



# **Evaluation of the Food Safety and Nutrition Quality Program 1999-2000 to 2011-2012**

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## List of Acronyms

AAFC	Agriculture and Agri-food Canada
AANDC	Aboriginal Affairs and Northern Development Canada
ADM	Assistant Deputy Minister
AMR	Antimicrobial resistance
AOAC	Association of Analytical Communities
BCS	Bureau of Chemical Safety (FD)
BFPI	Bureau of Food Policy Integration (FD)
BFSA	Bureau of Food Safety Assessment (PPIAD)
BMH	Bureau of Microbial Hazards (FD)
BMI	Body Mass Index
BNS	Bureau of Nutritional Sciences (FD)
BPA	Bisphenol A
BPIIGA	Bureau of Policy, International, Interagency and Governmental Affairs (FD)
CCHS	Canadian Community Health Survey
CEPR	Centre for Emergency Preparedness and Response (Public Health Agency of Canada)
CFEZID	Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (IDPC)
CFIA	Canadian Food Inspection Agency
CFS	Committee on Food Safety
CFSAN	Center for Food Safety and Applied Nutrition (USFDA)
CIHR	Canadian Institutes of Health Research
CIPARS	Canadian Integrated Program for Antimicrobial Resistance Surveillance
CMP	Chemicals Management Plan
CNF	Canadian Nutrient File
CNPHI	Canadian Network for Public Health Intelligence
Codex	Codex Alimentarius Commission
CPD	Community Programs Directorate (FNIHB)
DFATD	Department of Foreign Affairs, Trade and Development
DG	Director General
DM	Deputy Minister
DON	Deoxynivalenol
DPR	Departmental Performance Report
DRI	Dietary Reference Intake
DV	Daily Value
E. coli	Escherichia coli
EC	Environment Canada
ECCB	Exclusive Capturable Commercial Benefit
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EHRD	Environmental Health Research Division (PHCPHD)
EU	European Union
F&DA	Food and Drugs Act
F&DR	Food and Drug Regulations

F/P/T	Federal/Provincial/Territorial
FAO	Food and Agriculture Organization of the United Nations
FCSAP	Food and Consumer Safety Action Plan
FD	Food Directorate (HPFB)
FEAC	Food Expert Advisory Committee
FERG	Foodborne Disease Burden Epidemiology Reference Group (WHO)
FIORP	Canada Foodborne Illness Outbreak Response Protocol
FNFNES	First Nations, Food, Nutrition and Environment Study
FNIHB	First Nations and Inuit Health Branch (Health Canada)
FPTFSC	F/P/T Food Safety Committee
FPTGN	F/P/T Group on Nutrition
FSA	Food Safety Assessment
FSANZ	Food Standards Australia New Zealand
FSAP	Food Safety Assessment Program
FSNQ	Food Safety and Nutrition Quality
FSNQP	Food Safety and Nutrition Quality Program
FTE	Full Time Equivalent
FY	Fiscal Year
GFN	Global Foodborne Infections Network
GM	Genetically Modified
GPHIN	Global Public Health Intelligence Network
HECSB	Healthy Environments and Consumer Safety Branch (Health Canada)
HPB	Health Protection Branch (Health Canada)
HPFB	Health Products and Food Branch (Health Canada)
HRA	Health Risk Assessment
IAPSD	Interprofessional Advisory and Program Support Directorate (FNIHB)
IDC/CODEX	Interdepartmental Committee on the Codex Alimentarius (Health Canada)
IDPC	Infectious Disease Prevention and Control (Public Health Agency of Canada)
IMA	Interim Marketing Authorization
IO	Internal Order number
IT	Information Technology
IYH	It's Your Health
JECFA	Joint FAO/WHO Expert Committee on Food Additives
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
LFZ	Laboratory for Foodborne Zoonoses (IDPC)
LONO	Letter Of No Objection
LRS	Canadian Listeriosis Reference Service
ML	Maximum Level
MMC	Microbiological Methods Committee
MoU	Memorandum of Understanding
MRL	Maximum Residue Limit
MRRS	Management, Resources and Results Structure
NAFTA	North American Free Trade Agreement
NCP	Northern Contaminants Program
NESP	National Enteric Surveillance Program
NGO	Non-Governmental Organization

NHP	Natural Health Product
NML	National Microbiology Laboratory (IDPC)
OCAPI	Office of Consumer and Public Involvement (HPFB)
OECD	Organisation for Economic Co-operation and Development
OIE	Office International des Epizooties (World Organisation for Animal Health)
ONPP	Office of Nutrition Policy and Promotion (HPFB)
P/T	Provincial/Territorial
PAA	Program Alignment Architecture
PCPA	Pest Control Products Act
PHCPHD	Primary Health Care and Public Health Directorate (FNIHB)
PMRA	Pest Management Regulatory Agency
PMRS	Program Management Reporting System
PPIAD	Policy, Planning and International Affairs Directorate (HPFB)
QUAD	Quadrilateral countries (Australia, Canada, New Zealand and US)
RAPB	Regions and Programs Bureau (Health Canada)
RTE	Ready-to-Eat
RPP	Report on Plans and Priorities
SCDH	Special Committee of Deputy Heads
SOP	Standard Operating Procedure
StatCan	Statistics Canada
TFTF	Trans Fat Task Force
TMAL	Temporary Marketing Authorization Letter
UK	United Kingdom of Great Britain and Northern Ireland
UKDEFRA	UK Department for Environment, Food and Rural Affairs
UKFSA	UK Food Standards Agency
UKHSE	UK Health and Safety Executive
UL	Upper Limit
US	United States of America
USCDC	US Centers for Disease Control and Prevention
USEPA	US Environmental Protection Agency
USFDA	US Food and Drug Administration
VDD	Veterinary Drugs Directorate (HPFB)
WG	Working Group
WHO	World Health Organization
WTO	World Trade Organization

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## Executive Summary

This evaluation covered the Food Safety and Nutrition Quality Program (FSNQP) for the period from 1999 to 2012. The evaluation was undertaken in fulfillment of the requirements of the Treasury Board of Canada's *Policy on Evaluation (2009)*.

### Evaluation Purpose and Scope

The purpose of the evaluation was to assess the relevance and performance of the FSNQP. The evaluation was also designed to highlight accomplishments and lessons learned as well as challenges experienced by the Program.

The evaluation covers all of the activities of Health Canada's Food Directorate (FD), the Bureau of Food Safety Assessment, and regional offices and laboratories as well as the incrementally funded activities of the First Nations and Inuit Health Branch, the Pest Management Regulatory Agency (PMRA) and the Public Health Agency of Canada, namely nutrition and food security related activities, surveillance and risk analysis pertaining to the chemical safety of traditional foods, and health promotion activities focussed on the prevention of enteric disease outbreaks in First Nations communities; the re-evaluation of technical active ingredients as well as active ingredients in end-use products registered prior to December 31<sup>st</sup>, 1994; and, enteric disease surveillance, targeted investigations, laboratory services, information management of food safety issues, and foodborne illness outbreak investigation and response. The evaluation does not cover activities associated with the Biotechnology, Bovine Spongiform Encephalopathy and Healthy Living initiatives, the activities of Health Canada's Office of Nutrition Policy and Promotion and the Veterinary Drugs Directorate, and enforcement and compliance activities carried out by the Canadian Food Inspection Agency (CFIA).

### Program Description

The Program's mandate derives from the *Food and Drugs Act (F&DA)*, the *Food and Drug Regulations*, the *Department of Health Act*, the *Pest Control Products Act*, the *Public Health Agency of Canada Act*, and the *Canadian Food Inspection Agency Act*. The Program carries out activities aimed at preserving and promoting the health of Canadians, which include conducting assessments of food industry submissions; developing, updating and disseminating policies, guidelines, regulations, standards, strategies, and consumer information; conducting health risk and benefit assessments to manage food safety incidents and assessing the effectiveness of CFIA activities related to food safety;<sup>i</sup> conducting surveillance and monitoring; conducting applied scientific research and method development to support food and nutrition policy decision-making; and, coordinating priorities and risk management approaches within Canada's food safety system.

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<sup>i</sup> As of October 2013, CFIA has joined the Health Portfolio. A recent Order in Council has designated the Minister of Health as the appropriate Minister with respect to CFIA for the purposes of the Financial Administration Act.

## CONCLUSIONS - RELEVANCE

### Continued need

#### **The Program continues to address a demonstrable need.**

Program activities are designed to address known and emerging FSNQ issues. On-going scientific developments, market changes, and evolving consumer preferences, will continue to present challenges, which the Program is in the best position to address. Its legislative framework has been under pressure over the last decade to become a more integrated and flexible tool that can allow the Program to better operate internally and more quickly react to evolving scientific and market needs.

### Alignment with Government Priorities

#### **The Program is aligned with government priorities.**

Speeches from the Throne over the years have recognized the importance of FSNQ and identified federal priorities aimed at strengthening Canada's food safety system and ensuring nutrition quality. The Program seeks to address these federal priorities through an inclusive approach reflected in relevant Program planning documents. Program objectives are aligned with relevant strategic outcomes from Health Canada and the Public Health Agency of Canada.

### Alignment with Federal Roles and Responsibilities

#### **The Program is aligned with federal roles and responsibilities.**

The Program operates within a legislative framework designed to address priorities through policy development and standard setting, health promotion activities, risk and disease prevention, disease investigation, research and monitoring as well as national and international cooperation. Relevant Acts identify roles and responsibilities that enable key Program participants to operate within the established federal parameters. The Program acts as the umbrella under which federal activities related to the FSNQ are managed.

## CONCLUSIONS - PERFORMANCE

### Achievement of Expected Outcomes (Effectiveness)

#### Immediate Outcomes

**While Canadian food safety performance is high, issues of timeliness, in particular with respect to pre-market submission reviews, may be delaying the entry of foods into the market.**



Overall, pre-market submission assessments are not meeting the regulated time standards (61% increase between FY 2007-2008 and 2012-2013) while some volumes (novel food and food additive) declined between FY 2011-2012 and the third quarter of 2012-2013. During this last period, submissions without regulated time standards saw an increase in some volumes (food packaging and food processing aids) and a decrease in others (incidental additive). FD uses a collaborative approach to submission assessment; however, the evaluation identified several issues contributing to the submission review backlog. Among these, outstanding petitioner information as well as timeliness and communications with respect to the submissions review process are of particular concern to industry stakeholders and contribute to delays.

Trend analysis data points to an increase in CFIA requests for technical advice, which combined with existing FD challenges related to Health Risk Assessment (HRA) preparation may put pressure on future performance.

**Changes in awareness and understanding were difficult to assess since the Program does not measure uptake of the information it produces. There are areas where further information or education is needed to improve consumer understanding. Some information delivery mechanisms may not be as effective in relaying information to the intended targets/populations.**

The impact of the Program's products and activities on public awareness and understanding cannot be determined since the Program does not measure or track uptake by audience and time period (with the exception of the Listeria social marketing strategy). A key challenge to understanding impact is a lack of alignment between delivery mechanism and target population preferences. This limited "information tailoring" may negatively impact awareness and understanding by reducing communication effectiveness and contributing to uneven public awareness and understanding. Areas requiring further information/education include food safety, nutrition and healthy eating, nutrition labelling, trans fats, and genetically modified foods.

**The Program actively engages in international standard development. Its scientific and regulatory research has made important contributions to the international community.**

The Program is active in international collaboration. The Program's contributions to the development of international standards are widely recognized. Most international work is conducted through Codex Alimentarius. The Program is also involved in activities with other international organizations (e.g., the World Health Organization) and has played a leading role in the creation of the International Food Chemical Safety and Microbial Food Safety Liaison Groups.

**There are some examples of knowledge development by the Program such as research for the enhancement of methods of analysis and testing as well as the development of guidelines and standards. The Program uses this improved knowledge to support regulatory and policy development as well as collaborative work.**

Knowledge development by the Program is exemplified through method development and validation. There are guidelines, standards, frameworks and policies in high priority areas that have been impacted or developed due to advancement in scientific and regulatory research. There are concerns related to the need for increased laboratory capacity to satisfy current and emerging demands, to remain abreast of scientific advances, and to increase internal expertise in a number of fields (e.g., biostatistics, epidemiology, electro-microscopy, bioinformatics, etc.).

**The Program coordinates priorities and risk management approaches within Canada's FSNQ system and contributes to improved collaboration with partners and stakeholders. There are some issues to be addressed with respect to communications and procedures related to Food Safety Assessments (FSAs) and HRAs.**

The Program engages in coordination and collaboration through committees and initiatives that include key Program participants, partners and stakeholders. While Health Canada has enhanced the efficiency and reliability of its HRA process to respond to CFIA requests, there are some opportunities to enhance communications and information exchange between Health Canada and CFIA. In the case of FSAs, Health Canada/CFIA collaboration has experienced a number of procedural, planning and operational challenges. A number of events, including the change in the reporting relationship of CFIA to the Minister of Health and the discontinuation of the FSAP Advisory Committee, are also likely to have an impact on the conduct of FSAs

### **Intermediate Outcomes**

**While it is not known if consumers have made healthier food choices as a result of Program efforts, evidence points to issues of concern related to the dietary intake of the general population and of First Nations and Inuit communities.**

Consumer choices suggest high calorie intake from fat and snacks, vegetable and fruit consumption below the recommended daily minimum, a tendency towards fast food and commercially prepared food consumption, and sodium intakes in excess of the Upper Limit. In the case of First Nations on-reserve and Inuit communities, sodium intakes exceed recommended limits and the consumption of certain food groups is below recommended levels; some food decisions may be affected by food insecurity and its influencing factors, including environmental changes, poverty and high food costs. Data on the success of food labels is inconsistent.

**The number of cases of reported enteric diseases appears to have declined over the past decade, while compliance rates for chemical residue testing have remained overall high. While the change in exposure to nutritional risks could not be ascertained, some Program initiatives appear to be contributing to risk reduction in certain areas.**

The number of cases of reported enteric diseases appears to have declined over the past decade (by 48% according to C-EnterNet data and by 42% according to Notifiable Diseases Online), while compliance rates for chemical residue testing have remained overall high (at or above 95%). Program initiatives, such as awareness campaigns, efforts on trans fat reduction and food fortification, have, in theory, effected changes in the exposure to certain nutritional benefits.

**While it was not possible to identify a change in the level of adoption, there is evidence of adherence by Canada to international standards. Other countries' membership in international standard setting organizations denotes an interest in harmonization.**

There is evidence of Canadian adherence to international standards. Some delays in adhering to these standards have been linked to lengthy regulatory approval processes (e.g., approval of asparaginase as a food additive) or to concerns with international approaches that may not reflect the Program's position.

**The Program seeks a more integrated approach to Federal/Provincial/Territorial (F/P/T) food safety and nutrition priorities and activities by collaborating with F/P/T partners and stakeholders.**

The Program actively collaborates with key Program participants, partners, and stakeholders by exchanging information, fostering dialogue, consulting, and coordinating priorities and risk management approaches. More structured stakeholder communications and improved transparency regarding Program activities are needed (e.g., to clarify roles and responsibilities between the Program and its P/T partners).

### **Long-Term Outcomes**

**According to available evidence, the nutritional status of Canadians does not appear to have improved over the period of the evaluation.**

Among the general population, there are a number of concerns related to high energy intake, high fat intake, nutrient insufficiency, sodium intakes associated with an increased risk of adverse health effects, and rising Body Mass Index. While information on First Nations on-reserve and Inuit communities has been limited, evidence points to low intake of some important vitamins and minerals, high sodium intakes and obesity prevalence.

**Food-related illnesses appear to have decreased over the past decade. Nutrition-related illnesses among the general Canadian population appear to have increased during the same period. The rates of diabetes among First Nations on-reserve are higher than those of the overall Canadian population but seem not to have increased for the last several years (high blood pressure rates have also remained relatively stable). Rates of diabetes and high blood pressure among Inuit populations approach those of the overall Canadian population.**

The number of cases of reported enteric diseases appears to have declined over the past decade, while compliance rates for chemical residue testing have remained overall high. The rates of hypertension, diabetes and heart disease among the general population, three chronic conditions related to nutrition, have increased over the last decade. For First Nations on-reserve, the rates of diabetes are high compared to the overall Canadian population, although these do not appear to have increased for the last several years (similar to high blood pressure rates). Rates of diabetes and high blood pressure among Inuit populations approach those of the overall Canadian population.

**The Program contributes to safer food products in international trade. Adoption of international standards by other countries is expected to contribute to international food safety.**

The Program is engaged with international regulatory partners and participates in international fora as part of efforts to standardize, harmonize and increase food safety. Adoption of international standards by other countries is expected to contribute to maintaining and improving food safety.

**Through the activities/contribution of the Program, Canada is viewed as a responsible participant and scientific expert in an international context.**

The Program's expertise and contribution to the international community are recognized through its involvement in standard development, as a host of international collaborating centres and laboratories, and as a partner in international capacity development.

**The Program seeks to maintain an integrated system for FSNQ in Canada through consultation and collaboration with partners and stakeholders. There are challenges to the responsiveness of the regulatory framework, which recent legislative amendments and Program strategic plans are expected to address.**

The Program's approach to consultation and collaboration seeks to engage all partners and stakeholders and is expected to continue to enhance system integration. Government Directives are in place to guarantee a consultative, coordinated and cooperative approach to regulatory development. The level of responsiveness of the regulatory framework, while challenged, may be improved by recent amendments to the F&DA (e.g., Incorporation by Reference).

