australia, the University of Glasgow (which focuses on quantitative methods) and the Royal Veterinary College in the United Kingdom, and North Carolina State University in the United States with its soon-to-be-offered certificate program.

Table 6.7

Comparison of Veterinary School Training on Risk Assessment

Veterinary Schools	Undergraduate level		Graduate level		Other teaching activities/information
	Specific course on risk assessment	Covered in different courses	Specific course on risk assessment	Covered in different courses	
CANADA					
University of Calgary	No	Yes	No	Yes	Postgraduate courses that will focus on elements of public health and risk assessment are in development. Related courses are available through other Faculties.
University of Guelph	No	Yes	No	Yes	
Université de Montréal	No	Yes	No	Yes	In the MPH program, specific courses on the topic are under development.
University of Prince Edward Island	No	Yes	No	Yes	The AVC offers short professional risk assessment courses for Canadian and international risk assessors. A full, graduate-level course on risk analysis is in development.
University of Saskatchewan	No	Yes	No	Yes	
AUSTRALIA					
Murdoch University	No	Yes	Yes	Yes	Half of a semester is on risk assessment and puts emphasis at the interface between human and animal health.
University of Adelaide	No	No	NA	NA	There is a Presentation Day in which students are exposed to the topic. Since it is a new school, the program has not started for DVM yet.
University of Sydney	No	Yes	Yes	Yes	
University of Queensland	No	Yes	NA	NA	A day visit to the beef abattoir and introduction to microbiological food safety, animal welfare, etc. are offered.

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Table 6.7 *(continued)*

Comparison of Veterinary School Training on Risk Assessment

Veterinary Schools	Undergraduate level		Graduate level		Other teaching activities/information
	Specific course on risk assessment	Covered in different courses	Specific course on risk assessment	Covered in different courses	
IRELAND					
University College Dublin	No	Yes	No	Yes	
NEW ZEALAND					
Massey University	No	Yes	No	Yes	Undergraduate – End of year research paper course is offered. Graduate level – End of year research paper course and a possibility to participate in research contracts are offered.
UNITED KINGDOM					
Bristol University	No	Yes	No	Yes	A One Health Initiative is in the planning phase.
Royal Veterinary College	No	Yes	Yes	Yes	Some modules of M.Sc. are offered at the graduate level.
University of Glasgow	No	Yes	Yes	Yes	A M.Sc. is almost all exclusively on the interface between animal and human health.

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Table 6.7 *(continued)*

Comparison of Veterinary School Training on Risk Assessment

Veterinary Schools	Undergraduate level		Graduate level		Other teaching activities/information
	Specific course on risk assessment	Covered in different courses	Specific course on risk assessment	Covered in different courses	
UNITED STATES					
Colorado State University	No	No	No	Yes	Two different short courses that deal with risk assessment are offered, in cooperative agreement or sponsored by USDA:APHIS and USDA:FAS.
Iowa State University	No	No	Yes	No	
Michigan State University	No	No	No	Yes	
North Carolina State University	No	No	Yes	Yes	A specific certificate is under development with three specific courses on risk assessment and related topics.
Ohio State University	No	No	No	Yes	
Purdue University	No	No	No	Yes	
University of California Davis	No	No	Yes	No	
University of Florida	No	No	No	No	
University of Minnesota	No	No	No	Yes	Short courses are offered by USDA and JIFSAN.
Washington State University	No	Yes	No	Yes	

(Council of Canadian Academies)

6.3.3 Applied Animal Health Research Funding in Canada

Funding to support research related to animal health risk assessment is delivered through numerous funders and programs in Canada. This section highlights examples of the major potential sources of this funding, and outlines each program's objectives, priorities, and eligibility criteria (see Tables 6.8 to 6.10). The information in the tables is meant to be illustrative, rather than to provide an exhaustive list of all potential sources of funding for research that supports animal health risk assessment. There are a number of individual or joint programs offered by Canada's Tri-Council funding agencies[31] (e.g., strategic initiatives, networks of centres of excellence), the Canada Foundation for Innovation, and provincial and federal bodies that will support applied animal health research. These programs, however, do not specifically target applied animal health research, and only occasionally are these research activities encompassed by more broadly stated priorities.

Two of the sub-questions in the charge to the Panel dealt with the issue of "integrated animal-human health research." Integration of animal and human health research is in complete accord with the widely accepted principles of the "one health" approach (see Section 4.1) and is essential if animal health risk assessments are to include a consideration of human health consequences. With respect to the federal Tri-Council funding agencies, the Panel believes that researchers in Canada may face an obstacle in developing integrated animal-human health research programs because animal health research is mainly the responsibility of NSERC whereas human health research mainly falls under the CIHR (Science.gc.ca, 2010a). The Panel acknowledges that some efforts are being made to fund projects across Tri-Council areas of responsibility (Science.gc.ca, 2010b; Science.gc.ca, 2010c), but feels there would be value in coordinating integrated animal-human health research funding under a single organization or agency, as has been done in some of the domestic and international examples provided in Tables 6.8 through 6.11.

[31] The Tri-Council consists of the NSERC, the CIHR, and the Social Sciences and Humanities Research Council of Canada.

Table 6.8

Examples of Potential Federal Funding Sources for AAHR

NSERC Discovery Grants	
Major Objectives	Support ongoing programs of research with long-term goals
Priority Areas	• Promote/maintain diversified, high-quality research capacity • Provide stimulating environment for research training
AAHR Priority Targeted?	No
Eligibility	All researchers with projects that fit into the 12 evaluation groups are eligible. None of these evaluation groups is a natural home for the population-based, animal health research required to support AAHR.
Additional Information and Examples	The projects are evaluated on past research excellence, proposal merit, contribution to training HQP, and relative cost of research. This program is designed to support research of the highest quality within Canada. It is not tied to wider strategic objectives or to commercial application. It is NSERC's hallmark funding program. (Source: http://www.nserc-crsng.gc.ca/professors-professeurs/grants-subs/dgigp-psigp_eng.asp. Access date, August 2010.)
NSERC Project Grants Program	
Major Objectives	Increase research and training in targeted areas with the potential to enhance Canada's economy/environment/society
Priority Areas	• Advanced communications and information management • Biomedical technologies • Competitive manufacturing • Health environment and ecosystems • Quality foods and novel bioproducts • Safety and security • Sustainable energy systems Priorities/sub-priorities of the Federal S&T Strategy
AAHR Priority Targeted?	No
Eligibility	To be eligible, projects must fall into targeted areas, be one to three years in length, and feature partnership between academic researcher and supporting organization.
Additional Information and Examples	Tends to favour projects with commercialization potential and industrial partners. (Source: http://www.nserc-crsng.gc.ca/professors-professeurs/rpp-pp/spg-sps_eng.asp. Access date, August 2010.)

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Table 6.8 *(continued)*

Examples of Potential Federal Funding Sources for AAHR

NSERC Collaborative Research and Development (CRD) Grants	
Major Objectives	Provide firms with access to knowledge and highly qualified personnel Train students in technical skills required by industry
Priority Areas	Not applicable
AAHR Priority Targeted?	No
Eligibility	Projects must involve partnerships with Canadian firms, industry associations, and public utilities. They have to be one to five years in length.
Additional Information and Examples	The Canadian firm must contribute to at least the same amount requested from NSERC. (Source: http://www.nserc-crsng.gc.ca/Professors-Professeurs/RPP-PP/CRD-RDC_eng.asp. Access date, August 2010.)
CIHR	
Major Objectives	Aid in the generation of high-quality research that translates into improved health of Canadians
Priority Areas	• Biomedical • Clinical • Health systems services • Social, cultural, environmental, and population health
AAHR Priority Targeted?	No
Eligibility	All researchers with projects that fit within the CIHR mandate are eligible.
Additional Information and Examples	General CIHR funding is designed to support research of the highest quality within Canada. It is not tied to wider strategic objectives or to commercial application. (Source: http://www.cihr-irsc.gc.ca/e/805.html. Access date, December 2010.)
CIHR/NSERC: Collaborative Health Research Projects Program (CHRP)	
Major Objectives	Translate research results to end users and stakeholders Encourage the NSERC and CIHR communities to collaborate and integrate their expertise in their novel research activities Advance interdisciplinary research leading to knowledge and technologies useful for improving the health of Canadians Train highly qualified personnel in collaborative and interdisciplinary research of relevance to health

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Table 6.8 *(continued)*

Examples of Potential Federal Funding Sources for AAHR

CIHR/NSERC: Collaborative Health Research Projects Program (CHRP)	
Priority Areas	Not applicable
AAHR Priority Targeted?	No
Eligibility	The participation of two or more independent researchers with complementary expertise is required. Team composition must include expertise in the natural sciences or engineering and expertise in the health sciences. New and genuine collaborations between researchers in the natural sciences and engineering and medical researchers, clinicians, social scientists and researchers in the humanities are strongly encouraged.
Additional Information and Examples	Previous three years of program have not funded animal health research outside of biomedical research into human disease using animal models. (Source: http://www.nserc-crsng.gc.ca/Professors-Professeurs/grants-subs/CHRP-PRCS_eng.asp. Access date, August 2010.)
Agri-Science Clusters Initiative	
Major Objectives	Provide industry-drive agricultural firms with a means to harness scientific resources to support innovation and sector competitiveness
Priority Areas	Not applicable
AAHR Priority Targeted?	No
Eligibility	Eligibility is limited to not-for-profits with stakeholder (agri-sector) involvement in governance.
Additional Information and Examples	Projects must include applied science, technology transfer, and commercialization strategies. These must be national and industry-led. Half the funding must come from a non-governmental source. (Source: http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1301594536360&lang=eng#genproc0. Access date, March 2011.)
Public Health Agency of Canada: National Collaborating Centres	
Major Objectives	Establish and support a network of National Collaborating Centres for Public Health (NCCPH)
Priority Areas	Three centres of potential relevance to AAHR: • Environmental Health • Infectious diseases • Methods and Tools
AAHR Priority Targeted?	No
Eligibility	Consists of occasional calls for proposals for targeted areas.
Additional Information and Examples	(Source: http://www.phac-aspc.gc.ca/media/nr-rp/2005/2005_15bk1-eng.php. Access date, April 2011.)

(Council of Canadian Academies)

Table 6.9

Examples of Potential Provincial Funding Sources for AAHR

Atlantic Innovation Fund	
Major Objectives	Aid Atlantic Canadians in competing in the global knowledge-based economy
Priority Areas	• Increase R&D in Atlantic Canada research facilities leading to the launch of new products, processes and services • Strengthen the region's innovation system by supporting R&D and commercialization partnerships and alliances between private-sector enterprises, universities, research institutions and other organizations in Atlantic Canada • Enhance the region's ability to access national R&D programs • Support applied research in salmon aquaculture (focus on developing infrastructure for on-farm evaluation of health problems) and dairy industry (focus on milk quality)
AAHR Priority Targeted?	No
Eligibility	Eligible applicants include universities, research institutions, and private-sector businesses where projects are compatible with Atlantic Innovation Fund objectives.
Additional Information and Examples	(Source: http://www.acoa.ca/English/ImLookingFor/ProgramInformation/AtlanticInnovationFund/Pages/AtlanticInnovationFund.aspx. Access date, September 2010.)
Ontario Ministry of Agriculture, Food and Rural Affairs and University of Guelph Partnership	
Major Objectives	Support agri-food research at the University of Guelph
Priority Areas	• Agricultural and rural policy • Bioeconomy industrial uses • Emergency management • Environmental sustainability • Food for health • Product development and enhancement through value chains
AAHR Priority Targeted?	Yes
Eligibility	Principal Investigator must be based at University of Guelph.
Additional Information and Examples	Emergency management is directly applicable to AAHR researchers. The subcategories are: • Threat identification and prioritization • Detection and surveillance • Pathway analysis • Prevention and control of disease • Cost-benefit analysis (Source: http://www.uoguelph.ca/research/omafra/Call/index.shtml. Access date, August 2010.)

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Table 6.9 *(continued)*

Examples of Potential Provincial Funding Sources for AAHR

Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec Agri-food Innovation Support Program	
Major Objectives	Aid the agri-food industry in contributing to development, food security, animal health, and environmental protection
Priority Areas	• Food safety • Environmental protection and resource conservation • Socio-economic analysis of agri-food production systems • Diversification of agricultural production • Zoosanitary and phytosanitary stakes/issues
AAHR Priority Targeted?	Yes
Eligibility	Includes all research institutions. Projects must have a maximum length of four years.
Additional Information and Examples	(Source: http://www.mapaq.gouv.qc.ca/Fr/Productions/md/Programmes/Pages/Soutieninnovationagroalimentaire.aspx. Access date, September 2010.)
Alberta Innovates – Biosolutions	
Major Objectives	Support the research and innovation priorities of the Government by providing leadership and coordination for research and innovation that supports the growth and diversification of Alberta's agriculture, forestry and life sciences sectors
Priority Areas	• Industrial biorefining • Food for health • Sustainable production systems • Fibre conversion technologies
AAHR Priority Targeted?	Not directly, but is considered under *food for health* and *sustainable production systems*. It also supports Alberta Prion Institute and works with the Alberta Livestock and Meat Agency.
Eligibility	Includes all research institutions.
Additional Information and Examples	(Source: http://www.albertainnovates.ca/bio/introduction. Access date, September 2010.)

(Council of Canadian Academies)

Table 6.10

Examples of Potential Industry Funding Sources for AAHR

Poultry Industry Council	
Major Objectives	Finance research and education for the benefit of the Canadian poultry industry
Priority Areas	• Commercializable applied research relevant to poultry
AAHR Priority Targeted?	Yes
Eligibility	Principal investigator must be in Canadian institution.
Additional Information and Examples	(Source: http://www.poultryindustrycouncil.ca/research/applications.php. Access date, September 2010.)
Beef Science Cluster	
Major Objectives	Finance research for the benefit of the Canadian beef cattle industry
Priority Areas	• Food efficiency • Beef quality • Forages and grassland • Disposal of Specified Risk Material (BSE related) • Animal health and welfare • Food safety
AAHR Priority Targeted?	Yes
Eligibility	Includes all institutions. The projects must be one to three years in length.
Additional Information and Examples	Is a Partnership between beef industry and Agriculture and Agri-Food Canada. Projects must be relevant to R&D priorities of the Beef Cattle Research Council and aid the competitiveness and sustainability of the beef sector. (Source: http://www.cattle.ca/information-for-researchers-essential-documents. Access date, September 2010.)

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6.3.4 Animal Health Risk Assessment Research Funding in Other Countries

Other countries have mobilized and targeted funding for research relating to animal health risk assessment as well as to the interface between animal and human health. Recognizing the economic, health, and national security benefits of such research, some have launched targeted funding programs specifically dedicated to promoting these benefits. The Animal Health Program of the U.S. National Institute of Food and Agriculture (NIFA) and the U.K. Animal Welfare Research Program are two such examples. Australia has taken another route by making such funding available through a Centre of Excellence for Risk Analysis. Meanwhile, New Zealand has followed an integrated approach by creating an entire biosecurity strategy, with priority funding for animal health risk assessment as a major component. Further details of these approaches are summarized in Table 6.11.

Table 6.11

Examples of International Funding Sources for AAHR

UNITED STATES	
Central Institution	**National Institute of Food and Agriculture**
Major Objectives	Advance knowledge for agriculture, the environment, and human health and well-being
Priority Areas	• Peer-reviewed basic and applied research, and education proposals • Laboratory infrastructure • Small-scale research in animal disease response • Targeted animal diseases of state/regional importance • Dissemination of animal health information
Coordinated Agricultural Project	
AAHR Priority Targeted?	No
Eligibility	Includes research institutions, individuals, states, and regions.
Additional Information and Examples	Large-scale, multimillion dollar collaborative projects (Source: http://www.csrees.usda.gov/about/glossary.html#cap. Access date, September 2010.)
Food Safety Program	
AAHR Priority Targeted?	Yes
Eligibility	Includes land grant institutions, non-profits, private business, and individuals.
Additional Information and Examples	Improve safety of food supply **Budget: $20 million** (Source: http://www.csrees.usda.gov/fo/foodsafetyicgp.cfm. Access date, September 2010.)

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Table 6.11 *(continued)*

Examples of International Funding Sources for AAHR

Foundational Program	
AAHR Priority Targeted?	No
Eligibility	Includes land grant institutions, non-profits, private business, and individuals.
Additional Information and Examples	Build foundational knowledge in areas of societal challenge **Budget: $64 million** (Source: http://www.nifa.usda.gov/funding/rfas/pdfs/11_afri_foundationaL_final_1-7-11.pdf. Access date, April 2011.)
Multistate Research Projects	
AAHR Priority Targeted?	No
Eligibility	Must engage multiple stakeholders from two or more states.
Additional Information and Examples	Control of emerging and re-emerging poultry diseases Domestic surveillance, diagnosis, and therapy of spongiform encephalopathies (Source: http://www.csrees.usda.gov/business/awards/formula/10_hatch_multi_final.pdf. Access date, September 2010.)
UNITED KINGDOM	
Central Institution	**Department for Environment, Food and Rural Affairs**
Major Objectives	Provide scientific evidence for policy Support U.K. negotiating position
Priority Areas	• Improve the welfare of animals reared for food • Develop and improve breeding, selection, transport, and slaughter systems
Animal Welfare Research Program	
AAHR Priority Targeted?	Yes
Eligibility	Includes universities and other research institutions.
Additional Information and Examples	On-farm welfare Welfare of companion animals Welfare during slaughter and transport **Budget: £2.99 million** (Source: http://www.rdfunding.org.uk/queries/ListGrantDetails.asp?GrantID=16432. Access date, September 2010.)

continued on next page

Table 6.11 *(continued)*

Examples of International Funding Sources for AAHR

AUSTRALIA	
Central Institution	**Australian Centre of Excellence for Risk Analysis**
Major Objectives	Develop the practice of risk analysis by creating and testing methods, protocols, analytical tools and procedures
Priority Areas	• A focus on biosecurity risk analysis, but no specific priorities per se
AAHR Priority Targeted?	Yes
Eligibility	Is open to all researchers.
Additional Information and Examples	"Allocating surveillance effort in the management of invasive species: A spatially-explicit model" "Protecting islands from pest invasion: Optimal allocation of biosecurity resources between quarantine and surveillance" **Budget: A$2 million** (Source: http://www.acera.unimelb.edu.au/about.html. Access date, September 2010.)

