



## **Risk Analysis Framework to address Animal Health, Plant Health and Food Safety Risks within the Canadian Food Inspection Agency**

### **Executive Summary**

As part of an Integrated Risk Management Framework (as defined by Treasury Board<sup>1</sup>) Government organizations have been requested to establish a systematic and holistic approach to manage risks. This Risk Analysis Framework has been developed to address Animal Health, Plant Health and Food Safety Risks within a broader Risk Management Framework for the Canadian Food Inspection Agency (CFIA).

As reported in the 2003-2004 Report on Plans and Priorities<sup>2</sup>, the Agency (CFIA) is mandated to safeguard Canada's food supply and the plants and animals upon which safe and high-quality food depends. In carrying out this mandate, it directly contributes to the Government of Canada's priorities as well as the public good by protecting Canadians from preventable health risks, providing a fair and effective regulatory regime that contributes to the growth of Canada, contributing to sustainable natural resources and promoting the security of Canada's food supply. The development and implementation of "risk-based inspection systems" to address these activities require an understanding of and capability for risk analysis within the CFIA. Inspection Systems, in this context, refers to all of the activities involved in the development and implementation of policies and programs related to animal and plant health and food safety. Import, Export and Domestic programs are included as are all activities in support of these programs, e.g., laboratory support, scientific support, audits, etc.

Risk Analysis, as defined by the Codex Alimentarius Commission, the Office Internationale des Épidémiologies et Santé and the International Plant Protection Convention, involves three major activities - Risk Assessment (being the determination of the degree of risk involved); Risk Management (establishing if and what measures are required to mitigate the risk); and Risk Communication (ensuring that stakeholders are involved in the process). A graphical representation of this framework (based on guidelines and recommendations of these three international standard setting bodies) is included in the document along with definitions for terms commonly used in Risk Analysis. Other Risk Analysis or Risk Management models

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<sup>1</sup>Integrated Risk Management Framework, April 2001. Treasury Board of Canada Secretariat. See also Treasury Board Website [http://www.tbs-sct.gc.ca/pubs\\_pol/dcgpubs/riskmanagement/rmf-cgr\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/dcgpubs/riskmanagement/rmf-cgr_e.asp).

<sup>2</sup>2003-2004 Estimates, Part III : Report on Plans and Priorities. Treasury Board of Canada Secretariat, 2003.

have been developed which incorporate all of the above elements, e.g. Health Canada's *Decision Making Framework for Identifying, Assessing and Managing Health Risks*. While there may be some differences in terminology used in these frameworks, reflecting the diversity of activities of the parent organizations, the activities and the principles described therein tend to be the same. This Risk Analysis Framework has been developed to ensure that it reflects the approaches taken by these international standard setting bodies.

Risk analysis activities have been applied both formally and informally in the development of inspection systems across all disciplines within the CFIA. These systems are designed to meet CFIA's objectives - safe food, consumer protection and the protection of plants and the health of animals in Canada. This document separates the various programs into three main categories - Animal Health, Plant Health and Food Safety. Fish Inspection programs are included in the Food Safety category, as matters related to fish health are not normally part of the Animal Health responsibilities and remain the mandate of the Department of Fisheries and Oceans. Feed and fertilizer programs are included in the plant and animal risk analysis activities as appropriate. Issues related to biotechnology are addressed within their respective areas of animal health, plant health or food safety.

This Risk Analysis Framework may be used to estimate the human, animal or plant health risks associated with the scenario being evaluated and to select and implement appropriate measures to control such risks as effectively as possible. While the impact on plant, animal or human health is the primary consideration in the risk analysis process, there are often a number of other values that are potentially placed in jeopardy as risk management policies are developed. For example, the economic impact of risk management decisions on persons, groups or agricultural sectors can be significant, while other values such as basic human rights or legal rights, animal or environmental welfare, etc. can also be significantly impacted. In this Risk Analysis Framework, the Risk Assessment phase estimates the health risks associated with the scenario being evaluated; the Risk Management process selects the most appropriate option to satisfactorily deal with the health risks while considering the impact of such decisions on the other values; and Risk Communication occurs throughout the process to ensure appropriate involvement of stakeholders at various steps in the process.

This document establishes a strategy or framework to deal with situations which are best resolved using a formal risk analysis process, and describes the roles and responsibilities of the various participants within such a framework. Such situations may include a desire for a risk assessment of a particular product or process to determine the need for risk mitigation; a desire to develop risk management options for the control of a particular hazard; the need to identify or quantify a critical limit for a critical control point in an HACCP plan; or the need to establish a standard for the importation of an animal, plant, food or product derived therefrom.

The principles and methodology described in this framework are applicable to a wide range of animal health, plant health and food safety issues for which the Agency must make decisions. As part of a proactive, formal change mechanism, considerable time may be

allocated to the thorough application of all aspects of this framework. In a reactive, emergency mode, e.g., in a potential recall situation, the same types of activities may occur, however they are often performed over a compressed period of time. Protocols have been established for specific activities, such as an emergency response to an outbreak of a foreign animal disease or a food safety recall. These protocols clearly delineate the responsibilities of key stakeholders, including the Office of Food Safety and Recall, Operations Branch staff, Commodity Program Divisions and Technical specialists. The framework can be adapted to situations involving major projects with several stakeholder groups involved, or it may be applied to smaller risk analysis projects involving two or more CFIA staff.

The application of this framework within each of the commodity sectors may vary, reflecting the need to respect various international agreements, as well as agreements with other government organizations, e.g., Health Canada, Environment Canada, and other stakeholders. The framework has been developed taking into consideration current structure and function of the Agency, and as such, its formal application should not result in significant resource requirements.

This document has been prepared in consultation with the Bureau of Food Safety & Consumer Protection; Animal Health & Production Division; Fish & Seafood Production Division; Food of Animal Origin Division; Plant Health & Production Division; Food of Plant Origin Division and staff within the Operations Branch.

## **The Risk Analysis Process - a Brief Overview**

The following briefly describes the Risk Analysis Process to be applied. Each step is described in greater detail later in the document along with a description of the roles of the key players in each activity.

International standard setting bodies for Animal Health, Plant Health and Food Safety describe Risk Analysis as a process consisting of three separate but integrated components - Risk Assessment, Risk Management and Risk Communication (see Figure 1). Within each of these components are a number of elements that are interactively and iteratively applied at various stages of the process. To facilitate the development of this Risk Analysis Framework, these elements have been organized in a chronological fashion as per Figure 2.

The process of Risk Analysis normally begins with the identification and description of issues, problems or scenarios potentially posing a risk to human, animal or plant health. These arise through a variety of means, e.g., program review, incident reports, audit results, international activity. While many of these issues are easily and quickly resolved, others may require a more extensive application of this framework. A priority is assigned to each, and further activity is initiated according to this priority. A Risk Assessment is then undertaken to answer three basic questions - what could go wrong? how likely is it to happen? and, what would be the consequence if it did happen? The results of the Risk Assessment are evaluated and a decision made respecting the need for risk mitigation or changes to existing risk mitigation approaches. While human, animal and plant health are the primary determinants for decisions regarding Risk Management, such decisions must clearly delineate their impact on other values placed at risk. Elements of the Risk Management component are applied to define, evaluate and eventually select the appropriate risk management option(s) for implementation and evaluation. Throughout the above listed activities, effective Risk Communication is maintained to ensure that stakeholders are involved and informed.

While this Risk Analysis process is depicted in Figure 2 as a linear process, it should be emphasized that at each arrow, a decision is made to repeat one or more of the preceding steps; to proceed on to the next step; or to stop the process. In the evaluation of risk management options and the evaluation of the implementation of the selected option(s), risk assessment activities are required to determine how the risk has been modified, including an assessment of new risks introduced with the risk management activity. Risk analysis is truly an iterative process. Even after completion of the risk analysis process and implementation of specific risk mitigation activities, reevaluation of the situation is justified to review the impact of new information.