### **Demonstration of Economy and Efficiency**

**Program performance and financial information was insufficient to properly demonstrate efficiency and economy.**

Financial data available for the evaluation was insufficient to support an analysis of efficiency and economy. As a result, the evaluation could not assess the extent to which Program resources were used as planned, whether Program outputs were produced efficiently, or whether expected outcomes were produced economically. The collection of performance data does not appear to be consistent or follow a Program approach to its analysis; there are a variety of measures and formats used and efforts tend to focus on tracking mainly Program outputs. There are a number of Program areas where process performance may be affecting efficiency (e.g., the pre-market submission assessment process, the HRA process and its infrastructure, stakeholder communication effectiveness, laboratory research capacity, the FSA process, and regulatory modernization). The Program makes limited use of public-private partnerships and outsourcing while it lacks a cost recovery framework to better manage the costs of its pre-market processes.

## RECOMMENDATIONS

### **Recommendation 1. FD should examine options to enhance the efficiency and transparency of its food pre-market submission activities.**

Overall, pre-market submission assessments are not meeting the regulated time standards (61% increase between FY 2007-2008 and 2012-2013) while some volumes (novel food and food additive) declined between FY 2011-2012 and the third quarter of 2012-2013. During this last period, submissions without regulated time standards saw an increase in some volumes (food packaging and food processing aids) and a decrease in others (incidental additive). FD uses a collaborative approach to submission assessment; however, the evaluation identified several issues contributing to the submission review backlog. Among these, outstanding petitioner information as well as timeliness and communications with respect to the submissions review process are of particular concern to industry stakeholders and contribute to delays.

### **Recommendation 2. FD should examine and improve its HRA tracking processes.**

Trend analysis data points to an increase in CFIA requests for technical advice, which combined with existing FD challenges related to HRA preparation may put pressure on future performance.

### **Recommendation 3. Health Canada should conduct impact assessments of its public outreach initiatives to determine uptake.**

The impact of the Program's products and activities on public awareness and understanding cannot be determined as uptake by audience and time period is not measured. A key challenge to understanding impact is a lack of alignment between delivery mechanism and target population preferences.

### **Recommendation 4. Health Canada should develop a coordinated Program approach to performance measurement with a Health Portfolio perspective.**

The collection of performance data does not appear to be consistent or follow a Program approach to its analysis; there are a variety of measures and formats used and efforts tend to focus on tracking mainly Program outputs.

# Management Response and Action Plan

## Evaluation of the Food Safety and Nutrition Quality Program 1999-2000 to 2011-2012

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability
1. FD should examine options to enhance the efficiency and transparency of its food pre-market submission activities.	Agree	<p>The FD conducts mandatory pre-market submission reviews for infant formula, food additives and novel foods, as well as pre-market evaluations for other products (e.g. functional food, processing aids, packaging materials, etc.) as part of its proactive guidance to industry i.e. on a non- mandatory basis.</p> <p>As part of the effort to reduce the backlog of submissions that were past the performance standard for review, the following actions were taken:</p> <ul style="list-style-type: none"> <li>Established targets to reduce the backlog by 75% by September 2014</li> <li>Clearly and transparently informed industry of a new policy for mandatory pre-market submissions with outstanding deficiencies that have been awaiting response from petitioners for over 6 months to manage the predictability of the pre-market submission process.</li> <li>Clearly stating criteria for which petitioners could keep their file active as well as criteria by which the FD would close the file. The 30 day Deficiency Response Initiative for Food Additive, Infant Formula and Novel Food Submissions has been implemented.</li> <li>A real-time workflow monitoring of pre-market reviews would facilitate transparency to petitioners by providing instantaneous information about the status of a review and consequently add predictability to the process, by identifying the time remaining for completing the review within the performance standards. The FD completed a business requirement document for a submission management database proposal and received support through the Department's Investment Plan process (IP 106). It is expected that this system would evolve towards a web enabled database providing petitioners with real time updates on their submission processing.</li> </ul> <p>HC supported legislative amendments of the Food and Drugs Act and subsequent regulatory amendments to enable a faster process for</p>	1. Submission management database implemented (IP 106A)	September 2014	FD
			2. Updated guidance to industry on preparation of food additives as a result of modernized additives framework.	September 2014	FD
			3. Publication of an enhanced transparency regulatory framework that covers food premarket decisions, in alignment withz the HC transparency framework.	December 2014	FD
			4. 75% of the food pre-market submission backlog eliminated.	October 2014	FD
			5. Service Standards for scientific assessment of mandatory food premarket reviews established.	December 2014	FD

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability
		<p>regulatory approval of food additives in Canada. This process reduces the timelines of regulatory handling from over 18 months to about 3-4 months (<a href="http://www.hc-sc.gc.ca/fn-an/securit/addit/list/index-eng.php">http://www.hc-sc.gc.ca/fn-an/securit/addit/list/index-eng.php</a>).</p> <p>As part of on-going program improvements, HC will proceed with subsequent updates to Division 16 of the Food and Drugs Act pertaining to food additives, and will issue an updated guidance document for industries on the preparation of food additives under the modernized regime.</p> <p>The FD will also leverage advice provided by its Food Expert Advisory Committee to engage stakeholders on and launch an 'enhanced transparency framework for food regulatory decisions'. The framework will encompass actions specific to food pre-market activities and will include measures such as the systematic publication and engagement on outcomes of the scientific assessment underpinning HC's food premarket approvals as well as systematic publication of the list of premarket submissions made to HC's Food Directorate upon concurrence of petitioners.</p>			
2. FD should examine and improve its HRA tracking processes.	Agree	<p>The FD has been conducting 100% of the HRAs at CFIA's request within time standards over the past 3 years.</p> <p>The FD will work with IM/IT on IT infrastructure issues as per established IM/IT processes.</p>	6. Develop a Business Requirements document in alignment with IM/IT processes to support an IT enabled HRA tracking tool which will be submitted for departmental approval.	December 2014	FD
3. Health Canada should conduct impact assessments of its public outreach initiatives to determine	Agree	<p>Health Canada has developed an evaluation framework in 2010 to evaluate the Nutrition Facts Education Campaign (2010-2013). The evaluation will measure the effectiveness of the campaign, including a change in Canadians' awareness, knowledge and use of % Daily Value in the Nutrition Facts table, the collaboration process for working with partners, and the design and implementation of the NFEC activities.</p>	7. Report. This information will enable improvements to the campaign and inform further campaigns.	April 2014	ONPP
		<p>Health Canada developed an Evaluation Framework in 2012 to guide the evaluation and monitoring of healthy eating awareness and</p>	8. Report. This information will enable improvements to the	April 2015	ONPP

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability
uptake.		education initiatives (2012 onwards). The effectiveness of the Eat Well Campaign on food skills, including increase in awareness, understanding and knowledge of Canadians, will be measured.	campaign and inform further campaigns.		
		Health Canada will complete an outcome assessment of Eating Well with Canada's Food Guide – First Nations, Inuit and Métis.	9. Report. This information will allow FNIHB to better understand who is using the food guide, how it is being used, and how it is being integrated into policies and programs.	September 2014	FNIHB
4. Health Canada should develop a coordinated Program approach to performance measurement with a Health Portfolio perspective.	Agree	Health Canada is member of the interdepartmental working group on food system performance led by CFIA and includes the PHAC, and AAFC as an observer. The objective of the working group is the development of a Health Portfolio System Results Model with associated performance measures. This group was convened on February 26, 2014.	10. Common performance indicators will be developed by the interdepartmental working group for review by the ADM Committee on Food Safety.	June 2014	FD
		The FD is working with the University of Guelph to update a study on performance of food safety systems, including the Canadian food standard setting system, as a follow-up to a 2010 study publication.	11. Funding to support a study update on performance of food safety systems including the Canadian food standard setting system.	April 2014	FD



## 1.0 Evaluation Purpose

The purpose of the evaluation was to assess the relevance and performance of the Food Safety and Nutrition Quality (FSNQ) Program (henceforth referred to as FSNQP or the Program) for the period of 1999 to 2012. The evaluation was also designed to highlight accomplishments and lessons learned as well as challenges experienced by the Program.

The evaluation was required by the Treasury Board of Canada's *Policy on Evaluation* (2009)<sup>400</sup> as well as requirements linked to dedicated funding requests.

## 2.0 Program Description

### 2.1 Program Context

To preserve and promote the health of Canadians, the federal Minister of Health is empowered to develop standards, policies and regulations to help ensure the safety and nutritional value of all foods sold in Canada, to promote conditions that enable healthy eating and to provide information to help Canadians in making healthy eating choices. The Program's mandate derives from the *Food and Drugs Act* (F&DA), the *Food and Drug Regulations* (F&DR), the *Department of Health Act*, the *Pest Control Products Act* (PCPA), the *Public Health Agency of Canada Act*, and the *Canadian Food Inspection Agency Act* (CFIA Act). The mandate includes the following key activities:<sup>103,102,79,35,386,106,105,182,485,63,64,357,68,93,402,394,358</sup>

- Conducting assessments (scientific evaluations) of food industry submissions.
- Developing, updating and disseminating policies, guidelines, regulations, standards, strategies, and consumer information. This includes:
  - o providing information to Canadians on healthy eating as well as the risks and benefits associated with food;
  - o promoting food safety practices; and,
  - o representing Canada on international food collaboration and standard setting bodies and contributing to the development of international standards.
- Conducting health risk and benefit assessments to manage food safety incidents and assessing the effectiveness of CFIA activities related to food safety.<sup>ii</sup>
- Conducting surveillance and monitoring. This includes:
  - o contributing to the prevention and control of chronic and infectious diseases through public health surveillance and promotion;
  - o participating in the response to public health events related to food; and,
  - o re-assessing pesticides currently on the market to ensure these meet current scientific standards.
- Conducting applied scientific research and method development to support food and nutrition policy decision-making.

<sup>ii</sup> As of October 2013, CFIA has joined the Health Portfolio. A recent Order in Council has designated the Minister of Health as the appropriate Minister with respect to CFIA for the purposes of the Financial Administration Act.<sup>381</sup>

- Coordinating priorities and risk management approaches within Canada’s food safety system. This includes:
  - o planning and administering food and nutrition surveillance, and monitoring sub-programs to support standard setting; and,
  - o providing advice and assistance to other Federal/Provincial/Territorial (F/P/T) departments/organizations related to food safety and nutrition.

## 2.2 Program Profile

The core activities of the FSNQP rest within the Food Directorate (FD) at the Health Products and Food Branch (HPFB) of Health Canada. The FSNQP also includes relevant activities from the following key Program participants:<sup>iii</sup>

- Health Canada:
  - o HPFB: Bureau of Food Safety Assessment (BFSA),<sup>iv</sup> Policy, Planning and International Affairs Directorate (PPIAD); Office of Nutrition Policy and Promotion (ONPP); and, Veterinary Drugs Directorate (VDD).
  - o Regions and Programs Bureau (RAPB): Regional offices and laboratories.
  - o First Nations and Inuit Health Branch (FNIHB): Community Programs Directorate (CPD) and Primary Health Care and Public Health Directorate (PHCPHD). As a result of the branch’s reorganization in April 2012, these Directorates have merged and have been renamed the Interprofessional Advisory and Program Support Directorate (IAPSD)
  - o Pest Management Regulatory Agency (PMRA).
- Public Health Agency of Canada:<sup>v</sup>
  - o Infectious Disease Prevention and Control (IDPC):<sup>vi</sup> Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (CFEZID), Laboratory for Foodborne Zoonoses (LFZ), and National Microbiology Laboratory (NML).
  - o Health Security Infrastructure: Centre for Emergency Preparedness and Response (CEPR), previously under the Infectious Disease and Emergency Preparedness Branch.
- CFIA.

The activities of these key Program participants contribute to the implementation of the FSNQP in the following manner:<sup>vii</sup>

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<sup>iii</sup> The term “key Program participants” refers to those organizations that carry out the core activities of FSNQP.

<sup>iv</sup> BFSA is no longer part of the Program.,

<sup>v</sup> The Public Health Agency of Canada was established in 2004. Previous to this date, the Health Protection Branch and the Laboratory Centre for Disease Control were the precursors for the Agency’s contribution to the FSNQP.

<sup>vi</sup> Previously the Infections Disease and Emergency Preparedness Branch.

<sup>vii</sup> The relevant activities of each key Program participant are included in this evaluation except for ONPP and VDD. Please refer to **Section 3.1**.

- FD conducts assessments of food industry submissions; develops, updates and disseminates policies, guidelines, regulations, standards, strategies and consumer information to support Canadians in their decisions about food and diet; performs health risk benefit assessments; conducts surveillance and monitoring; conducts research and method development in support of programs; and, coordinates priorities and risk management approaches within Canada's food safety system. In the case of a foodborne illness outbreak in more than one province, FD supports the Public Health Agency of Canada and CFIA as part of the coordinated federal investigation and response by providing Health Risk Assessments (HRAs) to inform decision-making.
- BFSA assessed the effectiveness of CFIA's activities related to food safety. Its objectives were to provide advice and guidance to CFIA on its food safety activities as well as offer feedback to assist Health Canada in carrying out its role of developing food safety and nutrition policies and standards as mandated under Section 11(4) of the CFIA Act.
- ONPP is the focal point for public health nutrition within the federal government and drives the agenda to promote healthy eating amongst Canadians. ONPP works closely with FD and other partners, within and external to the Health Portfolio,<sup>viii</sup> to provide Canadians with consistent, credible, evidence-based policies, guidelines and resources on healthy eating. To this end, ONPP carries out research and monitoring, policy and promotion activities related to public health nutrition.
- VDD conducts pre- and post-market assessments of industry submissions on veterinary drugs, and conducts monitoring and standard setting activities associated with the safety, quality and effectiveness of drugs used in animals. VDD develops standards, policies and regulations concerning the sale of veterinary drugs for use in food-producing animals and the resulting drug residues in foods derived from animals such as meat, milk, eggs and honey. VDD provides assistance to CFIA in managing food safety incidents related to the presence of "violative" [*sic*] veterinary drug residues.
- RAPB is responsible for the regionally based programs and laboratories. Food related laboratories exist in four regions and food policy liaison officers represent the Program in each region through six regional offices.
- FNIHB's IAPSD supports the development and delivery of nutrition-related policies, programs and services for First Nations on-reserve and Inuit communities. IAPSD is also responsible for surveillance and risk analysis pertaining to the chemical safety of traditional foods and health promotion activities focussed on the prevention of enteric disease outbreaks in First Nations communities.
- PMRA is responsible for pest management regulation through the administration of the PCPA. PMRA's primary objective is to prevent unacceptable risks to Canadians and the environment from the use of pest control products; this includes scientific evaluations of food-use pesticides and setting science based Maximum Residue Limits (MRLs) for each pest-crop combination.

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<sup>viii</sup> The Health Portfolio comprises Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research (CIHR), the Hazardous Materials Information Review Commission, the Patented Medicine Prices Review Board, and Assisted Human Reproduction Canada. CFIA has joined the Health Portfolio as of October 2013.

- IDPC, within the Public Health Agency of Canada, is responsible for health risk surveillance and assessment activities. The Public Health Agency of Canada maintains surveillance systems that track foodborne illness pathogens in animals (and their products) and in plant products. The Agency also tracks human illnesses and diet-related chronic diseases, and works in the coordinated management of food-borne illness outbreaks. The Public Health Agency of Canada also undertakes Antimicrobial Resistance (AMR) surveillance activities through the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), which supports VDD's pre- and post-market risk assessment of the use of antimicrobials in food animals. The Public Health Agency of Canada also conducts epidemiological and laboratory-based research. In the case of a foodborne illness outbreak in more than one province, the Public Health Agency of Canada is the lead that coordinates F/P/T investigation and response supported by CFIA and FD.
- CFIA enforces policies, regulations and standards, set by Health Canada, governing the safety and nutritional quality of all food sold in Canada through activities that include the registration and inspection of abattoirs and food processing plants as well as the testing of products. If a food safety event occurs, CFIA, in partnership with Health Canada, provincial agencies and the food industry, operates an emergency response system. In the case of a foodborne illness outbreak in more than one province, CFIA supports FD and the Public Health Agency of Canada as part of the coordinated F/P/T response by conducting the food safety investigation led by the Public Health Agency of Canada.

The FSNQP also collaborates with a wide range of partners and stakeholders (see 0), including other Health Canada branches and offices, other government departments, Provincial/Territorial (P/T) governments, Non-Governmental Organizations (NGOs), and several international organizations such as the World Health Organization (WHO), the Food Agriculture Organization of the United Nations (FAO), the Codex Alimentarius Commission (Codex).

The Program operates through the activities implemented by these key Program participants with FD as the lead. There is no umbrella governance body for the Program as a whole; however, there are a number of committees where key Program participants collaborate (see immediate outcome # 5).

## 2.3 Program Logic Model and Narrative

The ultimate outcome for the Program is to maintain and improve the health of Canadians.