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6.4 BUILDING ANIMAL HEALTH RISK ASSESSMENT KNOWLEDGE CAPACITY IN CANADA

There are two closely interrelated ways of building knowledge and research capacity: funding research and training researchers. Funding research attracts talent; developing talent attracts research funding. Canada has an established base in animal health research and in animal health risk assessment research. Human capital in the form of trained individuals can be found across the different levels of government, in academia, and in industry. Within the CFIA itself, there is a core of expertise in animal health risk assessment based on university training, on-the-job experience, and short professional courses. The Panel's survey of the training experience of CFIA staff involved in animal health risk assessment, and its review of course offerings, raised the question of whether there could be more training and professional development opportunities made available to experts in risk assessment through the university system.

Canada compares favourably at the DVM program level compared to its international partners and, in some cases (compared, for example, to the United States), is doing better. The Panel concluded, however, that more directed training may be of benefit at the DVM level in terms of preparing veterinarians for on-the-ground risk assessment. It is of note that the World Organisation for Animal Health (OIE) is working toward identifying essential required competencies for national service veterinarians, and an ad hoc working group has clearly identified the importance of competency in risk analysis (OIE, 2010e).

Canada did not have as much training available at the graduate program level as some of its major international trading partners (see Table 6.7). This appears to be an area in which Canada can improve. The program information provided by the veterinary colleges suggests that this has been recognized and is starting to be addressed.

The bibliometric analysis suggested that Canada is doing reasonably well in creating relevant new knowledge compared to its major trading partners. As discussed in Chapters 1 and 3, however, there are gaps in the specific knowledge required to generate comprehensive and fully supported risk assessments in many individual cases. This raises the question as to the overall global adequacy of research in this area.

Within Canada, the two major barriers identified in conducting research in animal health risk assessment were lack of time, which relates to the number of people engaged in research in this area, and funding for research and graduate education. As highlighted in Table 6.11, many countries are addressing these issues through targeted funding, which can increase specific research activity and human capital (more research trainees) in many areas. As shown in Figure 6.9, the majority of funding for relevant animal health risk assessment research comes from industry and provincial and federal departments. This is not surprising because they are the major stakeholders in animal health risk assessment and in utilization of the knowledge generated. Yet research supported by stakeholders tends to prioritize their specific needs. And though this can produce very relevant research, it may also leave unanticipated gaps in foundational knowledge.

There are advantages to engaging arm's length funders (e.g., the Tri-Council) to support the generation of required data. For example, it can often address more fundamental and crosscutting research. Funding for interdisciplinary research, which is required to continue developing an integrated, multidimensional approach to animal health risk assessment and to provide the data required to permit such risk assessments to expand, is often a challenge and may require collaborative, joint funding initiatives to be most effective (Hall *et al.*, 2006).

Review of Key Findings

Risk Assessment Expertise in Canada

- Risk assessors and risk managers in the AHRA unit at the CFIA have considerable knowledge and practical experience in the conduct of animal health risk assessments, much of which has been garnered from on-the-job experience, informal mentoring in the workplace, and short courses. DVM training and relevant graduate training were the most common academic background.
- Canada's academic research quality, quantity, and intensity rank relatively well when compared to developed countries with large livestock sectors. This suggests that we have an underlying relevant expertise that compares favourably with other countries.

Production of New Knowledge

- Surveillance and research activities in animal health risk assessment are predominantly funded by provincial and federal government departments and industry.
- Surveillance organizations and researchers in animal health risk assessment face time and resource constraints that limit the production of animal health risk assessment knowledge and student training opportunities.
- Relevant animal health research is not necessarily conducted to directly support risk assessment, but much of the research output is recognized to contribute to these processes.

Training and Research Programs in Canada

- All veterinary schools in Canada offer some training in risk assessment in DVM programs. No program, however, currently offers a curriculum that fully reflects the importance of integrated animal-human health risk assessment. In contrast, animal health risk assessment training in graduate programs in veterinary colleges in other countries, such as the United States and United Kingdom, appears to be more specialized and extensive.
- Canada's current research funding programs rely on stakeholder support (government departments and industries) and general funding programs. Canada's international peers tend to make greater use of programs targeted to support applied animal health research that can support risk assessment.

Building Knowledge Capacity in Canada

- Increasing training of risk assessment in DVM programs and in graduate programs across Canada will enhance expertise and ensure ongoing knowledge capacity in Canada to meet risk assessment delivery needs.
- Capitalizing on other risk analysis expertise in Canada can expand available disciplinary expertise.
- Increasing the number of trained researchers in academic institutions can help enhance research output and address time constraints.
- Targeted funding supporting integrated animal-human health research and applied animal health research is one potential mechanism for knowledge generation in these areas.

7

Challenges in Achieving Integrated Animal-Human Health Risk-Based Decision-Making

7 Challenges in Achieving Comprehensive, Integrated Animal-Human Health Risk-Based Decision-Making

Key Message

A structured and transparent system could ensure that routine risk assessments, as well as those required for policy decisions and strategic planning, are completed in a timely fashion. The conditions for effective, comprehensive, integrated animal-human health risk assessment will be affected by a range of factors such as institutional arrangements and resource constraints, but risk assessment organizations should work to align processes to ensure efficiency, transparency, communication, integration, and continuity.

The preceding chapters have discussed approaches to animal health risk assessment, particularly with regard to incorporating a broader and deeper assessment of human health, environmental, and other consequences. The Panel recognizes that applying all or part of these approaches requires consideration of the resources available, the organizational structures that support risk assessment, and the political or societal expectations (e.g., how individuals and groups view risk, which risks society is willing to accept, and how those risks should be addressed). To assist in these areas, the Panel examined the challenges relating to (1) prioritization of risk assessments, and (2) the organizational structures for achieving comprehensive, integrated animal-human health risk assessments.

The intent of this chapter is to provide an overview of these challenges as part of evaluating the current state and comprehensiveness of animal health risk assessment in Canada. Section 7.1 outlines the various reasons for conducting risk assessments, and the means by which such assessments can be prioritized. Section 7.2 examines the three basic organizational structures through which comprehensive, integrated animal-human health risk assessments may be achieved. Although the Panel acknowledges the importance of including environmental consequences and interactions, this discussion focuses on the animal-human health dimensions of risk assessment. The chapter concludes with a case study of animal-human health risk assessment in Canada during the recent H1N1 pandemic.

Overall, the Panel found that the key challenges in prioritization of animal health risk assessment and integration of comprehensive animal-human health risk assessments relate to:

1. developing a systematic means of providing sufficient resources for conducting forward-looking assessments and ensuring that the scope of such assessments is appropriate;
2. identifying the optimal institutional arrangements for conducting comprehensive, integrated animal-human health risk assessments;
3. ensuring transparency in the prioritization and in the comprehensiveness of the integrated animal-human health risk assessments; and
4. incorporating surveillance and strategic planning processes to help appropriately direct prioritization decisions.

Countries and organizations have developed a range of approaches to the prioritization and integration of animal and human health risk assessments, and these are discussed throughout this chapter. The best approach for each country or organization depends on a variety of factors, including the social and institutional context in which the risk assessment is being conducted, as well as the nature of the individual risk assessment. The approach chosen, however, should always be structured, transparent, and consistent with overarching national objectives and political, legal, and jurisdictional realities.

7.1 THE NEED FOR PRIORITIZATION OF RISK ASSESSMENTS

This section looks at how a country or organization decides to undertake a risk assessment, how extensive and comprehensive that risk assessment should be, particularly with regard to the inclusion of the many potential consequences (as outlined in Chapter 5), and the number of steps to be completed. The discussion does not deal with how to prioritize risks in general, because this is a larger set of issues that should be resolved at the level of social values and policy decisions.

There are never enough resources to carry out all risk assessments related to animal health within the timeframe desired. Import risk assessments are often time sensitive and driven by policy requirements (review of risk assessments and interviews with experts). Yet risk assessments that support policy development also need to be completed. The Panel asserts that this is why there needs to be a structured and transparent system in place, so as to ensure that risk assessments addressing the most important animal health issues that a country is or may

be facing are completed in a timely fashion. In addition, once hazards or risks have been identified and/or risk assessments completed, it is necessary to have a mechanism for prioritizing such animal health issues for action at the policy or risk management level. Otherwise, the results of risk assessments will not contribute to decisions in an effective way.

The Panel recognizes that there is a strong political component in prioritization decisions, and that the nature of prioritization may be strongly influenced by the category of risk assessment. Generally speaking, it observes there are three such categories. First, there are risk assessments that are required to ensure that trade and commerce obligations are met in such a way that the economy is sustained (e.g., can we import this product or animal?). Second, there are risk assessments carried out to respond to urgent policy and risk management decisions (e.g., H1N1, salmonella in turtles). Often these first two categories of assessments are required to support specific operational risk management decisions. Third, there are those that are carried out to ensure adequate preparation for future and emerging threats (e.g., a risk assessment for bovine spongiform encephalopathy (BSE) prior to its discovery in Canada). Many in this third category can contribute to policy-based risk management decisions. To ensure that these forward-looking assessments are not continually pushed aside by risk assessments for import/export and other short-term priorities, it is important to have a structured prioritization framework in place. Potential frameworks for prioritization are discussed below.

7.1.1 Prioritization Frameworks

The Panel defines two layers of prioritization for animal health risk assessments (see Box 7.1). First, requests for individual risk assessments may be prioritized at the administrative level *(administrative protocols)*. This layer relates to the order in which the requests for risk assessments are undertaken and the manner in which resources are allocated to conduct such assessments. Second, risk assessments may be prioritized according to their role in achieving strategic goals or preparing for future policy decisions *(strategic frameworks)*. This layer may range from explicit government objectives to implicit political imperatives.

Administrative Protocols

The administrative layer of prioritization typically features two ways of arranging risk assessment priorities: legislative acts and management discretion. The method in place at any given agency is a function of the regulatory or administrative framework of its organization or country, and may vary with type of pathogen or institutional mandate.

Box 7.1

Layers of Prioritization for Animal Health Risk Assessments

1. **Administrative Protocols**
   i. **Legislative Acts** – Where a risk assessment is required by law whenever a particular pathogen has been identified within the country or a bordering country.
   ii. **Management Discretion** – Where risk managers make discretionary decisions about the selection and timing of individual risk assessments.
2. **Strategic Frameworks**
   i. **Ad hoc Frameworks** – Where a risk assessment is prioritized according to high-level national objectives or political imperatives that may be tangential to the assessment itself.
   ii. **Evidence-based Frameworks** – Where a risk assessment is undertaken according to a well-developed scientific framework.

Animal Health Risk Assessment Prioritization		
Day-to-Day Management	Administrative Protocols	Legislative Acts
		Management Discretion
Strategic Risk Assessment	Strategic Frameworks	Ad hoc Frameworks
		Evidence-based Frameworks

(Council of Canadian Academies)

Legislative Acts

In this layer of prioritization, risk assessment is required by law or regulation whenever a particular pathogen has been identified within the country or a bordering country. In Canada, the *Health of Animals Act* (1990) and associated regulations require veterinarians, laboratories, and animal owners to report certain diseases to the Canadian Food Inspection Agency (CFIA) (Minister of Justice, 1990; 2009; CFIA, 2010c). This information helps the CFIA to undertake appropriate action for disease containment and eradication. Although risk assessment techniques are typically used for analysis and the development of risk management strategies, there is no legislative requirement for a risk assessment. The decision to conduct a risk assessment is a policy decision, undertaken at management discretion.

In other countries, the decision to perform a risk assessment does sometimes fall under a legislative act or regulation. For example, the U.S. *Animal Disease Risk Assessment, Prevention, and Control Act* of 2001 requires the Secretary of Agriculture to submit a report to Congress containing information such as "the economic impacts associated with the potential introduction of foot-and-mouth diseases (FMD), bovine spongiform encephalopathy (BSE), and related diseases into the United States; the risks to public health from possible links of BSE and other spongiform encephalopathies to human illnesses; actions by U.S. federal agencies to prevent FMD, BSE, and related diseases; and the sufficiency of legislative authority to prevent or control FMD, BSE, and related diseases" (U.S. Department of Justice, 2001).

Another example is the U.K. Department for Environment, Food and Rural Affairs (Defra). Defra conducts qualitative risk analyses "on animal diseases that are not present in the United Kingdom, and which could have a significant impact on animal health if introduced" (Defra, 2005). Defra's policy states that a risk assessment is performed when it is "officially notified of an outbreak of animal disease in a member state of the European Union (EU), a country on the border of the EU or one of the U.K.'s trading partners worldwide, a risk assessment is undertaken." If an unofficial report of disease outbreak is received, however, Defra seeks "clarification from the European Commission or the country which may be affected before starting a risk assessment" (Defra, 2005).

Management Discretion

Management discretion is an internal process that helps to determine priorities for conducting risk assessments. What is often lacking, in cases where such processes are identifiable, is how the identified factors are to be taken into account or weighted. For routine risk assessments (e.g., import decisions) in Canada, prioritization takes place mostly on a first-come, first-served basis. For more urgent matters, senior managers decide which assessments are to be done first and by whom, and which are to be delayed by resource constraints. Although certain risk assessments, such as those relating to import risk analysis, are guided by international agreements and regulations, the decisions to undertake other risk assessments at the CFIA are often influenced by requests from other departments (e.g., Health Canada) or by input from policy-makers (review of CFIA risk assessments and interviews with CFIA staff).

The Panel identified two issues with the current approach in Canada: a lack of transparency in decision-making regarding prioritization; and difficulty in assigning resources for risk assessments not related to immediate issues (e.g., import requests or specifically identified current risks). The CFIA is putting new procedures in place to help direct the prioritization decisions and ensure input from multiple stakeholders (interviews with CFIA staff). As well, these procedures will help to establish the priority of risk assessments based on agency workloads and stakeholder timeframes, and provide the stakeholder with an estimated time of completion. Decisions about whether to include or partner with human health agencies (e.g., Health Canada/the Public Health Agency of Canada) on specific risk assessments remain largely ad hoc (i.e., driven by personal communication and recognized need rather than by a structured prioritization process) (interviews with experts).

Many other countries also rely on management discretion for short-term prioritization. At the European Food Safety Authority (EFSA), for instance, the organization may respond to requests from the European Community, the European Parliament or member states, or may initiate its own assessments (EFSA, 2010). The U.K. Human Animal Infections and Risk Surveillance (HAIRS) group has adopted a systematic and integrated approach. It conducts surveillance to identify emerging and potential zoonotic infections that may pose a threat to public health in the United Kingdom (HAIRS, 2008). Potential threats are then discussed within the group and, depending on the estimated risks, a risk assessment may be initiated. Such an approach provides a continuing means for gathering input from multiple perspectives, thus potentially providing essential foresight regarding current and emerging threats (HAIRS, 2008).

Strategic Frameworks

The management of day-to-day administrative tasks and immediate policy risk assessments can often consume the bulk of an organization's time and resources. The Panel's concern is that this appears to be the case for many animal health risk assessment organizations in Canada and in many other countries. Nonetheless, many agencies around the world have begun to recognize the need for strategic risk assessments in spite of the significant challenges associated with prioritizing resources for these types of assessments.

A review of different countries' practices seems to suggest that such forward-looking assessments tend to be driven in many cases by the political recognition of an issue, as opposed to a formal evidence-based framework that incorporates the

requirement to undertake such assessments. The former case-by-case approach may be referred to as *ad hoc prioritization*, a reactive approach to unfolding events. The latter approach, based on a formal consideration of various factors built into a strategic framework, may be referred to as *evidence-based prioritization*, a more proactive approach used for assessing potential emerging threats. The specific type of framework adopted or in place reflects the type of risk assessment conducted, and is a partial function of legislative environment, historical agency development, and national objectives.

Ad Hoc Frameworks

Ad hoc prioritization is driven by high-level national objectives or issues brought forward in response to political imperatives. For example, the European Commission has linked its *Animal Health Strategy (2007–2013)* to several broad strategic goals including economic growth, national competitiveness, and sustainable development (European Commission, 2007). Elsewhere, the first step in the Animal Health Australia risk assessment process requires identifying the relationship between strategic objectives of the organizations involved (federal/state/territorial government, and agricultural and industry organizations) and the associated risks (Animal Health Australia, 2005).

Evidence-based Frameworks

Evidence-based prioritization involves some sort of feedback procedure or framework built on identification, estimation, and management. The Department for Infectious Disease Epidemiology at the Robert Koch Institute, the German public health department, for example, prioritizes pathogens according to a standardized methodology based on an explicit set of criteria and common weights (Krause *et al.*, 2008). In the United Kingdom, the Animal Health and Welfare Decision Support Tool provides a Veterinary Surveillance Profiles Database to "inform decisions on relative resource allocation for animal health issues" (Defra, 2010a). In this database, "[a] 'profile' for each disease captures defined data from which the tool calculates, for each disease considered, a score for the risk and epidemiology, and a score for the disease's impact on public health, international trade, animal welfare and 'wider society' (rural economy, biodiversity, environment), derived from 39 key criteria" (Defra, 2010a). Information on other forms of evidence-based prioritization can be found in *Approaches to the Prioritisation of Diseases: A Worldwide Review of Existing Methodologies for Health Priority Settings* (EU/Discontools, 2009).

7.1.2 Tools to Support Strategic Frameworks

Although prioritization is a difficult task, there are some tools that can be used to support a strategic prioritization framework. Such tools may include surveillance, strategic planning exercises, and other supporting activities and resources. These tools are only provided as examples; comparing or endorsing specific approaches was outside the scope of this report.