# RISK ANALYSIS

Normative Interactive Iterative

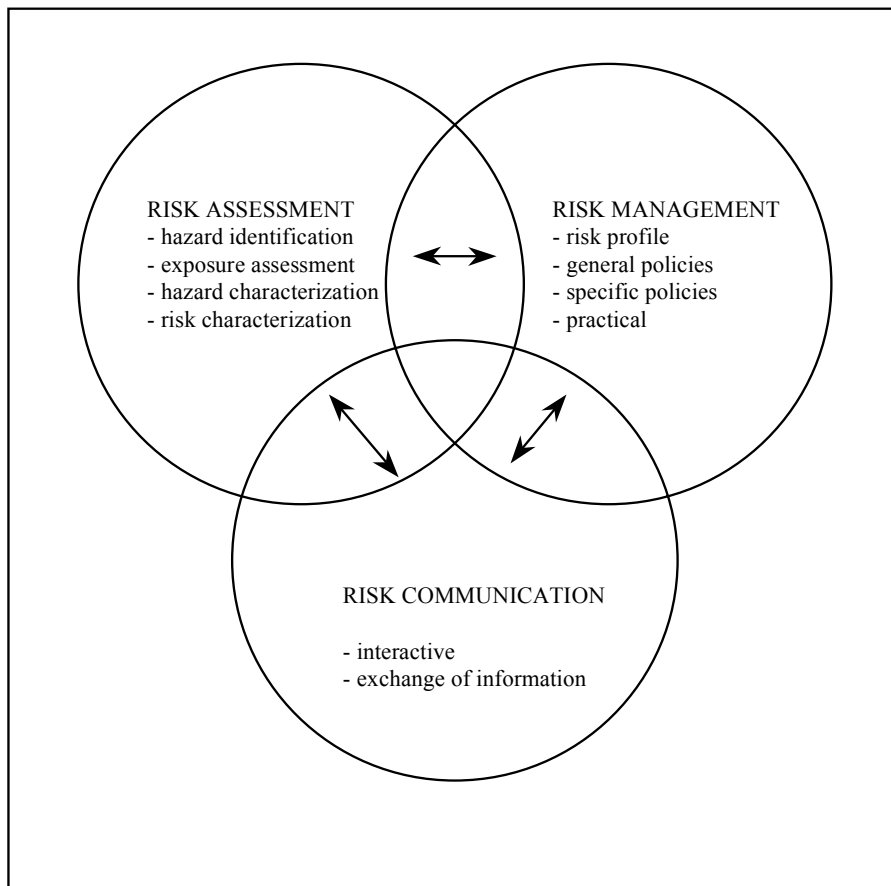


Figure 1. Schematic Diagram of Risk Analysis

# CFIA Risk Analysis Process

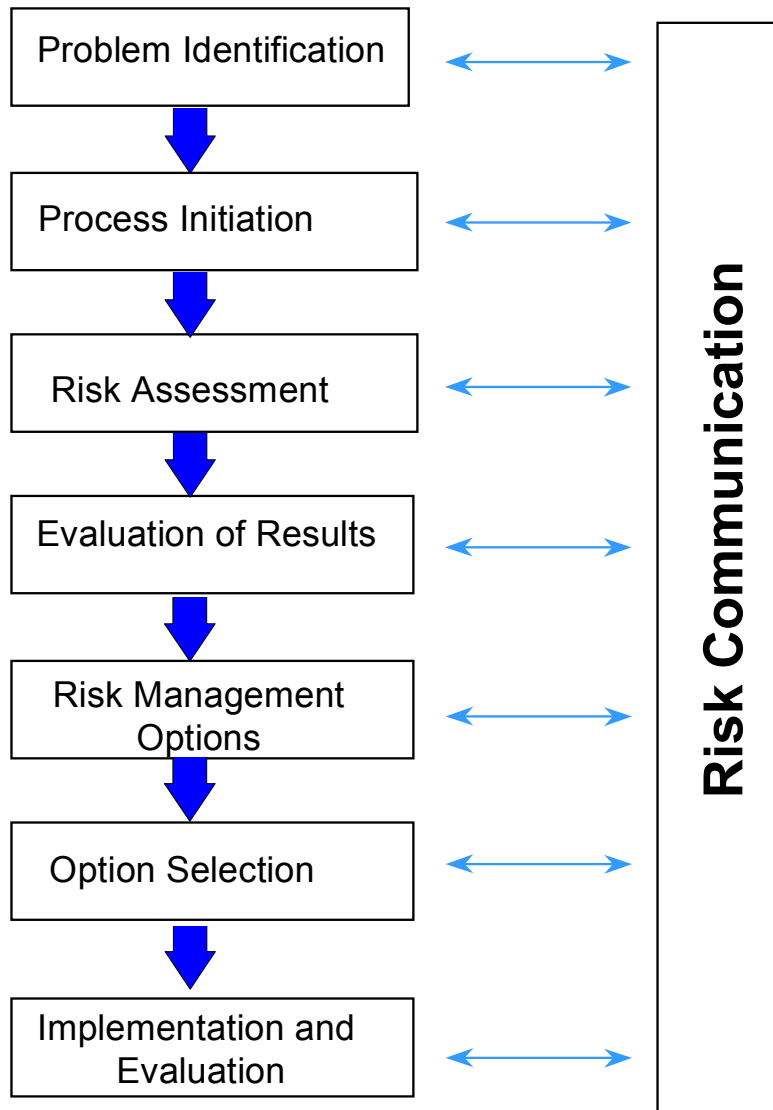


Figure 2

# **The Risk Analysis Process in Detail**

## **Problem Identification and Definition**

Issues or problems involving Plant Health, Animal Health or Food Safety are normally identified by Programs or Operations staff. These arise from a variety of internal and external sources, including the results of program review, from specific requests from importers, the need to identify or quantify a critical limit in an HACCP program, the requirement for a standard subsequent to an incident, etc. Not every issue needs to go through a formal risk analysis process, and some, e.g., emergency response or food safety recall issues have a separate process by which they may be addressed. Many day to day decisions are made using less formal risk analysis approaches that are completely adequate to consistently control the risks for which the various programs have been established.

## **Risk Analysis Profile**

Regardless of the issue or problem, it is necessary to clearly define it and establish its relative importance. To assist in this process, a Risk Analysis Profile is developed. The Risk Analysis Profile is designed to provide information regarding the commodity, product or scenario of concern, the values placed at risk in the scenario described, the distribution of risks and benefits, management characteristics of the hazard or stakeholders, commodity profile--basically a what, where, when, how and why description of the situation requiring risk analysis support. The Risk Analysis Profile is developed by Commodity Program and/or Operations staff and is based on their current knowledge of the situation. Risk Analysis personnel either within or outside of CFIA may be contacted to provide input into these profiles.

It should not be construed that the Risk Analysis Profile is an in-depth literature review of the issue, nor should it be perceived as a labourious undertaking. The intent of the issue profile is to describe what the initial identifier (and/or the appropriate program officer) knows about the issue, of course with scientific substance. It should be specific in describing the issue, the reason for concern, and context for the evaluation by others involved in further determining the appropriate management of the issue. Where appropriate, the originators may seek input from scientists, risk assessors and stakeholders as they compile this information, however, this activity should not be an overwhelming task in itself.

The Risk Analysis Profile is considered a "living document," in that it is updated throughout the Risk Analysis process as information is gathered and analysed. It is considered the starting point for a more in-depth examination of the issue. Risk Assessors are required to verify that, to their knowledge, all hazards are identified. Risk Managers are responsible for reviewing Risk Profiles to ensure that, to their knowledge, stakeholders are identified.

The Risk Analysis Profile assists Commodity Program or Operations staff to determine the need for a more formal approach to resolve the issue, i.e., in many cases, the issue may be resolved using information in the Risk Analysis Profile alone. The Risk Analysis Profile is also useful to identify specific information gaps for inclusion in the annual research planning process.

Appendix I outlines a Risk Assessment Request Form that may be used to initiate a risk assessment. The Preliminary Risk Analysis Profile and Commodity Profile are the two major components of this document.