Program activity areas (regulatory/policy development and communications, pre-market submission assessments, health risk and benefit assessments, surveillance and monitoring, research, and priority/risk management coordination) produce outputs (e.g., regulations, guidance, regulatory decisions/opinions, methods and national strategies) that have an intended reach (e.g., industry, consumers, health professionals, regulators/other federal government departments, F/P/T organizations and international organizations). The successful implementation of these processes leads the Program towards the achievement of its immediate, intermediate and long-term outcomes, namely:

- Immediate outcomes:
  - o Increased availability of safe and nutritious foods for Canadians.
  - o Increased awareness and understanding of food safety- and nutrition-related risks and health benefits.
  - o Enhanced contribution to international standards that are supported by scientific evidence.
  - o Improved knowledge and its use to support policies, guidelines, standards, regulations, strategies, CFIA inspections and assessments.
  - o Improved collaboration with F/P/T partners and stakeholders.
- Intermediate outcomes:
  - o Healthier food choices made by consumers.
  - o Reduced exposure to microbial, chemical and physical hazards and nutritional risks.
  - o Increased adoption of international standards by Canada and other countries.
  - o More integrated approach to F/P/T food safety and nutrition priorities and activities.
- Long-term outcomes:
  - o Improved nutritional status of Canadians.
  - o Reduced food- and nutrition-related illnesses.
  - o Safer food products in international trade.
  - o Canada viewed as a responsible participant and scientific expert in an international context.
  - o A sustainable and integrated system for FSNQ in Canada.

The achievement of these outcomes (from Program efforts to establish a safe and knowledgeable environment where collaboration and information exchange are key, to improved decision-making and reduced risks as a result of integration and harmonization efforts, to reduced risks and sustainability) then allow the Program to meet its ultimate outcome. The connection between these activity areas and the expected outcomes is described in the logic model in **Section 2.3.1**. The evaluation assessed the degree to which the defined outputs and outcomes were being achieved over the evaluation timeframe.

### 2.3.1 Description of the logic model<sup>ix</sup>

The FSNQP uses the following resources (inputs) to deliver its activities, produce outputs and accomplish its outcomes: funding; human resources; facilities, infrastructure; Acts, regulations, policies and priorities; Memoranda of Understanding; and, administrative support.

The FSNQP consists of six main activities delivered by the Program partners, namely:

- Assessments of food industry submissions.

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<sup>ix</sup> To obtain a copy of the Logic Model graphic please use the following e-mail “Evaluation Reports HC - Rappports Evaluation@hc-sc.gc.ca”.

- Development, update and dissemination of policies, guidelines, regulations, standards, strategies and consumer information.
- Health risk and benefit assessments and evaluations of CFIA activities.
- Surveillance and monitoring.
- Research and method development in support of programs.
- Coordination of priorities and risk management approaches within Canada's food safety system.

It should be noted that there is a strong interaction between health risk and benefit assessments and evaluations of CFIA activities, surveillance and monitoring, and research and method development activities in support of programs.

These activities are targeted at different groups, namely:

- Assessments of food industry submissions:
  - Industry; consumers; and, animal health professionals.
- Development, update and dissemination of policies, guidelines, regulations, standards, strategies and consumer information:
  - Industry, international organizations; media; health professionals; F/P/T partners/stakeholders, CFIA; consumers; and, Health Canada regulators.
- Health risk and benefit assessments and evaluations of CFIA activities:
  - CFIA; F/P/T partners/stakeholders; international organizations; other Health Canada branches; and, industry/producers.
- Surveillance and monitoring:
  - CFIA; F/P/T partners/stakeholders, CIHR; health professionals; Statistics Canada; and, international organizations.
- Research and method development in support of programs:
  - CFIA; academia; industry; F/P/T partners/stakeholders; CIHR, international organizations; and, Health Canada regulators.
- Coordination of priorities and risk management approaches within Canada's food safety system:
  - CFIA; F/P/T partners/stakeholders; consumers; industry; and, Agriculture and Agri-Food Canada.

As a result of each activity, the Program generates a number of products and/or services, namely:

- Assessments of food industry submissions:
  - Decisions (approvals/rejections); and, communications.
- Development, update and dissemination of policies, guidelines, regulations, standards, strategies and consumer information:
  - Guidelines; policies, regulations; regulatory amendments; standards; strategies; and, consumer information.
- Health risk and benefit assessments and evaluations of CFIA activities:
  - Assessment reports; decisions; advice and guidance; and, feedback to Health Canada.
- Surveillance and monitoring:

- o Reports; information/advice; data; and, strategies/protocols.
- Research and method development in support of programs:
  - o Publications; expert advice; data; trend analysis; and, published methods.
- Coordination of priorities and risk management approaches within Canada's food safety system:
  - o Reports, national strategies, guidelines and common initiatives.

The implementation of the activities identified above corresponds with specific immediate, intermediate and long-term outcomes. In the immediate term, health risks and benefit assessments and evaluations of CFIA activities together with surveillance and monitoring as well as research and method development in support of programs are expected to lead to improved knowledge and its use to support policies, guidelines, standards, regulations, strategies, CFIA inspections and assessments. This latter outcome in combination with the development, update and dissemination of policies, guidelines, regulations, standards, strategies and consumer information are expected to enhance the Program's contribution to standards that are supported by scientific evidence. The development, update and dissemination of policies, guidelines, regulations, standards, strategies and consumer information is also expected to lead to increased awareness and understanding of food safety- and nutrition-related risks and health benefits, which in combination with assessments of food industry submissions are expected to lead to increased availability of safe and nutritious foods for Canadians. The coordination of priorities and risk management approaches with Canada's food safety system is expected to lead to improved collaboration with F/P/T partners and stakeholders.

The achievement of these immediate outcomes is expected to lead to the achievement of intermediate outcomes. In this manner, increased availability of safe and nutritious food for Canadians together with improved knowledge and its use to support policies, guidelines, standards, regulations, strategies, CFIA inspections and assessments as well as increased awareness and understanding of food safety- and nutrition-related risks and health benefits are expected to lead to a reduced exposure to microbial, chemical and physical hazards and nutritional risks. Increased awareness and understanding of food safety- and nutrition-related risks and health benefits is also expected to lead to healthier food choices made by consumers. The Program's enhanced contribution to international standards that are supported by scientific evidence is expected to lead to increased adoption of international standards by Canada and other countries. Improved collaboration with F/P/T partners and stakeholders is expected to lead to a more integrated approach to F/P/T food safety and nutrition priorities and activities.

In the long term, intermediate outcomes of healthier food choices made by consumers and a reduced exposure to microbial, chemical and physical hazards and nutritional risks are expected to contribute to the improved nutritional status of Canadians and to a reduction in food- and nutrition-related illnesses. The increased adoption of international standards by Canada and other countries is expected to contribute to safer food products in international trade and to Canada's image as a responsible participant and scientific expert in an international context. Finally, a more integrated approach to F/P/T food safety and nutrition priorities is expected to contribute to a sustainable and integrated system for food safety and nutrition quality in Canada.

The ultimate outcome of the Program is to help ensure that the health of Canadians is maintained and improved.

## 2.4 Program Alignment and Resources

The Program forms part of two Program Alignment Architectures<sup>x</sup> (PAAs) and contributes to the attainment of several strategic outcomes. The Program contributes to Health Canada’s strategic outcomes “Canadians are informed of and protected from health risks associated with food, products, substances and environments, and are informed of the benefits of healthy eating” and “First Nations and Inuit communities and individuals receive health services and benefits that are responsive to their needs so as to improve their health status” under the following PAA programs and sub-programs:<sup>224</sup>

- 2.2 Food safety and nutrition:
  - o 2.2.1 Food safety; and,
  - o 2.2.2 Nutrition and healthy eating.
- 2.7 Pesticide safety.
- 3.1 First Nations and Inuit primary health care:
  - o 3.1.1 First Nations and Inuit health promotion and disease prevention; and,
  - o 3.1.2 First Nations and Inuit public health protection.

The Program also contributes to the Public Health Agency of Canada’s strategic outcome “Canada is able to promote health, reduce health inequalities, and prevent and mitigate disease and injury” under the following PAA programs and sub-programs:<sup>411</sup>

- 1.1 Science and technology for Public Health
- 1.2 Surveillance and population health assessment
  - o 1.2.1 Public health surveillance
  - o 1.2.2 Population health assessment
- 1.3 Public health preparedness and capacity
  - o 1.3.2 Preparedness
- 1.5 Disease and injury prevention and mitigation
  - o 1.5.3 Infection disease prevention and control
- 1.6 Regulatory enforcement and emergency response
  - o 1.6.2 Emergency operations

For financial data on the Program spanning the years 1999 through 2012 please refer to **Section 4.5**.

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<sup>x</sup> Previously known as Program Activity Architecture, the PAA reflects how organizations are structured and how accountabilities are managed; it also defines how Programs contribute to Strategic Outcomes.



## 3.0 Evaluation Description

### 3.1 Evaluation Scope and Issues

The scope of the evaluation covers the period from April 1<sup>st</sup>, 1999 to March 31<sup>st</sup>, 2012; while mostly data generated during these years was used to address the core issues, data from other years (i.e., previous to 1999 and more recent 2013 data) was also considered when deemed relevant.<sup>xi</sup>

The evaluation covers all of the activities of FD, BFSA and regional offices and laboratories (see **Section 2.2**) as well as the incrementally funded activities of FNIHB, PMRA and the Public Health Agency of Canada, namely:

- FNIHB: nutrition and food security related activities (including the Food Mail Pilot Projects, which were partially funded by the Program until 2006-2007), surveillance and risk analysis pertaining to the chemical safety of traditional foods, and health promotion activities focussed on the prevention of enteric disease outbreaks in First Nations communities.
- PMRA: re-evaluation of technical active ingredients as well as active ingredients in end-use products registered prior to December 31<sup>st</sup>, 1994.
- Public Health Agency of Canada: enteric disease<sup>xii</sup> surveillance, targeted investigations, laboratory services, information management of food safety issues, and foodborne illness outbreak investigation and response.<sup>xiii</sup>

The evaluation does not cover the following:

- activities associated with the Biotechnology, Bovine Spongiform Encephalopathy and Healthy Living initiatives as they have been assessed under separate evaluations;
- activities of ONPP and VDD as they have been addressed under separate evaluations; and,
- enforcement and compliance activities carried out by CFIA as they did not reside within the Health Portfolio during the period of the evaluation.

<sup>xi</sup> While the evaluation was originally designed to cover the period from April 1st, 1999 to March 31st, 2008, the scope was extended to cover additional areas and accommodate requests from key Program participants

<sup>xii</sup> Infectious enteric disease refers to gastrointestinal illnesses that result from ingesting bacteria, viruses or other parasitic micro-organisms (e.g., Salmonella, E. coli, Listeria and Giardia), which may be traced back to food, water, animals or an infected person.<sup>52</sup>

<sup>xiii</sup> Incremental funding was received in 1999 by what was then the Laboratory Centre for Disease Control to implement an enhanced surveillance capacity for foodborne disease and a limited surveillance capacity for zoonotic diseases transmitted by food. These activities were transferred to IDPC with the creation of the Public Health Agency of Canada. Within the Public Health Agency of Canada, the funding was split equally between CFEZID and NML.

The specific evaluation questions used in this evaluation were based on the five core issues prescribed in the Treasury Board of Canada’s *Directive on the Evaluation Function* (2009).<sup>81</sup> These are noted in **Table 1**.

**Table 1 Core Evaluation Issues and Questions**

Core Issues	Evaluation Questions
<b>Relevance</b>	
Issue #1: Continued Need for Program	Assessment of the extent to which the program continues to address a demonstrable need and is responsive to the needs of Canadians <ul style="list-style-type: none"> <li>• Does the Program continue to address a demonstrable need?</li> <li>• Is the Program responsive to the needs of Canadians?</li> </ul>
Issue #2: Alignment with Government Priorities	Assessment of the linkages between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes <ul style="list-style-type: none"> <li>• Are Program objectives aligned with federal government priorities and departmental strategic outcomes?</li> </ul>
Issue #3: Alignment with Federal Roles and Responsibilities	Assessment of the role and responsibilities for the federal government in delivering the program <ul style="list-style-type: none"> <li>• Is the Program aligned with federal roles and responsibilities?</li> </ul>
<b>Performance (effectiveness, efficiency and economy)</b>	
Issue #4: Achievement of Expected Outcomes (Effectiveness)	Assessment of progress toward expected outcomes (incl. immediate, intermediate and ultimate outcomes) with reference to performance targets and program reach, program design, including the linkage and contribution of outputs to outcomes <ul style="list-style-type: none"> <li>• To what extent have assessments of submissions from industry and HRAs led to an increase in the availability of safe and nutritious foods in Canada?</li> <li>• To what extent has awareness and understanding of food safety risks and nutrition quality benefits increased as a result of Program activities?</li> <li>• To what extent has the Program influenced international standards?</li> <li>• To what extent has the knowledge base (research) and its use improved as a result of Program activities?</li> <li>• To what extent has collaboration with F/P/T partners and stakeholders improved?</li> <li>• To what extent have consumers made healthier food choices based on Program activities?</li> <li>• To what extent has exposure to microbial, chemical and physical hazards and risks been reduced and nutrition benefits been increased?</li> <li>• To what extent have international standards been adopted by Canada and other countries?</li> <li>• To what extent has the Program increased the integration of FSNQ priorities and activities?</li> <li>• To what extent has the nutritional status of Canadians improved based on Program activities?</li> <li>• To what extent have Program activities contributed to the reduction of food- and nutrition-related illnesses?</li> </ul>

Core Issues	Evaluation Questions
	<ul style="list-style-type: none"> <li>• To what extent have Program activities contributed to safer food products in international trade?</li> <li>• To what extent is Canada viewed as an active participant and scientific expert in an international context?</li> <li>• To what extent has the Program contributed to a sustainable and integrated system for FSNQ in Canada?</li> </ul>
Issue #5: Demonstration of Efficiency and Economy	<p>Assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes</p> <ul style="list-style-type: none"> <li>• Have alternate delivery structures been considered as part of Program implementation and delivery?</li> <li>• Has the Program designed and implemented a Performance Measurement Strategy?</li> <li>• Has the budget allocated to the Program and its expenditures been suitable for the Program to achieve its outcomes?</li> </ul>

## 3.2 Evaluation Approach and Design

An outcome-based evaluation approach was used for the conduct of the evaluation to assess the progress made towards the achievement of the expected outcomes, whether there were any unintended consequences and what lessons were learned.

The objectives and requirements specified in the Treasury Board of Canada's *Policy on Evaluation* (2009) guided the identification of the evaluation design and data collection methods. The specific non-experimental design used was based on the *Evaluation Framework for the Food Safety and Nutrition Quality Program – Summative Evaluation*<sup>189</sup> (henceforth referred to as the Evaluation Framework), which detailed the evaluation strategy for this Program and provided consistency in the collection of data to support the evaluation.

An Evaluation Working Group (WG) was established with representation from the Evaluation Directorate, all key Program participants and some partners (e.g., the Office of Consumer And Public Involvement [OCAPI]) to collaboratively develop the Evaluation Framework. This WG remained active during the planning, conduct and reporting phases of the evaluation to ensure continuous Program input and validation of findings by knowledgeable individuals.

## 3.3 Data Collection and Analysis Methods

The evaluation used multiple lines of evidence to increase the reliability and credibility of the evaluation findings. Data collection methods used in this evaluation included (see 0).<sup>xiv</sup>

- Literature review.
- File review.

<sup>xiv</sup> Literature and file review were conducted throughout the period of the evaluation while interviews were conducted between October and December 2009. Although the formal interview process took place in 2009, the evaluators maintained an open communication channel with Program representatives to confirm the validity of the information presented in the report.

- Interviews with key informants, partners and stakeholders (n=152).
- Case studies:
  - o Acrylamide in foods.
  - o Food packaging material assessment.
  - o FSNQ programs in selected countries.
  - o Health Canada's approach to raw milk cheese.<sup>xv</sup>
  - o Health Canada's support for community-based research in regard to mercury contamination in the Grassy Narrows community.
  - o Trans fatty acids.
  - o Health Canada's response to the 2008 Listeriosis outbreak.

Analysis methods used in this evaluation included:

- Content analysis: systematic compilation, review and summarization of data obtained from multiple sources.
- Statistical analysis: basic descriptive statistics of data obtained through file review to analyze distributions and historical trends.
- Case study analysis: review and summarization of data obtained through literature and file review as well as interviews.
- Inductive analysis: review of data obtained from all data collection methods to discover patterns, themes and relationships.
- For the demonstration of economy and efficiency, an allocative approach was attempted as this is a long-established Program that should have achieved long-term outcomes.

The use of these analysis methods allowed for the triangulation of information gathered from multiple lines of evidence in order to compare and contrast data. This approach was implemented according to the phases identified in the original *Summative Evaluation Work Plan*.<sup>91</sup>

### 3.4 Limitations and Mitigation Strategies

Most evaluations face constraints that may have implications on the validity and reliability of evaluation findings and conclusions. The following **Table 2** outlines the limitations in the design and methods for this evaluation. Also noted are the mitigation strategies put in place to ensure that the evaluation findings can be used with confidence to guide Program planning and decision-making.

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<sup>xv</sup> Cheese made from unpasteurized milk, also known as “raw milk cheese.”

