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Framework for Initiating and Conducting Risk Analysis Activities on Microbial Hazards in Food

January 2017

Bureau of Microbial Hazards, Food Directorate,
Health Products and Food Branch, Health Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Statement of Purpose

Health Canada's Decision Making Framework (HC-DMF) is a process for identifying and managing risks to health[1]. It is a logical, systematic way of thinking, working and problem-solving. The decision-making environment, its clients and the public require a high level of rigour as well as an evidence-based process to support Health Canada's work and decisions.

This document is intended to describe the current practices and future direction at the Bureau of Microbial Hazards, Food Directorate in undertaking *major risk analysis activities*. The proposed framework has been developed to ensure that the initiation and completion of these major risk analysis activities are in line with the HC-DMF. Additionally, the risk analysis process is based on the principles described in the Canadian Standards Association document, *Risk Management: Guideline for Decision-Makers*[2], as well as those principles described in the Codex Alimentarius Commission *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*[3].

A visual representation of the HC-DMF can be found in Figure 1. Generally speaking, the process begins at the top of the diagram, and proceeds clockwise through the other steps. The process is flexible in that one may move back and forth between steps or revisit steps based on available information. For example, a previous step may be revisited when new information becomes available and needs to be considered. In the same way, the following Framework for Initiating and Conducting Risk Analysis Activities on Microbial Hazards in Food may involve the dynamic movement between stages after a project has been commissioned. See Figure 2 for a visual representation of this process.

HEALTH CANADA DECISION MAKING FRAMEWORK

Issue Identification
- Identify the issue and put it into context

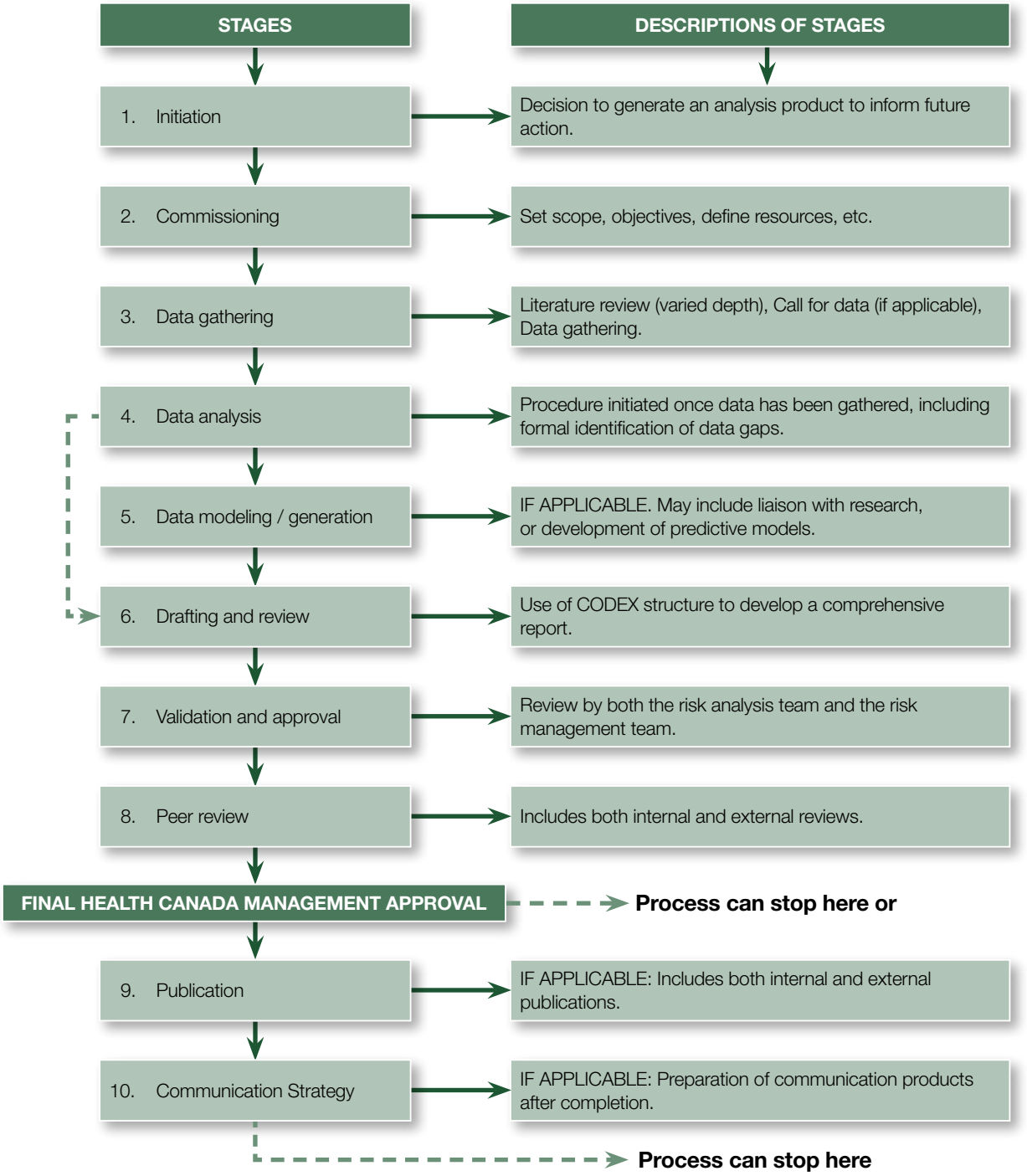
Risk Assessment
- Assess risk and benefits