### **Process Initiation:**

Not every plant health, animal health or food safety issue or problem requires a formal risk analysis approach. Many issues are resolved by the appropriate Commodity Program staff with minimal or no involvement of others within or outside of CFIA. As industry is currently being charged a fee for certain animal and plant health risk assessment activities, it is important that such decisions are consistent and transparent to avoid criticism from those stakeholders experiencing these charges.

As a formal risk analysis is resource intensive, it is necessary to prioritize such requests. The CFIA has developed a priority setting process which considers both the immediate impact on human, animal or plant health and the impact on other values, as appropriate. Priority will be based first on estimations of the immediate impact on health. Where there is no immediate impact on health, the priority assigned to the risk analysis request will then be determined by examining other relevant factors, e.g., the impact on proponent and opponent industries, economic and social impacts on the general public, trade impacts, urgency and other factors which may be identified. Where an emergency exists placing human, animal or plant health at immediate risk without appropriate action, such issues would be given immediate priority and managed through such systems as the Food and Agriculture Emergency Response System<sup>3</sup>.

Appendix II provides a process which may be used to assist in the prioritization of requests for risk analysis.

Risk analysis priorities are determined by commodity program staff in an effort to implement the appropriate allocation of resources. A mechanism has also been established to permit ad hoc, urgent requests to be processed as required. A log of risk analysis requests is completed to ensure that requests are processed according to established priorities.

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<sup>3</sup>More information regarding the Food and Agriculture Emergency Response System by be found at the following Website:

<http://www.inspection.gc.ca/english/anima/heasan/fad/faerse.shtml>



Once priorities have been established and a list of projects generated, formal risk assessment and risk management procedures are initiated.

## **Risk Assessment**

Using the Risk Assessment models of the Animal, Plant and Food Risk Analysis Network (APFRAN)<sup>4</sup>, staff within the Science Branch will undertake the requested risk assessments. In the case of risk assessments related to human health and safety, such risk assessments will directly involve Health Canada staff.<sup>5</sup> Other government departments may be involved, as appropriate, e.g., Environment Canada. The outcome of the risk assessment is an estimate of the animal, plant or human health risk associated with the product or process--this may be qualitative or quantitative depending on the situation and the information available.

Risk Assessment basically answers three questions - what could go wrong? how likely is it to happen? and, what would be the consequence if it did happen? These questions are addressed through four related procedures - Hazard Identification, Hazard Characterization, Exposure Assessment and Risk Characterization (see definitions at the end of this section). The application of these four procedures varies slightly, depending on the commodity or scenario being assessed. Such variations reflect slightly different international approaches to the risk analysis process, however these four components are completed regardless of the approach taken. The output of the Risk Assessment may be expressed in terms of the number of animals, plants or humans experiencing specific adverse events over a specific period of time; or the direct and indirect costs associated with these adverse events over the same period of time, e.g., direct animal health or productivity losses plus indirect losses associated with the loss or reduction in domestic or international trade.

It is possible, following a preliminary review of the Risk Profile and review of appropriate literature, that sufficient information is available for the development of risk management approaches without further risk assessment activity. Such decisions are made keeping in mind international concerns regarding the transparency of the process, and the need to take international norms into consideration in the assessment and/or decision making process. As information is obtained regarding the scenario, the Risk Analysis Profile is modified to reflect new information obtained, e.g., hazards not previously identified, potential factors influencing mitigation of risk, etc.

Where value judgements and policy choices are required in the risk assessment process,

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<sup>4</sup>Details of the Animal Health and Production Risk Analysis Framework may be found on the CFIA Website at <http://www.inspection.gc.ca/english/sci/ahra/rianfrwk/rianfrwke.shtml>

<sup>5</sup>Details of the Health Canada Decision Making Framework for the Identification, Assessment and Management of Risks to Health may be found on the Health Canada Website at [http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk\\_cp\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_cp_e.html)

e.g., what population should be considered at risk, how specific safety standards should be applied, reference is made to established Risk Assessment Policy. In order to maintain the scientific integrity of risk assessments, Risk Assessment Policy is established and appropriately documented with full collaboration between staff responsible for development of risk management approaches and staff responsible for the risk assessment.

## **Evaluation of Results**

The risk assessment delivers a quantitative or qualitative estimate of the plant, animal or human health risk associated with a particular scenario. By itself, this estimate is not judgmental, i.e., it does not indicate whether the risk is too high, acceptable, etc. Where applicable, these results are compared to existing standards established to determine the requirement for further Risk Analysis activity. Alternatively, staff responsible for introducing the question review the results of the Risk Assessment to determine if further Risk Analysis activity is required. In the case of Food Safety issues, results may be reviewed with appropriate Health Canada staff to establish the need for further action.

In some cases, it is appropriate to maintain the status quo with respect to programs and policies currently in place to deal with the situation. If, however, such an approach is not appropriate, formal Risk Management procedures are initiated to examine and select appropriate measures to be implemented. A more complete description of the Risk Management Framework is given in Appendix III.

## **Risk Management Options**

Risk Management is the process of weighing policy alternatives in the light of the results of risk assessment, and, if required, selecting and implementing appropriate control options, including legislative, regulatory and policy measures. Given the mandate of CFIA (to safeguard Canada's food supply and the plants and animals upon which safe and high-quality food depends), human, animal and plant health are the primary determinants for decisions regarding Risk Management. However, such decisions must also reflect the impact on other values placed at risk.

While many of the issues addressed by this framework are resolved with the involvement of two or three CFIA representatives, management of more complex issues requires greater involvement by various stakeholders. In such cases, the establishment of a Risk Management Working Group is recommended. In both cases, it is necessary to determine the level of consultation required and develop protocols for information exchange. Should a Risk Management Working Group be set up, terms of reference for the group are established using information arising from risk profiles, risk assessments and other information. With clear definition of the problem, the working group establishes specific, concrete, measurable management goals or objectives and looks for risk management options that will aid in meeting these objectives.

## **Application of Precaution in the Risk Analysis Process**

CFIA believes that the “Canadian Framework for the Application of Precaution in Decision Making”<sup>6</sup> reflects current practice within the Agency. This Framework outlines guiding principles for the application of precaution to science-based decision making in the areas of health and safety, environment and natural resources. The application of precaution recognizes that the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm.

CFIA applies precaution in all of its risk management decision making and supports the Framework as described. CFIA activities in risk analysis reflect fundamental policy positions espoused over the years by a number of international regulatory fora, e.g., World Trade Organization, OIE, Codex Alimentarius, IPPC. The Agency continues to participate in discussions within these fora regarding the application of precaution. It will also continue to take advantage of relevant opportunities, both internally and with stakeholders, to discuss the use of precaution within the Agency.

### **Option Selection**

A number of decision making techniques are available to assist in determining which option or set of options best addresses the objectives of the group while meeting specific criteria established for such a decision. The application of risk management measures for one hazard often has an inadvertent impact on other risks, resulting in their increase or decrease. For each risk management option, not only is the planned reduction of risk estimated, but potential changes in other risks are also estimated. The impact of risk management options on other areas of concern, e.g., economic impact on an agricultural sector, are also evaluated. Where risk management options involve various levels of risk to human health, and questions arise regarding acceptable limits of risk, Health Canada is involved--the lead department ultimately responsible for setting Canadian health and food safety standards. The final decision regarding the preferred option and the implementation of this option is left with the appropriate program/operations staff.

### **Implementation and Evaluation**

Once the choice of appropriate option(s) is made, an implementation plan with specific action items, responsibility and time frame for the completion of each is drafted and implemented. As with any other program, evaluation of the risk control program provides feedback not only on the effectiveness of the program itself, but also on the process used to develop and implement the program.