**Table 2 Limitations and Mitigation Strategies**

Limitation	Impact	Mitigation Strategy
Although FSNQ activities have involved the collaboration of key Program participants for many years, a logic model for the Program as a whole had never been developed until this evaluation.	All linkages between activities, outputs and outcomes may not have been identified. Indicators identified under each outcome may not be the most appropriate to provide relevant evidence.	The evaluation WG developed a Program logic model that would, to the extent possible, accurately reflect activities, outputs, reach and outcomes.
Sources for the literature review were identified through an environmental scan process that combined expertise from Health Canada’s Science Library staff and that of evaluators. However, the scope was limited and follow up investigative work was minimal due to time and resource limitations.	Information collected to address the indicators identified under each outcome may not have been comprehensive. Some relevant information may not have been identified.	The search criteria used to identify relevant documents was based on a list of key words and terms identified through preliminary research. The key words and terms were used in different combinations through a set of Boolean operations that produced multiple document lists. Each list was further refined through a review process.
Data available for the evaluation did not address all evaluation indicators and, often, was circumstantial. In many cases the data was incomplete or used a multiplicity of reporting formats.	Lack of appropriate data to allow evaluators to accurately address the results of Program initiatives and their contribution to expected outcomes made it difficult to determine if the Program had achieved several of its intermediate and long-term outcomes.	The evaluation WG was engaged to identify relevant indicators and sources of data that would permit, through analysis, an assessment of the achievement of Program outcomes. Multiple sources of evidence were triangulated to increase the robustness of the analysis and seek cohesiveness across reporting formats. Areas where information was deemed insufficient were of particular focus during the interviews and case studies.
The large number of Program partners and stakeholders made it impractical to collect representative information. While valuable, interview data reflected individual opinions/perspectives relevant at the time of the interviews (October to December 2009). Lack of valid contacts, lack of coverage of some groups (i.e., cost-shared managers, health promotion and international stakeholders, in particular the WHO and Codex), and poor response limited the comprehensiveness of the information gathered through this method.	While interview data was mostly used to provide background and context to the findings, in cases when documented evidence was not available the reliance on interview data was higher, thus leading to potential bias.	Evaluators used a stratified purposive sampling <sup>xvi</sup> approach and engaged key Program participants to generate a list of individuals knowledgeable about FSNQP <sup>xvii</sup> across all identified organizations. In this way, although the sample was not representative of the population or produced statistically significant results, the information collected allowed evaluators to delve into areas requiring clarification and to obtain information where documented evidence was insufficient. By triangulating interview information with other sources, the potential for bias was reduced to the extent possible. However, in cases when documented evidence was not available and the analysis relied more heavily on interview information (and, therefore, depended on the high level of knowledge of the individuals interviewed) this fact has been noted in the report.  Although the formal interview process took place in 2009, the evaluators maintained an open communication channel with Program representatives to confirm the validity of the information presented in the report.

<sup>xvi</sup> Purposive sampling is a type of non-probability sampling in which the sample is hand-picked to address areas of interest relevant to the research in question. The sampling can be stratified (e.g., key Program participants, partners and stakeholders) to reflect groups that vary according a key dimension (e.g., level of participation with or contribution to the Program).

Limitation	Impact	Mitigation Strategy
<p>Case study limitations included:</p> <ul style="list-style-type: none"> <li>• Acrylamide in foods – Detailed data on the health impacts of acrylamide (long term toxicology studies) have not been completely elucidated. No international interviews were conducted.</li> <li>• Food packaging material assessment – There was a lack of Health Canada/CFIA performance indicators that could have driven a sound quantitative analysis of performance information. Attempts to schedule interviews with relevant industry associations were unsuccessful (i.e., individuals declined to participate or were unavailable).</li> <li>• FSNQ programs in selected countries – Sources used were the best official public domain information available on the organizations selected for review.<sup>xviii</sup> However, comparisons were restricted by the scope of organizational functions, documentation content (dependent on reporting relationships) and availability of information online. Information and level of detail related to budgets, Full Time Equivalent (FTEs) and resource allocations differed by organization; in some cases, the information was limited to consolidated results (i.e., the organization as a whole as part of a larger body such as a department). No international interviews were conducted.</li> <li>• Health Canada’s approach to raw milk cheese – Information on consumer awareness of the issue was limited.</li> <li>• Trans fatty acids – No international interviews were conducted to assess Canada’s approach and situation versus that of other countries.</li> </ul>	<p>Information collected for analysis may not have been comprehensive. Some relevant information may not have been identified.</p>	<p>Documents collected from key Program participants were supplemented with international reports, when available, related to each of the issues covered by the case studies.</p>
<ul style="list-style-type: none"> <li>• Health Canada’s approach to raw milk cheese – Information on consumer awareness of the issue was limited.</li> <li>• Trans fatty acids – No international interviews were conducted to assess Canada’s approach and situation versus that of other countries.</li> </ul>		
<p>Financial and human resources information was severely limited in its accuracy and scope.</p>	<p>Demonstration of efficiency and economy was limited.</p>	<p>Key Program participants were engaged throughout the evaluation to obtain information and clarify available data. Available information has been presented in the report and analyzed to the extent possible.</p>

<sup>xvii</sup> Key Program participants provided names of individuals that were or had been involved with the Program or were knowledgeable about it as a result of organizational interactions.

<sup>xviii</sup> Although online information was sometimes out of date, this approach was preferred over a combination of other approaches (e.g., interviews) due to financial constraints.

## 4.0 Findings

### 4.1 Relevance: Issue # 1 – Continued Need for the Program

**Does the Program continue to address a demonstrable need? Is the Program responsive to the needs of Canadians?**

**The Program continues to address a demonstrable need. Addressing known and emerging issues related to food production, processing and distribution is a key priority of the Program's activities.**

FSNQ plays an important role in Canadians' health status. The Program, in an effort to maintain and improve this health status, is in a continuous state of evolution to address current and emerging issues, partner and stakeholder perceptions/expectations, and legislative requirements. Addressing known and emerging issues related to food production, processing and distribution is a key priority of the Program's activities. These activities include regulatory development and communication, pre- and post-market assessments, scientific research, surveillance and monitoring, risk analysis, health promotion, disease prevention and control, and coordination of FSNQ initiatives. All of these activities, in combination or singularly, are designed to address relevant Program areas. The following areas of on-going concern demonstrate the need for the Program:

- Traditional microbial (e.g., bacteria such as Salmonella and Listeria monocytogenes [L. monocytogenes]) and chemical food safety hazards (e.g., food-processing-induced chemicals).<sup>356,148,110</sup>
- Emergent and re-emergent pathogens as a result of multiple factors such as food manufacturing processes that may introduce unwanted agents; agricultural processes that may allow for the introduction of food-related pathogens; microbial adaptation/AMR to interventions (e.g., treatment-resistant pathogens, antimicrobial resistant genes); and, globalization of the food supply (e.g., population migration, travel, diverse food safety infrastructure among food producers, etc.).<sup>356</sup>
- New technologies, the determination of their acceptable risk (tolerance), and the development of new detection methodologies, for example: pesticides; heavy metals, growth hormones, antibiotics, fertilizers, Genetically Modified (GM) organisms and their derivatives (e.g., GM foods, transgenic animals and cloning), biotechnology, nanotechnology, irradiation, and additives.<sup>356,337,22,433,174,156,148</sup>
- New use of food as a health delivery agent, for example functional foods (e.g., nutraceuticals) and non-traditional micronutrients (e.g., lycopenes, beta-carotenes and isoflavones).<sup>356,359,15,156</sup>
- By-products from food safety and nutritional quality approaches, their identification and risk assessment, such as:
  - o Undeclared allergens, natural toxins (e.g., mycotoxins in cereals), trans fats, and endocrine disruptors.<sup>174,156,148</sup>

- o Obesity, diabetes, and dietary needs of the general Canadian population as well as vulnerable population groups.
- Unpredictable hazards, e.g., adulterants: melamine, malachite green, Sudan dyes, etc.
- Food security issues in First Nations and Inuit communities, including the potential for higher exposure to environmental chemicals through some traditionally harvested foods.

Other perspectives on Program activities reveal broader areas for continued Program involvement. For example, in the case of the legislative framework, *A review of Canadian food safety policy and its effectiveness in addressing health risks for Canadians* (2002) found that the legislative framework was non-prescriptive, allowing programs to determine its implementation, thus subject to economic, political and other pressures that may lead to conflicting directives. The same review suggested that food safety regulations were having difficulties keeping pace with many of the new developments.<sup>356</sup> Also, a 2011 survey on Canadians' awareness, attitudes and behaviours with respect to food safety (n<sub>1</sub>=1,003, n<sub>2</sub>=1,001, n<sub>focus groups</sub>~36) reported that while 89% of Canadians were at a minimum moderately confident in the food system, there were concerns that it was over-burdened and there was some confusion about how the system works.<sup>343</sup>

In the case of surveillance, concerns over the safety of imported products appear to have been increasing in recent years.<sup>180,181,195,343</sup> Some key Program participants and partners believed that improvements could be made in the level of safety of the non-registered sector and imported foods.

With respect to food safety information, testimony provided in the *Beyond the Listeriosis Crisis Report* (2009) remarked on the weakness of the Canadian food safety system on providing risk communications while suggesting that “the public does not have much knowledge about our food standards and food safety programs and that the government should focus on educating the public.” Further testimony recommended that “communication be harmonized, integrated, and planned between industry and government and urged that on-going investment is required to deliver food safety messaging to consumers” as “campaigns aimed at changing behaviour can take 20 to 30 years to gain significant traction in the marketplace.”<sup>28</sup>

Finally, with respect to nutrition labelling, a 2007 report by the Advisor on Healthy Children & Youth (henceforth referred to as *Reaching for the Top*) identified portion size as a significant contribution to the obesity problem. The same report stated that in “the absence of a Canada-wide system, food companies and health organizations have created their own individual labelling systems which are confusing for consumers.”<sup>344</sup> The Heart Health Strategy and Action Plan Steering Committee report *Building a Heart Healthy Canada* (2009) remarked that while Canada is an international leader in mandatory food labelling on packaged foods, only 61% of women and 52% of men “always or usually” read the nutrition facts panel on product labels, and those who do often find the information confusing. One of the main weaknesses in Canada's nutrition facts panel is that there is no standard serving size.<sup>47</sup> The 2010 report delivered by the Sodium WG commissioned by Health Canada under the title *Sodium Reduction Strategy for Canada* observed that food product labels present challenges to consumers, including interpretation of the % Daily Value (DV) and the specific amount of food presented on labels.<sup>229</sup>



## 4.2 Relevance: Issue # 2 – Alignment with Government Priorities

**Are Program objectives aligned with federal government priorities and departmental strategic outcomes?**

**Federal priorities related to FSNQ include strengthening Canada’s food system to address emerging issues and risk factors thus protecting the health of Canadians, which are in line with Program objectives. Departmental and Agency objectives are aligned with strategic outcomes related to the Program area.**

Speeches from the Throne over the years have recognized the importance of FSNQ by identifying federal priorities related to strengthening Canada’s food safety system, increasing oversight of food, addressing risk factors (including nutrition), and introducing measures to ensure Canadians’ have confidence in the quality and safety of the food on their tables.<sup>122,123,124,125,126,132,128</sup>

The Program seeks to address federal priorities through an inclusive approach, which has as its goal the risk-based identification and prioritization of issues. This approach is reflected in several of the Program’s planning and reporting documents such as annual reports, business plans, departmental operational plans, Reports on Plans and Priorities (RPPs), and Regulatory Directives. These documents identify areas for action related to each of the Program’s key activities.

For example, Health Canada documents identify areas for action related to microbial and chemical food safety (e.g., emerging pathogens, extraneous materials in foods, pesticide re-evaluation), nutritional quality (e.g., food fortification and claims), food surveillance and monitoring, consumer information (e.g., providing food safety advice or dietary guidance to First Nations and Inuit communities), research and FSNQP coordination (national and international). In the case of the Public Health Agency of Canada, documents address areas related to the prevention and control of infectious diseases, preparedness to respond to emerging infectious diseases and initiatives related to food safety (including collaboration), among others.<sup>148,156,174,305,314,338,387,391,388,389,390,392,412,413</sup>

These Program objectives are aligned with strategic outcomes (see **Section 2.4**) “Canadians are informed of and protected from health risks associated with food, products, substances and environments, and are informed of the benefits of healthy eating,” “First Nations and Inuit communities and individuals receive health services and benefits that are responsive to their needs so as to improve their health status” and “Canada is able to promote health, reduce health inequalities, and prevent and mitigate disease and injury.”<sup>224,411</sup>

### 4.3 Relevance: Issue # 3 – Alignment with Federal Roles and Responsibilities

Is the Program aligned with federal roles and responsibilities?

**Program objectives are aligned with federal roles and responsibilities. All federal FSNQ activities are contained within the Program. These activities are not duplicated by other programs.**

The federal government has created an intricate legislative framework to enable the Program to operate. Components of this framework identify a number of priorities related to policy development and standard setting, health promotion activities, risk and disease prevention, disease investigation, research and monitoring as well as national and international cooperation among others. The same components also identify roles and responsibilities that enable key Program participants to operate within the established federal jurisdiction, for example:

- The *Department of Health Act* sets responsibilities for the Minister of Health, including public health promotion, preservation and protection from risks and diseases, investigation and research (including disease monitoring), collection of data, and cooperation with provincial authorities with the goal of coordinating efforts intended to preserve and improve public health.<sup>79</sup>
- Health Canada’s mission is stated as “...the federal department responsible for helping the people of Canada maintain and improve their health.”<sup>3</sup>
- The F&DA assigns responsibility to Health Canada for establishing policies and standards relating to the safety and nutritional quality of food sold nationally.<sup>103</sup>
- Under the PCPA “the Minister’s primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.”<sup>386</sup>
- The *Public Health Agency of Canada* was established for the purpose of assisting the Minister of Health in exercising or performing the Minister’s powers, duties and functions in relation to public health as described in the Department of Health Act, including: health protection and promotion, health surveillance, disease prevention, emergency preparedness and response, and F/P/T and international consultation. The Public Health Agency of Canada Act also describes the role of the Chief Public Health Officer.<sup>404</sup>
- The CFIA Act defines the roles of the Agency in the area of effectiveness and efficiency of federal inspections and related services for food, animal and plant health, consumer protection, uniformity and consistency of approach to safety and quality standards and risk-based inspection systems, and collaboration between F/P/T governments.<sup>35</sup>

A review of the issues and approaches surrounding FSNQ as identified in previous sections presents a complex, expansive and continuously changing environment. Dealing with this environment requires a holistic approach that brings together all federal FSNQ activities under a single umbrella to allow their coordination. The Program acts as this umbrella under which federal activities related to FSNQ are managed.

## 4.4 Performance: Issue # 4 – Achievement of Expected Outcomes (Effectiveness)

### 4.4.1 To what extent have the immediate outcomes been achieved?

#### Immediate Outcome # 1: Increased Availability of Safe and Nutritious Foods for Canadians

**To what extent have assessments of submissions from industry and HRAs led to an increase in the availability of safe and nutritious foods in Canada?**

**Canada's food safety performance has been deemed superior due in part to the effectiveness of its food safety regulations and governance. Pre-market assessments of industry food submissions and HRAs play a crucial role in the availability of safe and nutritious foods in Canada. Nonetheless, issues of timeliness, in particular with respect to pre-market submission reviews, may be delaying the entry of foods into the market.**

#### PRE-MARKET ASSESSMENTS

Health Canada's pre-market assessments of industry food submissions play a key role in ensuring the availability of safe and nutritious foods in Canada and, as a consequence, have an effect on the increased availability of said foods. An industry submission is a request to Health Canada from an importer or manufacturer (the petitioner) to market a new food product in Canada. FD assesses these submissions according to regulatory requirements to help ensure that the food product is safe (except for health claims for which the department determines whether the claim is truthful and not misleading).<sup>190</sup>

FD is responsible for the pre-market assessment of submissions related to 10 different categories of food products. These are, by process owner:<sup>171</sup>

- Bureau of Chemical Safety (BCS):
  - o Food additive (other bureaux involved: Bureau of Microbial Hazards [BMH], Bureau of Nutritional Sciences [BNS], and the Bureau of Policy, International, Interagency and Governmental Affairs [BPIIGA]).
  - o Processing aid (other bureaux involved: BMH, BNS, and BPIIGA).
  - o Food incidental additives (other bureau involved: BNS and sometimes BMH for aspects related to effectiveness).
  - o Food packaging material.
  - o Food irradiation (other bureaux involved: BMH, BNS, and BPIIGA).
- BMH:
  - o Novel foods (other bureaux involved: BNS and BCS).
- BNS:
  - o Infant formula (other bureaux involved: BMH and the Bureau of Food Surveillance and Science Integration).
  - o Novel fibre.

- o Food fortification (other bureaux involved: the Bureau of Food Surveillance and Science Integration and BPIIGA).
- o Health claim (other bureau involved: BPIIGA).