Risk Management
- Identify and analyze options, select a strategy, implement the strategy and monitor and evaluate the results

Figure 1. Health Canada Decision Making Framework (HC-DMF)

The sections described herein are not intended to be prescriptive, but provide a structure around which food safety authorities can achieve timely and effective risk analysis. Examples of projects at the Bureau of Microbial Hazards, which follow this framework, are included in Table 1 at the end of this document. Examples of specific terminology are also provided at the end of this document in the Glossary.

Figure 2. Flow Diagram representing the Framework for Initiating and Conducting Risk Analysis Activities on Microbial Hazards in Food



1. Initiation

The initiation step involves the establishment of the administrative details of the process. In this step, issues are identified, the risk analysis team is established and the process of identifying stakeholders is begun. The initiation step links the decision-maker to the risk management process and the rest of the risk analysis team, by involving them with the establishment of time frame, reporting requirements, and resources for the process.

Triggers for this step can be varied. These may include: a policy imperative or a management initiative/directive but can also include outputs of risk ranking/risk prioritization, outputs of periodic reviews, routine monitoring, a food safety incident, public complaints, stakeholder requests, new regulations, among other external or internal events.

The initiation process ideally includes the following elements:

a. Identify the issue (problem or opportunity).

b. Establish the team.
   - Assign responsibility, authority, resources.

c. Identify the stakeholders.

d. Identify decisions to be made.

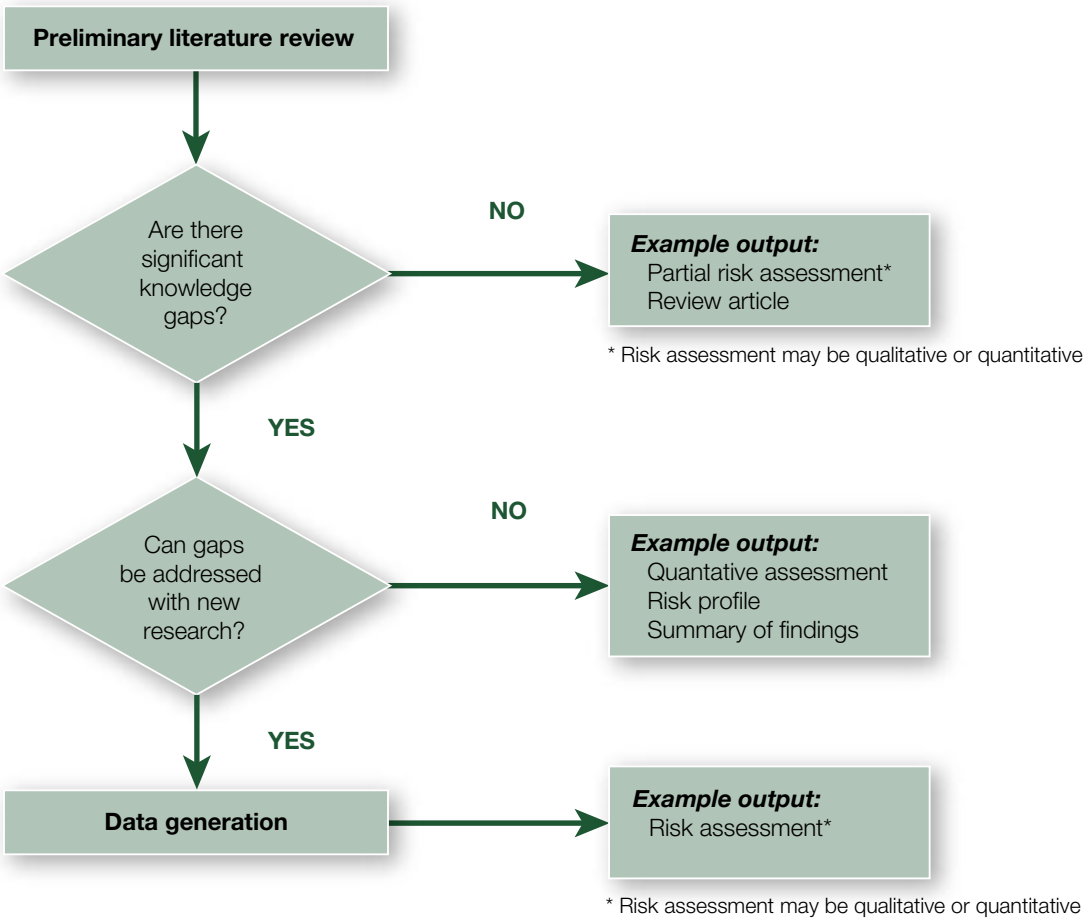
e. Documentation.
   - The technical issue should be laid out as clearly as possible. Often this involves breaking the issue into stages, showing the interaction between elements which affect risk.
   - The context of why the risk analysis is being undertaken should be clearly outlined in the issue identification document.