### **Risk Communication**

An integral part of the risk analysis framework is the involvement of stakeholders at

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<sup>6</sup>This document is available on the Canadian Food Inspection Agency Website at the following address: <http://www.inspection.gc.ca/english/reg/precaut/precaute.shtml>

appropriate points in the risk analysis. A more complete framework for the application of Risk Communication within CFIA is included in Appendix IV.<sup>7</sup>

As mentioned previously, many issues are easily resolved with the involvement of a Programs representative with input from Operations and/or scientific support staff. At a minimum, stakeholders should be kept informed of such activities through appropriate communication activity, e.g., direct or indirect notification of the intent to begin a specific risk assessment. Where more complex issues are being addressed, the number of stakeholders involved will obviously increase and a more formal approach may be required. Stakeholders include all those who have a significant and legitimate interest in the risk management issue and the decisions which may be made. They include not only regulatory staff (CFIA Programs and Operations staff as well as other Government agencies at the international, federal, provincial and municipal level), but also a myriad of industry groups and the general public. The involvement of stakeholder groups early in the risk analysis process is important to obtain their insight into the issue and input into the development of the most feasible and cost-effective options so that they have ownership in the regulatory decisions made. Failure to do so may undermine the credibility of the initiative and may result in political (high visibility) crisis at a time when risk management decisions are being applied. The challenge, therefore, is to establish a risk communication framework that effectively involves the stakeholders while ensuring timely and efficient resolution of the issue.

The following table illustrates where in the Risk Analysis framework stakeholder consultation would be appropriate:

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<sup>7</sup>See also “Risk Communication and Government: Theory and Application for the Canadian Food Inspection Agency” on the CFIA Website:  
<http://inspection.gc.ca/english/corpaffr/publications/riscomm/riscomme.shtml>

Risk Analysis Activity	Stakeholder Consultation Activity
1. Problem Identification	1. Discuss issue with stakeholders identifying risk. Develop risk analysis profile using input from stakeholders.
2. Process Initiation	2. Discuss need for risk analysis and prioritization of issues with stakeholders. Stakeholder input regarding ad hoc urgent processing of specific requests.
3. Risk Assessment	3. Request information or comments as appropriate from stakeholders. Provide copy of complete risk assessment to stakeholders Request input
4. Evaluation of Results	4. Stakeholders may be involved in the determination of the requirement to proceed further. Acceptability of risk, including risk/benefit/cost distribution to be discussed.
5. Risk Management	
a) Develop risk management options	request comments on options - provide opportunities for full input from stakeholders. Collate comments for input into risk management decision
b) Option Selection	
c) Implementation and evaluation	distribute copies of finalized risk management plan, with rationale, to stakeholders.
	maintain ongoing communications with stakeholders on implementation activities. Encourage continued input on concerns arising from implementation of risk management plan. Request stakeholder evaluation of implementation of risk management plan.

## Roles and Responsibilities in Risk Analysis

This Risk Analysis framework involves staff from Science Branch, Programs Branch and Operations Branch. Programs staff includes Commodity Program staff (staff within the Animal Products Directorate and Plant Products Directorate, including Program Network staff) and staff within the Food Safety Directorate; Science Branch staff include Laboratory staff and Science Strategies Directorate staff; and staff within the Operations Branch include those at both the headquarters and Area levels. Among other duties, the Science Strategies Directorate has been tasked with providing risk analysis support to the CFIA in the area of Animal and Plant Health. Health Canada plays a major role in providing risk assessment support and establishing food safety standards for issues impacting on human health and safety.

Most frequently, Commodity Program and Operations staff initiate the process, through the identification of problems that require resolution using the Risk Analysis framework. Coordination of Risk Assessment activity is the responsibility of the Science Strategies Directorate with appropriate support provided by Laboratory staff and Programs and Operations staff as appropriate. Risk Assessments are undertaken within a framework that takes into consideration international and domestic agreements or arrangements. Where evaluation of human health risks is required, CFIA staff work closely with Health Canada staff, keeping in mind Health Canada's role in the conduct of human health risk assessment and setting of food safety and nutrition policy (for additional information, see "*Health Canada/Canadian Food Inspection Agency Linkage in Policy Development and Management of Food Safety and Nutrition Issues - A Framework*"<sup>8</sup>). Commodity Program and Operations staff are involved in the development and delivery of Risk Management options, with Commodity Program staff responsible to incorporate risk mitigation activities in the development of specific policies and procedures for food safety, animal health or plant health programs. Where in-depth evaluation of economic and/or social impacts of the proposed options is required, other CFIA staff or other Departmental staff (e.g., Market and Industry Services Branch of Agriculture and Agri-Food Canada) may become involved in the process. The use of formal risk communication approaches, e.g., Consultative Committees, ensures the involvement of stakeholders throughout the process.

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<sup>8</sup>Draft prepared for the HC/CFIA Sub-committee on Food Safety and Nutrition Standards and Policies, March 5, 2003.

## DEFINITIONS

**Risk** - a function of the probability of an adverse health<sup>9</sup> effect and the magnitude of that effect, consequential to a hazard; the likelihood of the occurrence and the magnitude of the consequences of an adverse event.

**Hazard** - A thing or action that can cause adverse health effects in animals (including fish), plants or humans.

**Risk Analysis** - a process consisting of three components: risk assessment, risk management and risk communication (see Figure 1)

**Risk Assessment** - the scientific evaluation of the probability of occurrence and severity of known or potential adverse health effects resulting from exposure to hazards. The process consists of the following steps: (i) hazard identification (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

**Hazard Identification** - the identification of known or potential health effects associated with a particular agent in a given scenario.

**Hazard Characterization** - the qualitative or quantitative evaluation of the nature of the adverse effects associated with the hazard. Where data is available, a dose-response assessment should be performed.

**Exposure Assessment** - the qualitative or quantitative evaluation of the degree of exposure likely to occur in a given scenario.

**Risk Characterization** - the integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse health effects likely to occur in a given population, including attendant uncertainties.

**Risk Communication** - the interactive exchange of information and opinions concerning risks and risk-related factors among risk assessors, risk managers and other interested parties, with one objective being the achievement of better understanding of risk and risk related issues and decisions.

**Risk Management** - the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options.

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<sup>9</sup>In this and subsequent definitions, health refers to human, animal or plant health. While other values may be placed at risk, e.g., economic and social values, such values are considered when evaluating options for management of the health risks.

# RISK ASSESSMENT REQUEST FORM

(completed by Programs Division)

## ***ADMINISTRATIVE INFORMATION***

**To:**

**From:**

**Priority:**

**Date Submitted  
Date**

**Desired Return Date**

**Estimated Return**

## ***PRELIMINARY RISK ANALYSIS PROFILE***

**Commodity/product Scenario or Hazard to be Assessed:**

**Brief History & Background of the Request:**

**Value(s) Potentially at Risk:**

**Potential Negative Consequences:**

**Public Perception of the Risk(s):**

**Risk Producer-Beneficiaries:**

What groups in Canada benefit from taking the risk?

**Risk-Bearers:**

What groups bear the risk and would benefit from risk management?

**Risk-Benefit Distribution:**

Describe the distribution of the risks and benefits in Canadian society.

**Risk Internalization and Voluntary Self-Management Options:**

Describe how groups or individuals within Canada might voluntarily manage the risk.

**Known Management Characteristics of the Risk:**

**Known Management Characteristics of the Risk-Producer:**

**Known Management Characteristics of the Risk-Bearer:**



**COMMODITY PROFILE:**

**What:**

Exactly what is the commodity / product scenario in question?  
What volume and distribution is expected?

**Where:**

Define as precisely as possible from where (what situation) the commodity will come and to where (what situation) the commodity will go.

**How:**

Briefly, how is the commodity expected to be selected, harvested, processed, stored, distributed and prepared, including testing and food safety control measures?

**When:**

Describe expected time frames.

**Why:**

Note why the commodity is being moved, its intended use in Canada, and what impact it might have on the Canadian economy.

Short, mid and long term objectives of the plan.

Expected and potential market of enterprise (time frame)

Expected and potential employment of enterprise (time frame)

Expected and potential benefits to Canadian public.

**Familiarity and Substantial Equivalence:**

Is the Programs Division familiar with this commodity/pathway/disease situation?

How is it similar to other situations the Programs Division has dealt with?

How does the Programs Division consider it to be substantially different from those situations and thus requiring risk assessment?

**International Trade Agreements:**

Describe restrictions (if any) imposed by international trade agreements.