Food additive, food irradiation, novel food, infant formula, novel fibre and food fortification submissions must go through the submission review process. Novel food, infant formula and novel fibre submissions go through pre-market notification, which consists of a safety assessment to demonstrate that the food is safe and nutritious before entry into the market. Food additive, food irradiation and food fortification submissions first go through a safety assessment process after which, if successful, a management committee decides if the submission should proceed through the regulatory phase leading to amendments to the F&DR. Market access to food additives, food irradiation and food fortification is approved after amendments have been published in the Canada Gazette Part II or if an Interim Marketing Authorization<sup>xix,xx</sup> (IMA) is granted. Health claim submissions go through a similar regulatory process as some submissions may lead to decisions that require amendments to the F&DR. A submission review is not explicitly required in the case of processing aids, food incidental additives and food packaging materials.<sup>171,275</sup>

The F&DR establish timelines for Health Canada to formally respond to submissions and notifications for certain types of foods, namely food additives, infant formula and food containing human milk substitutes, and novel foods. According to the timelines in the F&DR, FD has established the performance standards for screening and for IMAs presented in **Table 3**. FD articulated in 2007 a target of processing 90% of the submissions in a category within the time shown in the table.<sup>169</sup>

An audit conducted in 2007 found that assessments of these submissions were not meeting the regulated time standards and that many submissions had been on file for longer than the specified standards.<sup>190</sup> **Table 4** provides the age of submissions in June 2007 and in December 2009 (FD only began tracking submissions in April 2007).<sup>222</sup> It can be seen that while the number of submissions older than 3 years has been reduced considerably over the two and a half year period (from 22% to 9%), other volumes have remained relatively stable (some submissions and proposed regulatory amendments have been outstanding for over 20 years<sup>293</sup>). It is also evident that there has been a shift in the ages of food additive and infant formula submissions, with the latter experiencing an increase in the volume of older submissions while the former has experienced a decrease.

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<sup>xix</sup> An IMA “bridges the time between the completion of the scientific evaluation of certain enabling amendments (e.g., expansion of uses of food additives already listed under Division 16 of the F&DR) and publication of the approved amendments in the Canada Gazette Part II.”<sup>104</sup>

<sup>xx</sup> The enabling authority to issue IMAs was repealed in 2012.

**Table 3 FD’s Pre-market Submission Review Performance Standards (in accordance with F&DR Timelines)**

Submission Type	Performance Standards (in calendar days)				
	Screening <sup>xxi</sup>	Review <sup>xxii</sup>	2 <sup>nd</sup> Screening <sup>xxiii</sup>	2 <sup>nd</sup> Review <sup>xxiv</sup>	IMA <sup>xxv</sup>
Food Additives	45	90	14	90	60
Infant Formula	45	90	14	90	N/A
Novel Foods	45	45	14	90	N/A

**Table 4 Pre-market Submission Reviews in Progress (June 2007 and December 2009 for Submissions with F&DR Timelines)**

Date	Type of Submission	Age of Submissions				Total	
		Less than 1 year	1 to 2 years	2 to 3 years	More than 3 years		
June 21, 2007	Food Additive	25	13	11	10	59	51%
	Infant Formula	15	7	0	0	22	19%
	Novel Foods	11	6	3	15	35	30%
	Total	51	26	14	25	116	100%
December 31, 2009	Food Additive	24	6	4	7	41	33%
	Infant Formula	22	23	8	2	55	44%
	Novel Foods	21	5	2	2	30	24%
	Total	67	34	14	11	126	100%
		53%	27%	11%	9%	100%	

The status of food additive, novel food and infant formula submissions between 2007-2008 and 2012-2013 is presented in **Table 5** (data for years 2009-2010 and 2012-2013 is partial). The status of six types of pre-market submission assessments between 2011-2012 and 2012-2013 is presented in **Table 6**. The number of submissions at the end of each Fiscal Year (FY) includes submissions carried over; while the number of these submissions appears to be significant, data was not available for all FY.<sup>221,222,205,225,226,227,266,275,276,298,299,300,306</sup>

<sup>xxi</sup> Verification within the first 7 days to ensure that appropriate scientific information to meet regulatory requirements is included in the submission so that the review can be initiated.

<sup>xxii</sup> From date of acceptance of a submission for review to evaluate whether all scientific information submitted based on regulatory requirements demonstrates the safety, efficacy and/or quality of the food product.

<sup>xxiii</sup> If required, for a response to a Screening Deficiency Notice which identifies deficiencies, omissions or inadequacies preventing the review of the submission are identified.

<sup>xxiv</sup> If required, for a response to a Deficiency Notice, which identifies major deficiencies preventing the continuation of the submission review.

<sup>xxv</sup> If required, for an IMA Notice on certain cases when a submission involves a new or a higher level of use for a permitted food additive.

**Table 5 Status of Pre-market Submission Reviews (2007-2008 to 2012-2013 for Submissions with F&DR Timelines)**<sup>xxvi, xxvii</sup>

Food Additive, Novel Food and Infant Formula submissions	2007-2008	2008-2009	2009-2010	2010-2011 <sup>xxviii</sup>	2011-2012	2012-2013
Number of new submissions received	69	78	55	74	87	73
Number of decisions/opinions issued <sup>xxix, xxx</sup>	85	72	49		84	63
Number of total submissions at end of FY	101	117	126		162	163

**Table 6 Status of Six Types of Pre-market Submission Reviews**<sup>xxxi</sup> (2011-2012 and 2012-2013)<sup>xxxii, xxxiii</sup>

All submissions	Food Additive		Novel Food		Infant Formula		Food Packaging		Incidental Additive		Processing Aid	
	2011-2012	2012-2013	2011-2012	2012-2013	2011-2012	2012-2013	2011-2012	2012-2013	2011-2012	2012-2013	2011-2012	2012-2013
Number of new submissions received	25	19	27	13	35	41	1,543	958	405	129	103	71
Number of decisions/opinions issued <sup>xxxiv, xxxv</sup>	27	12	24	18	33	33	1,227	1,030	205	297	113	75
Number of total submissions at end of FY	50	40	28	26	84	97	790	960	338	40	49	85
Percentage change		-20%		-7%		15%		22%		-88%		73%

The tables show an increasing trend in the number of submissions with F&DR timelines awaiting completion at the end of each FY. While the outstanding volumes for novel food and food additive submissions showed marked declines between FY 2011-2012 and the third quarter of FY 2012-2013 (-7% and -20%, respectively), the number of infant formula submissions awaiting completion increased by 15% during the same time period. Similarly, for those submissions

<sup>xxvi</sup> Only those submissions in the safety/efficacy phase are reported for food additives, novel foods and infant formulas.

<sup>xxvii</sup> Only quarters one to three were available for years 2009-2010, 2010-2011 and 2012-2013.

<sup>xxviii</sup> No other data available.

<sup>xxix</sup> Decisions include approval, refusal and withdrawal of a submission as well as a food additive submission entering the regulatory phase.

<sup>xxx</sup> Multiple decisions/opinions may be issued for any given submission.

<sup>xxxi</sup> The table does not include other submissions (e.g., novel fibre, health claims, food fortification, food irradiation) due to lack of data. According to FD, the number of these types of submissions was negligible in 2011-2012 and the first three quarters of 2012-2013. Food irradiation submissions were not being received during this period.

<sup>xxxii</sup> Only those submissions in the safety/efficacy phase are reported for food additives, novel foods and infant formulas.

<sup>xxxiii</sup> Only quarters one to three were available for year 2012-2013.

<sup>xxxiv</sup> Decisions include approval, refusal and withdrawal of a submission as well as a food additive submission entering the regulatory phase.

<sup>xxxv</sup> Multiple decisions/opinions may be issued for any given submission.

without F&DR timelines, the outstanding volume of incidental additive submissions decreased considerably (-88%) due in part to fewer new submissions received during the first three quarters of FY 2012-2013; however, the outstanding volumes for food packaging and processing aid submissions increased considerably (22% and 73%, respectively).

In the case of food packaging submissions, the increase reflects growing reliance by the food industry on FD's Letters of No Objection (LONOs). The F&DR do not require mandatory approval of food packaging products<sup>xxxvi</sup> and put the onus on the food seller (manufacturer, distributor, etc.) to ensure that packaging materials used in the sale of food products will meet these requirements.<sup>384</sup> Packaging materials can be submitted voluntarily by the food seller to FD for a pre-market assessment of their chemical safety; in return, FD may provide a LONO expressing a favourable opinion, which can be used by the food seller to assure its customers that the products have been evaluated by FD and deemed acceptable.<sup>384</sup> All packaging materials produced in Canada or imported into Canada for use in CFIA federally registered establishments<sup>xxxvii</sup> must go through the same CFIA approval process as long as they are covered by CFIA administered Acts.<sup>xxxviii, xxxix</sup> In the case of imports, depending on the country of origin, there may be similar regulated or standard requirements and Canada may perform some audits when controls may be significantly lower in other countries. CFIA is proposing to remove the mandatory requirement to pre-approve packaging material.<sup>xl</sup>

While FD uses a collaborative approach to submission assessment (as evidenced by the involvement of multiple Bureaux with most submissions) to address the complexity and cross-cutting nature of many submissions as well as to increase overall efficiency and timeliness, the evaluation identified several issues contributing to the submission review backlog:

- Insufficient coordination between bureaux and divisions as recently as 2009, which has led to process inconsistencies and the lack of a coordinated mechanism to screen and prioritize submissions. The pre-market submission assessment process operated on a first-in/first-out basis with no formal, risk-based priority process or triage, although exceptions did occur (e.g., asparaginase).
- Until recently, FD had no performance standard for completing submissions dealing with categories of food products not covered by the F&DR (e.g., processing aid, health claims) and had not required petitioners to respond to requests for additional information within a set time.<sup>315,151,190</sup>

<sup>xxxvi</sup> The safety of materials used for packaging foods is controlled under Division 23 of the F&DR, section B.23.001, which prohibits the sale of foods in packages that may yield to its contents any substance that may be injurious to the health of a consumer of the food. The F&DR (B.23.002 to B.23.008) also restrict the use of some ingredients, like polyvinyl chloride containing an octyltin chemical, vinyl chloride and acrylonitrile.

<sup>xxxvii</sup> An establishment registered under the *Meat Inspection Act*, *Fish Inspection Act* or the *Canada Agricultural Products Act* and which is permitted to ship food products from province to province as well as out of Canada.

<sup>xxxviii</sup> A list of acceptable polymers is available through Health Canada's Web site<sup>355</sup> and a list of accepted packaging materials is provided on the CFIA Web site.<sup>36</sup>

<sup>xxxix</sup> The regulations repealing Subsection 2(2) of Schedule 1 of the *Fish Inspection Regulations* and paragraphs 8(2)(t) and 9(33)(a) of the *Egg Regulations* (which required registration of certain materials and chemicals) came into force on April 26, 2013.

<sup>xl</sup> FD, personal communications, e-mail, February 15<sup>th</sup>, 2013.

- The F&DR do not make reference to any penalties in the case that Health Canada does not meet its performance standards (i.e., any sanctions to provide incentives to comply with performance standards).<sup>102</sup>
- Health Canada does not accept novel food and food additive pre-market submission assessments performed and approved in other jurisdictions (although these are considered by FD's Food Rulings Committee)<sup>xli</sup> while this is done by some international counterparts.<sup>xlii</sup> Health Canada has encouraged industry to make joint submissions to speed the process.<sup>223,293</sup> Recognizing food additive and health claim submissions made in other jurisdictions has been an issue raised at the Food Supply Chain Stakeholders meetings,<sup>xliii</sup> while accepting credible scientific reviews from other jurisdictions has been identified as an outstanding issue by other sources.<sup>100,484,28,223,293</sup>
- The timelines specified in the F&DR do not appear to align with the level of effort related to some submission types (e.g., 45 days and 90 days for novel food and food additive submissions, respectively, are considered insufficient due to the inherent complexity of said submissions). These timelines have not been benchmarked against those adopted by other international food regulatory agencies.
- The regulatory approval/amendment process is lengthy and lacks the legal human resources (e.g., lawyers, legal aids) necessary to address regulatory challenges or changes (in 2010, there were over 90 regulatory amendments outstanding, which FD has bundled into alike packages with the expectation of expediting them<sup>223</sup>).<sup>87,99,98,190,227,269</sup>
- A lack of human resources (i.e., assessors).
- Outstanding petitioner information.

The issues of outstanding petitioner information as well as timeliness and communications with respect to the submissions review process are of particular concern to industry stakeholders and

<sup>xli</sup> For example, Health Canada's *A Guide for the Preparation of Submissions on Food Additives* states "In the event that the substance has undergone evaluation by other domestic, foreign or international scientific bodies, their outcomes and possible legal implications should be submitted as a part of the request. In particular, summaries and pertinent details of evaluations conducted by the Joint FAO/WHO Expert Committee on Food Additives and/or other national jurisdictions such as the US Food and Drug Administration, the European Union food safety authorities, and Food Standards Australia and New Zealand should be provided. The status of the food additive according to the Codex Alimentarius may also be provided. Such evaluations do not replace the requisite national assessments by Canadian authorities. However, such information is included in the internal documents considered by the Food Rulings Committee, a senior management committee of the Food Directorate, regarding the use of the additive in foods offered for sale in Canada..."<sup>307</sup>

<sup>xlii</sup> For example, in the case of the US, "under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by [US]FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive."<sup>119</sup> Similarly, in the case of FSANZ, "For high-level health claims, suitable authoritative reviews that address the diet/disease relationship of interest may be used to support claim substantiation, simplifying the claim substantiation process for the applicant... FSANZ considers the following as credible sources of information: reports conducted by international governments, international agencies or internationally recognized scientific bodies (e.g., World Health Organization), where the evaluations have been conducted with a comparable degree of rigour to the FSANZ's substantiation framework and are thus of an appropriate quality (i.e., based on a systematic or structured analysis of suitable evidence with assessment of totality of evidence); or, national diet policy publications..."<sup>51</sup>

<sup>xliii</sup> Regular meetings held with food supply chain stakeholders. Meetings are led by Health Canada and may include other federal government representatives (e.g., CFIA).



contribute to delays.<sup>293,223,294</sup> While FD makes use of engagement activities (e.g., meetings, workshops) to communicate with stakeholders and has been improving its efforts to make processes clearer (e.g., by posting policies, guidance and check lists on Health Canada’s Web site), the effectiveness of these efforts remains unclear. According to interviews, some industry respondents believed that scientific requirements for submissions (data requirements) were unclear, thus leading to the re-submission of information or the need for additional research (specific problems have been encountered with health claims and novel foods); at the same time, some FD representatives believed that rejections of submissions were due to insufficient scientific data (e.g., in the case of additives) provided by petitioners. Other issues related to clarity, such as the difference between food additive and processing aid as well as the lack of a definition for adulteration, may also contribute to experienced delays, for example:<sup>223,294</sup>

- Like all substances used with food, the use of a processing aid<sup>xliv</sup> is ultimately controlled by section 4, part I of the F&DA.<sup>194</sup> However, “there is no regulatory definition of food processing aid in Canada” and “most processing aids are not mentioned in the regulations.”<sup>194</sup> Although FD has developed a decision tree to identify food additives and processing aids,<sup>194</sup> “the regulatory definition of ‘food additive’ is the primary basis for differentiating food additives and processing aids: a substance is a food additive if it is used in a manner that would cause it to meet this definition” (i.e., “a substance in and of itself is not necessarily a food additive or a processing aid” but “the conditions surrounding its use may cause it to be one or the other”).<sup>194</sup> Although the definition of food additive is encompassing of processing aid applications, it has been the practice of Health Canada to not subject the latter to mandatory pre-clearance.<sup>194</sup>
- Although the F&DA does not offer a definition of the term “adulterated,” it indicates in clause 30(1)(a) that the Governor in Council may make regulations “declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted therefrom.”<sup>103</sup> According to Bill C-28, which was introduced in the House of Commons by the Minister of Health in November 2004 and approved in October 2005, “a food may be considered as adulterated only if it contains a substance prescribed in the regulations and is present in amounts other than the specified levels.”<sup>30</sup> The same Bill permits foods with higher than allowable limits of agricultural chemicals, veterinary drugs or pesticides to be sold if they have been issued an IMA by the Minister of Health “if he or she determines that the food would not be harmful to the health of the purchaser or consumer.”<sup>30</sup>

As part of efforts to address these challenges, in 2007 FD began a process to integrate and standardize the pre-market submission assessment process for infant formula, novel foods and food additives.<sup>207</sup> This process would then be used for other submissions as improvements became evident. A consultation process was held and industry comments invited on a *Draft Guidance Document – Management of Pre-Market Submissions* (2007).<sup>169</sup> Although the document did not address submission prioritization, the evaluation found that the coordination process was being improved through the engagement of what was then the Bureau of Food

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<sup>xliv</sup> Substances that are used during food processing and manufacture.

Policy Integration (BFPI) as the lead in communicating new submissions to all relevant bureaux and by holding assessor meetings.

In 2010, FD established a Submission Management and Information Unit for novel foods, infant formula and food additives followed by the implementation of a new process for monitoring older submissions.<sup>227,225,226,228</sup> Health Canada also devoted efforts to reduce the regulatory backlog for submissions where scientific assessments had been completed, thus moving forward the authorization of food applications (substances/uses) where regulatory amendments were pending, and delaying entry into the Canadian market (between January 1, 2009 and March 31, 2012, 23 food additive regulatory amendments were published in Canada Gazette Part II and 34 food additive IMAs were published in the Canada Gazette Part I<sup>xlv</sup>).