Surveillance

Veterinary surveillance can be broadly described as the continuing collection and dissemination of data related to animal health and disease (Defra, 2011). It is vital to the protection of both animal and human health, and is an important tool for risk management. This tool is included in the strategic frameworks of several countries (e.g., HAIRS, 2008; Defra, 2011). In Canada, surveillance is performed at the national and provincial levels. At the national level, the CFIA coordinates with a network of surveillance programs to protect animals and humans against diseases and infections that pose a threat to health or the economy. The Canadian Animal Health Surveillance Network (CAHSN) (CFIA, 2009a) and the Canada and Alberta Bovine Spongiform Encephalopathy (BSE) Surveillance Program (CABSESP) (Alberta Agriculture and Rural Development, 2011) are examples (see also Section 2.6 and Box 2.4).

At the provincial level, the Alberta Veterinary Surveillance Network (AVSN) strives to protect the agricultural industry, animal welfare, and public health. It specifically targets livestock and poultry, and aims to reduce the economic, social, and animal welfare impacts of diseases affecting animals. The AVSN also provides producers and veterinarians with the necessary infrastructure to detect and respond to disease-related issues (e.g., Veterinary Practice Surveillance). The intent of the AVSN is to ensure that any irregular condition found in an animal or group of animals is dealt with promptly so that potential health risks are minimized (Alberta Agriculture and Rural Development, 2010; 2011; interviews with experts).

It is essential to perform surveillance within Canada and monitor the surveillance conducted by our trading partners to establish a foresight strategy for emerging diseases, and to inform decision-making in import and export risk assessment.

Strategic Planning for Risk Assessment in the United States and Canada

Over the past decade, events such as the 2003 severe acute respiratory syndrome (SARS) outbreak and the 2009-10 H1N1 pandemic have highlighted an ever-growing need for contingency management plans and policy options that are

responsive to rapidly shifting conditions and emerging events. Since roughly 75 per cent of emerging infectious diseases derive from animals (Taylor *et al.*, 2001), it is essential that public health managers and their organizations have immediate access to a set of thoughtful, ready-made contingency plans to respond to multiple potential adverse animal health-related events. There are several different approaches to strategic planning for risk assessment, of which foresight analysis is one example.

Foresight analysis is a structured procedure for using a range of tools and techniques to better understand future opportunities and challenges (Fore-CAN, n.d.). One such technique is to construct multiple scenarios considering various economic, environmental, social and political factors to project different possible "futures," which can, in turn, help to assess the efficacy of various management and policy decisions (Willis *et al.*, 2007). A key aspect of foresight is to "capture the interdisciplinary knowledge generated…[and] to relate this knowledge to risks and opportunities that might arise in the future, and to use it to provide fully evidence-based policy advice" (King & Thomas, 2007).

Foresight analyses can offer tangible policy suggestions to prevent and control the spread of infectious zoonotic disease (King & Thomas, 2007). Since 2002, for example, the U.K. Foresight program has commissioned 10 projects, including the 2006 report, *Infectious Diseases: Preparing for the Future*, which highlighted the efficacy of handheld disease-monitoring devices to gauge the spread of infectious disease (Donaldson, 2006), and influenced the U.K. government's decision to set up an £800,000 program to develop these devices (King & Thomas, 2007). Other outcomes from the report included informing the 2006 G8 summit, contributing to the development of the Southern African Centre for Infectious Disease Surveillance (SACIDS), and helping to secure an additional £55 million for the production of "new rapid diagnostic tests and point-of-care devices for the detection and identification of infectious agents in both humans and animals" (BIS, 2011).

In Canada the Chemical, Biological, Radiological-Nuclear and Explosives (CBRNE) Research and Technologies Initiative (CRTI) funded a three-year foresight project to develop new approaches and strengthen existing Animal Health Emergency Management (AHEM) systems in 2008 (DRDC, 2010). This project, Foresight for Canadian Animal Health (Fore-CAN), is a partnership between multiple governments and organizations — the CFIA, the Public Health Agency of Canada (PHAC), Agriculture and Agri-Food Canada (AAFC), the provinces of Alberta and Ontario, Canada's veterinary colleges, and the Dairy

Farmers of Canada — and was also a highly participatory forum for a host of other stakeholders (Vanderstichel *et al.*, 2010). Through participation in several workshops and a spring 2010 symposium, Fore-CAN participants were able to identify challenges to existing AHEM systems, posit the consequences of these challenges across a spectrum of scenarios, design and evaluate potential management and policy contingency options, and offer recommendations for further strategic planning involving all relevant stakeholders (Vanderstichel, *et al.*, 2010).

Supporting Strategic Frameworks

The above strategic planning initiatives demonstrate the potential benefits and application of a forward-looking approach to animal health issues. Academic literature about prioritization also offers a number of useful tools, including sophisticated estimation techniques (multiple criteria decision analysis, probability inversion methods, etc.) and novel indicators (quality-adjusted life years, cost-of-illness, social sensitivity, etc.) (Ruzante, 2010; Krause, 2009; and Mangen *et al.*, 2010). Generally, this literature makes use of country-level data and institutional context when suggesting new directions for prioritization or criticizing approaches. In this sense, the academic literature can be most useful for identifying current best practices and potential future directions in prioritization practices. Other tools that can be used for prioritization of diseases, stakeholders, and consequences are not discussed here because they are beyond the scope of this report.

Developing clear contingency plans and options before crises hit can enable stakeholders, organizations, and countries to respond much more rapidly, thus mitigating potential adverse consequences, enhancing risk management, and generally improving future policy outcomes.

7.2 ACHIEVING COMPREHENSIVE, INTEGRATED ANIMAL-HUMAN HEALTH RISK ASSESSMENTS

The CFIA and the PHAC have recently worked toward improving collaboration, by organizing several joint conferences aimed at increasing their degree of interaction and minimizing duplication in surveillance and assessment efforts. After discussions with CFIA and PHAC officials, the Panel noted that while there is an ever-increasing commitment to integrating animal and human health risk assessments, there is not a structured approach to ensure it occurs.

Christopher McDougall, a health policy researcher, has argued that "counterproductive respect for jurisdictional boundaries, limited resources at the Public Health Agency of Canada, and the use of weak policy instruments [have led to a system characterized by] duplication and competition, [in which

research is conducted within] institutional silos that use incompatible information systems and produce incommensurable data, and shared through informal and voluntary rather than mandated and automatic mechanisms" (McDougall, 2009). Although McDougall's comments concerned the wider public health arena, this same general logic applies to the challenges of ensuring effective, comprehensive animal and human health risk assessments.

Broadly speaking, there are three basic models that can be employed for achieving comprehensive, integrated animal-human health risk assessments. Risk assessments for animal and human health can be undertaken (1) by independent organizations, (2) jointly in a centralized organization, or (3) as interrelated risk assessments overseen by a common process or committee (NRC, 1983; Panel review of risk assessments). These three models, each offering its own set of advantages and drawbacks, are discussed below.

1. By independent organizations

As outlined in Chapter 2, animal and human health risk assessments typically have been conducted independently of one another in Canada. The CFIA, the PHAC, and Health Canada have been the main departments or agencies responsible for these activities. The CFIA is primarily responsible for animal health risk assessment as it pertains to economic and trade consequences. The PHAC is ultimately concerned with animal health only insofar as it contributes to general public health. Although certain responsibilities may overlap when it comes to zoonotic diseases, the overarching mandates that elicit these responsibilities are distinct. Take, for instance, the responsibility for surveillance of infectious disease. The CFIA undertakes surveillance to help ensure that animal diseases transmissible to humans are controlled within animal populations (CFIA, 2011a), whereas the PHAC performs this task in the context of public health (PHAC, 2011a, 2011b).

Independent agencies can permit each group to direct its energy and capabilities in a defined area, thus developing a focused expertise. In addition, such an approach enables each agency to prioritize in its particular area of animal, human, or ecological health. This model remains consistent with the model for managing risk; that is, risk managers for animal and human health tend to function independently and likely focus on risk assessments within their domain of expertise.

In general, the Panel felt that having independent agencies may simplify and streamline the process for each risk assessment. However, in its discussions with representatives of the two organizations, the Panel heard that differences in the institutional mandates and consequences of risks being assessed by the CFIA and

the PHAC also created challenges for the integration of animal and human health risk assessments. While the CFIA operates in a framework in which it must make timely decisions on matters such as whether an import can proceed or whether an animal herd must be quarantined or destroyed, the PHAC operates in the context of risks to human health, thereby creating a different set of priorities and risk tolerance. As discussed in Chapter 1, these differences in responsibilities and institutional cultures are magnified by the use of differing terminologies.

Thus independent agencies may not be the most effective way to generate a comprehensive, integrated understanding of the full range of consequences surrounding an animal or human health issue, or toward establishing common ground and common terminology. These challenges were raised by stakeholders in both the federal and provincial governments who told the Panel about specific instances when terminology differences, jurisdictional challenges, and data protection had limited or prevented animal health and public health groups from working together effectively and developing common strategies for addressing risk (interviews with experts).

Completely independent organizations may also hamper the understanding of how decisions on management of human health risks can have significant impacts on animal and ecological health, and vice versa. Establishing priorities for resources across independent organizations can be a significant challenge as well. Another challenge identified relative to having two independent organizations is that each organization may ultimately develop its own perspective or culture, making communication and coordination more difficult.

An approach that encourages greater interaction, while maintaining independent risk assessments, can be found in the exchange of the independently created animal and human health risk assessments. Organizations can then, at least, appreciate each other's perspective and share data, which may influence the assessments. This can also build a type of external review into the process. An integrated assessment is not, however, produced as a result, and a consensus is not necessarily achieved.

These observations support the need for a closer working relationship between animal and human health agencies, as described in the 2008 report of the Auditor General of Canada. It recommended that "to improve their ability to anticipate

and control zoonotic diseases, the Public Health Agency of Canada and the Canadian Food Inspection Agency should jointly assess the possible risks to human and animal health, clarify how the responsibilities will be divided, and act on joint surveillance objectives and priorities" (Auditor General of Canada, 2008).

2. Jointly in a centralized organization

Conducting animal and human health risk assessments jointly in a single organization is another option for achieving a comprehensive, integrated approach, which may lead to improved communications and promote the sharing of information and resources. This must be balanced against the time and resources that may be consumed by the planning and coordination necessary to achieve this type of integration.

Establishing a single organization requires the adoption of a common language and the development of common approaches to risk assessment. It also brings together a range of disciplines and expertise, and ultimately requires that a common understanding be achieved. Situating national risk assessment within a single organization also creates another challenge: the structure and allocation of resources needs to be developed in a way that allows for the independent activities of different groups, while supporting centralized operations.

Government organizations, such as the U.K. HAIRS group, have adopted this type of model (see Section 7.1.1) and found it works well in their national context (Walsh & Morgan, 2005). Biosecurity New Zealand is another example. As part of the Ministry of Agriculture and Forestry, Biosecurity New Zealand plays a role in the economic, social, cultural, health, and environment outcomes, and prevents, eliminates, or manages the harm to the economy, environment, and health that pests or diseases can generate (Biosecurity New Zealand, 2010). To do this, the agency assumes the role of leadership across the biosecurity system; develops policy, standards, and regulations; conveys effective interventions; and promotes wider participation and collaboration efforts. This system is composed of several groups and organizations working collectively. Examples include other ministries or departments (e.g., Ministry for the Environment, Ministry of Tourism, Tourism New Zealand, Ministry for Economic Development, Ministry of Foreign Affairs); primary producers (e.g., farmers and food plants); industry sectors (e.g., importers, exporters, marine and tourism operators); regional councils and local government; the public health sector; and environment groups (Biosecurity New Zealand, n.d.).

3. Interrelated risk assessments integrated under a common process or committee

The third option envisioned by the Panel is to design and conduct animal and human health risk assessments separately and then merge them within a predetermined framework. A joint committee could be used to oversee the process and the product. Within the context of the system characteristics described in earlier chapters, the agencies involved could participate as continuing stakeholders throughout the process, or alternative approaches could be used. This differs from the first model in that the merging of risk assessments occurs earlier in the process. The key is that a single, merged risk assessment (as opposed to separate risk assessments) is produced at the end. This is somewhat similar to the NRC's Red Book recommendations for producing this type of joint risk assessment in cases "[w]hen two or more agencies share interest in and jurisdiction over a health hazard" (NRC, 1983).

The merged comprehensive, integrated risk assessment should ultimately include the impact of management options on both animal and human health. There are several possible approaches to achieving this goal. One approach is the development of two separate risk assessments that are reviewed and integrated by a joint panel into one assessment, which then informs the overall risk analysis. An alternative approach is to have one organization create a complete risk assessment, which is then sent to the other organization for review and input prior to being finalized. Regardless of the approach, an integrated risk assessment would be created through a defined framework and presented to managers and policy-makers as such.

Effective coordination depends on systems and people. The systems need to facilitate the gathering, integration, and analysis of data, as well as the coordination of resources, in an efficient way. The people need to work with one another to overcome obstacles, share information and resources, and complete the tasks at hand. In addition, a common agreed-upon language, such as that proposed in this report, should be adopted.

If this approach is to be considered as a mechanism for improving integration and interaction, it is also essential that the process is formalized so that it is ready when needed. It cannot be developed and adopted only when a specific problem arises. Such a sporadic approach would do little to improve the integration and common understanding that is required. The view of the Panel is that the most effective integration and sharing of knowledge will occur when there is a joint review of the risk assessment at some stage in the process.

7.3 COMPREHENSIVE, INTEGRATED ANIMAL AND HUMAN HEALTH RISK ASSESSMENTS: A CASE STUDY

The different perspectives toward risk assessments for animal and human health were highlighted during the recent H1N1 outbreak in the spring of 2009. When H1N1 was reported in swine in Alberta, a public health event became an animal health event as well (CFIA, 2009b). With high levels of uncertainty, intense public scrutiny, and overlapping jurisdictions, addressing this outbreak was a challenge in assessment, execution, and communication. This episode highlights the need for a coherent and comprehensive approach.

The H1N1 Pandemic in Canada

Detected first in the Mexican town of La Gloria, Veracruz in mid-February 2009 (Fraser *et al.*, 2009), a new swine-origin influenza A (H1N1) virus emerged across North America and subsequently spread worldwide to more than 200 countries (WHO, 2010b). Because of the rapid human-to-human transmission and the global spread, on 11 June 2009 the WHO raised its pandemic alert to Level Six, declaring it a global pandemic (WHO, 2009). This call to action placed the preparedness of governmental pandemic plans under an intense spotlight. Public health officials had to enact such plans in the face of uncertainty over the disease virulence and spread (Louie *et al.*, 2009).

The Canadian government (Health Canada and the PHAC), with the cooperation of provincial and territorial governments, followed both Canada's official Pandemic Influenza Plan and the WHO's early advice in rolling out one of the largest mass vaccination program in the history of the country in order to mitigate the potential adverse effects of the virus in humans (CBC, 2009; Sander *et al.*, 2010). The pandemic resulted in 428 deaths and 8,678 hospitalizations related to the two waves of influenza H1N1 in Canada as of April 17 (PHAC, 2010), while the cost of the public health response was estimated at more than $2 billion (Waldie & Alphonso, 2009).

As the pandemic initially unfolded, it was considered primarily a public health event. The report of an infected swine herd in Alberta, however, brought animal health and animal-human transmission into the picture. Risk assessments for animal health and for animal-human and human-animal transmission were required as were risk management processes that took into account animal and human reservoirs or sources of infection.

The Canadian Response: Animal-Human Health Risk Assessment in Practice

As discussed in Chapter 2, responsibility for animal health-related events is shared between the PHAC, Health Canada, the CFIA, provincial and territorial governments, and a number of other institutions. In terms of the H1N1 pandemic, public health concerns were dealt with jointly by the PHAC and Health Canada (PHAC & Health Canada, 2010), while direct animal health concerns were dealt with by the CFIA (CFIA, 2009e).

The first response to the outbreak included managing the initial cases and enhancing surveillance while conducting research on the virus. This approach, in keeping with WHO advice (WHO, 2009b), effectively managed cases in a similar manner to seasonal influenza: not treating the majority of cases experiencing a mild, self-limiting illness and offering antivirals to those considered at higher risk of experiencing severe disease (PHAC, 2009c). Public education to encourage behaviours that would minimize spread of the virus was undertaken on a large scale, along with a mass immunization and communication program (PHAC & Health Canada, 2010). The PHAC coordinated the vaccination of the Canadian population, in conjunction with the provinces, territories, and local health authorities (PHAC & Health Canada, 2010) achieving 41 per cent coverage (Glimour and Hoffman, 2010) and helped to inform the public about safety practices such as "hand-washing, coughing into one's arm, and staying home if sick" (PHAC & Health Canada, 2010).

On 5 May 2009 the CFIA notified the OIE that influenza H1N1 had been confirmed on a swine farm in Alberta (OIE, 2009). The first step was to quarantine the herd while the infection was confirmed and risk assessments for animal and human health were considered (CFIA, 2009b; Panel review of risk assessment). This created challenges for the swine producer, including overcrowding that necessitated an initial culling of 500 mature animals to meet animal welfare conditions, followed by the eventual mass cull of the entire herd as a result of a perceived inability to sell the animals even on resolution of the clinical disease (Alberta Farmer Express, 2009).

Upon reporting the infection and quarantining the herd, there was a drop in swine prices (Johnson, 2009; Gietz, 2010). Imports were limited by certain countries. There was also concern by the public over possible exposure, despite the fact that there was no indication of any food safety risks from consuming pork.

By 15 May 2009 scientists at the CFIA's National Centre for Foreign Animal Diseases (NCFAD) had "mapped the full genetic sequence of the virus found in the swine from Alberta" (CFIA, 2009c). This confirmed that the virus was the

same as that was circulating among humans. The CFIA produced an animal health risk assessment for H1N1 in swine and provided it to the PHAC. The PHAC completed a risk assessment in humans with input from CFIA. The two organizations communicated throughout the process (review of risk assessments).

By mid-July, in accordance with OIE recommendations, it was decided quarantines were no longer necessary, as affected animals would be managed using the same veterinary and biosecurity practices employed for other swine influenza viruses (CFIA, 2009d). These included procedures to limit virus transmission among animals and to humans, and reliance on the existing inspection points in the Canadian slaughter system.