\_\_\_\_\_  
Initiating Officer  
Name      Date

\_\_\_\_\_  
Director Programs Division

## Appendix II

# Prioritization Of Requests For Risk Analysis

## INTRODUCTION

CFIA Commodity Program staff are under continuous pressure to develop or modify inspection systems and related services. While there is often considerable information regarding the general impacts of such changes on the various affected industry and consumer groups, there is often incomplete information regarding how such changes would impact on animal, plant or human health. For this reason, formal risk analysis approaches may be required to assist in developing and evaluating proposed changes.

As formal risk analyses can be resource intensive, there is a need to prioritize these requests to decide the order in which these activities will be conducted. Prioritization is the responsibility of the Commodity Program Divisions, with appropriate input from Operations and other CFIA staff. The following process has been developed to allow prioritization within each the three major program areas, Animal Health, Plant Health and Food Safety, i.e., there is no intention to compare animal health concerns to human health or plant health concerns for the purpose of prioritizing risk analysis activities.

Keeping in mind CFIA's mission to safeguard Canada's food supply and the plants and animals upon which safe and high-quality food depends, it would be prudent to place appropriate priority on requests in which the impact on health (human health, animal health or plant health) is of immediate concern. (Note that emergency situations are normally dealt with through an Emergency response mechanism and are not subject to this prioritization process.) Where more than one such request is being considered, priority may be based on the relative human, animal or health impact anticipated in the scenario. Where two scenarios have equal health impact, priority may then be assigned according to other values placed in jeopardy, e.g., industry concerns, trade issues, impact on CFIA, etc.

In most situations, health impacts are not of immediate concern, i.e., the risk analysis may be requested to examine a specific import scenario or proposed change to a specific element of a program. In such cases, it may be assumed that the Risk Analysis process will appropriately manage any risks identified in the scenario. In these cases, priority is established on the impact of the scenario on other values placed at risk. Such values include the degree to which proponents and opponents of the activity may be affected, the impact of such an activity on the CFIA, trade impacts, etc. For example, when comparing the relative priority of a request to consider the importation of a small lot of processed meat products from one plant in a country, versus a request to open the border for all animal products from the same country, the latter would have a significantly larger impact on stakeholders involved. With both proposals, the risk from animal hazards might be exactly the same, however the risk analysis process will assess these health risks, and address them through the risk management options that become part of the policy decisions.

This system is designed to help prioritize the allocation of CFIA risk analysis resources. It is not a system to prioritize risk management activities within the CFIA, i.e., it is not a risk based resourcing exercise.

Finally, as discussed previously, issues may arise that require immediate attention. Such issues may override the priority established by this process, however a mechanism must be established to allow for their introduction. The following process is simply a tool to assist Commodity Programs to prioritize their requests, and it must be flexible enough to allow modifications as appropriate.

## **METHOD**

The priority of each proposal requiring Risk Analysis activity, is determined using the following weighted additive scoring system.

For requests in which an immediate concern regarding animal, plant or human health is expressed, priority will be given to those requests for which health risks are considered greatest. Where requests have similar priority, other factors (as listed below) are used to assist in prioritizing requests.

Scores ranging from 0 to 10 are assigned to the following factors to describe the relative impact (positive or negative) of each factor, if the proposed changes were allowed to proceed. Because of the varied nature of the programs, the relative adjectives used in the scoring of these factors, e.g., significant, big, and important, are not specifically defined. It is up to the commodity program staff to further define these factors for application within their area of responsibility. Each factor has been weighted (from 1 to 100) to reflect the relative importance of these criteria. Each score is multiplied by its respective weighting factor and the products are summed across all weighted factors, to create an overall index for each Risk Analysis request. The requests are subsequently ranked in descending order by their overall indices, and Risk Analysis activities are conducted in that order.

## **FACTORS**

- 1. IMMEDIATE HEALTH CONCERN**
- 2. PROPONENT INDUSTRY/GROUP BENEFITS**
- 3. OPPONENT INDUSTRY/GROUP LOSSES**
- 4. CHANGE IN TRADE**
- 5. PUBLIC ECONOMIC/SOCIAL IMPACT**
- 6. IMPACT ON CFIA**
- 7. URGENCY**
- 8. UNIQUE CONCERNS**

## **ASSIGNMENT OF FACTOR SCORES (0 TO 10)**

## **1) IMMEDIATE HEALTH CONCERNS**

### Score

How significant are the immediate health concerns associated with the request? While the actual health risks will be estimated as part of the risk analysis process, priority must be given to requests involving significant potential risks of an immediate nature. Score zero if there is no immediate risk, e.g., the request involves permission to import a product, but importation is dependent on a decision made after the risk analysis process has been completed. Score 10 if significant health impact is anticipated without appropriate Risk Analysis to determine the risk and develop appropriate risk mitigation approaches.

## **2) PROPONENT INDUSTRY/GROUP BENEFITS**

### Score

How important is the success of the proposal to the proponent industries/groups?

## **3) OPPONENT INDUSTRY/GROUP LOSSES**

### Score

How damaging is the success of the proposal to opponent industries/groups? This score assumes the successful management of the health risk involved in the proposal.

## **4) CHANGE IN TRADE**

In the medium to long term, will there be a big change in trade patterns, if the proposal is successful? Trade could include both international and domestic.

### Score

A high score indicates a big change in trade patterns for affected industries, either a net shift from imports to exports (i.e., important) or a large net shift from exports to imports (i.e., important). A score of "0" indicates no expected change in trade patterns.

## **5) PUBLIC ECONOMIC/SOCIAL IMPACT**

Will there be a gain or loss of jobs, strengthening or weakening of the economy, raising or lowering of consumer prices, or a change in the quality of life within Canada?

### Score

Score high if there is a marked public good or harm, if the proposal goes through?

## **6) IMPACT ON CFIA**

Will there be a considerable impact on resources within CFIA, e.g., significant increase in resources required, or significant decrease in resources required should the proposal succeed.

### Score

Score high if the "successful" proposal would have a significant impact on resource utilisation within the CFIA.

## **7) URGENCY**

### Score

Score high if the "window of opportunity" is short for the specific proposal.

## **8) UNIQUE CONCERNS**

Certain proposals may involve subjects for which certain individuals or special interest groups have expressed concern, e.g., environmental impact, animal welfare, use of food additives, sustainability, etc. not specifically related to the health risks involved. Such issues will normally be addressed as risk management options are identified and considered.

### Score

Score high if the proposal deals with subjects for which considerable special interest group activity is expected.

The following table may be used as a template for comparing risk analysis requests.

## Prioritization of Risk Analysis Requests

<b>Criteria</b>  (weighting factor)	<b>ISSUES FOR RISK ANALYSIS</b>					
	Issue 1 weighted score		Issue 2 weighted score		Issue 3 weighted score	
Immediate Health Concerns  (100)						
Proponent Industry Benefits  (9)						
Opponent Industry Damage  (9)						
Trade Impacts  (10)						
Public Economic / Social Impact  (5)						
Impact on CFIA  (7)						
Urgency  (10)						
Unique Concerns  (8)						
<b>Total Score</b>						

### Prioritization of Risk Analysis Requests (Example)

<b>Criteria</b>  (weighting factor)	<b>ISSUES FOR RISK ANALYSIS</b>					
	Cdn Equestrian team returning Argentina score	weighted score	Commercial Alpaca importation - Chile score	weighted score	Bovine embryo import - Brazil score	weighted score
Immediate Health Concern  (100)	7	700	0		0	
Proponent Industry Benefits  (9)	10	90	10	90	7	63
Opponent Industry Damage  (9)	2	18	1	9	1	9
Trade Impacts  (10)	0	0	2	20	8	80
Public Economic / Social Impact  (5)	2	10	4	20	0	0
Impact on CFIA  (7)	0	0	5	35	2	14
Urgency  (10)	8	80	6	60	4	40
Unique Concerns  (8)	2	16	4	32	0	0
<b>Total Score</b>		914		266		206

# RISK MANAGEMENT FRAMEWORK

## Introduction

Risk Management is essentially the process of making and implementing decisions designed to mitigate risks posed by hazards. This risk management framework is a decision support, which, when implemented, provides an effective and efficient methodology to resolve problems and issues. It is applicable across all commodities and risk agents. The framework also provides a means whereby the decision-making process is made transparent, objective and improved, and the allocation of CFIA resources is justified. Use of the framework also provides a better understanding of the system within which CFIA operates, thereby enabling managers to identify and correct weak links in the system, and prevent or minimize future problems.