f. Preliminary analysis.
   - An issue (problem) exists – action required.
   - Insufficient information to determine – need detailed studies or more data.
   - There is no issue/problem – no action required.

The type of risk analysis product that can be generated depends largely on the information and data available. Figure 3 is an example of a simplified decision diagram of the type of risk analysis products that can be generated.

OUTCOME:	*Management concurrence and approval on required action based on the preliminary analysis.*
OUTPUT:	*Issue identification document.*

Figure 3. Simplified decision diagram of the type of risk analysis that can be generated



2. Commissioning of the Risk Analysis Activity

The commissioning stage involves the development of a charge document. A charge document defines the overall scope of the issue/problem, including key assumptions and the importance of the issue to Health Canada.

This document is the risk management charge to the risk analysis team and ideally contains the following:

a. The specific risk management problem or question, including the scope (assumptions/objectives).

- This should clearly state the Food Directorate's goal(s) regarding what assessment information is required by the risk managers in order to make a decision.

b. The risk analysis question(s).

c. The type of risk analysis to be conducted (i.e., risk profile or risk assessment).

d. Background information on the hazard or human health impact relevant to analysis.

e. Expertise needed to conduct the analysis.

f. Resources allocated.

g. Timeline.

h. List of members of the risk analysis, management and communication teams with the leader (contact) individual clearly identified.

OUTCOME:	*Determine scope of work and risk management question(s) to answer.*
OUTPUT:	*Charge document.*

3. Literature Review, Call for Data, and Data Gathering

A. LITERATURE REVIEW

The risk analysis team approaches to literature review (published and unpublished) can vary and may depend on the specific risk analysis activity under way. These strategies can take the form of a *Rapid review,* or could be as complex as a *Systematic review and meta-analysis*.

B. CALL FOR DATA (IF APPLICABLE)

Formally called a Health Canada Request for Scientific Data and Information, this activity is intended to support Health Canada's *risk assessment* and scientific investigation processes. A call for data may be conducted to gather all available data including unpublished data that may be relevant to the ongoing work.

C. DATA GATHERING

This stage involves the establishment of a data repository to collect and format the scientific data gathered. This should include data from the literature review, as well as submitted through the call for data outreach activities.

OUTCOME:	*Summary of findings from the information and data gathering activities that will be used for the risk assessment activity.*
OUTPUT:	*Document summarizing the published literature reviews, the criteria used to include/exclude data or information, etc.*

4. Data Analysis

The risk analysis process continues once all the information and data are obtained. The data analysis process varies with the approach selected by the risk analysis team and could be a traditional data analysis, however alternative approaches may also be considered.

Data gaps are to be expected in each stage/parameter of the risk analysis. Identifying the data gaps and their relative importance in the risk analysis is part of the evaluation process. For example, if no empirical data is available, expert opinion/judgement may be useful to inform a model or a decision.

OUTCOME:	*Analysis of data informs the conclusions and recommendations that will be part of the risk analysis.*
OUTPUT:	*The data analysis output may have varied output formats. A validated dataset may be one output that can be used to populate the modelling approach and identification of data gaps and their relative importance in risk analysis.*

5. Data Generation and/or Modeling *[If Applicable]*

At this stage in the process of risk analysis, it may be necessary to generate more data to reach a conclusion. The data generated can be directly in line with the data gaps identified in the "Data Analysis" stage or the data may be gathered ad hoc.