Challenges of the Response

Through its review of risk assessments, interviews with experts, and other research, the Panel identified some clear lessons from the response to the pandemic and the role of animal health risk assessment:

1. Engagement of both the animal and human health risk assessment communities was required to identify and manage risks effectively.
2. Since this was a fast-moving situation (which must be taken into account in any consideration of the response), having a more structured, formal process in place for facilitating collaboration between the animal and human health communities is likely to have been beneficial.
3. There were considerable differences in perspectives and language in approaching this problem. The solution appears to have followed the path of two separate risk assessment approaches rather than an integrated approach (review of risk assessments). This experience highlights the challenges that can be created by not having a well-defined formal process that supports integration.
4. The approach employed appears to have enabled appropriate decisions, but did not integrate human health consequences into the animal health risk assessment. The broader consequences, such as the psycho-social consequences and the secondary impacts of the herd quarantine, were not given extensive consideration (review of risk assessments).

Advancing Prioritization and Comprehensive Animal-Human Health Risk Assessments

Effective and timely use of resources is required to achieve the goal of protecting animal and human health. A clear system of prioritization for conducting risk assessments and framing the comprehensiveness of the risk assessments can assist

with this objective. Such a system should cover not only the decision to conduct a risk assessment, but also the extent to which all possible outcomes and the implications of the management options are considered.

When animal and human health function as independent fields, the implications of how decisions affect populations and the environment are less obvious. A more integrated and comprehensive approach is essential. The Panel feels this is best achieved by ongoing integration rather than by sporadic collaborations initiated under urgent circumstances. The Panel maintains that the latter approach would leave in place barriers in organizations and differences in language that could limit both effectiveness and efficiency. This could leave important risk assessments undone and stakeholders frustrated.

Prioritization decisions must follow a structured and transparent process that ensures that immediate and future threats or risks are addressed. In addition, the decision-making process must engage the appropriate stakeholders and not be left to the sole discretion of risk managers. This chapter has reviewed some examples, but the most important finding, in the view of the Panel, is the need to have a defined process to achieve, when appropriate, a comprehensive risk assessment that brings together animal, human, and environmental considerations. The Panel did not identify one specific approach as superior as each approach has its own strengths and weaknesses. A defined step at which integration and exchange of information and perspective occurs, however, is seen as an advantage.

Review of Key Findings

- Prioritization is an important element of effective animal-human health risk assessment. It facilitates effective use of resources and should ideally provide a means for allocating resources to strategic risk assessments.
- A transparent and efficient model for prioritization needs to be established because this offers the best way to respond quickly, efficiently, and systematically, and to use the human and monetary resources adequately.
- Animal health risk assessments, where appropriate, should consider and integrate both animal and human health consequences. While there are different organizational structures for achieving this, an integration step that brings together animal and human risk assessors can provide a better understanding of risks and an improved ability to assess and manage the full range of consequences.

8

Conclusion

8 Conclusion

The charge to the Panel asked: *What is the state and comprehensiveness of risk assessment techniques in animal health science, specifically pertaining to risks which may impact human health?* The answers to this question, and to the sub-questions, form much of the content of this report. What follows in this chapter is a consolidation, drawn from the main text, of the Panel's response to each of these questions.

8.1 MAIN QUESTION

> *What is the state and comprehensiveness of risk assessment techniques in animal health science, specifically pertaining to risks which may impact human health?*

Animal health risk assessment occurs within the context of international agreements, stakeholder expectations, and complex socio-political considerations. Emerging disease and food safety are now a greater part of the public consciousness. The impact of globalization and urban expansion on animal and human health is beginning to be understood. Climate change is affecting disease spread and disease range. Societal expectations and our knowledge base are changing. We are in an era of rapid travel and communication. All this means that the context and demands of, and for, animal health risk assessment are changing. These considerations must be taken into account when addressing the state and comprehensiveness of animal health risk assessment, particularly as it may impact human health.

Animal health risk assessments are conducted and/or contributed to by all levels of government in Canada, as well as by universities, industries, and stakeholder groups. The overlap between provincial and federal responsibilities, the institutional mandates of national agencies (the Canadian Food Inspection Agency, CFIA; the Public Health Agency of Canada, PHAC), and the distribution

of animal health risk assessment activities across a range of government, academic, and stakeholder groups add complexity to an assessment of the current state and comprehensiveness of this activity in Canada. The drivers of animal health risk assessments range from relatively routine animal importation requests to requests for assessment to help establish overarching policy direction (review of risk assessments and interviews with CFIA staff). The context and constraints (e.g., need to comply with international agreements) for risk assessments may vary; however, there are some general approaches that can be, and are being, applied to animal health risk assessments conducted for this range of purposes. The Panel considered the overall state and comprehensiveness of animal health risk assessment, and did not limit itself to import assessments or to activities of the CFIA. However, as the CFIA plays a major role in animal health risk assessments in Canada, it therefore serves as the primary example for these concluding comments. It should be noted that the Sponsor (the CFIA) was not looking for a "how to" guide on specific techniques for risk assessments, but rather for a broader understanding of the general approaches. This has been the guiding principle for the Panel's deliberations.

Animal health risk assessment in Canada is built on a solid foundation of knowledge and expertise. The Panel's review confirmed that the CFIA primarily conducts animal health risk assessments to meet international trade obligations and to support immediate operational decisions that protect animal and human health. Risk assessments are also conducted to support policy decision-making that protects against current and future threats to animal and human health.

A structured, systematic approach ensures the appropriate consideration of risk. Risk assessment is part of risk analysis to support risk-based decision-making. For the purpose of this report, the Panel defined risk analysis as having four key components:

- hazard identification;[32]
- risk assessment;
- risk communication; and
- risk management.

[32] Hazard identification may be considered an integral part of the risk assessment process itself in some paradigms; whether or not it is considered a separate step, hazard identification is essential to risk assessment.

Traditionally, risk assessors have completed their work separately and independently from stakeholders and consideration of risk management decisions, which have remained largely the purview of risk managers (CFIA, 2005; interviews with CFIA staff). As described in Chapter 4, however, there is generally a recognition now that greater exchange of information and perspective between risk assessors, risk managers, stakeholders, and decision-makers before a risk assessment (during question and consequence scoping) and in a structured manner during the process (e.g., employing an advisory body or a review stage) leads to a risk assessment that is more relevant and useful. When well managed, this can improve efficiency and help to ensure that the full range of management options is considered in the risk assessment process. The CFIA has embraced part of this change in that there is ongoing communication between risk assessors and risk managers during the risk assessment process (see Chapter 3).

The systematic process of animal health risk assessment is commonly described as having four steps, the description of which varies among organizations. (See Chapter 2 and Appendix B for an outline. These differences will be reviewed in response to the sub-questions below.) The CFIA conducts systematic risk assessments within a structured risk analysis framework that is consistent with international guidelines e.g., the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code*, the World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (see Box 2.2, Figure 3.2, and Appendix F).

While the CFIA has capabilities in quantitative risk assessment, the majority of risk assessments conducted are qualitative and, while they may consider a range of consequences, the major focus is on the economic and trade consequences of introducing animal disease into Canada (see Chapter 3). Major drivers for qualitative risk assessments appear to be gaps in quantitative data and the speed at which the risk assessment can be completed.

There is a growing recognition of the need to consider the full range of consequences in animal health risk assessments (see Chapters 4 and 5). Potential human health consequences are considered in the CFIA's animal health risk assessments, but this is primarily limited to situations where direct zoonotic disease transmission is possible. Environmental and ecosystem impacts are not generally examined in depth (review of risk assessments and interviews with experts).

The Panel's review of 30 risk assessments conducted by the CFIA suggested that there is an opportunity to enhance the assessment of these and other consequences. The Panel recognized that its review was limited by the public accessibility of completed risk assessments, and that the CFIA is continuing to evolve its risk assessment processes.

The Panel's major finding was that an integrated, multidimensional approach that considers the appropriate range of potential animal, human, and environmental consequences, as well as risk management outcomes, in the risk assessment process is likely to produce an assessment that provides increased value to risk managers, decision-makers, and stakeholders (see Chapter 4). Considering not only the consequences of the initial animal health event or hazard exposure, but also the consequences of the steps taken to mitigate the risk, is important to providing a comprehensive assessment of the risks. Further, risk-based decision-making and subsequent risk communication and management can benefit from an increased engagement of stakeholders in establishing risk assessment questions, scope, and consequences, and from improved access to expertise and knowledge among risk assessment practitioners. Because risk assessment is part of a broader risk analysis process that comprises hazard identification, risk assessment, risk communication, and risk management, all four phases need to be effectively carried out to maximize the benefits of the risk assessment component.

The Panel identified several contributions to achieving an integrated, multidimensional approach in animal health risk assessment:

1. ***integration:*** increase the breadth and depth of consequences considered in risk assessments; and address consequences for animals, humans, and the environment;
2. ***multidimensional approach:*** include consequences of management options in the risk assessment; and
3. ***transparency:*** use risk managers and stakeholders strategically in the risk assessment process, have a clearly articulated prioritization process, document decisions, and maximize risk communication.

While the CFIA is the main federal agency with responsibility for conducting animal health risk assessments, the PHAC is the main federal agency with responsibility for conducting human health risk assessments (see Section 2.6).

Testimony of expert witnesses confirmed that differences in terminology, perspectives, and organizational as well as disciplinary cultures between animal and human health risk assessment groups pose challenges for collaborations. As discussed in the introduction to Chapter 1, adoption of a common set of agreed-upon definitions will help to facilitate and ensure a comprehensive animal-human health risk assessment in Canada. The Panel proposed a common set of definitions in Chapter 1 and has striven to use these consistently throughout this document.

The CFIA and the PHAC are seeking to improve collaboration in order to ensure their collective resources are employed with maximum efficiency and effectiveness to address animal-human health interactions (interviews with experts). As discussed in Chapter 7, there are different ways to achieve this; but a desired endpoint is increased integration between assessment of animal and human health risks associated with animal health events. Adoption of an integrated, multidimensional approach that produces a single integrated risk assessment, however, can help achieve the goal of comprehensive animal-human health risk assessments. The CFIA principles for risk assessment presented in Box 3.2 are consistent with the adoption of such an approach.

8.2 SUB-QUESTIONS

On what basis are risks prioritized and selected for assessment?

Prioritization and selection of risks for assessment is an important step and varies from country to country. Until recently, prioritization was primarily the responsibility of the National Manager at the AHRA unit. Unless designated as urgent by senior management, most requests were filled on a first-come first-serve basis. The CFIA has recently worked towards constructing a new framework for prioritization, which remained in development at the time of this report. The conclusions here therefore relate to the overall issue of prioritization.

Risk assessments are undertaken for a variety of reasons, including, but not limited to, trade imperatives, policy planning, and management discretion. As discussed in Chapter 7, there needs to be a structured and transparent system in place to ensure that routine risk assessments, as well as those required for policy decisions and strategic planning, are completed in a timely fashion. Clarity and transparency should come first and foremost in any prioritization framework or set of protocols.

A clearly articulated prioritization framework supports risk communication and the efficient and effective use of resources. A prioritization framework can also help ensure that resources are directed toward strategic foresight and planning — a priority that may otherwise end up being sacrificed in keeping up with short-term needs.

The key challenges in prioritization and comprehensiveness of risk assessments relate to:

1. developing a systematic means of providing sufficient resources for conducting forward-looking assessments and ensuring that the scope of such assessments is appropriate;
2. identifying the optimal institutional arrangements for conducting the assessments;
3. ensuring transparency in the prioritization and in the comprehensiveness of the assessments; and
4. incorporating surveillance and strategic planning processes to help direct prioritization decisions.

Are risks to animal health that also impact human health (e.g., zoonoses) assessed using the same techniques employed for those impacting only animal health?

The Panel observed that in general the same analytical techniques are employed by the CFIA and other risk assessment organizations (national and international) when considering risks to animal health that also impact human health (review of risk assessments and risk assessment frameworks). There are considerable differences, however, in the approaches (see Chapters 4, 5, and 7) that are taken, depending on the organization (e.g., the PHAC versus the CFIA) or country. Key differences include the extent to which direct and indirect human health consequences are considered, the emphasis on economic considerations, and the intent of the risk assessment in the decision-making process. In terms of integrating animal and human health into a comprehensive risk assessment, the Panel identified four key challenges in Canada:

1. Terminology can vary among practitioners, researchers, and jurisdictions (i.e., the CFIA and the PHAC, federal and provincial governments).
2. Jurisdictional issues pose some barriers to the efficient integration of data, knowledge, and risk assessments conducted by different agencies or organizations.

3. Perspectives vary on the relative importance or severity of consequences, as well as which consequences form the primary focus of the risk management decisions (that the risk assessment is designed to support).
4. Differences exist in the focus of decision-making to be supported by the risk assessment (e.g., risk assessments within the CFIA are generally conducted with the intent of making operational or policy decisions, whereas risk assessments within the PHAC are conducted with the intent of identifying gaps in knowledge that affect decision-making) (review of risk assessments and interviews with experts).

Overall, the Panel believes that communication is the main barrier to the integration of animal and human health risk assessments. It is not enough for institutions to rely on goodwill, interpersonal relations, and ad hoc consultations. There also needs to be consistent and coordinated mechanisms for continuing collaboration across organizations and levels of government.

The Panel found that the general approaches for assessing animal health risks, regardless of whether or not there are associated human health consequences, are similar. When different organizations try to work together, however, the differences in terminology can become significant. For example, the CFIA considers hazard identification as a pre-risk assessment step, and release assessment as the first step in the formal risk assessment process (CFIA, 2005). In contrast, hazard identification is commonly identified as the first step in risk assessment by many human and public health organizations (PHAC, 2009b). The difference in practice is not significant in terms of determining the risk estimation, but it can lead to communication challenges (review of risk assessments and interviews with experts).

The techniques employed in a risk assessment are determined by the nature of the hazard (for example, chemical versus biological risk agent); the available data; and the consequences of risk. Since the range and measures of consequences addressed are generally broader in scope for animal-human risks when considered together, different techniques and tools may be employed (see Chapter 4 and Appendix E).

The Panel felt that the incorporation of methods from non-traditional disciplines into the measurement of consequences (both in terms of considering the breadth and depth of consequences, and of quantifying such consequences) was of particular value. This is an important part of an integrated, multidimensional approach.

Does animal health risk assessment contribute to prioritization, planning and coordination of integrated animal-human health research in Canada?

The Panel observed that integrated animal-human health research in Canada is primarily driven by specific events, intellectual curiosity, and sources of research funding rather than by the information or questions that arise because of animal health risk assessments. There are two factors. First, animal health risk assessments conducted in Canada are not widely accessible. Second, there is little prioritization, planning, and coordination of animal-human health research at a high level. Because industry represents a significant source of research funding, or tends to be an important partner in government funded research for animal health (see Chapter 6), many research projects reflect the immediate concerns of the private sector. This may leave animal-human health research that has important, but longer-term, socio-economic benefits underfunded. Other countries have addressed some of these gaps by creating and funding specific research opportunities in this area (see next sub-question). There are also some examples in Canada, such as the Alberta Prion Research Institute (APRI, n.d.) and the Networks of Centres of Excellence programs (NCE, 2011), which have specifically supported integrated research. There does not appear, however, to be the type of overall coordination that could occur if one of the current Tri-Council agencies, or another organization, was given the mandate for animal health and integrated animal-human health research.

What, if any, gaps exist with regard to integrated animal-human health research that may have an impact on human health?

The Panel identified that the gaps in animal-human health knowledge were extensive but also specific to the risk assessment being conducted. A comprehensive cataloguing of gaps was not possible and was determined not to be useful because it would be dependent on specific risk assessments provided. For example, the Panel noted that there were gaps in available evidence in 15 of the 30 CFIA animal health risk assessments that it reviewed. In each case, the nature of the gaps was explicitly stated in the assessment. Examples included: "uncertainties with regard to species susceptibility, prevalence, pathogenesis;" "uncertainties with respect to routes of transmission in other species;" and "lack of available data on risks." Rather than creating an incomplete and highly specific catalogue of gaps, the Panel instead addressed gaps in research capacity and expertise in animal health risk assessment (Chapter 6) as an indicator of where the overall gaps exist.

Canada compares reasonably well with other major livestock-producing countries in terms of research productivity, impact, and intensity in overall applied animal health research (see Section 6.1.2 and online *Bibliometric Analysis of Research Contributing to Animal Health Risk Assessment*).[33] A coordinated approach to funding animal-human health research that supports risk assessment, however, does not exist in Canada. Enhanced training and research are required to support animal health risk assessments. The Panel observed that dedicated funding sources and organizations have been utilized in some provinces and in other countries to address this issue. As noted above, the development of a federal institutional research structure or mechanism with a mandate for supporting applied animal-human health research could improve Canada's capacity in this regard (see Section 6.3).

[33] Available at www.scienceadvice.ca/en/animal-health.aspx

How do risk assessment techniques employed in Canada compare to those used by Canada's major trading partners?

In its interviews and research, the Panel did not find significant differences in the formal process of risk assessment across the countries examined — all major trading nations follow the regulations and protocols of the OIE and the WTO. The differences pertain to the methodologies, disciplines, and stakeholders that contribute to the risk assessment process; the institutional contexts in which risk assessments are conducted; the resources for conducting risk assessments and related research; the means of prioritizing risk assessments; and the breadth and depth of consequences considered in risk assessments.

The Panel identified several countries that more commonly integrate animal-human-environment risk into one assessment (notably some European Union countries and New Zealand). As discussed in Chapter 7, a variety of organizational models exist for integrating animal and human health risk assessments. The Panel concluded that although integration into a single risk assessment was important, the organizational model chosen would depend on a number of factors. Whichever approach is considered, however, the Panel's research and experience suggested that a consistent and formal means of collaboration on the process and integration of the results is very important to ensuring a valuable risk assessment.

One area where Canada lacks consistency with practices in other countries is in the degree of transparency in the risk assessment process. Many other countries make public a broader range of risk assessments (for example, see FVO, n.d.; Biosecurity New Zealand, 2011, and EFSA, 2009a). The Panel recognized that a significant challenge in the Canadian context is that many risk assessments undertaken at the CFIA are requested and supported financially by private stakeholders. Nevertheless, there was a consensus among Panel members, taking into account the views of experts consulted in the process, that increased transparency is important in advancing animal health risk assessment and engaging stakeholders in the process.