A number of values considered important when developing the following risk management framework are listed at the end of this appendix.

## STEPS IN THE RISK MANAGEMENT PROCESS

In the development of the following risk management process, it is assumed that the scope of the issue, problem or scenario has been appropriately defined, i.e., a risk analysis profile has been completed. It is further assumed that a Risk Assessment has been completed and that CFIA management has assigned an official to be responsible for completing the risk management process.

The following process outlines activities that can be performed by one person or many people, depending on the complexity of the issue. The one underlying caveat is that the ultimate responsibility for selecting and implementing a risk management option(s) resides within CFIA. The use of advisory groups, steering committees, working groups, etc. to assist in this process is often appropriate, and desirable. However, CFIA cannot abdicate its responsibility for decision making within this framework.

### 1. Review Issue Definition

The responsible CFIA official reviews the issue (problem, scenario) as outlined in available documents, including the risk analysis profile, to ensure that there is a clear definition of the issue for which risk management is required. Special emphasis is placed on the values placed at risk, distribution of risks and benefits and other information which assists in determining who should be involved in subsequent risk management activity.

### 2. Establish Risk Management Group

The responsible CFIA official organizes a working group (the risk management group) and determines which stakeholders will be immediately included in the working group and those who will be involved through the risk communication (consultation) process. The risk



management group is tasked with reviewing all pertinent information, providing technical and other advice and making recommendations regarding the risk management approach to be considered by CFIA.

Most issues are easily resolved with a small team involving appropriate Commodity Program staff and other CFIA staff, e.g., Operations, technical staff. Other issues are more appropriately addressed through the direct involvement of a multidisciplinary group including key stakeholders. The benefits of direct involvement, including stakeholder buy-in through direct participation, are weighed against the cost of this process, including the time and effort required to manage diverse groups.

For the purpose of this document, the term "risk management group" is used to refer to both the small and large risk management groups involved in this process. The following steps are applicable to all risk management groups and are designed to ensure a consistent and transparent approach to resolution of the issue. In all cases, the legal ramifications of decisions taken must be considered.

### **3. Develop Risk Communication Plan**

The risk management group establishes a risk communication plan to ensure appropriate consultation and information exchange with stakeholders. Having a written communication plan encourages efficient information exchange which is critical to the success of the consultation\negotiation process. This risk communication plan should be established early in the process with the understanding that modifications will be required as the risk management process unfolds to reflect the possibility that other stakeholders will be impacted by options being considered.

### **4. Development of Terms of Reference**

The risk management group establishes terms of reference for their involvement in the risk management process. Using information provided in the risk profile, risk assessment and other documentation, the risk management group determines their respective roles and responsibilities, scope of activities taken by the group, decisions to be made, etc. Appropriate documentation of all aspects of their activity is necessary to establish an auditable trail of their activities.

### **5. Formulation of Objectives**

Keeping in mind the terms of reference and CFIA's responsibilities, the risk management group establishes goals or objectives which are specific, concrete, and measurable, for example, "to reduce the number of shell eggs samples which test positive for *Salmonella spp.*", "to reduce the number of incidents of salmonellosis attributable to consumption of table eggs" or whatever appropriate, measurable parameters can be identified. If standards exist for a given hazard, they may provide a target for risk managers to meet. Various standards of safety, e.g., zero tolerance, maximum hazard limits, as low as reasonably achievable (ALARA), may apply across the various commodities involved. Human health and safety standards are the responsibility of Health Canada.

It is important to avoid using what is really a management option as an objective. To do so will immediately narrow the range of solutions. For example, "reduce the number of *Salmonella*-positive environmental samples taken from egg-laying facilities" is an objective; "initiate an education program on *Salmonella* control for poultry producers" is a management option.

The team should work together, using stakeholder input as established in the risk communication plan, to formulate an objective with which all members can agree. This ownership of the issue increases team commitment and solidarity. If at this step, the best course of action is evident, there is no need to continue the decision-making process.

## **6. Identifying Risk Management Options**

There are a number of techniques which may be used to assist the risk management group to generate risk management options. Where risk management measures are currently being applied, they are reviewed to see if they could form the basis for a risk management option. Where appropriate, stakeholder involvement in the process of identifying potential risk management approaches is sought.

## **7. Selection of Option(s)**

A formal decision process is used to assist in the evaluation and selection of one or a combination of options to address the issue. A number of formal Decision Making techniques are available to assist the risk management group in selecting the option(s) that most appropriately meet their objectives.

Information that should be considered when evaluating options include:

- What are the assumptions associated with each option?
- What are the uncertainties associated with each option?
- What are the residual risks (human health, economic, plant/animal health, environmental, legal, social) associated with each option? (Residual risks are those that remain subsequent to the application of the risk management option(s).
- Are new risks introduced by the option?
- What are the advantages (benefits) associated with each option?
- What are the costs associated with each option? Costs include resource and time requirements as well as money. What impact will the resource requirements have on other CFIA programs?
- What is the ease and cost of reversing the situation if things go wrong?

In most cases, the option(s) selected are those which require the fewest resources and are least restrictive to trade, while meeting the objectives of the risk management group.

It is frequently possible to eliminate many of the options after a cursory examination of their feasibility, cost, etc. In some instances the best choice among the remaining options is evident; in other instances there are several options which appear to have more or less equivalent advantages and disadvantages. In the latter case, it is necessary to identify

observable, measurable criteria which the risk management plan must fulfill. The criteria are ranked as high (must be met), medium (desirable or preferable that the option chosen meets them), and low. Each option is evaluated against the criteria and any option that does not meet criteria ranked as high is eliminated. Of the remaining options, the one that best meets the medium and low criteria is chosen. If no viable option is found, the risk management group goes back to Step 4, examines the issue again, produces a new objective, and continues with the risk management process.

In some cases a number of options which are not mutually exclusive are generated. This is more likely to be the case where the issue is complex, and social, legal, and economic concerns must be addressed in addition to technical problems. In such cases options may be grouped under headings such as regulatory action, education, and technological, and the best options under each heading chosen.

The stepwise introduction of control options is often considered, e.g., the introduction of costly, short-term options for immediate control of a situation, followed by less costly, long-term options for subsequent control activities.

It should be stressed that the final decision regarding the Risk Management option(s) to be selected is the responsibility of CFIA officials. Where there is any doubt on the part of the CFIA official leading the Risk Management Group, regarding the acceptability of specific risk management options, advice should be sought through the appropriate CFIA Decision Making committee, e.g., Program Management Committee.

## **8. Development of Implementation Plan**

The timely and effective application of the selected risk management options usually requires the coordinated involvement of Commodity Program, operations and other support staff. For this reason, those responsible for direct implementation of options are included in the risk management group. Depending on the situation, the structure of the risk management group is adjusted to include greater representation of those responsible for implementation of the option(s).

An implementation plan is generated, broken down into specific action items, with responsibility and a time frame assigned for completion of each item. The team sets specific milestones which are tied to the project objective and specifies what will happen if the milestone results are not forthcoming.

## **9. Implementation and Evaluation**

The responsible CFIA official will assume responsibility to ensure that the risk management option is appropriately implemented as per the implementation plan described above and that subsequent evaluation of its impact follows.

Evaluation of the risk control program is essential. Evaluation provides feedback which improves the risk management process and helps to keep the project on track. The milestones identified in the implementation plan provide a mechanism for periodic

evaluation of the plan. Modifications may be necessary to the risk management plan or the implementation measures if milestones are not being met. Frequently risk management activities provide additional data on the nature and magnitude of the risk being managed. Indeed, the risk assessment itself may need review as more information becomes available. Ultimately, under the impact of the regulatory process as it becomes implemented, the nature of the hazard as well as the magnitude of the risk should change for the better.