Some examples of data generation processes to support risk analysis are:

- Liaison with laboratory researchers to develop empirical evidence.
- Development and/or usage of a model to quantitatively estimate concentration of bacteria, exposure, and/or risk.

OUTCOME:	*Development or usage of models, collaboration plans with researchers to gather data, or other approaches to obtain the data required and that can be applied to risk management scenarios to respond to the charge.*
OUTPUT:	*Documentation of data generated (i.e., model or spreadsheet).*

6. Drafting and Review

A report is drafted based on guidelines developed by the FAO/WHO Codex Alimentarius Commission[3,4]. For example, in *risk assessments*, the report would be comprised of the four elements: Hazard Identification, Exposure Assessment, Hazard Characterization and Risk Characterization. In *risk profiles*, the FAO/WHO Codex Alimentarius Commission[3] recommends six elements:

1. Hazard-food commodity combination(s) of concern.
2. Description of the public health problem.
3. Food production, processing, distribution and consumption.
4. Other risk profile elements.
5. Risk assessment needs and questions for the risk assessors.
6. Available information and major knowledge gaps.

OUTCOME:	*Preliminary report summarizing the findings, the assumptions, the conclusions of the investigation, potential recommendations and responses to the risk management questions.*
OUTPUT:	*A draft report.*

7. Validation and Approval

The draft report (output from previous stage), is reviewed by the risk analysis team and the risk management team. It is important to discuss the risk analysis output at this stage and final strategies for validating the conclusions. The approval process for the final draft should be initiated at this stage in order to minimize delays for final approval after the peer review.

OUTCOME:	*Risk management concurrence on the final draft of the report describing the findings, conclusions, recommendations and responses to risk management questions.*
OUTPUT:	*Final draft of the report.*

8. Peer Review

A. INTERNAL PEER REVIEW

Final draft of the report will be sent for internal peer or food programme reviews. The intent of this stage of peer review is to ensure that a broader point of view is applied to the risk analysis that was completed, and that the relevant additional contexts are considered (i.e., food policy, food directorate operations, etc.). Revisions will be completed as needed.

B. EXTERNAL PEER REVIEW [IF APPLICABLE]

Internally reviewed draft is sent for an external peer review prior to publication. Revisions are completed and sent for final approval.

OUTCOME:	*Final peer reviewed report summarizing the findings, the assumptions, the conclusions of the investigation, potential recommendations and responses to risk management questions.*
OUTPUT:	*Final report for publication.*

FINAL HEALTH CANADA MANAGEMENT APPROVAL

A final approval should be sought at this stage, as change may occur after peer review.

9. Publication
[If Applicable]

A. INTERNAL PUBLICATION

Report is published via the Health Canada website, or other internal publication mechanism such as distribution via email. Translations are done concurrently.

B. EXTERNAL PUBLICATION

Report is redrafted for publication to an external provider such as a Journal publication. Translations may need to be done concurrently.

OUTCOME:	*Final report is published summarizing the findings, the assumptions, the conclusions of the investigation, potential recommendations and responses to the risk management questions.*
OUTPUT:	*Publication of the final report.*

10. Communication Strategy
[If Applicable]

This communication strategy section is specific to the formal communication activities initiated after completion of the publication. As per the HC-DMF, there will be ongoing communication between stakeholders, the risk management team and the risk analysis team throughout the risk analysis project.

At this final stage, the risk assessment and risk management team discuss the communication strategy and develops communication products as appropriate.

OUTCOME:	*A communication strategy is developed appropriate for the issue.*
OUTPUT:	*Responsive and reactive communication products are developed.*

11. Other Risk Management Actions
[If Applicable]

The risk management response to the risk analysis activity can vary with each issue. In broader terms, the risk management response can take the following forms:

A. REGULATORY FRAMEWORK

A decision may be taken to proceed towards amendment of the Food and Drugs Regulations. This process involves the highest level of federal government action.

B. GUIDANCE DOCUMENT

A decision may be taken to produce guidance for stakeholders in industry, food service, or consumers regarding practices or interventions which can be performed in order to support food safety.

C. STANDARD SETTING

A decision may be taken to develop new performance objectives, food safety objectives, or microbiological criteria for a food and or food-hazard combination.