How could strategic foresight be applied to animal health risk assessment in Canada?

The Panel recognizes that the majority of animal health risk assessments are conducted to meet specific trade requirements. Although this is unlikely to change, the Panel also acknowledges the value of animal health risk assessments that address potential future animal health risks and that support the broader risk-based decision-making informing public policy development. Time and resources are often consumed by day-to-day administrative requirements and immediate operational risk assessments. While agencies around the world appear to have recognized the need for strategic risk assessments, having a well-defined prioritization system that balances immediate and long-term objectives is expected to facilitate the process of ensuring engagement in such assessments. In considering risk assessments, emerging and prospective risks, and broader strategic objectives, must enter the discussion; otherwise, risk assessments will respond primarily to short-term needs.

8.3 FINAL THOUGHTS

The Panel's report on the state and comprehensiveness of animal-health risk assessment suggests that if Canada were to move toward a more integrated, multidimensional animal health risk assessment approach, the utility of risk assessments in risk-based decision-making, in risk mitigation, and in supporting integrated animal-human health research would also increase. An integrated, multidimensional approach would include increasing the breadth and depth of consequences considered, including the consequences of risk mitigation measures, expanding the techniques and perspectives, and increasing transparency. Animal health risk assessment in Canada currently appears to be meeting the majority of our needs with regard to import assessments and international trade obligations, but there are opportunities to enhance our ability to protect animal, public, and ecosystem health. We should remember to also consider future and emerging animal health events and their possible consequences for animal and human health. Canada can then continue to enjoy the benefits of our domestic and wild animal populations, increase our economic prosperity, and maintain our public health.

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Appendix A List of Experts Consulted

The Panel thanks the following individuals and organizations for providing information and advice as guest speakers during its meetings:

- Alain Goudreau (Defence Research and Development Canada)
- Marten Koops (Fisheries and Oceans Canada)
- Colin Nicholson (Natural Resources Canada)
- Bruce McNab (Ministry of Agriculture, Food and Rural Affairs, Ontario)
- François Milord (Régie régionale de la santé et des services sociaux, Quebec)
- Francine Lord (Canadian Food Inspection Agency)
- Mark Raizenne (Public Health Agency of Canada)
- Greg Paoli (Decisionanalysis Risk Consultants)
- John Berezowski (Alberta Veterinary Surveillance Network)
- Craig Stephen (University of Calgary, Centre for Coastal Health)
- Susan Cork (University of Calgary)
- Primal Silva (Canadian Food Inspection Agency)
- Fonda Munroe (Canadian Food Inspection Agency)
- Sylvie Farez (Canadian Food Inspection Agency)
- Nancy Rheault (Canadian Food Inspection Agency)
- A group of 10 risk assessors and risk managers from the Canadian Food Inspection Agency

Appendix B Definitions from Organizations Involved with Risk Assessment

This appendix contains a more detailed explanation of the rationale for the definitions adopted by the Panel and provided in Box 1.3 in Chapter 1 of the report. The following definitions are based on a review of the three major organizations concerned in this assessment: the Canadian Food Inspection Agency (CFIA), the World Organisation for Animal Health (OIE), and the Public Health Agency of Canada (PHAC), as summarized in Table B.1. The Panel also considered usage by other international organizations and other countries, including the European Union (EU), the United States, Australia, and New Zealand.

Hazard: *a risk agent (e.g., chemical, physical, or biological) or event (e.g., an animal importation) that may change the health status of an animal, human, or plant. An animal health hazard is a hazard that alters the health status of individual animals or populations of animals.*

This definition reflects how *hazard* can be used in two ways: as a term for a risk agent, or as a term to describe an event that might lead to a risk agent being introduced. This definition is broader than that used by the OIE, which specifies that it refers only to an agent (OIE, 2004). The CFIA definition refers to agents, elements, or events (CFIA, 2005). In the view of the Panel, hazards are not just infectious agents, and certain events or actions should be covered by the term *hazard*. Please also see the definition of signal for further explanation.

Hazard identification: *the process of identifying hazards (i.e., agents, events). Hazard identification is typically part of the decision process for engaging in a risk assessment within the field of animal health risk assessment.*

While the National Research Council (NRC) Red Book defines this as the first step in a risk assessment (NRC, 1983), *hazard identification* traditionally precedes engagement in a full risk assessment, as described by the OIE (2010c) and the CFIA (2005).

Risk: *the likelihood of the occurrence of an event and the likely magnitude of the consequences (e.g., animal, human, environmental, economic) to the system of concern following exposure to a hazard.*

Note that in this definition, *risk* is not defined as pertaining only to animals, but also includes human health, environmental, and economic consequences. This definition is similar to the first part of the CFIA definition (CFIA, 2005) and to the

definition of several international organizations (OIE 2004, 2010c; Biosecurity New Zealand, 2006), but is significantly different from the PHAC definition (see Table B.1). *Risk* is also used as an identifier of the causative agent or hazard, and, quite commonly, is used synonymously as probability or likelihood (Defra, 2000). A recent NRC report states that "risk can be a hazard, a probability, a consequence, or a combination of probability and severity of consequence" (NRC, 2009). Thus, it is quite possible for all three of the above definitions of *risk* to be employed within the same document, which can cause considerable confusion. Therefore, the Panel has restricted the use of the term *risk* to designate the combination of likelihood of occurrence and the magnitude of the consequences.

Risk analysis: *the comprehensive process comprising hazard identification, risk assessment, risk management, and risk communication.*

There is considerable variation in the definition of *risk analysis*, especially between that of the CFIA and of the PHAC. This can be seen as having the potential to confound communication between these two organizations. The PHAC definition of risk analysis is closer to the definition of risk assessment used by the CFIA. The recent *Science and Decisions* report (NRC, 2009) recognized the confusion that can arise between the *risk analysis* and *risk assessment* terms, with risk analysis "sometimes used synonymously with risk assessment but sometimes used more broadly." The NRC report chose to use "risk assessment to describe the process leading to a characterization of risk." The definition proposed by the Panel is the definition used by the OIE (2004, 2010c) and other organizations (e.g., Biosecurity New Zealand, 2006). It is not the definition of the Codex, which is more consistent with the definition found in the CFIA document (Codex Alimentarius Commission, 1999, 2008).

Using the Panel's proposed definition of *risk analysis* separates *hazard identification* from risk assessment. Although the PHAC's definition uses an almost reverse definition of risk analysis and *risk assessment* (see Table B.1), it also recognizes that there is a distinction between risk (or hazard) identification and the process of determining the likelihood of occurrence and the magnitude of the consequences. This provides further support for adopting the four activities in the risk analysis process and clearly separating this broader context from risk assessment.

Risk assessment: *a structured, systematic process to determine the likelihood of the occurrence of an event and the likely magnitude of the consequences following exposure to a hazard. (Note: while risk assessment employs scientific data, it is not strictly a scientific process.)*

The Panel elected to use the narrow definition of *risk assessment* that is more consistent with the CFIA's definition (CFIA, 2005). As noted above, the definition of risk assessment is closer to the PHAC's definition of risk analysis (PHAC, 2009b). It also maintains consistency with the *risk analysis* definition described earlier, which separates hazard identification from risk assessment. Furthermore, in keeping with the opinion expressed by the Panel, limiting risk assessments to consideration only of adverse events is removed as the Panel strongly felt that the total of positive and negative (or adverse) events must be considered during a risk assessment.

The Panel's proposed definition aligns better with the definition used by the OIE (OIE, 2010c), which is a key partner or recipient of risk assessments carried out by the CFIA: "The evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country." The OIE definition, however, does not include the qualifiers that this is a structured, systematic process, qualifiers that are part of the EU, Codex, and European Food Safety Authority (EFSA) definitions (Codex Alimentarius Commission, 1999, EFSA, 2009b, European Commission, 2000). Other organizations also describe risk assessment as a scientific process. It was the consensus of the Panel that while risk assessment uses and is based on science, it is not strictly a scientific process.

The Panel also concluded that the risk assessment process must take into account the risk management options, and that a proper risk assessment process requires effective risk communication during the process, particularly between the assessors and the managers, with the policy-makers, if appropriate, and with stakeholders. Hazard identification, risk management, and risk communication are, however, part of the broader risk analysis process.

While risk assessment is often described as having four steps, the exact names and nature of these four steps vary. The Red Book defines the four steps as (1) hazard identification, (2) dose-response relationships, (3) exposure assessment, and (4) risk

characterization (NRC, 1983). These steps have arisen from the focus on chemical exposures, in which clear dose-response relationships (risk characterization) could be established and in which it was often possible to measure or predict specific exposures (i.e., measure concentrations in the environment). As discussed in Chapter 2, application of these four categories in the context of animal and human health when dealing with infectious disease may be problematic in that strictly quantitative parameters are often not available (e.g., dose-response assessment can be difficult).

The Codex describes the four steps as (1) hazard identification, (2) hazard characterization, (3) exposure assessment, and (4) risk characterization (which could also be described as identification of risk factors) (Codex Alimentarius Commission, 1999). The OIE *Terrestrial Animal Health Code* (see Box 2.2) describes the four steps as (1) release assessment, (2) exposure assessment, (3) consequence assessment, and (4) risk estimation (OIE, 2010c). There are other existing descriptions of the four steps; this is not an exhaustive listing of examples.

Generally speaking, these different descriptions align as follows:
Hazard identification = release assessment
Dose-response assessment = hazard characterization = consequence assessment
Exposure assessment is consistent
Risk characterization = risk estimation

While having these four steps as guiding principles appears appropriate, they are purposely excluded from the definition of *risk assessment* here. This reflects the Panel's view that risk management and risk communication, while not strictly part of the risk assessment process, are integral to its success and must be capitalized on to assure the most appropriate and comprehensive risk assessment. Moreover, the Panel felt it was important that these not be considered as independent steps or tasks, however they were defined. Nevertheless, the Panel has attempted throughout to adhere to the OIE usage and specified that hazard identification, while a necessary ingredient for risk assessment, is a step or activity that precedes the actual risk assessment. It provides information that is required to complete a risk assessment.

Risk management: *a systematic approach to setting the best course of action based on a risk assessment, and subsequently monitoring and evaluating the consequences of the management strategy.*

This definition includes consideration of the risk assessment as part of the risk management paradigm, in the same way that risk management must be included in the risk assessment paradigm. Both of these paradigms concur with the view of the Panel that these are interrelated activities that should not be isolated. This was given particular emphasis in the *Science and Decisions* report (NRC, 2009), and was taken a step further in the deliberations of the Panel.

The Panel's proposed definition also does not place any restrictions around the types of actions or measures taken (i.e., does not require them to be specific policy or regulatory measures) (Rother District Council, 2003), and allows the risk assessment to proceed with a range of management options.

Risk communication: *the continuing, open exchange of information and opinion between risk assessors and managers, policy-makers or decision-makers, and stakeholders (including the public), at all stages of the risk analysis process.*

The CFIA currently defines *risk communication* as "the open exchange of information and opinion, leading to a better understanding of risk and risk related decisions; the processes by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries" (CFIA, 2005). Several other organizations define *risk communication* as "the interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties" (Codex Alimentarius Commission, 1999; OIE 2004, 2010c). The PHAC's definition focuses on communications with stakeholders, while Health Canada's definition includes any dialogue regarding risk.

Therefore, the Panel has proposed a definition closely related to the CFIA definition of risk communication, with some modifications. This definition clearly identifies risk communication as an integral part of the risk assessment process, as well as of risk management.

Table B.1

Definitions Used by the CFIA, the OIE, and the PHAC

	CFIA (Protocol of the Animal Health & Production Division…) (CFIA, 2005)	**OIE** (Handbook on Import Risk Analysis for Animals and Animal Products) (OIE, 2004)	**OIE** (Terrestrial Animal Health Code) (OIE, 2010c)	**PHAC** (PHAC Integrated Risk Management Standard) (PHAC, 2009b)
Risk	The likelihood of the occurrence and the magnitude of the consequences of an adverse event; a measure of the probability of harm and the severity of impact of a hazard.	The likelihood of the occurrence and the likely magnitude of the consequences of an adverse event to animal or human health in the importing country during a specified time period.	The likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health.	The effect of uncertainty on objectives.
Risk Analysis	The process that includes risk assessment, risk management and risk communication.	The process composed of hazard identification, risk assessment, risk management and risk communication.	The process composed of hazard identification, risk assessment, risk management and risk communication.	Systematic process to comprehend the nature of risk and to deduce the level of risk.
Risk Assessment	The process of identifying a hazard and estimating the risk presented by the hazard. It is the process of identifying a hazard and evaluating the risk of a specific hazard, either in absolute or relative terms.	The evaluation of the likelihood and the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of an importing country.	The evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country.	The overall process of risk identification, risk analysis and risk evaluation.

continued on next page

Table B.1 *(continued)*

Definitions Used by the CFIA, the OIE, and the PHAC

	CFIA (Protocol of the Animal Health & Production Division…) (CFIA, 2005)	**OIE** (Handbook on Import Risk Analysis for Animals and Animal Products) (OIE, 2004)	**OIE** (Terrestrial Animal Health Code) (OIE, 2010c)	**PHAC** (PHAC Integrated Risk Management Standard) (PHAC, 2009b)
Risk Communication	The open exchange of information and opinion, leading to a better understanding of risk and risk related decisions; the processes by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing or exporting countries.	Risk communication is the interactive exchange of information on risk among risk assessors, risk managers and other interested parties.	Is the interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties.	(and consultation) Continuous or iterative process that an organization conducts to provide, share and obtain information and to engage in dialogue with stakeholders regarding the management of risk.
Risk Evaluation	The process of interpreting risks, including levels of risks acceptable to individuals, groups or society as a whole. The risk management aspect concerned with the initial decision to request a risk assessment is included in this definition.	The process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.		The process of comparing the results of the risk analysis against risk criteria to determine the level of risk.

continued on next page

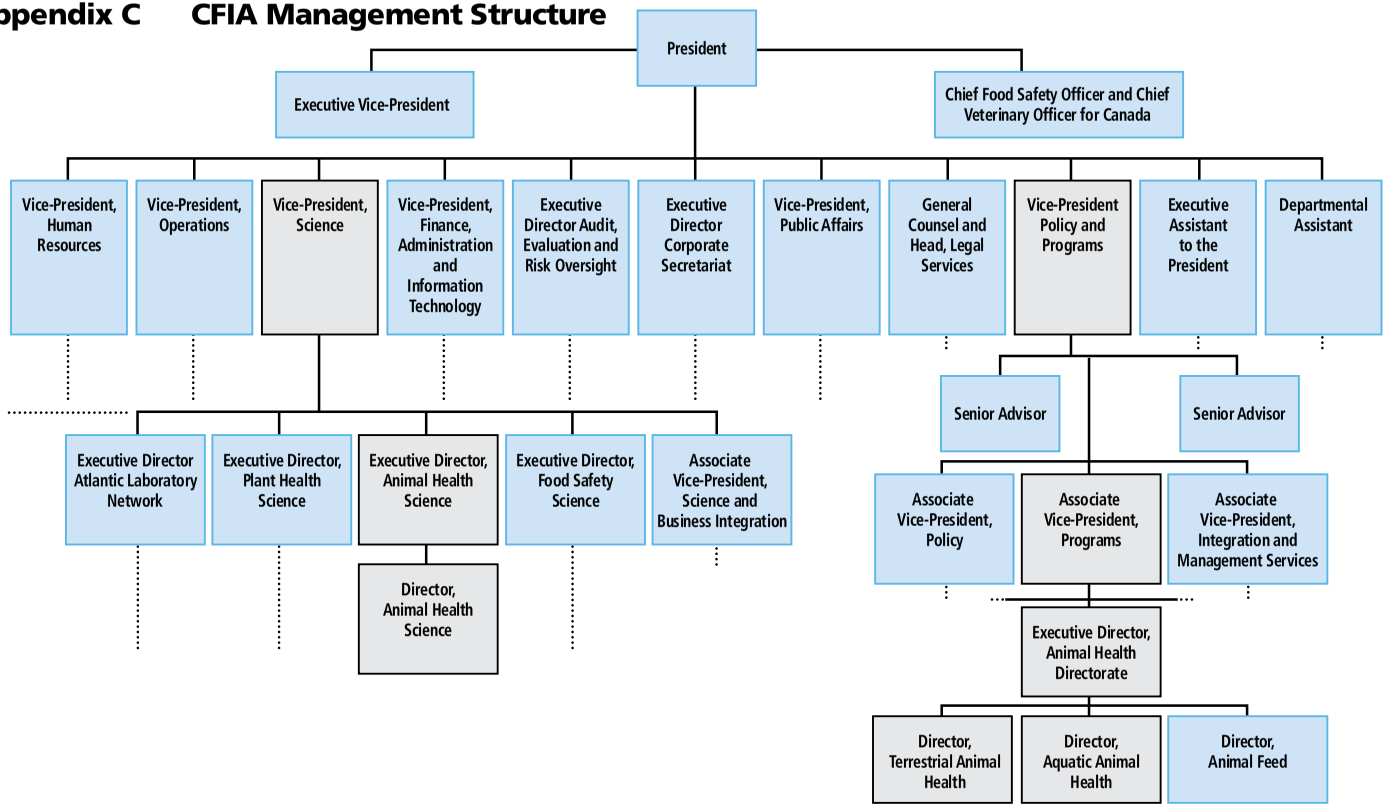
Table B.1 *(continued)*

Definitions Used by the CFIA, the OIE, and the PHAC

	CFIA (Protocol of the Animal Health & Production Division…) (CFIA, 2005)	**OIE** (Handbook on Import Risk Analysis for Animals and Animal Products) (OIE, 2004)	**OIE** (Terrestrial Animal Health Code) (OIE, 2010c)	**PHAC** (PHAC Integrated Risk Management Standard) (PHAC, 2009b)
Risk Management	The process of identifying, evaluating, selecting and implementing alternatives to mitigate risk. It is the pragmatic decision-making process concerned with regulating the risk.	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.	A systematic approach to setting the best course of action in an uncertain environment by identifying, assessing, understanding, acting on and communicating risks.
Hazard	An agent that can cause adverse effects (e.g., an organism that is a necessary cause of an animal disease). A hazard is an element or event that poses potential harm; an adverse event or adverse outcome.	Any pathogenic agent that could produce adverse consequences on the importation of a commodity.	A biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health effect.	
Hazard Identification	The process of identifying the biological agents which could potentially be introduced with a commodity or activity and for which pathways exist for exposure of the agents to susceptible animals and man.	The process of identifying the pathogenic agents which could potentially be introduced in the commodity considered for importation.	The process of identifying the pathogenic agents which could potentially be introduced in the commodity considered for importation.	