## **Documentation**

Documentation is an operational procedure that provides transparency in tracking. It assists in ensuring that the process is objective and repeatable. The documentation listed below provides a valuable record of the process and is a useful tool for handling future risk management issues. The responsible CFIA official should ensure that documentation is maintained in a single file registry and is kept as simple and concise as possible using table or point form where appropriate.

Documentation includes:

- the risk analysis profile; or a separate description of the issue, including nature of the hazard, commodities involved, stakeholders identified, risk management procedures currently in place, etc.
- the risk assessment
- composition of the risk management team
- terms of reference and objectives of the risk management team
- the communication plan
- risk management options identified
- advantages, disadvantages, costs, uncertainties, and assumptions associated with each option
- risk management decision, including rationale
- implementation plan (including contingency plans if appropriate)
- evaluation plan

## VALUES DRIVING THE RISK MANAGEMENT PROCESS

In the development of this risk analysis framework, and in particular the section dealing with the risk management process, the following values were considered:

### **1. There should be functional separation between Risk Assessment and Risk Management**

In the risk analysis process, risk assessment and risk management are described as two distinct processes. The functional separation of these two elements is essential to maintain the scientific integrity of the risk assessment process. Risk assessment, as a decision-making tool, is a scientific process which should not be influenced by social, economic, or political considerations. These latter aspects of risk analysis are dealt with in the risk management process.

While these activities are functionally separate, there is a necessary and planned interaction between risk assessors and risk managers to ensure that the risk assessment addresses the needs of the risk managers. Interaction prior to the risk assessment is required to develop and document risk assessment policy, i.e., specific statements that provide direction regarding how to deal with value judgements and policy choices which may arise in the risk assessment process, e.g., what population should be considered at risk, how specific safety standards should be applied.<sup>10</sup>

Later in the process, risk assessors and risk managers may further interact for the purpose of evaluating proposed risk management options or to refine risk assessments according to modifications in the scope or objectives of the risk management process.

It is important to ensure that where such interaction is required, the decision process is transparent and documented. It is more important to ensure the “unbiasedness” of the process rather than stress the distinctions between assessor and manager.

### **2. Stakeholders Should Have Input into the Risk Management Process**

A stakeholder is defined as any individual or group with significant and legitimate interest in a given risk management issue. The broad range of issues that CFIA staff manage results in a large number of potential stakeholders, including primary producers, processors, importers and exporters, consumers, as well as a myriad of international, federal, provincial, territorial and municipal governments.

Stakeholders should be involved in the decision-making process to the extent practicable and reasonable. At a minimum, appropriate communications strategies should be

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<sup>10</sup> Readers may also refer to the Report of the WHO Expert Consultation held in Kiel, Germany, March 2000, entitled, “The Interaction between Assessors and Managers of Microbiological Hazards in Food”, found at the following Website:  
<http://www.who.int/foodsafety/publications/micro/march2000/en/>

established to keep stakeholders informed. In some cases, it is appropriate to invite stakeholders to participate in the risk management group. In most cases, stakeholder involvement is addressed through ongoing, reciprocal communications. The degree to which stakeholders participate depends on the magnitude of the risk, the extent to which a given stakeholder's interests are involved in the issue, the existence of individuals or groups which can effectively represent the interests of the stakeholder, the knowledge, expertise, and authority of stakeholder representatives, the financial resources available for consultation, and the time available for making and implementing a risk management decision.

The effective involvement of stakeholders requires a proactive risk communication strategy. A communications network based on a co-operative approach to problem-solving should be established with potential stakeholders before there is an urgent need for it. A risk management plan always includes a communication plan which specifies how information is to be exchanged within the management team and amongst other stakeholders, and clarifies each team member's role and responsibilities for communications.

### **3. Effective Risk Management Requires a Team Approach**

A team approach is necessary for the successful management of risks because no one individual has the authority or the knowledge needed to make and implement effective risk management decisions. Each team member, should, as a member of a group or agency, be able to contribute knowledge, experience, and (though not necessarily money) resources to the risk management effort.

Another advantage of team management is that it broadens the frame of reference within which a problem is managed. Individuals and organizations inevitably view an issue through their own frames of reference and this leads to biased and narrow views which reduce the number of risk management options generated. Input from a variety of stakeholders broadens the frame of reference and increases the chances of arriving at an effective solution, provided that momentum and a sense of direction are maintained. While some stakeholders see an issue as mainly a technical one, others frame the problem in social, economic, or political terms.

The most critical requirement of an effective team is commitment to a common goal. This commitment fosters a team synergy which will greatly facilitate the risk management process.

### **4. Distribution of Risk**

This framework highlights the need for the distribution of risk benefits and costs to be clearly described. Distribution of risk is an important factor in determining who should manage risk and who should pay for risk management activities. Risk producers are those stakeholders whose actions produce a risk. The risk beneficiary is the individual or group which benefits from the risk-producing activity. Risk bearers are the stakeholders who bear the risks associated with any negative consequences arising from an action. In some cases the same stakeholder group is the producer, beneficiary, and/or bearer of a given

risk, while in others, these roles are split among different stakeholder groups. For example, the major benefits associated with the importation of an animal may go to a particular producer while the major risks may be borne by a complete sector of the agricultural community, e.g., dairy producers.

Risk bearer groups are most likely to perceive a risk as unacceptable when the same group or individual is both the risk producer and the risk beneficiary, while the risks are borne by a third party. Those who stand to benefit from a risk-producing action are likely to favour a risk-taking stance; those who do not benefit, but bear the risk, are likely to be risk averse.

An issue related to that of risk distribution is the question of which stakeholders assume responsibility for control of a risk. There are two aspects to this issue. The first is the question of which stakeholder is the risk producer, and the second is the question of which stakeholder is in the best position to control the risk. Animal and plant importers may be in a position to reduce most import risks, but the economic costs of doing so may be excessive. Consumers may be in a position to reduce some risks associated with food but not all. If a stakeholder stands to benefit from taking a risk, but does not bear the negative consequences of that risk, the stakeholder could be held responsible for costs to reduce the risk, or to prove that the risk is within acceptable limits (burden of proof).

## **5. Costing**

Risk management measures inevitably involve expenditure of resources. Because cost is an important factor in determining the feasibility of a risk management option, risk management options are costed as part of the evaluation process. Costing in advance minimizes the chances of becoming entrapped in projects and programs which consume resources greater than the benefits they provide.

Costing for this purpose may not always require a detailed inventory of all possible costs, provided reasonable estimates of funds, equipment, and human resources are provided. It is important that medium and long term costs rather than only short term costs are included, to avoid risk management strategies which offer an attractive short term solution, but prove very costly long term. Costing also provides a tool against which implementation of the risk management plan may be evaluated.

A complete risk management plan may involve the use of several options--one or more short term, but expensive measures, being succeeded by others which are longer term, and less expensive.

# RISK COMMUNICATION FRAMEWORK

## Introduction

The purpose of this section is to provide a framework for the application of risk communication principles throughout the risk analysis process.

The CFIA operates in an international and domestic environment which demands effective and extensive communications with stakeholders. As inspection agencies gain experience in the application of Risk Analysis, the critical role of Risk Communication is being recognized. Without good risk communication, stakeholder opinion (particularly public stakeholder opinion) can influence the allocation of risk management resources in ways which are ineffective in mitigating risks. Without effective stakeholder participation, potential risk management options may be missed while evaluation of others may be inadequate. Poor risk communication hampers or prevents the implementation of rational risk management programs.

## Defining Risk Communication

**Risk communication** has been defined as, “an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties.”

Risk communication is probably the most misunderstood and least examined aspect of risk analysis. It involves a two-way or multi-way exchange of information and ideas among regulators and stakeholders. It is not the one-way dissemination of information that attempts to “educate” the public, or persuade stakeholders to agree to a particular risk management approach. It involves the interactive exchange of ideas among stakeholders who may be affected by decisions made at various steps in the risk analysis process.