In 2011, FD established an Internal Committee on Submission Governance to develop backlog reduction strategies. By the end of 2011, FD expected to finalize a guidance document on the pre-market submission management process and to establish realistic service standards for food additives, novel foods and infant formulas.<sup>285</sup> The same year, FD began the Food Business Systems Modernization (FBSM) project with the goal of “improving the Directorate’s core Information Management (IM) functions, capabilities, and processes.” Part of the project aims to modernize “the processes and tools used for the management of pre-market submissions for food additive, infant formula and novel food submissions.” As part of the work, FD began the development of an “up-to-date submission management tracking system” to improve “the timeliness, predictability, transparency, and responsiveness to stakeholders for the pre-market review of food submissions.”<sup>275</sup> FD committed to reduce the backlog by 25% in 2012,<sup>293</sup> however, according to the data presented in **Table 5** and **Table 6**, FD may have been unable to attain this target.

FD has also begun implementing an administrative system for priority scheduling and expedited handling of certain submissions. This system is aimed at moving eligible food additive, food irradiation, novel food and food processing aid submissions through the pre-market safety evaluation phase and, where possible, the authorization phase, more quickly. In order to be considered, submissions must demonstrate a capacity to enhance the microbiological safety of foods as stated in the 2011 policy on *Priority scheduling and expedited handling of submissions that have the capacity to enhance food safety*.<sup>277,266,269</sup> As a result of this new policy, Health Canada has begun to receive submissions requesting priority scheduling and expedited handling.<sup>133</sup> In 2011, FD also finalized a guidance document on preparing submissions for health claims using existing systematic reviews prepared by regulatory or scientific organizations with standards of evidence similar to those of Health Canada.<sup>269,285,286</sup>

Health Canada has implemented other regulatory strategies to reduce approval timelines for safe additives and for other food safety interventions. One strategy consisted of posting Web consultations of intended amendments, instead of publishing these intents through the Canada Gazette Part I, and notifying trading partners while regulations are being drafted.<sup>133</sup>

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<sup>xlv</sup> FD, personal communications, February 6<sup>th</sup>, 2013.

Particular efforts by FD to enhance transparency, communications and engagement with industry have led to a number of initiatives:

- The organization of regular Food Supply Chain Stakeholders meetings, where pre-market processes are discussed and input is sought on ways to improve them.<sup>293,223,294,295</sup>
- The publication “Food Times,” a newsletter aimed at providing regular updates to stakeholders on FD’s activities, including reports on food regulatory decisions (particularly those stemming from pre-market submissions).<sup>293,275,276,298,299,300,306</sup>
- The Food Risk Analysis Journal, a joint venture between FD and Food Standards Australia New Zealand (FSANZ), used as the venue to communicate scientific assessments, especially those linked to development of major standards.<sup>293</sup>

FD has been providing guidance to industry through the delivery of LONOs associated with applications that require pre-market submissions (e.g., processing aids and specific health claims).<sup>102,228</sup>

## HEALTH RISK ASSESSMENTS

FD conducts HRAs as a result of in-house surveys or other available data sources on microbial pathogens and contaminants in foods. FD also conducts HRAs at the request of other groups within Health Canada as well as other government departments and agencies such as CFIA.<sup>111</sup> CFIA uses these HRAs to make decisions on food recalls as part of its responsibility for enforcing food-related standards.<sup>133</sup>

HRAs involve determining if the presence of a certain substance or micro-organism in food (e.g. chemical contaminant, natural toxin, allergen, unapproved food additive, bacteria, virus or parasite) poses a health risk to consumers. Several internal documents as well as the *Compendium of Microbiological Safety and General Cleanliness of Foods* (or *Compendium of Analytical Methods*) identify the components of a risk assessment process (i.e., hazard identification, exposure assessment, hazard characterization and risk characterization) and provide definitions for each component.<sup>201</sup> The development of this and other compendia (e.g., the *Compendium of Food Allergen Methodologies* and the *Compendium of Methods for Chemical Analysis of Foods*) reflects the integration of sound science in the risk assessment process and provides ready reference for industry on HPFB’s methodologies.

If it is found that a substance or micro-organism in food poses a human health risk, risk management actions are taken to reduce or possibly eliminate any risk that is posed to people who consume the food in question.<sup>111</sup> The *Compendium of Analytical Methods* and the *Food Directorate Standard Operating Procedures for Providing Health Risk Assessments to the CFIA in the Context of Food Safety Investigations* (2011) identify three health risk characterization categories together with advice on risk management based on a precautionary approach.<sup>xlvi, 255</sup> Both documents identify the health risk categories and provide advice on post-market actions.<sup>201</sup>

<sup>xlvi</sup> “There are differing views about when to advise the public about potential food contamination. Some advocate for a precautionary approach, based on epidemiological evidence, to protect the public from potential harm. Put simply, this means that, in the absence of absolute certainty, it is better to err on the side of caution, using reasonable and probable grounds.”<sup>144</sup>

The Standard Operating Procedures (SOPs), updated in 2011, identify service standard times according to which FD Bureaux should provide a written HRA response to CFIA, namely:<sup>xlvi</sup>,<sup>255</sup>

- potential Health Risk 1 situations: within 8 hours;
- potential Health Risk 2 situations: within 24 hours; and,
- potential Health Risk 3 situations: within 48 hours (on business days).

The identification of a health risk leads to the development of a risk management approach (i.e., option identification and analysis, strategy selection and implementation, and monitoring and evaluation of results) in consultation with key Program participants (i.e., CFIA and the Public Health Agency of Canada). Actions in the proposed approach are aligned with the level of risk identified and consider hazard severity and potential exposure.<sup>201</sup>

In 2010, FD began reporting the number of HRAs in response to CFIA requests as part of HPFB’s quarterly performance reports. While FD reports 100% compliance with delivering these HRAs within service standards, the number of HRAs identified in the documentation provided by the Directorate on this issue is inconsistent.<sup>xlvi</sup> **Table 7** provides a summary of HRAs prepared by BMH and BCS for FYs 2008-2009 to 2011-2012 (first two quarters) based on available documentation.<sup>225,226,227,266,269,285,267</sup> Health Canada’s *Food and Nutrition Safety Program Strategic Plan 2012-2015* identified the completion of timely HRAs as one of its on-going activities.<sup>305</sup>

**Table 7 HRAs in Response to CFIA Requests (2008-2009 to 2011-2012)**

	FY				Total
	2008-2009	2009-2010	2010-2011	2011-2012 <sup>xliv</sup>	
HRAs	131	174	209 to 263	164	?

FD conducted a review of its HRA activities in 2011 covering FYs 2008-2009 to 2010-2011. In this review, FD attempted to identify trends (if any) from the requests of HRAs, and to define and track food safety incidents according to whether they led to HRA requests or simply to considerations of health risk opinions. Further efforts are underway to better track and analyze data stemming from the HRA activity conducted by the FD.

According to this trend analysis, during FYs 2008-2009 to 2010-2011, *L. monocytogenes* and “meat and poultry” were involved in approximately half of the microbial HRAs conducted, requests related to allergens increased (as a result of the enhanced labelling regulations coming into force in August 2012), and requests from CFIA for technical advice (sampling plans,

<sup>xlvi</sup> These times are based on the moment when the responding Bureau determines that the information provided by CFIA is sufficient to conduct the assessment; if the information provided by CFIA is incomplete, the Bureau should advise CFIA within 24 hours. Also, in cases when the complexity of the science may lead to additional time required to complete the assessment, the responding Bureau should advise CFIA.<sup>255</sup>

<sup>xlvi</sup> While some HPFB quarterly review documents provide HRAs and a statement regarding level of completion within service standards, this is not always the case. Moreover, a HRA trend analysis conducted by FD in 2011 provides numbers different from those found in HPFB’s quarterly reviews.

<sup>xliv</sup> Only quarters one and two were available.

interpretation of standards and guidelines) increased. Information from this analysis has been fed back into assessments of emerging issues and associated impacts that affect FD's Bureaux.<sup>267</sup>

The same analysis identified several challenges related to HRA activity, namely:<sup>267</sup>

- absence of a single repository of HRA information across the Directorate;
- complicated datasets and complex sources of information with absence of Information Technology (IT) enablers to support real-time information handling;
- largely paper- and text-based information; and,
- multiple stakeholders.

Recommendations stemming from the 2008 Listeriosis outbreak<sup>206,484,28</sup> and commitments made by FD through a dedicated funding request have led to work force (additional hires and on-going training/cross-training) and facility enhancements (high-capacity statistics and bioinformatics laboratory – Biostats Lab) to continue to provide timely, 24/7 risk assessments in response to CFIA requests.<sup>273,133,282,280,28,284,313,220,246</sup> Similarly, FD has conducted work on tools, methods and approaches to risk assessment to ensure these remain current, accepted, validated, and that they meet international standards. Work in this area has been delivered through peer-reviewed publications,<sup>61,483</sup> joint assessments (*Joint FDA/Health Canada quantitative assessment of the risk of Listeriosis from soft-ripened cheese consumption in the United States and Canada*) and at several national and international fora (e.g., Statistical Society of Canada, International Symposium on Problems of Listeriosis, Society for Risk Analysis).<sup>437,281,438,250,317,321,318,324,325,326,440,441,312,322,375,268,236,374,117,436,118,139,435,477</sup>

## LEVEL OF SAFETY OF FOOD IN CANADA

According to the Food Safety Performance World Ranking Initiative, an independent academic study of 17 countries belonging to the Organisation for Economic Co-operation and Development (OECD), Canada is ranked among the top five in the world for overall food safety performance.<sup>57</sup> This study used four evaluation categories (consumer affairs,<sup>i</sup> biosecurity,<sup>ii</sup> governance and recalls,<sup>iii</sup> and traceability and management<sup>iiii</sup>) to determine an overall performance grade (i.e., superior, average or poor) for each country. **Table 8** shows the overall safety performance ranking and grades for four selected OECD countries as developed by the Initiative for years 2008 and 2010.<sup>58,57</sup>

<sup>i</sup> Consumer affairs measured policies and outcomes that allowed the initiative to assess how well countries were connected with their own consumers; it considered surveillance efforts, hygiene practices and information accessibility as main indicators.

<sup>ii</sup> Biosecurity focused on a country's capacity to contain all relevant risks related to food safety, namely biosecurity measures for plants and livestock, including the rate of agricultural chemicals use, the rate of veterinary drug use, and the use of science-based data.

<sup>iii</sup> Governance and recalls assessed the effectiveness of domestic regulations and governance related to food safety. The number of public/private partnerships, number of business-funded projects, the existence of risk management plans, the level of clarity of food recall programs and the number of food recalls were some of the metrics considered for this category.

<sup>iiii</sup> Traceability and management measured the ability of a country to identify the past or current location of food items, as well as to know a food item's history. It measured the level of harmonization between jurisdictions, the prominence of world-known programs and the depth of traceability programs.

**Table 8 OECD Overall Safety Performance Ranking and Grade (2008 vs. 2010)**

Country	Overall Performance		Consumer Affairs		Biosecurity		Governance & Recalls		Traceability & Management	
	2008	2010	2008	2010	2008	2010	2008	2010	2008	2010
Australia	4 Superior	2 Superior	7 Average	5 Average	1 Superior	11 Average	7 Average	2 Superior	2 Superior	7 Superior
UK	1 Superior	3 Superior	4 Superior	7 Average	10 Superior	9 Average	4 Superior	6 Average	1 Superior	5 Superior
Canada	5 Superior	4 Superior	3 Superior	2 Superior	14 Average	11 Average	4 Superior	1 Superior	13 Average	15 Poor
US	7 Average	4 Superior	2 Superior	1 Superior	13 Average	9 Average	2 Superior	3 Superior	16 Poor	16 Poor

Of the 17 countries compared, Australia was ranked the highest and Canada was ranked fourth; overall, there were minor changes among the four countries between 2008 and 2010. The best rankings for Canada were in consumer affairs and governance & recalls. Canada received lower marks for biosecurity for its “medium, but not too-high use of chemical products and generally reasonable bioterrorism [program].” The lowest ranking for Canada was on traceability & management, which also shows a drop since 2008, since Canada does not have “well-established farm-to-fork traceability systems for any food product – although [it is] working on creating one.”<sup>57</sup>

### **Immediate Outcome # 2: Increased Awareness and Understanding of Food Safety- and Nutrition-Related Risks and Health Benefits**

**To what extent has awareness and understanding of food safety risks and nutrition quality benefits increased as a result of Program activities?**

**The Program employs a wide variety of products and engagement activities in its awareness building efforts. It is not known if awareness and understanding have increased as the Program lacks a mechanism to assess the success of its public awareness and understanding efforts (with the exception of a best practice); however, a number of areas requiring further information (e.g., nutrition and healthy eating) have been identified. There are a number of Program approaches to information dissemination that may not be as effective in relaying information to the intended targets/populations.**

Key Program participants collaborate in the development and implementation of information products and tools designed to inform a wide audience on issues related to FSNQ as well as on Program activities. The lead may change depending on the situation: Health Canada is responsible for informing Canadians about potential risks to their health, while the Public Health Agency of Canada acts as the first point of contact at the federal level for issues related to actual or potential foodborne illness outbreaks. With respect to nutrition, both Health Canada and the Public Health Agency of Canada have a role to play: Health Canada as the primary food standard-setting body related to the safety and nutritional quality of all food sold in Canada, and the Public Health Agency of Canada as part of its role to promote health.

## AWARENESS BUILDING

The number of information products generated by the Program is large and addresses a variety of FSNQ topics. Some of these products include (see 0 for further details):

- Involving You: HPFB’s decisions on health priorities, policies and programs as well as related information from other branches with similar regulatory responsibilities.
- It’s Your Health (IYH): Fact sheets for the general public written by FD in consultation with scientists/experts from Health Canada and the Public Health Agency of Canada.
- C-EnterNet Reports:<sup>liv</sup> Annual reports providing a summary of reported infectious enteric disease cases in humans.
- Canadian Nutrient File (CNF):<sup>lv</sup> Online searchable database on the nutrient values for specific foods.
- Brochures and posters.
- Toolkits: Nutrition Labelling Toolkit for Educators– First Nations and Inuit Focus.

The Program also develops specific information products in response to emerging health issues and on-going concerns, for example:

- Acrylamide: the Program published a description of the mechanism of formation of acrylamide in food to engage industry and other governments in finding methods of reducing acrylamide formation in foods. *Involving You* was used to provide information on proposed meetings between Health Canada and key figures in the food industry to “map out strategies for dealing with the issue” and on the formation of acrylamide. Web site pages were created and updated to explain the issue and how to reduce the risk of exposure in foods.<sup>5,6,147</sup>
- Raw milk cheese: a Tip Sheet for Raw Milk<sup>230</sup> stated that pregnant women, young children, the elderly and people who are immune-compromised should avoid eating raw milk cheese, including soft and semi-soft cheeses as potential foodborne bacteria could cause serious health effects.
  - o As part of the consultation process started in 2010 to update the existing requirements to enhance the protection of the health of Canadians who consume soft and semi-soft cheese made from raw milk, Health Canada has developed a number of products to facilitate the consultation process with provincial health and agriculture agencies, experts as well as interested and affected stakeholders.<sup>250,311,309,317,323,325,327,440,441,312</sup>
- Listeriosis: as a result of the 2008 Listeriosis outbreak, Health Canada developed brochures and posters targeted to Canadians in general and at-risk or vulnerable populations in particular (i.e., seniors, people with weakened immune systems, pregnant women and parents of children under six years of age).<sup>263, 134</sup>

<sup>liv</sup> C-EnterNet receives funding from multiple sources, including the Agricultural Policy Framework and FCSAP.

<sup>lv</sup> <http://www.hc-sc.gc.ca/fn-an/nutrition/fiche-nutri-data/index-eng.php>

- Bisphenol A (BPA): Health Canada has provided regular updates on key commitments made by the Program such as the publication of progress on food-related interventions associated with Canada's Chemicals Management Plan (CMP)<sup>lvi</sup> (e.g., updates on BPA) on Health Canada's Web site.<sup>197,211,213,214,215,216,218,232,234,301,296,434,193</sup>

Products have also been developed to enhance transparency with partners and stakeholders, for example:

- The Program worked with international counterparts (mainly FSANZ) to launch the International Food Risk Analysis Journal in 2011, an online publication aimed at becoming the repository of the Program's comprehensive risk assessment documents supporting standard setting.<sup>271, lvii</sup>
- FD introduced "Food Times" in 2011, its quarterly newsletter delivered via e-mail to all domestic and international stakeholders. Food Times contains a summary (and a repository) of the FD's publications, scientific assessments, regulatory decisions, pre-market authorizations, risk communications, consultations as well as information on upcoming stakeholder engagement.<sup>275,276,298,299,300,306</sup>

## DELIVERY MECHANISMS

Information products are delivered through a variety of mechanisms (see 0), the most common including print, e-mail, online and social media.