As discussed in Chapter 1, the terminology used for risk assessment varies from one organization to another. This table shows the definitions used by the Canadian Food Inspection Agency (CFIA), the World Organisation for Animal Health (OIE), and the Public Health Agency of Canada (PHAC).

Appendix C CFIA Management Structure



(Reproduced with permission from CFIA, 2010)*

Figure C.1

CFIA Management Structure

This figure represents the management structure of the CFIA. Grey boxes indicate relevant departments for this assessment. Dashed lines indicate that the management structure continues; however, these portions are not shown in this figure for reason of space. (Figure as of 2010-09-02)

Appendix D Multiple Criteria Decision Analysis

Multiple criteria decision analysis (MCDA) emerged from the field of operations research (OR) in the 1960s and 1970s, combining insights from the decision sciences, economics, mathematics, and other disciplines. Since then, it has been among the fastest growing areas of applied OR (Floudas & Paradalos, 2001; Figueira *et al.*, 2005a), and is now used in fields such as environmental assessment, health policy, defence research, and various areas of risk analysis (see Alvarez-Guerra, 2009; Goetghebeur *et al.*, 2010; Linkov *et al.*, 2009; Felli *et al.*, 2009).

MCDA has been employed in a wide variety of risk assessments. As outlined by MCDA pioneer Bernard Roy and others (Roy, 1996; Belton & Stewart, 2002; Figueira *et al.*, 2005b), potential applications for MCDA include the following:

- choices — a choice from a simple set of alternatives;
- sorting — sorting actions or options into broad groups such as "definitely acceptable," "possibly acceptable but need more information," and "definitely unacceptable;"
- ranking — placing management options in a preference ordering that need not be complete;
- description — describing options in a formalized and systematic manner so that they may be easily evaluated and are transparent;
- design — creating or designing new alternatives to meet goals; and
- portfolio — choosing a sub-set of alternatives from a larger set, and taking into account both individual option characteristics and the interaction of positive and negative synergies.

Further, MCDA provides a record-keeping method and framework to allow for capturing assessment attributes for review.

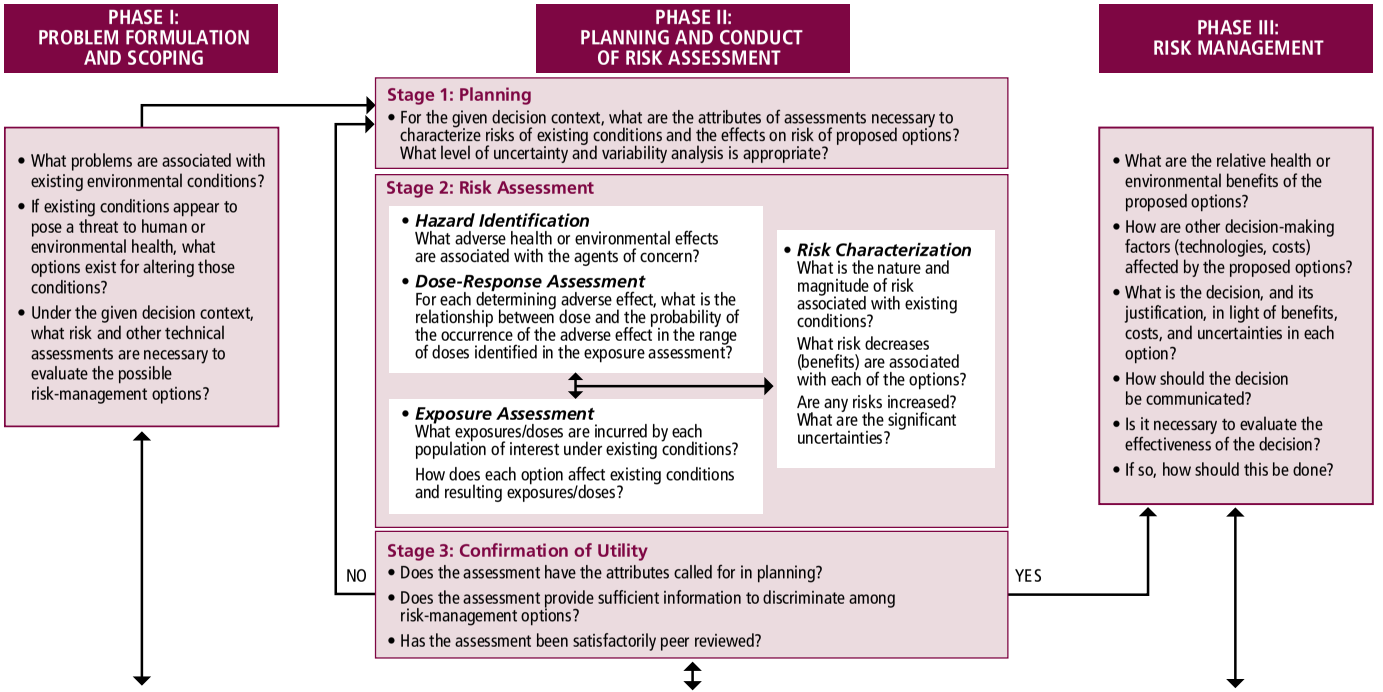
D.1 PARALLELS WITH RECENT DEVELOPMENTS IN RISK ASSESSMENT

From the perspective of animal health risk assessment, an MCDA framework aligns closely with a number of the key recommendations of both the National Research Council (NRC) *Science and Decisions* report (2009) and the Panel's proposals for adopting an integrated, multidimensional approach (outlined in Chapter 4). The NRC report called for expanded engagement of internal and external stakeholders

throughout the risk assessment process, as well as improved transparency in analysis and decision-making (NRC, 2009). The Panel concurs, and further concludes there is a need for broadening the range and depth of consequence assessment; incorporating a wider range of disciplinary perspectives as appropriate; and considering the complex interactions among the interrelated components of animals, humans, and the environment and the key components (signals/hazards, consequences, management options, and outcomes).

The usefulness of the MCDA framework in advancing these proposals can be seen through the three phases of the MCDA process identified by Belton and Stewart (2002): (1) problem identification and structuring; (2) model building, use, and validation; and (3) development and evaluation of action plans. As can be seen in Figure D.1 and Box D.1, these three MCDA phases align closely with the three phases of risk analysis defined within the *Science and Decisions* report: (1) problem formulation and scoping, (2) planning and conduct of risk assessments, and (3) risk management (NRC, 2009).

Both these frameworks support a systems-level thinking and approach to risk analysis, where the three phases — problem formulation (Phase One), planning and conduct of risk assessment (Phase Two), and risk management (Phase Three) — are set in the systems context. As illustrated in Figure D.1, these phases have a formal provision for internal and external stakeholder involvement. This reflects a systems-science approach where all relevant stakeholders are involved in the risk analysis process. The result is a more robust process with deeper analysis, wider understanding of the issues, and a greater likelihood for engaging support for the proposed management options and solutions.



(Reproduced with permission from NRC, 2009)

Figure D.1

Framework for Risk-Based Decision-Making from the *Science and Decisions* Report

Note that in this paradigm, hazard assessment is considered part of the risk assessment process, while in the CFIA framework, hazard identification occurs prior to the formal risk assessment and would be considered part of the problem formulation and scoping phase. The four equivalent steps in the CFIA framework would then be release assessment, consequence assessment, exposure assessment, and risk estimation (see Figure 3.2 and accompanying text). Risk communication is largely represented by the box at the bottom and highlights the engagement of stakeholders.

Box D.1

The Three Phases of MCDA and Risk Analysis

1. **Problem identification and structuring*** (or *Phase One — Problem formulation*): Before the analysis can begin, the stakeholders need to develop a common understanding of the problems, the management options or decisions that can be made, and the criteria by which these decisions will be judged and evaluated. This phase makes it clear that expanded stakeholder and advisory input is a necessary condition for effective problem structuring, decision-making, and transparency. In the language used in this assessment and that of the CFIA, hazard identification would be considered part of the problem formulation phase.
2. **Model building, use, and validation** (or *Phase Two — Planning and conducting the risk assessment*): Once the parameters of the analysis are set, formal models of the decision-makers' objectives, value judgments, preferred trade-offs, and so on, need to be established so that alternatives can be compared in a systematic and transparent manner. In the context of an integrated, multidimensional approach to animal health risk assessment, this phase would correspond to conducting the risk assessment, where the data, tools, and analysis would be coordinated and employed within the limitations established in the problem formulation phase.
3. **Development and evaluation of action plans** (or *Phase Three — Risk management*): After completion of the analysis, a decision can be implemented as a plan of action. The results of such plans then can be monitored and evaluated to provide information for improving future decisions. This phase would be led by risk managers, but should involve stakeholder input and transparent communication to achieve optimal long-term performance.

(Adapted from Belton and Stewart, 2002; NRC, 2009)

* MCDA phases are shown in bold text, and NRC phases of risk analysis are italicized.

Figure D.1 conveys the various interrelationships of the stages of risk analysis. As shown in this figure and described above, to perform effective risk analysis, the problem formulation stage (Phase One) must include an understanding of the system and its interactions within its operating environment. Phase Two and Phase Three then follow to increase knowledge of the system as the risk assessment

is planned and conducted, and management options considered. Information is gained by moving through these iterative phases, leading to a deeper understanding of the system and its interactions, thereby increasing overall system knowledge, robustness, and reliability.

As discussed in the next three sub-sections, this three-phase process provides a structured framework for adopting an integrated, multidimensional approach to animal health risk assessment. As the risk managers, risk assessors, and stakeholders consider the interrelated components of animals, humans, and the environment, they also evaluate the key areas of decision (signals, consequences, and management option outcomes). This structured movement through the multidimensional space is a way to formally identify and organize the problem, or risk assessment, at hand, which is the first phase of MCDA. As the risk assessors move into Phase Two and are developing the assessment model, they would also use the multidimensional framework as an approach to build the model. And, finally, as action plans are being developed and evaluated by risk managers and other stakeholders, the multidimensional framework would be used to select, implement, and monitor the results of such plans.

D.1.1 Problem Identification and Structuring *(Phase One — Problem Formulation)*

The risk analysis process starts with problem (or hazard) identification and structuring. By accurately and effectively describing, defining, and structuring the problem of study, appropriate limitations can be placed on the system of interest and the subsequent risk assessment. These system limitations in turn help the risk assessors with developing the model and conducting the risk assessment. They also enable the risk managers to understand management options within these limitations and help stakeholders to have a more complete understanding of the outcomes. This iterative process is fundamental to the concept of an MCDA approach to risk assessment (Belton & Stewart, 2002).

Beginning with the problem formulation phase, and continuing across the other two phases of the MCDA framework, three distinct roles emerge in the decision processes:

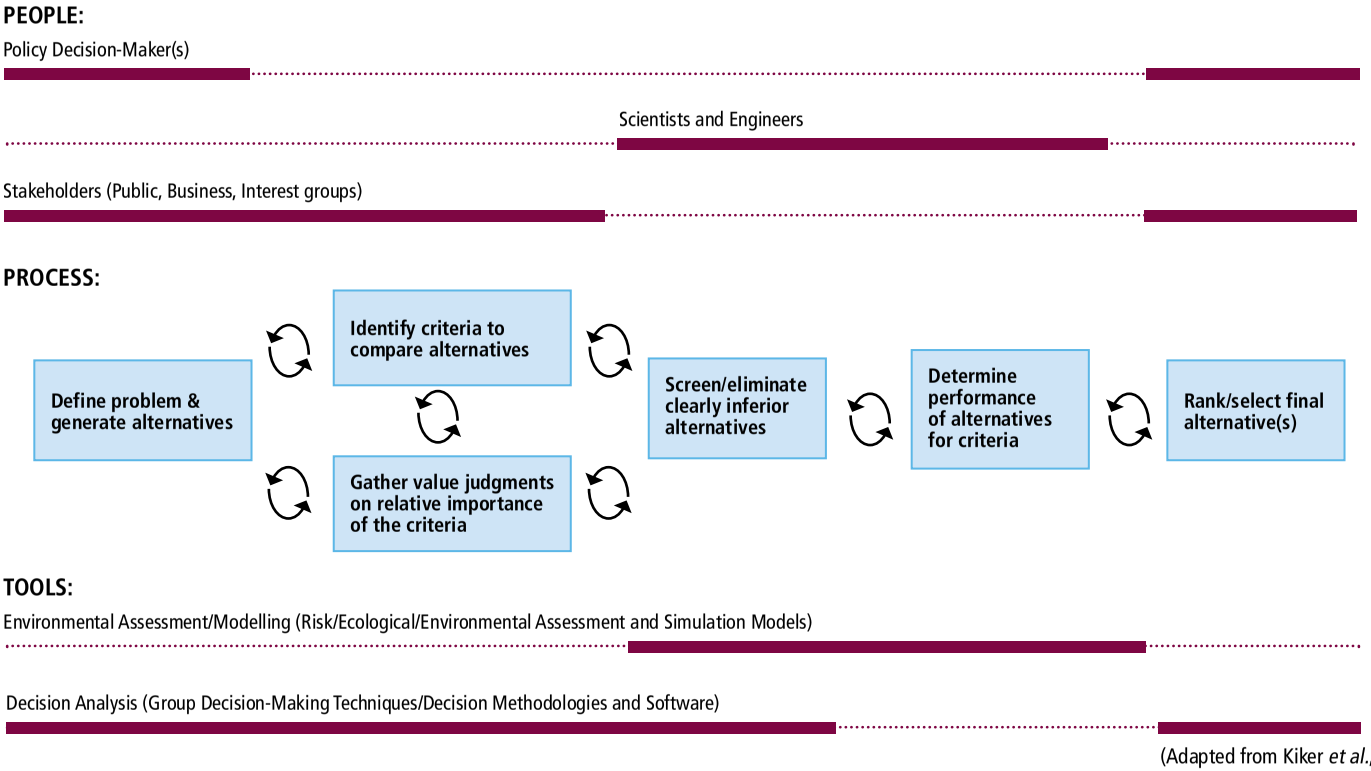
- decision-makers — those who have the responsibility for a decision;
- analysts — those who guide and assist decision-makers; and
- stakeholders — those who may or may not have a direct role in decision-making, but who are affected to some degree by the decision and its consequences.

(Belton & Stewart, 2002; Kiker *et al.*, 2005; interviews with experts)

Figure D.2 is a schematic outlining how decision-makers, analysts, and stakeholders can work in concert to implement MCDA directed at risk assessment questions. As Kiker *et al.* (2005) illustrate here in an environmental assessment context, the participants — policy decision-makers, stakeholders, and scientists and engineers (i.e., risk assessors) — are developing their collective understanding of the scope and limitations of the risk assessment issue. In this way, the entire range of stakeholders is describing the current state of the system to be analyzed.

As part of the development of the problem formulation (Phase One), scope, and limitations, possible changes to the state of a system can be better delineated by asking scenario-structuring questions such as: "What can go wrong?" "What is the likelihood?" and "What are the consequences?" (as posed by Kaplan & Garrick, 1981). Their scenario-structuring approach parallels the three-pronged approach outlined in the NRC report (NRC, 2009) (see Figure D.1). These and other scenario-structuring or boundary critique questions can help all stakeholders in the process — decision-makers and analysts — to define the state of the system, including boundaries. In addition, the questions can work in concert with the integrated, multidimensional approach (described in Chapter 4) where risk managers, risk assessors, and other stakeholders consider the interrelated components of animals, humans, and the environment, and the key areas of decision (signals, consequences, and management option outcomes).

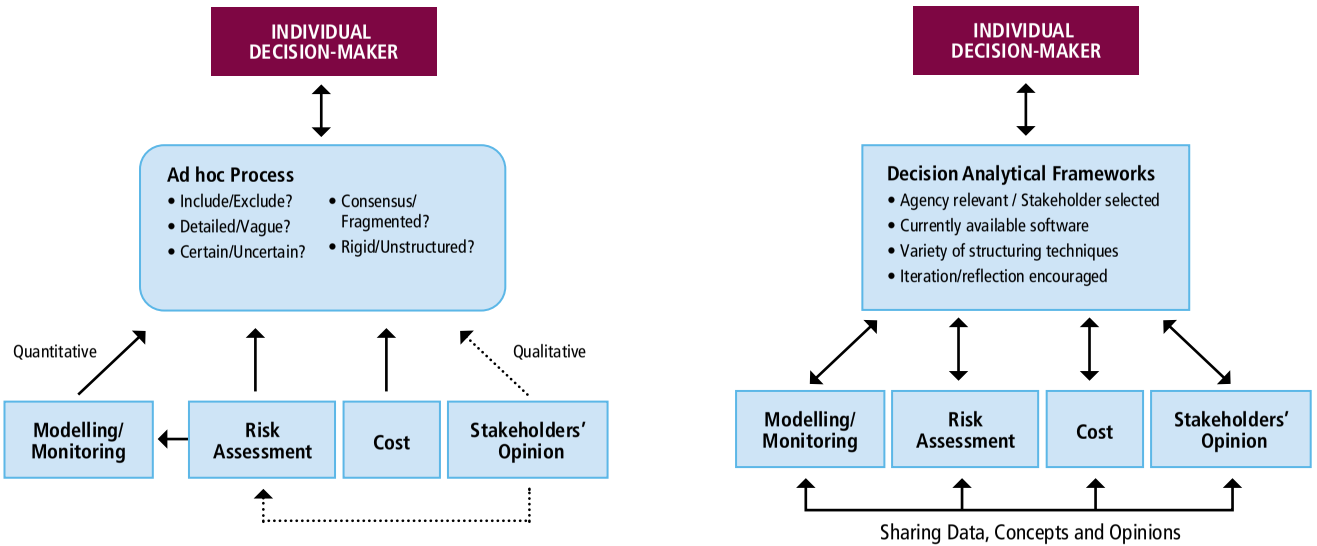
Figure D.3 conveys the context in which complex system-level decisions must be made and how the system state might be described in a general sense. The combination of methods conveyed by Figures D.1 to D.3 provides a visual context for using MCDA to address a risk analysis problem. Others have also explored the use of MCDA in complex systems analysis (see Kiker *et al.*, 2005; Kiker *et al.*, 2008; Rogers & Seager, 2009; Felli *et al.*, 2009; Karvetski *et al.*, 2010 for examples). This approach will help to frame the system state in a particular scenario and provide system-level insight for analysts in Phase Two and further for the risk manager (i.e., decision-maker) in Phase Three (see Figure D.1).