12. Glossary

The following glossary is not meant to be an extensive resource for risk analysis terminology and concepts. It is limited to only definitions that are relevant to this document, so that there is freedom for those conducting risk analyses to develop and implement the terminology and lexicons that are appropriate for their organization. It is important to recognize the need for harmonization and common risk analysis terminology, however, the primary goal is to have those participating in the analysis agree upon the meaning of the concepts that are most relevant.

RISK ASSESSMENT

Risk assessment in the food context can be mapped to the stage of the HC-DMF pertaining to "Assess risks and benefits." Risk assessment is the process of identifying and characterizing hazards in order to determine the probability of an event and the severity of its impact.

The four elements of a risk assessment based on guidelines developed by the FAO/WHO Codex Alimentarius Commission are: Hazard Identification, Exposure Assessment, Hazard Characterization and Risk Characterization[3,4]. These steps can be completed in a qualitative, or a quantitative sense.

When a risk assessment is done in a qualitative sense, the knowledge of the hazard and exposure can be captured in narrative form, and this approach is suitable for both describing the risk in relative terms and informing risk management decisions.

For risk scenarios where there is enough data on relevant parameters related to the hazard and exposure, it is possible to provide a statistically based estimate of risk, reported as probability of illness per serving or per year, for example.

- Qualitative risk assessment example: Health Canada, Responsive HRA service.
- Quantitative risk assessment example: Risk Assessment of Shell Eggs Internally Contaminated with *Salmonella Enteritidis,* available in the International Food Risk Analysis Journal[5].

RISK PROFILE

Risk profiling in the food context can be mapped to the stage of the HC-DMF pertaining to "Identify the issue and put it into context."

A document describing a hazard scenario about which relatively little may be known. Elements typically include descriptions of: the hazard-food combination; the public health problem; the food production, processing, distribution, and consumption; current trade and regulatory considerations; a survey of the major knowledge gaps; and a recommendation as to whether a full risk assessment is required and feasible[3]. Significant elements essential to conducting a full risk assessment, such as the exposure assessment, may be lacking. The two goals of a risk profile are to identify data and knowledge gaps, and to determine whether the scenario is of sufficient concern to warrant pursuit of a risk assessment.

RISK ANALYSIS ACTIVITIES

Risk analysis activities are actions taken to enable development of risk management options. For example, these actions can take the form of a risk profile, a qualitative risk assessment, or a quantitative risk assessment[1]. These activities could also be viewed broadly as representing the approaches for assessing public health risk[6].

RAPID REVIEW

A rapid review is a type of literature review produced using accelerated and streamlined systematic review methods[7].

SYSTEMATIC REVIEW AND META-ANALYSIS

A systematic review is a knowledge synthesis method which is used to "…answer a clearly defined and focused research question(s) using structured and replicable methods to identify, select, critically appraise, extract and analyze data from relevant primary research studies"[8,9,10].

A systematic review should contain descriptive analysis of the included studies and when a suitable amount of data is collected, a meta-analysis can be performed. "Meta-analysis is the statistical combination of results of multiple individual studies[9]."

13. References

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Table 1: Example Tracking Table of Output Documentation for Selected Risk Analysis Activities at the Evaluation Division of the Bureau of Microbial Hazards, for a given date

Topic	Output					
	Initiation (Issue ID)	Action (Yes/No)	Charge	Call for Data	Analysis activity type	Status
Steak Tartare	✓	Y			Health Canada Opinion Communicate to requestor	Complete Sent to requestor Sept 2014 Published July 2015
Non-O157 VTEC	✓	Y	✓		Risk Profile Publication in peer review journal	Complete Published Sept 2014
Mechanically Tenderized Beef		Y	✓	✓	Risk Assessment To inform regulatory change	Complete Published May 2013 CG II May 2014
Uneviscerated Fish	✓	Y	✓		Risk Analysis Activity To inform creation of Guidance	Initiated Data gathering
Gouda Cheese	✓	Y	✓	✓	Risk Assessment To inform creation of Guidance	Initiated Data modelling and analysis
Oysters (bivalve molluscan shellfish)		Y	✓	✓	Risk Assessment To support international relations	Initiated Drafting and Review stage
Balut eggs	✓	N			N/A	Complete No action required File closed Nov 2014
Sprouted seed powder (chia and flax)	✓	Y	✓	✓	Risk Profile To inform creation of Guidance	Initiated Call for data in progress
Cyclospora in leafy greens	✓	Y	✓		Risk Profile To inform creation of Guidance	Initiated Charge in progress
Dose-response project	✓	Y	✓		Risk Profile To inform creation of Guidance	Initiated Charge in progress