- Print.
- E-mail, online (Web sites) and social media.
- Publications in the peer reviewed scientific literature (summarizing outcomes of research or food surveillance activities that underpin risk assessment or standard setting<sup>275,276,298,299,300,306</sup>).
- Participation in multi-stakeholder initiatives such as Fight BAC!,<sup>lviii</sup> the Nutrition Facts Education Initiative/Campaign,<sup>134</sup> the Be Food Safe campaign, Children's Health and Safety, Safe and Informed Consumers, Hazardcheck and other initiatives.<sup>135</sup>
- Engagement activities such as meetings and workshops.

With respect to print media (e.g., articles and brochures), its effectiveness has been found to be limited when providing information on safe food handling:<sup>90</sup>

- Detailed articles:
  - o Only 39% of Canadians believe detailed articles to be an effective information source.

<sup>lvi</sup> The CMP is being implemented jointly by Health Canada and EC. Its purpose is to improve the degree of protection against hazardous chemicals through a number of new, proactive measures to make sure that chemical substances are managed properly. A key element of the CMP is the monitoring and surveillance of levels of harmful chemicals in Canadians and their environment.

<sup>lvii</sup> [http://www.intechopen.com/journals/international\\_food\\_risk\\_analysis\\_journal](http://www.intechopen.com/journals/international_food_risk_analysis_journal)

<sup>lviii</sup> <http://www.canfightbac.org/en/>



- Seniors are more likely to find this product effective while parents with children under six years of age do not.
  - 44% of Canadians believe detailed articles to be very or moderately effective. Of these:
    - 45% believe that Web sites and 41% believe that newspapers are the best delivery mechanisms.
    - Pregnant women and parents with children under six years of age prefer Web sites while seniors prefer newspapers.
    - 12% of Canadians believe Health Canada’s Web site to be the best place to obtain this information, mostly favoured by pregnant women.
- Brochures:
  - Only 26% of Canadians believe brochures to be an effective information source.
    - Seniors and parents with children under six years of age are more likely to find this product effective.
  - 45% of Canadians believe brochures to be moderately effective. Of these:
    - 57% believe that a retail/grocery store is the best place for these brochures followed by 42% who would prefer to receive this information by mail.
    - People with weakened immune systems are most likely to prefer this type of product.

In the case of online information (delivered through a Web site), the Program has built a considerable online presence (e.g., Health Canada’s Web site contains approximately 45,000 pages<sup>252</sup>). An examination of visits<sup>lix</sup> and views<sup>lx</sup> for five key Health Canada Web pages (**Table 9**) during FY 2008-2009<sup>lxi</sup> evidences limited use when compared to the Canadian population with access to the Internet (i.e., the user base).<sup>328, lxii</sup>

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<sup>lix</sup> A visit is a series of actions that begins when a visitor views the first page from the server and ends when the visitor leaves the site or remains idle beyond the idle-time limit (e.g., 30 minutes).

<sup>lx</sup> Number of times the page was viewed by visitors.

<sup>lxi</sup> Data for other years was not available.

<sup>lxii</sup> According to the Canadian Internet Use Survey from StatCan, in 2009 80% of Canadians had access to the Internet from any location, 77% had access from home and 34% had access from work; 41% of individuals 65 years of age and older used the Internet; and, 70% of individuals used the Internet to search for medical or health related information.<sup>446,444,447,445</sup>

**Table 9 Visits and Views for Five Health Canada Web Pages (English and French) for FY 2008-2009**

Web Page	Item	FY 2008-2009
Advisories, Warnings and Recalls	Visits	30,419
	Views	35,275
Allergy Alerts	Visits	7,164
	Views	7,695
Produce Safety	Visits	3,224
	Views	3,845
Food Allergen Labelling	Visits	20,035
	Views	25,374
Fight BAC!	Visits	4,635
	Views	5,695

A more detailed examination of the Food Safety Section (**Table 10**) for FY 2010-2011<sup>lxiii</sup> shows similar results.<sup>254,439</sup>

**Table 10 Visits and Views for Health Canada’s Food Safety Section (English and French) for FY 2010-2011**

Web Page	Item	FY 2010-2011
Safe Food Handling: Your Interactive Guide	Visits	6,419
	Views	8,318
Manipulation sécuritaire des aliments : Votre guide interactif - Santé Canada	Visits	1,938
	Views	2,866
Safe Food Handling: Your Interactive Guide (Flash Version)	Visits	2,158
	Views	3,299
Manipulation sécuritaire des aliments : Votre guide interactif (Version Flash)	Visits	799
	Views	1,468
Safe Food Handling in the Home	Visits	2,724
	Views	3,553
Les pratiques de manipulation sécuritaire des aliments à la maison	Visits	811
	Views	1,391
Safe Food Handling at the Grocery Store	Visits	828
	Views	1,404
Les pratiques de manipulation sécuritaire des aliments à l’épicerie	Visits	308
	Views	796

<sup>lxiii</sup> Data for other years was not available.

In the case of vulnerable populations, the number of downloads of safe food handling documents during FY 2010-2011<sup>lxiv</sup> seems small (**Table 11**), especially in the wake of the 2008 Listeriosis outbreak.<sup>264,129,265,131,253,130,439</sup>

**Table 11 Downloads of Safe Food Handling Documents among Vulnerable Populations (English) for FY 2010-2011**

Online document	FY 2010-2011 (downloads)
Safe food handling for adults 60+	521
Safe food handling for people with weakened immune systems	413
Safe food handling for pregnant women	1,052

It should also be noted that the data presented in the previous tables is the result not only of direct access by interested users (e.g., as a result of an online search) but of re-directions or references earned through media, stakeholder and blog coverage of articles as well as links from other Web sites. According to research, the limited popularity of online food safety information sources may be related to stakeholder preferences, for example:

- Studies commissioned by Agriculture and Agri-food Canada (AAFC) in 2004 and 2006 (n=1600) found the following:<sup>331,332</sup>
  - o 59%/38% use traditional media (e.g., newspapers, television and radio) as the main source of food safety information;
  - o 11%/13%<sup>lxv</sup> of Canadians use the Internet as a source of food safety information; and,
  - o 4% of consumers use the federal government as a source for food safety information.
- According to a 2010 survey (n=1,536<sup>lxvi</sup>):<sup>90</sup>
  - o 42% of Canadians use traditional media (e.g., newspapers, radio, TV or other media) as their primary source of information for food issues.
    - 57% of seniors and 32% of parents receive information on food issues through traditional media.
  - o 24% of Canadians use Web sites as their primary source of food information.
    - 40% of pregnant women and 31% of parents obtain information on food issues through Web sites (40%).
  - o During a foodborne illness outbreak, 74% of Canadians refer to traditional media as a source of information, while only 16% use Web sites.
    - Seniors tend to be more heavily dependent on traditional media (89%).

<sup>lxiv</sup> Data for other years was not available.

<sup>lxv</sup> Variation between 2004 and 2006 is reported as two percentages, respectively for each year, separated by a forward slash (/).

<sup>lxvi</sup> A telephone survey divided among four at risk target groups and a general public comparison group: seniors aged 65+ (n=304), pregnant women and those who expect to become pregnant within one year (n=300), parents of children under six years of age (n=305), people with weakened immune systems (n=323) and the general public (n=304).

- o 25% of Canadians see the federal government as the most trustworthy source of food safety information.
- A 2011 survey ( $n_1=1003$ ,  $n_2=1001$ ,  $n_{\text{focus groups}}\sim 36$ ) estimates that:<sup>343</sup>
  - o television is the primary source for information on recalls (40%), followed by news (16%), radio (12%) and newspapers (11%); and,
  - o 9% of Canadians use the Internet as a source of food safety information.

Other factors limiting the effectiveness of FSNQP communications may be linked to the delivery format, for example:

- Fragmented information spread across multiple sites that have an inconsistent “feel” and post information with varying degrees of currency leading to consumer difficulty in finding relevant information. The creation of new information portals (e.g., Healthy Canadians, Food Safety) may help to centralize and standardize online information sources.
- According to evaluation interviewees, average consumer and some sub-populations (e.g., elderly, First Nations and Inuit, etc.) may find the information to be too technical.
- According to evaluation interviews, many First Nations and Inuit communities may have limited online access or limited access to the required peripherals that are available to the general population.

In the case of engagement activities, the evaluation could not obtain an accurate number of the activities conducted over the evaluation period or determine the success of said activities (e.g., the level of consumer participation); however, some evaluation interviewees (including key Program participants, partners and stakeholders) believed that there had been an increase in consumer participation. Evaluation respondents (key Program participants and stakeholders) engaged with First Nations and Inuit believed that consumer participation had increased as a result of relationship building with national organizations and community representatives as well as initiatives such as the Northern Contaminants Program (NCP); some also believed that there had been a change as a result of federal government organizations acting as the enabler and channel for communications between interested groups (e.g., researchers, community, etc.).

## LEVEL OF AWARENESS AND UNDERSTANDING

According to 2011 data, a large proportion of Canadians (64%) believe that the federal government “has done a good job of keeping Canadians informed of all relevant food safety issues” but 63% “still wish they had more information about food safety and how to protect themselves from foods that pose a health risk.”<sup>343</sup> In particular, there are a number of topics requiring more information or education, namely:

- Food safety – while 94% of Canadians appeared to be familiar with food safety guidelines,<sup>331,332</sup> and in 2011 76% believed they had sufficient information on food safety (84% in the case of pregnant women),<sup>90</sup> this awareness may not be translated into understanding. According to a 2011 survey ( $n_1=1003$ ,  $n_2=1001$ ,  $n_{\text{focus groups}}\sim 36$ ), “there is a general misconception among Canadians that most preventable contamination occurs outside of the kitchen;” when asked about food contamination, 52% of

Canadians “still believe that contamination occurs before food reaches their kitchens.”<sup>343</sup> The same survey notes that some misconceptions regarding food handling are more prevalent among at-risk groups (i.e., pregnant women, people with compromised immune systems, and seniors). According to a 2010 survey (n=1,536), only 60% of Canadians are aware of foodborne illnesses, awareness being higher among people with weakened immune systems and lower among parents with children under six years of age.<sup>90</sup>

- Nutrition and healthy eating – the number of Canadians confident in their nutrition knowledge decreased between 2006 and 2008 (87%<sup>34</sup> to 80%<sup>33</sup>) and, according to the *Sodium Reduction Strategy for Canada* (2010), “Canadians lack knowledge about calories and nutrients, which compromises their ability to select nutritious foods” (e.g., little understanding of the % DV and what would be considered “high” or “low” content of a nutrient).<sup>229</sup>
- Nutrition labelling – in a 2005 survey (n=1000), 40% of Canadians had difficulty reading nutrition labels on food packages;<sup>158</sup> similarly, a 2007 qualitative study found that nutrition labels are noticed but not always trusted or understood.<sup>180</sup> The report *Building a Heart Healthy Canada* (2009) stated that “although Canada is an international leader in mandatory food labelling on packaged foods, only 61% of women and 52% of men ‘always or usually’ read the nutrition facts panel on product labels, and those who do often find the information confusing.”<sup>47</sup> According to the report *Reaching for the Top* (2007), “in the absence of a Canada-wide system, food companies and health organizations have created their own individual labelling systems, which are confusing for consumers.”<sup>344</sup> The report *Building a Heart Healthy Canada* (2009) identified the lack of a standard serving size as one of the main weaknesses in Canada’s nutrition facts panel, which makes it difficult for consumers to compare the nutritional quality of similar food products.<sup>47</sup>
- Trans fats – according to a 2004 survey (n=1423), 36% of Canadians reported that they did not know what the term “trans-fats” signified;<sup>153</sup> according to the Canadian Council on Food and Nutrition’s *Tracking Nutrition Trends VII (2008)*, “32% of Canadians know that trans fatty acids have the same effect as saturated fats, 24% of Canadians believe that trans fats do not have the same effect as saturated fat, and 27% of Canadians simply do not know.”<sup>34</sup>
- GM foods – according to a 2004 survey (n<sub>8</sub>=1008 and n<sub>11</sub>=1003), 17% of Canadians had a poor understanding of GM foods, while 41% believed their understanding to be fair; an equal sized cohort said they had a good (29%) to very good (12%) understanding of these foods.<sup>160</sup>

In the specific case of First Nations, a survey conducted in 2007-2008 (n<sub>I</sub>=1502 and n<sub>II</sub>=1500 First Nations residents living on-reserve) found that 46% of First Nations people living on-reserve knew something about *Eating Well with Canada’s Food Guide – First Nations, Inuit and Métis*, which was launched in 2007.<sup>196</sup>

#### **BEST PRACTICE**

Funding received through the Food and Consumer Safety Action Plan (FCSAP) and a dedicated funding request to address recommendations<sup>206,28,484</sup> stemming from the 2008 Listeriosis

outbreak led the Program to develop a strategic and coordinated approach that sought to address several prevalent communication and information dissemination weaknesses. The Listeria social marketing strategy aimed to increase awareness and knowledge of the health risks associated with unsafe food handling practices and foodborne illnesses by influencing the knowledge, attitudes and behaviours of the general public and at-risk groups. Its immediate goal was to increase the use of safe food handling practices with the long term goal of decreasing the incidence of foodborne illness in Canada. To achieve its intended goals, the strategy employed a targeted and multi-pronged approach to information dissemination that went beyond a Web-only push: it included information in annual publications, mail inserts, print media, a radio campaign, and a strategic alliance (see 0 for further details).<sup>49,263,403,74,72,73,237,238,239</sup>

Key Program partners (i.e., Health Canada, the Public Health Agency of Canada and CFIA) worked together in an effort to harmonize and integrate information to make it more accessible to stakeholders. As a result, in 2010 the federal government launched several online Web portals identified in see 0. The same organizations also collaborated with P/T governments through the Council of Chief Medical Officers of Health to develop the document *Prevention of Listeriosis: Considerations for Development of Public Health Messages*, a document that “offers basic information on Listeriosis, and provides prevention advice for the general public, for vulnerable populations and for food service providers serving food to these populations.”<sup>133</sup> The document was made available to P/T governments in 2010 to use as guidance in creating communication messages within each jurisdiction.

The strategy also included a *Survey of Canadians’ Knowledge and Behaviour Related to Food Safety* (2010) (n=1,536) “designed to establish benchmarks to track the effects of the campaign and provide research intelligence” to “assist [Health Canada and the Public Health Agency of Canada] in the development of evidence-based communications strategies and tactics for use during an outbreak of a foodborne illness”.<sup>90,418</sup>

### **Immediate Outcome # 3: Enhanced Contribution to International Standards that are supported by Scientific Evidence**

**To what extent has the Program influenced international standards?**

**The Program actively engages in international standard development through a large number of agreements, fora and initiatives. The Program’s scientific and regulatory research has made important contributions to the international community. There are a number of initiatives in which the Program has played a role as a lead or contributor.**

#### **INTERNATIONAL AGREEMENTS**

The evaluation identified 22 international Memoranda of Understanding (MoUs), agreements and commitments signed by key Program participants during the period of the evaluation. The purpose of these international agreements is to enhance collaboration and information exchange in order to increase organizational knowledge and enable proper response mechanisms to current and emerging issues. The inherent level of collaboration with each of the organizations identified in the documents (e.g., the US Food and Drug Administration [USFDA], FSANZ, the

UK Food Standards Agency [UKFSA], and the European Centre for Disease Prevention and Control [ECDC]) also allows greater harmonization of approaches and standards.

## INTERNATIONAL FORA

The evaluation identified numerous international fora in which the Program participates to exchange knowledge, achieve consensus and develop standards supported by scientific evidence with the goal of harmonization. Some of these fora are discussed below.

### Codex Alimentarius

Codex is the forum for the development of international standards, guidelines and codes of practice on FSNQ. Canada's participation in Codex is coordinated through FD's Office of the Codex Contact Point for Canada.<sup>67</sup> Canada's Interdepartmental Committee on the Codex Alimentarius (IDC/CODEX) is comprised of representatives from Health Canada, CFIA, the Department of Foreign Affairs, Trade and Development (DFATD) and AAFC. The chair of IDC/CODEX rotates between Health Canada and CFIA. IDC/CODEX is used to review and make recommendations on Codex participation, and as a forum to develop and provide policy advice with respect to acceptance of Codex standards, recommendations and guidelines.<sup>146</sup> Canadian participation in active Codex committees covers 10 General Subject Committees (Health Canada and CFIA), five Commodity Committees (CFIA), one Regional Coordinating Committee (rotated between Health Canada and CFIA) and one Ad-hoc Intergovernmental Task Force (CFIA). More specifically, within Canada, Health Canada is the lead for the following committees and task forces:<sup>50</sup>

- Codex Committee on General Principles;
- Codex Committee on Food Hygiene;
- Codex Committee on Residues of Veterinary Drugs in Foods;
- Codex Committee on Contaminants in Foods;
- Codex Committee on Food Additives;
- Codex Committee on Methods of Analysis and Sampling; and,
- Codex Committee on Nutrition and Foods for Special Dietary Uses.

The evaluation identified a number of Codex-led initiatives where the Program played an important role in their development, either in a leading role or by providing a significant scientific contribution, namely:

- Standard for infant formula and formulas for special medical purposes intended for infants.<sup>163</sup>
- Discussion paper on the application of risk analysis to the work of the Committee on Nutrition and Foods for Special Dietary Uses.<sup>163</sup>
- Proposed draft code of hygienic practice for powdered formulae for infants and young children.<sup>168</sup>
- Standards to control levels of melamine in food and feed worldwide.<sup>225</sup>
- Melamine Codex Maximum Level (ML).<sup>135,65</sup>

- MLs for Deoxynivalenol (DON) and its acetylated derivatives in cereals and cereal-based products.<sup>135,66</sup>
- General Principles for the addition of essential nutrients to foods.
- Guidelines for use of nutrition and health claims.
- Risk assessment guidance regarding foodborne antimicrobial resistant organisms.