(Adapted from Kiker *et al.*, 2005)*

Figure D.2
Synthesis of Decision-Making Ingredients

* Application of multicriteria decision analysis in environmental decision making. Kiker, G. A., Bridges, T. S., Varghese, A., Seager, T. P., & Linkov, I. Copyright © 2005, John Wiley & Sons, Inc. Reproduced with permission of John Wiley & Sons, Inc.



(Adapted from Kiker *et al.*, 2005)*

Figure D.3

Ad hoc Versus Structured Analytical Frameworks

* Application of multicriteria decision analysis in environmental decision making. Kiker, G. A., Bridges, T. S., Varghese, A., Seager, T. P., & Linkov, I. Copyright © 2005, John Wiley & Sons, Inc. Reproduced with permission of John Wiley & Sons, Inc.

D.1.2 Model Construction, Use, and Validation (*Phase Two — Planning and Conducting the Risk Assessment)*

With the boundaries of the assessment established, the process then moves into the model construction, use, and validation phase. The analytic tools will be determined by a range of factors, including the interrelated components of animals, humans, and the environment, and the key areas of decision (signals, consequences, and management options and outcomes). Other factors may include the available resources, project timelines, and data requirements and accessibility. Using the MCDA framework allows all decision elements to be pulled together for a more transparent understanding of the risk assessment issue. And although the formal risk assessment process (described in Chapter 3) will remain the same for each assessment, the Panel encourages risk managers, risk assessors, and stakeholders to take a broad view of the potential methodologies, techniques, and disciplines that can contribute to the process. A tenet of the MCDA framework is the involvement of many different disciplines and an interdisciplinary approach to decision-making (Belton & Stewart, 2002).

D.1.3 Development and Evaluation of Action Plans *(Phase Three — Risk Management)*

As decisions are developed and implemented, risk managers and policy-makers can benefit from formal processes for selecting among the alternatives and capturing the results of lessons learned through experience. The Chapter 4 discussion of scenario analysis offers one approach to selecting among the alternatives. This section suggests a means for capturing results of lessons learned by incorporating an accounting and recording method (i.e., a system state vector perspective) in the risk analysis process.

The risk analysis process described by Morley *et al.* (2003) (see Section 3.1) and the method currently employed by the Animal Health Risk Assessment (AHRA) unit at the CFIA (see Section 3.2) are both examples of systems that might be adapted to the MCDA model. The current state of such systems can be defined in terms of a *system state vector* that characterizes and describes the system at a particular time (Haimes, 2011) — sort of an accounting or record-keeping, a framework to capture the known data about the system at a given time (see Box D.2). A system state vector could be used to give the description of an individual in time. The vector could include hair colour, weight, height, blood pressure, heart rate, and other similar attributes under a structured scenario. Such information would provide the nature of the individual and his or her performance under various conditions.

Box D.2

System State Vectors — A Part of Systems Science and an Element of the Proposed MCDA Framework

A state vector is an analytical concept employed in the field of systems science. State vectors describe the *characteristics* of a system at a particular point in time. Examining how state vectors respond to different events (or *perturbations of the system*) enables systems scientists to figure out how a system will react under various conditions. The information from these analyses then can be used to strengthen the system over time (Haimes, 2009, 2011).

Aerospace engineering regularly employs state vectors. An aircraft is an example of a complex system with a variety of characteristics (e.g., size, weight, engine capacity, airspeed, and so on). Some characteristics are relatively static, while others change depending on circumstance. By capturing how the aircraft system responds during an event (such as a take-off or landing) under different sets of conditions (such as rain or snow), aerospace engineers can use these data to continually improve the efficiency and safety of the *system* (e.g., by adjusting the aircraft speed, developing better tires, or redesigning the avionics).

The CFIA import risk assessment system provides another example of how a state vector perspective can be applied to help make a system more robust (see Figure D.4).

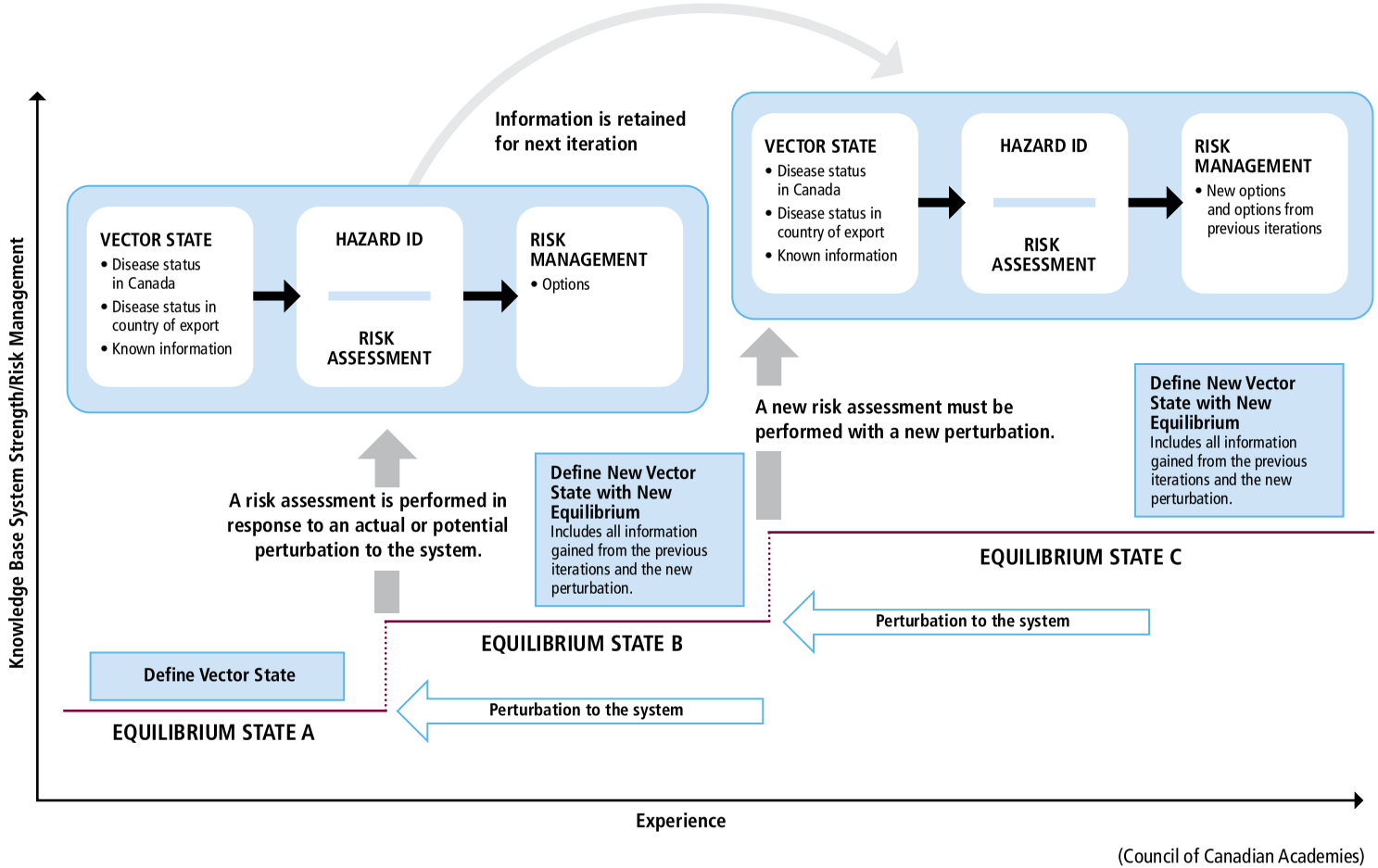
Using the MCDA approach with respect to animal health risk assessments, the system state vector would list as attributes any system models/monitoring data, current risk assessments (if available) and surveillance data, disease state of the country, associated costs/benefits, and critical stakeholder input. In the systems science context, a system will migrate to a steady state system equilibrium position and remain there indefinitely until perturbed (see Figure D.4). An animal or human health risk event would introduce a perturbation to the system that would *force* the system from its equilibrium state toward a new and different state. The perturbation could be caused by a change in monitoring, a change in costs, new information, a new import, or another new event.

The MCDA process can help analysts, managers, and stakeholders to develop system state vectors for both the equilibrium state and its new or perturbed state (see Figure D.4). This new vector would describe the system after perturbation and could include risk scenarios as well as management options. The stakeholders would have the opportunity to go through the phases of risk analysis (see Figure D.1) to analyze the effect(s) of the perturbed system state on the overall system. Using the MCDA process enables analysts, managers, and stakeholders to analyze effects in a systematic manner, and captures the information provided by this analysis. Decisions made related to the system perturbation are made within the context of system limitations (boundaries) and with the objective of bringing the system to a new equilibrium state. The information gained during the decision process can be added to the system vector state and form a starting point for the next perturbation to the system. This progression through various system states describes a truly iterative process that will yield a more robust and transparent system with each iteration. Therefore, future perturbations will be made against a more robust system — represented by its expanded system state vector — and will likely have less impact. Managing the risk assessment process using the MCDA framework within the systems science context would address the holistic nature of the system and its complexity, and assist risk managers, risk assessors, and other stakeholders in benefitting from the lessons learned through previous experiences.[33]

Once the system perturbation is fully described and the state vectors are constructed, the MCDA framework offers several techniques to assist the analysts, managers, and stakeholders in understanding and modelling the system, its perturbation, and management options within the risk analysis paradigm. Alternative outcomes are identified, and it becomes necessary to document factors that must be considered. As outlined in Belton and Stewart (2002), discussing the alternatives in the following context allows for a documentation of which criteria are most important:

- *Value relevance* — Managers and stakeholders need to correlate value, even in relative terms, with each of the criteria.
- *Understandability* — Assessors, managers, and stakeholders need to have a shared understanding of the criteria. The use of a system state vector, as previously described, should assist with overall system understanding.
- *Measurability* — Assessors and managers (and to a lesser extent stakeholders) need to be able to use some form of measurement to compare criteria and alternatives (see information on economic analysis in Appendix E).

[33] Note that one way of conceptualizing this overall movement is shown in Figure D.4 in the movement from equilibrium state B to equilibrium state C.



(Council of Canadian Academies)

Figure D.4

System State Vector Perspective on CFIA Import Risk Assessment Process

- *Non-redundancy* — Assessors, managers, and stakeholders need to determine if there are redundancies within criteria or factors and if there should be any redundancies (such as safety factors) within options.
- *Judgmental independence* — To the extent possible, managers and stakeholders need to keep criteria and factors independent; any dependencies among criteria should be disclosed for transparency.
- *Balance between completeness and conciseness* — As assessors, managers, and stakeholders move through the MCDA process to develop the risk assessment, all the important aspects of the problem should be captured to ensure completeness, but with the level of detail kept to a minimum.
- *Operationality* — Assessors and managers (and to a lesser extent stakeholders) should make sure the risk assessment being developed is usable with reasonable effort and does not place excessive demands on the problem solvers and decision-makers.
- *Simplicity versus complexity* — Related to the previous two factors, assessors and managers need to adopt a simple approach: "Complex but no more complex than required."

(Belton & Stewart, 2002)

Several techniques central to MCDA in the risk analysis context can assist assessors, managers, and stakeholders in ensuring that these factors are considered.

One general technique, referred to as multi-attribute value theory (MAVT), allows for the synthesis and assessment of the performance of alternatives against criteria separately or together, along with information that reflects the relative importance of criteria. This process yields an overall evaluation of each alternative reflecting stakeholder preferences. One example of the use of MAVT can be seen in Kiker *et al.* (2005) where the authors use the technique to assist in environmental decision-making. For a more in-depth discussion of the MAVT technique, see Belton and Stewart (2002).

Another technique used in MCDA is the goal-and-reference-point method. This goal programming technique (similar to linear programming used in the discipline of economics) has two requirements: (1) each criterion (e.g., management option) must be associated with a system attribute definable on a measurable scale; and (2) decision-makers and stakeholders need to express judgments for each criterion in terms of goals or measurable levels of performance. In this manner, goal programming is an optimization technique similar to linear or non-linear

programming. Goal programming may be helpful in policy scenarios or during the design phase of more complex problems by directing managers and stakeholders to think quantitatively about the system. For further details on goal programming techniques, see Lee and Olsen (1999); Tamiz *et al.* (1998); Chang and Lee (2010); Žgajnar *et al.* (2010).

A final technique, worth noting, used in implementation of the MCDA approach is called outranking. The product of this technique is not a value for each option but rather a ranked list that provides an analysis of how the alternatives or options rank relative to each other. If managers and stakeholders used the outranking approach associated with this ranked list, this combination may provide a way to capture more information on what basis was used to rank the alternatives and what information was considered during the ranking procedure. Outranking methods focus on comparing pairs of alternatives and are generally applied to discrete choice problems such as choosing a facility location. If, however, managers and stakeholders use some form of outranking for management options, for example, it might result in a more robust analysis from the assessor. For a further in-depth treatment of outranking methods, see both Roy (1996) and Belton and Stewart (2002).

This description of MCDA and its associated techniques is not meant to be exhaustive. The intent is to give examples and offer enticement for further study of the MCDA framework. The techniques described here are ones most often used by practitioners in the field, but there are many other less-used MCDA techniques. For more specific details, see Belton and Stewart (2002) and other reviews of MCDA techniques such as Figueira *et al.* (2005b).

Appendix E Examples of Disciplinary Contributions within an IMDA Framework

As noted in Chapter 4, contributions from many disciplines are a key feature of a framework for an integrated, multidimensional approach (IMDA). Broadening the breadth and depth of consequence assessment and stakeholder input is bound to require the use of a wide array of tools, methods, and disciplinary contributions. Table 4.1 provided a general overview of how several disciplines can contribute to animal health risk assessment. The following two sub-sections go one step further, providing examples of how the tools and methods from two specific areas — economics and public health sciences — can contribute to enhancing the range and depth of information that can be used to inform risk-based decision-making for animal health risk assessment.

E.1 ECONOMIC CONTRIBUTIONS TO ANIMAL HEALTH RISK ASSESSMENT

The field of economics is concerned with how individuals, governments, and private and not-for-profit firms — collectively referred to as economic agents or stakeholders — make decisions regarding the distribution of scarce resources. The existence of choice creates what economists term an opportunity cost; that is, deciding to use resources for one purpose precludes the use of those resources for another purpose. As a result, decisions have to be made based on the preferences of the stakeholders.

In the context of the consequences related to animal health events, decisions must be made about the allocation of resources and about possible interventions to reduce the impact on relevant stakeholders. For many economic decisions, while the net gain of such choices may be positive, some stakeholders will be dissatisfied because of perceived or real losses relative to other stakeholders. For example, a government decides to undertake a large-scale zoonotic disease eradication campaign that includes culling of cattle within a particular province. While the potential health benefits to society are expected to be positive, there will be some individuals who feel their net benefits are negative because of high personal losses. If the animals owned by a breeder of particularly valuable purebred beef cows are culled during the campaign, the owner may receive compensation based on the value of more common beef cows, which he or she feels greatly under-represents the true market value of the animals culled. Other examples of the complexities involved in risk-based decision-making in the context of animal health can be seen in Table E.1, showing the economic impact of events stemming from an animal

health event such as the import of a live boar infected with Nipah virus, and the ways in which economic data and analysis can contribute to understanding these complexities for the purposes of improved decision-making.

These examples illustrate the potential complexity of basic economic decision-making and underscore the need for including industry stakeholders in the risk assessment process. There are often no simple answers, but transparency of decision-making can be improved by incorporating an evaluation of the economic impact of probable outcomes into the process of qualitative and quantitative analysis, and by including relevant stakeholders in that process.

Since this appendix is not intended as an exhaustive manual on economic methods, it will not present details on various economic tools that can be used for an economic assessment. Interested readers may find the summary in Table E.2 of value for launching further reading. It should be noted that the oft-mentioned cost-benefit analysis is but one of many techniques possible in economic impact analysis.

Examples abound of how cost-benefit analysis has been used in policy evaluations and in theoretical models in connection with animal health-related events before, during, and after the event. Zinsstag *et al.* (2007), for instance, provided an example demonstrating that a potential Mongolian livestock brucellosis vaccination campaign, which would avert 51,856 human incidents, would generate a benefit-cost ratio of 3 to 2 spread across the agricultural and public health sectors, and with impacts on individual human health and indirect costs.

Theoretically, Ameden *et al.* (2009) used agent-based computational economic modelling to examine the question of importer and inspector behaviour for border enforcement and invasive species management. The model consists of four stages of an import process with different stakeholders (agents) participating at each stage:

- Stage 1 — The importing firm chooses the degree of pre-treatment before importation.
- Stage 2 — The government inspector chooses the level of inspection at the border.
- Stage 3 — If pests are found, shipments are destroyed or treated, with costs allocated to the importer.
- Stage 4 — Treated shipments are transported to a final market, where, if treatment was not completely successful, environmental damages may or may not occur.