## Objectives of Risk Communication

CFIA’s Risk Communication framework is designed to involve stakeholders in the risk analysis process from start to finish. It’s main objectives are as follows:

1. To establish and maintain channels for obtaining information on stakeholder knowledge, attitudes, and perceptions around risk issues, and for incorporating this information into the risk analysis process.
2. To provide an opportunity for stakeholders to review and comment on CFIA risk analysis policies, including risk assessment methods and standards of risk employed by the CFIA. Industry stakeholders have a right to know and to understand what the potential regulatory burden is before investing resources in regulated activities. Similarly, the public has a right to know and to understand the standards and policies used by the CFIA to safeguard the health of animals, plants and humans.



3. To provide an opportunity for stakeholders to review and comment on specific risk management policies and programs within the CFIA. Stakeholders have a right to know the rationale for such programs and policies, and how they will impact on stakeholder groups.

### **Benefits of Effective Risk Communication**

1. The quality of risk management decisions is improved with increased stakeholder input as it enlarges the information base on which risk management decisions are made and provides opportunity for formulation of more constructive management options.
2. Increased stakeholder participation throughout the risk analysis process results in greater stakeholder support and co-operation in applying risk management decisions.
3. Effective, reciprocal communication builds stakeholder networks which greatly facilitate the handling of future risk management problems, particularly in crisis situations.
4. In combination with a good risk management plan, effective risk communication provides risk managers with greater confidence in and control of the risk situation. While adverse publicity and stakeholder opposition cannot be eliminated, it may be reduced and more easily addressed.

### **Principles Of Effective Risk Communication**

1. Effective risk communication requires good faith on the part of all participants. Good faith is possible only when there is a genuine belief in the value of the process of interactive communication with stakeholders. Effective risk communication does not necessarily imply complete disclosure, but what is communicated to other stakeholders should be reliable within the limits of the communicator's knowledge.
2. Risk communication techniques cannot make up for poor risk assessment or poor risk management options. The information communicated must offer a reasonable basis for resolving the issue. The most carefully prepared and skilfully implemented risk communication plan will be of limited use if the other components of the risk analysis program are inferior.
3. Effective risk communication is interactive. It implies empowerment of the people who are consulted to have an influence on the final decision. It therefore involves responding to information and opinion as well as imparting information and opinion. Effective risk communication is based on an implicit understanding that the input of all participants is important.
4. Effective risk communication is proactive and ongoing. Risk communication links with stakeholders are established before there is an urgent need for them. This proactive approach facilitates the process of Risk Analysis by promoting goodwill and trust among stakeholders and giving them experience in dealing with issues of common concern.

5. Effective risk communication balances spontaneity and structure. Planning and organization are essential for effective risk communication, but the structure should not be so inflexible that it cannot respond quickly and competently to the unexpected situations that inevitably arise.

6. Internal communications, i.e., communications within each stakeholder group, are an essential part of an effective risk communication program. Individuals who represent stakeholder groups must ensure that their members are appropriately informed or consulted during the risk analysis process. It is often these members who are most affected by implementation of a risk management option.

7. Effective risk communication requires a recognition of the variety of perspectives that stakeholders bring to the consideration of a risk. Each stakeholder frames the facts in a different way, and therefore each stakeholder may be dealing with the same risk management issue from a different perspective.

8. Maintaining an up-to-date inventory of CFIA communication resources and skills, including current communication links with other stakeholders, available communications materials and tools, staff communications skills and training, and available communications support services enables CFIA to maintain and improve its risk communications capacity, and to respond quickly and effectively in a crisis.

9. Effective risk communication may not resolve all the differences among stakeholder groups. It may, however, enable stakeholder groups to better understand each other and may improve the chances of developing risk management options that are acceptable to all or most stakeholders. One has to recognize that there are often fundamental differences in the perspectives and objectives of the stakeholders which are not removed by risk communication.

10. Even with effective risk analysis procedures in place, including effective risk communication, criticisms and complaints from stakeholders are to be expected. Understanding the validity and significance of these comments helps to bring the criticism into perspective and provides insight into dealing with these concerns.

## **Consultation - A Risk Communication Approach**

Consultation is defined as seeking advice or information from, or asking guidance from. Consultation is one means by which regulatory agencies obtain information on stakeholder knowledge, attitudes, and perceptions of risk. In order to fulfill this vital role in risk communication, consultations must be planned and implemented effectively.

The mechanics of the consultation process will vary with each situation, however, the general principles outlined below are valid for all stakeholder consultations.

### **Principles of Effective Consultation**

1. Effective consultation requires clear and consistent consultation policies and plans.

2. Consultation should be genuine, rather than spurious.
3. The objective of the consultation and the consultation protocol should be formulated and communicated to all participants before the consultation process begins.
4. Limits should be set regarding the extent to which consultation influences regulatory decisions. Like other government agencies, CFIA has mandates and responsibilities which it cannot legally abdicate when these obligations conflict with the wishes or demands of particular stakeholder groups.
5. To establish stakeholder ownership in the risk management process and decisions arising therefrom, consultations should be initiated as early in the risk analysis process as possible.
6. No single consultation process meets the needs of all stakeholders and all consultation situations.
7. Stakeholders should have access to the information upon which risk analysis activities are based, except where release of such information violates security or confidentiality.
8. While effective stakeholder consultations may save time and money in the long run, they require an initial outlay of time and resources which must be considered when establishing the risk communication strategy.
9. The consultation process is not a public relations opportunity in which only positive information is presented. Presenting only positive aspects of an issue undermines consultations by producing stakeholder cynicism about the genuineness of the process.
10. Active stakeholder input, in a setting which encourages openness, is preferable to passive stakeholder input.
11. Feedback on the results of the consultation should always be provided to those consulted.

### **When and Whom to Consult**

Stakeholders who have a direct concern in the risk management decision should be included in the consultation process. When broad social values are involved in a risk issue or when a risk management decision would directly impact a specific group of public stakeholders, public input should be sought.

The following criteria should be used when deciding whether or not to consult, the extent of consultations, and the stakeholders to be consulted:

- the organizational readiness of the agency, including the experience and knowledge of agency staff relative to consultation
- the extent to which stakeholders are willing to engage in consultation with the

- agency
- the time available to make a risk management decision
- the resources available, in terms of money, human resources, and skills, for consultation

In situations where there is an urgent need for immediate action, where the optimal course of action is obvious, where the issue is entirely or mainly technical, or where the issue is trivial or routine, consultation before action may be unnecessary or inappropriate. In such situations, extensive risk communication may not be a viable option.

Consultation should be carried out only when there is a possibility that the input from the consultations will affect the risk management decision. If there is no real intent of allowing stakeholder input to influence the risk analysis process, there is little point in undertaking consultations. In these situations, the communication strategy should ensure that stakeholders are informed in an appropriate manner.

### **A Stakeholder Consultation Framework**

A proposed consultation mechanism is outlined in the following table. This framework provides for stakeholder input throughout the risk analysis process. Because risk situations vary so greatly, any generic framework must be tailored to fit the needs of each situation.

<b>Risk Analysis Activity</b>	<b>Stakeholder Consultation Activity</b>
1. Problem Identification	1. Discuss issue with stakeholders identifying risk. Develop risk analysis profile using input from stakeholders.
2. Process Initiation	2. Discuss need for risk analysis and prioritization of issues with stakeholders. Stakeholder input regarding ad hoc urgent processing of specific requests.
3. Risk Assessment	3. Request information or comments as appropriate from stakeholders. Provide copy of complete risk assessment to stakeholders Request input

4. Evaluation of Results	4. Stakeholders may be involved in the determination of the requirement to proceed further. Acceptability of risk, including risk/benefit/cost distribution to be discussed.
5. Risk Management	
a) Develop risk management options	a) request comments on options - provide opportunities for full input from stakeholders. Collate comments for input into risk management decision
b) Option Selection	b) distribute copies of finalized risk management plan, with rationale, to stakeholders.
c) Implementation and evaluation	c) maintain ongoing communications with stakeholders on implementation activities. Encourage continued input on concerns arising from implementation of risk management plan. Request stakeholder evaluation of implementation of risk management plan.