Table E.1

Examples of the Economic Analysis of Animal Health-Related Events Following Importation of Nipah Virus Into Canada

Event	Effect	Model Type	Model Predictions	Data Requirements
Sudden ban on all swine and swine products* exported from Canada	Creates a medium- to long-term limited demand for Canadian pork exports.	Partial equilibrium analysis Econometric estimation Computable general equilibrium	Canadian pork producers are now only selling to Canadian consumers; it is likely that the price of swine products will fall within Canada. As a result, consumer surplus increases while producer surplus decreases. This may result in lower levels of labour employment and/or increase inventories of swine products.	Swine product demand/supply; prices; labour productivity Export demand share
Rapid containment and ban on swine movement in Canada	Creates a short- to medium-term reduction in the supply of swine products.	Partial equilibrium analysis Econometric estimation Computable general equilibrium	Canadian producers have less ability to produce and sell swine products; it is likely that this supply shortage will increase prices. As a result, consumer surplus decreases while producer surplus may increase or decrease. This may result in lower levels of labour employment and/or increase inventories of swine products.	Swine product demand/supply; prices; labour productivity

continued on next page

Table E.1 *(continued)*

Examples of the Economic Analysis of Animal Health-Related Events Following Importation of Nipah Virus Into Canada

Event	Effect	Model Type	Model Predictions	Data Requirements
An escalation in the degree of public concern regarding the safety of animal products, the appropriateness of import standards or the quality of animal welfare	Induces a short- to medium-term change in consumer preferences.	Partial equilibrium analysis Econometric estimation Computable general equilibrium Revealed preference methods Mathematical programming Agent-based models	There is less demand for animal products; it is likely that prices will fall. As a result, consumer surplus increases while producer surplus may decrease. This may result in lower levels of labour employment and/or increase inventories of animal products.	Swine product demand/supply; prices; labour productivity Measures of consumer health and social preferences
Animal producers request public assistance for adversely affected incomes	Policy-makers must decide on the timing, magnitude, and distribution of assistance.	Cost-benefit analysis Partial equilibrium analysis Econometric estimation	Based on an analysis of market conditions and economic analysis of public-sector support, a decision option is suggested (i.e., timing, magnitude and distribution of support). A set of options are evaluated in terms of their impact on stakeholders.	Animal product demand/supply; prices Economic sector profile
A research breakthrough in veterinary science decreases incidence of disease in domestic animals	Producers' losses due to animal disease are less. Consumer confidence in the safety of animal products increases.	Partial equilibrium analysis Econometric estimation Computable general equilibrium Cost-benefit analysis	Because there is both greater supply and greater demand for animal products, the effect on price is uncertain. Consumer and producer surplus both increase. This may result in higher levels of labour employment.	Animal product demand/supply; prices; labour productivity Measures of consumer health and social preferences Research productivity data

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Table E.1 *(continued)*

Examples of the Economic Analysis of Animal Health-Related Events Following Importation of Nipah Virus Into Canada

Event	Effect	Model Type	Model Predictions	Data Requirements
A novel zoonotic disease places significant pressure on the demand for vaccine beyond the constant demand for seasonal vaccine	Producers must decide which demand to serve. Vaccine consumers are affected. Individuals and governments must decide whether to purchase novel, seasonal, or both, vaccines.	Computable general equilibrium Revealed preference methods	Producer production decisions and consumer purchase decisions are determined by vaccine demand (consumer preferences or public need), vaccine supply (production parameters), and price. Because demand is high, prices will likely increase. As a result, consumer (producer) surplus decreases (increases).	Vaccine demand/supply; prices; labour productivity Estimates of human health costs (incidence; HALYs; cost-of-illness)
A shortage of vaccine supply emerges after a zoonotic disease outbreak	A policy decision is required as to provincial distribution of vaccines and the identification of high-risk groups.	Cost-benefit analysis Partial equilibrium analysis Econometric estimation	Based on analysis of vaccine needs, supply and demand, transportation constraints, and other political factors, a decision option is suggested (i.e. timing and distribution of vaccines).	Vaccine demand/supply; prices; labour productivity Social determinants of health and vaccination uptake

(Council of Canadian Academies)

* Depending on the disease and species that are at risk of infection, a ban could include products from several species of livestock.

Table E.2

Economic Tools for Animal Health Risk Assessment

Tool	Use	Data and Knowledge Requirements	Technical Issues
Cost-benefit analysis	A process of ranking decision options by comparing the aggregate benefits and costs (consequences) that affect relevant stakeholders such as private individuals, firms, and governments. Depending on the nature of the problem, a decision-maker may weigh the benefits (costs) that accrue to different stakeholders. For example, more weight may be attached to the impact of SARS on youths than on adults. This approach makes value judgments explicit.	Depends on exactly what counts as a consequence (benefit or cost) and for whom (stakeholder type). Estimates of exogenous variables, such as individual disease burden, market prices, or trade volume, which partially determine the consequences.	Because the time at which costs or benefits occur may differ between alternatives, it is important that these future costs and benefits are discounted to make them comparable in present value terms (either NPV, BCR or IRR must be satisfied). For example, the higher the discount rate one chooses, the more a course of action with high initial costs and a low level of benefits over a long period of time will be penalized. The choice of weighting function.
Partial equilibrium analysis	The units of analysis in partial equilibrium models, rather than aggregated consequences, are direct market impacts (including labour) of animal health-related events or other exogenous factors (export bans, consumer preferences, production factors, etc.). A partial equilibrium analysis examines the changes in social welfare that result from exogenous shifts in demand and supply. The resulting changes in equilibrium quantities and price can be used to define changes in consumer welfare (consumer surplus) and firm profits (producer surplus). Under certain assumptions, this equilibrium outcome is expected to maximize social welfare.	Market demand/supply/price; labour productivity; economic sector profiles; trade data. Partial equilibrium analysis may be conducted with respect to one single market or multiple markets, and can focus on one or more regions. Multi-market models explicitly link related markets and can thus trace the impacts of a change in one market on output, prices, consumer welfare, and firm profits in related markets. Moreover, multiple types of individual consumers may be examined in multi-agent models to examine the distributional consequences of shifts in demand. Both types of partial equilibrium models have been widely used to analyze specific product markets, international trade, and agricultural policy.	A partial equilibrium model defines fixed functional relationships between the demand and supply of a specific good or service in a specific time and place. The market supply function embodies the explicit constraints on firm-level production of goods and services whereas the market demand function embodies consumer preferences over these products. Equilibrium in a product market requires equality between quantity demanded – the amount of a product that consumers are willing to purchase at a given price – and quantity supplied – the amount of a product that firms are willing to produce at a given price.

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Table E.2 *(continued)*

Economic Tools for Animal Health Risk Assessment

Tool	Use	Data and Knowledge Requirements	Technical Issues
Revealed preference methods	Elicit "individual preferences regarding the value of increased (decreased) health risk, such as injury at work, as a trade-off against increased (decreased) income, which represents all other goods and services that the person might consume" (Drummond *et al.*, 1997). The actual amount of risk an individual will actually accept is determined here by both labour market conditions – the wage or income received – and by general price levels in good markets in accordance with the reasoning discussed below in the context of general equilibrium models.	Data on choices made by individuals and the degree of information constraint. Proxy data for attitudes toward risk, and other perceptions/beliefs.	Eliciting individual preferences accurately is difficult in practice. Moreover, due to psychological and cognitive constraints on decision-making (Camerer *et al.*, 2004), individuals do not always make decisions in the way economic theory predicts. It is also plausible, in some instances, that revealed preferences may be a function of an individual's income level; that is, these trade-offs may depend, in part, on the a *priori* wealth level of an individual.
Computable general equilibrium	Computable general equilibrium models are able to capture a wide array of linkages across economic sectors, and ultimately allow policy-makers to gain insights into how a shock to the economy, say a BSE outbreak, transmits not only to the related product markets (as in partial equilibrium models), but also across all specified sectors in order to highlight the potential reverberations on national income, employment, and trade.	The basic structure of a computable general equilibrium model can be described as a set of equations that specify demand relationships, production technologies, relationships between domestic and imported goods, household income, and government revenue. As with partial equilibrium models, these models determine a set of equilibrium quantities and market prices (commodity prices, wages, interest rate, etc.).	The ability to explicitly model functional relationships in labour, capital, currency, and international trade markets (calibrating).

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Table E.2 *(continued)*

Economic Tools for Animal Health Risk Assessment

Tool	Use	Data and Knowledge Requirements	Technical Issues
Mathematical programming; Agent-based modelling Simulation	A model that determines an optimal solution to either individual/firm level decisions or to the social welfare problem given preferences or objectives, and constraints or weighting decisions. For example, this could involve determining the production levels required to maximize firm profits (subject to production and market constraints) or labour supply required in order to maximize individual well-being (indirect utility). Aggregated consequences of a given option are generally combined with an epidemiological model to conduct simulations under various conditions and scenarios.	Market demand/supply/price; labour productivity; economic sector profiles; trade data. Measurement of consequences.	A model that contains probability distributions and/or random elements in order to deal with uncertainty in consequences and outcomes. Multiple estimations (or simulations) of these models are required to provide insight into the nature of the variation.

(Council of Canadian Academies)

A very similar approach, found in other risk assessments, may be used to establish the prevalence of biologic agents, or the risk of importing those agents, and so on. Economic analysis of production, travel costs, treatment decisions, and other procedures are also incorporated; this makes the model intuitively appealing for animal risk importation assessment. In addition, this approach integrates the preference structures of different agents allowing for a degree of qualitative analysis. The functions used to estimate prevalence, rates of activities such as inspection, success rates, expected costs, and other such measures can be as complicated as desired. Randomness can be introduced into agent-based modelling with either continuous or discrete distributions within this framework.

In the above example, the model was able to show that when enforcement rates are low, marginal increases in inspection rates do not reduce damages. Furthermore, increasing the costs and effectiveness of pre-treatment is a good way to reduce damages. Models of this type can be quite useful to inform policy concerning importation risks and the efficacy of prevention strategies.

Bringing Economics into Risk Assessment

Expanding economic impact evaluation in the risk assessment process in Canada will progress a critically important element to the development of risk assessment. The concerns of stakeholders can be addressed more fully, and impacts not currently included will be incorporated. As well, the economic impact of decisions can be relayed to policy-makers — possibly the most important contribution from the perspective of industry stakeholders not otherwise affected by the particular risk event under consideration. This section has outlined briefly several reasons for incorporating economic analysis. Future refinements in the current Canadian Food Inspection Agency (CFIA) approach to risk assessment in Canada could consider incorporating some of these techniques as standard options.

E.2 PUBLIC HEALTH SCIENCE CONTRIBUTIONS TO ANIMAL HEALTH RISK ASSESSMENT

Public health science is another discipline that can make some important contributions to animal health risk assessment, particularly with respect to integrated animal-human health risk assessments. Cost metrics are one of the tools for estimating the impact of those decisions on human health. As discussed below, such calculations attempt to estimate the economic cost of illness and/or associated complications, and to generate a summary measure that reflects the time lost or quality of life compromised owing to such illness. These tools are presented here because of their high degree of popularity in the health economics literature and the ease with which they can convey complex information.

Incidence and Prevalence Rates

Incidence and prevalence rates are among the most common metrics for assessing the occurrence of human health events. An incidence rate measures the number of new cases of a disease over a *period of time* in a given population, while a prevalence rate measures the total number of *new and old* cases at a *point in time* in a given population (Bhopal, 2002).

While these metrics provide a general overview of impact, they do not necessarily allow for comparison across various diseases. Ultimately, an incident count does not always convey illness severity, thereby implying that disease affects all individuals to the same degree. Consider a decision-maker who wishes to compare the impact of a particular disease to that of another disease or other public health risk. In this case, an incident rate only conveys, for example, that there were 250 severe acute respiratory syndrome (SARS) infections, 1,600 cases of tuberculosis, or 8,000,000 occurrences of obesity in a given population. Such counts are fundamentally incomparable without significantly more detailed information.

Health-Adjusted Life Years

Health-adjusted life years (HALYs) are a class of indicators that provide a measure of the human health costs of illness, in terms of both mortality and morbidity, by combining the duration of a disease and its effect on quality of life (Gold *et al.*, 2002). In other words, a HALY is a direct measure of disease severity in terms of literal life years lost to disease (mortality) or implicit years lost by decreased quality of life (morbidity). In terms of the latter, an individual's health is ranked on a severity scale – generally from zero to one – and this health score (health state contingent valuation) is multiplied by the time duration of that state of health.

Two main variants of the HALY approach – quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs) – differ in terms of the application of health scores. In the QALY approach, the health score functions as a weight that reflects the relative desirability of each possible health state, ranging from zero (death) to one (perfect health) (Gold *et al.*, 2002). By contrast, in the DALY approach, the health score works the reverse of QALY — zero represents the perfect health state (i.e., no disability loss from disease), and one corresponds to death (Gold *et al.*, 2002). Although constructed in slightly different ways (Sassi, 2006; Krupnick, 2004), both metrics have the useful property of being additive; one can add up HALYs for a single individual over time or for a group or a population over a period of time. This property of HALYs is extremely important from a risk assessment perspective since it allows comparison in terms of impact severity across various animal health disease risks.

Cost-of-Illness

The cost-of-illness approach provides a measure of indirect costs that result from disease incidents (EPA, 2005). These exclude the mortality and morbidity costs quantified by HALYs, but include both direct health care costs (such as physician consultations, hospitalization, and pharmaceuticals) and costs not directly related to medical services (such as patient and family travel, informal care delivered by family members, and even home renovations). Although this metric demands a relatively extensive set of data, the ultimate calculation merely involves adding up all measureable costs — exactly the same procedure as calculating expenses on a balance sheet. The burden of these costs may be borne by individual patients, insurance firms, or the government, depending on the nature of national health care and insurance institutions.

Revealed Preference Approach

On its own, the HALY approach falls short of providing a monetary valuation of the impact on human health from animal health-related events. To do so requires estimating the statistical value of life – a precise, technical definition. The revealed preference approach to valuing a statistical life starts from the common sense observation that all individuals, at least implicitly, are willing to accept a certain degree of risk that could always be avoided at the expense of time, money, energy, and the like (Ashenfelter & Greenstone, 2004).[34] When expressed in monetary terms, this trade-off is referred to as the "statistical value of life" (Bellavance *et al.*, 2009), but is not intended to place a monetary value on a specific individual's life.

Once the statistical value of life has been calculated, one now has a way to compare, in monetary terms, the value of lives saved or lost (QALYs and DALYs) to all other consequences that arise from animal health-related events.[35]

E.3 SUMMARY

These examples illustrate ways in which the richness of an animal health risk assessment can be increased by bringing additional disciplinary expertise to bear. This is not to imply that such depth is required in every animal health risk assessment, but, when it is appropriate, the results can significantly increase the utility for decision-makers.

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[34] Consider, for example, the decision of how fast to drive on a highway. This decision involves a fundamental trade-off between time saved, or the pleasure of driving, and the increased risk of injuries and fatalities. In the case of U.S. Interstate highways, since the average speed of individual drivers, and the official speed limits imposed by state governments, well exceed a speed that would minimize the risk of injury, both drivers and governments have made an implicit trade-off between these benefits and costs.

[35] For more examples relating to animal-human health, see Haagsma *et al.*, 2008 and Kemmeren *et al.*, 2006.

Appendix F Agreement on the Application of Sanitary and Phytosanitary Measures

AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES[36]

("SPS Agreement")

[36] This appendix is the integral text of the SPS Agreement (WTO, 2010c).

SPS Agreement

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)[1];

Hereby agree as follows:

Article 1: General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.
4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2: Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

[1] In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

Article 3: Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[2] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.
5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

[2] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

Article 4: Equivalence

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result

in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.[3]
7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6: Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area — whether all of a country, part of a country, or all or parts of several countries — from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, inter alia, the level of

[3] For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.
3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7: Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8: Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9: Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10: Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.
2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.
3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.
4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11: Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.
2. In a dispute under this Agreement involving scientific or technical issues, a Panel should seek advice from experts chosen by the Panel in consultation with the parties to the dispute. To this end, the Panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.
3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12: Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.
2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.
3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.
4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefore, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.
6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.
7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, inter alia, to the experience gained in its implementation.

Article 13: Implementation

Members are fully responsible under this Agreement for the observance of all obligations setforth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or nongovernmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14: Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

ANNEX A: DEFINITIONS[4]

1. *Sanitary or phytosanitary measure* — Any measure applied:
   (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
   (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
   (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
   (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. *Harmonization* — The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. *International standards, guidelines and recommendations*
   (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

   (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

[4] For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. *Risk assessment* – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. *Appropriate level of sanitary or phytosanitary protection* – The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

   NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area* – An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

   NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area — whether within part of a country or in a geographic region which includes parts of or all of several countries — in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* – An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

ANNEX B: TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations[5] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.
2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:
   (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
   (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
   (c) risk assessment procedures, factors taken into consideration, as well as thedetermination of the appropriate level of sanitary or phytosanitary protection;
   (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals6 of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard,

[5] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;[6]

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

[6] When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:
    (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or
    (b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

ANNEX C: CONTROL, INSPECTION AND APPROVAL PROCEDURES[7]

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
    (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
    (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
    (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

[7] Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

(d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
(e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
(f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
(g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
(h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
(i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified. Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

Assessments of the Council of Canadian Academies

The assessment reports listed below are accessible through the Council's website (www.scienceadvice.ca):

- Canadian Taxonomy: Exploring Biodiversity, Creating Opportunity (2010)
- Honesty, Accountability and Trust: Fostering Research Integrity in Canada (2010)
- Better Research for Better Business (2009)
- The Sustainable Management of Groundwater in Canada (2009)
- Innovation and Business Strategy: Why Canada Falls Short (2009)
- Vision for the Canadian Arctic Research Initiative: Assessing the Opportunities (2008)
- Energy from Gas Hydrates: Assessing the Opportunities and Challenges for Canada (2008)
- Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale (2008)
- Influenza and the Role of Personal Protective Respiratory Equipment: An Assessment of the Evidence (2007)
- The State of Science and Technology in Canada (2006)

The assessments listed below are in the process of expert panel deliberation:

- The Integrated Testing of Pesticides
- Science Performance and Research Funding
- Women University Researchers
- The Sustainable Management of Water in the Agricultural Landscape of Canada
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