#### World Health Organization and the Food and Agriculture Organization of the United Nations

Work on food additives is conducted through the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In particular, Health Canada has been an active participant on the issue of acrylamide as a result of FD's work on the toxicology of and dietary exposure to acrylamide, which has contributed to the international body of knowledge (e.g., isolation of the major mechanism for the creation of acrylamide and its contributing factors) and has informed Health Canada's actions (e.g., method of measurement of acrylamide<sup>199</sup>) and implementation of an acrylamide monitoring program under the CMP. Other contributions include:

- Drafting of two monographs (standards) for Furan and Cyanogenic Glycosides.<sup>285</sup>
- Leading the resolution Advancing Food Safety Initiatives.<sup>134</sup>
- Conducting research on the acrylamide-asparaginase interaction.
- Holding an expert consultation to review the toxicological and health aspects of BPA (including food packaging materials).<sup>488</sup>

The Public Health Agency of Canada has been involved in foodborne illness surveillance and response activities coordinated through the WHO in collaboration with FAO. Some of the contributions include:

- Participation in the Global Foodborne Infections Network (GFN) and the Global Public Health Intelligence Network (GPHIN).
- Provision of risk assessments and risk management guidelines for several high priority food/pathogen combinations impacting foodborne illness through the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment.
- Work with the Foodborne Disease Burden Epidemiology Reference Group (FERG) on estimate reporting, epidemiological reviews, the development of estimate and cause attribution models, and the use of FERG models in the development of study tools.<sup>491</sup>
- Contribution to the Advisory Group on Integrated Surveillance of Antimicrobial Resistance to support and promote the development of programs internationally.

#### North American Free Trade Agreement and the Organisation for Economic Co-operation and Development

Health Canada and CFIA work collaboratively to address specific food regulatory issues between Canada, the US and Mexico as part of the implementation of the North American Free Trade Agreement (NAFTA). Some activities, such as those related to food labelling, are addressed by the Technical WG on Food Packaging, Labelling and Food Standards, which aims at enhancing the convergence and harmonization of food labelling provisions.<sup>457</sup> Other efforts on food regulatory decision harmonization are carried out under the auspices of OECD with participation



from Health Canada and CFIA. As part of the OECD Task Force for the Safety of Novel Foods and Feeds, efforts have been made to lead the development of harmonized guidance on the assessment of products and processes resulting from modern and innovative technologies such as novel foods, GM crops or products derived from nanotechnology.<sup>378</sup>

### International Food Chemical Safety Liaison Group and International Microbial Food Safety Liaison Group

In 2005, FD convened an international meeting of like-minded jurisdictions to investigate collaboration efforts around early warning and information sharing/dissemination associated with food chemical safety incidents. The International Food Chemical Safety Liaison Group was created as the vehicle to achieve these objectives with participation from FD, CFIA, USFDA's Center for Food Safety and Applied Nutrition (CFSAN), the European Food Safety Authority (EFSA), UKFSA, the Japanese Food Safety Commission and FSANZ.<sup>455</sup> This group was instrumental in coordinating the response to a number of other emerging issues from 2007 onward such as the occurrence of semicarbazide in baby jars, acrylamide in food, BPA in food and melamine contamination in the food supply.

Similarly, and as part of its response to recommendations following the 2008 Listeriosis outbreak, the Program established the International Microbial Food Safety Liaison Group in 2011. This group is intended as an informal forum for government organizations involved in the risk assessment, risk management, and/or risk communication of microbial food safety to discuss and collaborate on issues of mutual interest.<sup>456</sup> The forum held its first meeting in September 2011 with the participation of agencies from Australia, Canada, the European Union (EU), France, Italy, Japan, New Zealand, the UK and the US.<sup>9</sup>

### **BILATERAL AND MULTILATERAL INITIATIVES**

Knowledge exchange and standard development is also carried out by the Program through participation in bilateral and multilateral agreements, namely:

- **Quadrilateral (QUAD) meetings:** Food Safety QUAD meetings are held between Australia, Canada, New Zealand and the US. The chair and host country rotates every four years. Canada's participation includes representatives from Health Canada, CFIA and the Public Health Agency of Canada. These meetings provide a forum to discuss and collaborate on issues of mutual interest, thereby fostering communications, understanding and agreement. Results from these meetings include:
  - o Canada's leadership in relation to addressing trans fats, which has contributed to the sharing of analytical methods and information on claims, alternatives, monitoring, and risk communications.<sup>420,421,1</sup>
  - o The creation in 2008 of the Food Safety QUAD Group as a regulatory forum to facilitate collaboration and information sharing, support harmonization efforts on regulatory practices and standards, and consider common approaches to emergency preparedness and response among others.<sup>107</sup>
  - o A QUADs Food Safety Regulatory Economics Working Group led by FD that has held meetings since 2009 on issues related to economic analysis in food

safety regulation and behavioural economics in food safety and nutrition.<sup>423,83,84,422,108,85,86</sup>

### US National Academies

In an effort to harmonize nutrition recommendations in Canada and the US, Health Canada became one of the sponsors of a project coordinated by the Food and Nutrition Board of the Institute of Medicine in the US to synthesize relevant scientific evidence and provide updated nutrient recommendations, i.e., the Dietary Reference Intakes (DRIs). Canadian nutrition scientists have been involved in establishing these updated nutrient reference values, which replace the 1990 Recommended Nutrient Intakes in Canada and the 1989 Recommended Dietary Allowances in the US.<sup>473</sup>

### Regulatory Cooperation Council

The Regulatory Cooperation Council was created in 2011 with a two-year mandate to increase regulatory cooperation between Canada and the US and to look at ways of aligning regulations to ease the flow of goods between both countries. Relevant outcomes under the Agriculture and Food area include:<sup>4,428,429,430,427,32,458</sup>

- The assessment of similarities in food safety systems and the strengthening of existing bilateral regulatory alignment mechanisms to enhance food safety, minimize stakeholder burden, and enhance cooperation and information exchange during regulatory development.
- The development of joint processes and tools to ensure joint recognition of food safety laboratories, test results and methodologies.

### CONFERENCES AND SYMPOSIA

Beyond the above-mentioned bodies, the Program also collaborates with international counterparts through a number of conferences and symposia. The Program uses these venues to exchange and communicate scientific information, for example:

- Work on risk assessments and modelling methods has been carried out through the International Conference on Molluscan Shellfish Safety, the International Symposium on Problems of Listeriosis, and the Society for Risk Analysis.
- Dissemination of the document *Weight of Evidence: Factors to Consider for Appropriate and Timely Action in a Foodborne Illness Outbreak Investigation* was carried out at the International Association for Food Protection Annual Meeting.
- Participation in the Association of Analytical Communities (AOAC) international annual meetings related to the validation of food analytical methods.
- Participation in international events on toxicology research such as the annual meetings of the Society of Toxicology of Canada and the US Society of Toxicology.
- Work on the development of a food security side stream for the 2009 International Congress on Circumpolar Health.

**Immediate Outcome # 4: Improved Knowledge and its Use to Support Policies, Guidelines, Standards, Regulations, Strategies, CFIA Inspections and Assessments**

**To what extent has the knowledge base (research) and its use improved as a result of Program activities?**

**There are examples of knowledge development by the Program such as research for the enhancement of methods of analysis and testing as well as the development of guidelines and standards. Furthermore, knowledge exchange through a variety of media contributes to knowledge improvement. The Program uses this improved knowledge to support regulatory and policy development as well as to support collaborative work.**

**KNOWLEDGE IMPROVEMENT**

Knowledge Modernization

Health Canada publishes three Compendia of methods on its Web site. These methods provide a reference to Health Canada’s evaluated methodologies, which may be used by industry and government laboratories to determine compliance, assess quality and support foodborne disease investigation. The Compendia contain methods for food allergen testing as well as for the chemical and microbiological analysis of foods (see 05). **Table 12** lists the number of methods and the dates they were introduced or updated according to data posted on Health Canada’s Web site.<sup>59,11,379,330,340,370,371</sup> Health Canada no longer lists any nutrient methods on its Web site as of 2012; however, some examples of work in this area exist such as that carried out by BNS on the development of an analytical methodology for the measurement of trans fatty acids in foods and its acceptance by the AOAC.<sup>339</sup>

**Table 12 Compendia of Methods Created or Updated between 1999 and 2012**<sup>lxvii, lxviii, lxix</sup>

Methods	Year														
	Pre 1999	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Allergen	0	0	0	0	0	0	2	0	2	0	0	1	1	0	0
Chemical	117	0	0	0	0	0	0	0	1	1	3	0	0	0	0
Microbiological	41	2	2	12	3	11	4	3	19	6	3	5	10	16	12
Total all methods	158	2	2	12	3	11	6	3	22	7	6	6	11	16	12

The greater overall activity in microbiological methods may be a reflection of a larger number of events in this area (e.g., outbreaks, emerging threats, etc.); for example, BMH has been actively working on *Listeria* (spp. and monocytogenes) methods since 1996.<sup>459</sup> The increase in recent activity (2009-2012) has also been the result of efforts to address recommendations stemming from reports related to the 2008 Listeriosis outbreak and additional funding received by the

<sup>lxvii</sup> Supplements are not included.

<sup>lxviii</sup> Methods under review, archived or removed are not included as there is no issue date.

<sup>lxix</sup> Methods identified multiple times (through referencing) are only included once.

Program in this area. During this time, FD has validated and maintained 17 methods and laboratory procedures for the isolation and identification, enumeration and genequence of *Listeria* while at the same time developed guidelines and standards related to food microbiological methods to improve the method review process, for example:

- Guidelines for the relative validation of indirect qualitative food microbiological methods.<sup>283</sup>
- Service standard for the evaluation of microbiological methods submitted by industry, private laboratories or government laboratories for publication in the *Compendium of Analytical Methods*: 180-day period (not including responses with additional data or clarification from the submitter) for the Microbiological Methods Committee (MMC)<sup>lxx</sup> to accept or reject a method for publication.<sup>278</sup>
- Enhanced method for the confirmation of *Listeria*: provides results in three to five days (instead of the former seven to 10 days obtained with MFHPB<sup>lxxi</sup>-30); the method was validated in an AOAC-approved government validation study.<sup>274,227</sup>
- Examination of the effects of high-pressure processing on both *Listeria* and pathogenic *Escherichia coli* (*E. coli*) to understand how this technology affects the bacteria and where it could be used (for specific foods or under certain conditions in controlling these bacteria).<sup>133</sup>

With respect to the chemical safety of foods, BCS has also developed and published five laboratory procedures for surveillance since 2006 addressing the presence of benzene, acrylamide, BPA and melamine in various foods.<sup>199,165,186,198,202</sup> According to FD “a prioritization exercise is underway concerning review and potential re-validation of methods currently included in the *Compendium*” based on the following criteria: “status as an Official Method... ability to run the method using current (as opposed to older) technology and need to harmonize internationally.”<sup>272</sup> Related work includes the development of the following:

- Rapid methods for purification and screening of priority toxins including mycotoxins, phycotoxins and process-induced toxins in food and feed stocks.<sup>243,443,244,245</sup>
- Enhanced mass spectrometry method using multiple reaction monitoring capable of simultaneously detecting and quantifying 16 to 17 mycotoxins and metabolites in a single sample.<sup>242</sup>

Other examples of methods updated to continue to address evolving needs include: NML’s sub-typing and fingerprinting methods used during foodborne outbreaks (for which the laboratory is recognized as the government leader), and certification<sup>lxxii</sup> of PHCPHD’s Environmental Health Research Division (EHRD) laboratory testing, which has allowed testing for mercury in hair and has helped the Program in addressing mercury contamination on several reserves.

<sup>lxx</sup> The Committee is composed of a Steering Committee and Technical Groups with representation from Health Canada and CFIA.<sup>235</sup>

<sup>lxxi</sup> HPB Method (Health Canada’s *Compendium of Analytical Methods*).

<sup>lxxii</sup> International Organization for Standardization 17025 standards.

Many of these developments are achieved through collaborative efforts among key Program participants and with Program partners, for example:

- The establishment of a Health Canada/CFIA methods committee to review and endorse laboratory methods used in support of standard development/enforcement and to renew the governance of the MMC.<sup>228</sup>
- Work by Health Canada and the Public Health Agency of Canada on pathogen detection (e.g., *Listeria*, *Salmonella* and *E. coli*), which could be enhanced through research with AAFC's Guelph Food Research Centre on new food products and processes.<sup>133,136</sup>
- Joint studies by Health Canada and the Public Health Agency of Canada to develop a foundation of genetic evidence that can be used for future investigations. These studies use genomics technologies and *Listeria* isolates to investigate and understand the distribution and characteristics of *Listeria* populations that have previously been associated with outbreaks and contaminated food products.<sup>133</sup>
- Work by FD, in collaboration with the National Research Centre, to develop a "Lab on a Chip" that can perform sample isolation and detection. A prototype version has been produced and tested for *L. monocytogenes* and it is expected that the platform will be expanded to include other major foodborne pathogens (i.e., *Campylobacter*, *Salmonella*, *E. coli*, enteric viruses and parasites). The chip is anticipated to go from food to colonies within 48 hours, with a molecular "yes/no" or "presence/absence" screening response within the first six to eight hours of sample analyses.<sup>240,241,248</sup>

### Knowledge Exchange

Evidence collected during the evaluation identified hundreds of scientific publications, reports, conference proceedings and presentations related to FSNQ and used by key Program participants for knowledge exchange and collaboration. Access to much of this information is gained through departmental or agency Web sites as well as through a number of networks or Web-based systems such as (please refer to 0 for details on each system):

- Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS).
- Canadian Listeriosis Reference Service (LRS).
- Canadian Network for Public Health Intelligence (CNPHI).
- Canadian Nutrient File (CNF).
- C-EnterNet.
- First Nations, Food, Nutrition and Environment Study (FNFNES) Web site.<sup>lxxiii</sup>
- Global Foodborne Infections Network (GFN).
- Global Public Health Intelligence Network (GPHIN).
- National Enteric Surveillance Program (NESP).
- Network for First Nations Environmental Health Research and Communication.<sup>lxxiv</sup>
- Notifiable Diseases On-Line.
- PulseNet Canada.

<sup>lxxiii</sup> [www.fnfnes.ca](http://www.fnfnes.ca)

<sup>lxxiv</sup> Now the First Nations Environmental Health Innovation Network.

Many of these systems focus on Web-based surveillance technologies for disease detection for which Health Canada is recognized as a world pioneer.<sup>487</sup>

**KNOWLEDGE USE**

Use of scientific evidence and risk-benefit analysis in risk-management decision-making is part of the *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks*.<sup>145</sup> FD’s *Food Safety and Nutrition Policy Development in the Food Directorate - a reference manual* (2003) calls for the development of policy based on guidance provided by this framework,<sup>150</sup> while HPFB’s *Blueprint for Renewal* makes reference to risk-based regulatory approaches to improve system clarity, responsiveness and consistency.<sup>161,175</sup> The evaluation identified a number of guidelines, standards, frameworks and policies in high priority areas that had been impacted or developed as a result of advancement in scientific and regulatory research as well as consultation, which is in line with the above guidance documents; some of this evidence is presented in **Table 13**.

**Table 13 Policy and Regulatory Impact of Scientific and Regulatory Research**

Area	Time period	Trigger	Impact
Acrylamide in foods; asparaginase as a food processing aid	2002 to 2012	JECFA communication on the potential hazard of acrylamide in foods.  Asparaginase food additive submissions	<ul style="list-style-type: none"> <li>• Isolation of the major mechanism for the creation of acrylamide and its contributing factors (2002).</li> <li>• Acrylamide added to the List of Toxic Substances in Schedule 1 of the <i>Canadian Environmental Protection Act</i> 1999 (2007).</li> <li>• Update to Canada’s action response and risk management approach (2009) to acrylamide</li> <li>• Proposal to permit the use of the enzyme asparaginase in the processing of certain food groups by including it in Table V of Division 16 of the F&amp;DR (2009).</li> <li>• F&amp;DR amendment and revised exposure assessment of acrylamide in food (2012).</li> </ul>
BPA	2008	HRA of BPA from food packaging applications	<ul style="list-style-type: none"> <li>• Code of Practice: under development with USFDA and industry for infant formula.</li> <li>• Proposed <i>Order adding toxic substances to Schedule 1 to the Canadian Environmental Protection Act, 1999</i> published on in the Canada Gazette Part I as part of the CMP (2009).</li> <li>• <i>Bisphenol A – Fact Sheet</i>.</li> <li>• <i>Consumer information – Safety of Plastic Containers Commonly Found in the Home</i>.</li> </ul>

Area	Time period	Trigger	Impact
CFIA's food safety activities	1999 and on-going	BFSA assessments of CFIA's food safety activities	<ul style="list-style-type: none"> <li>• Technical advice (2002-2004) to BMH and BFPI on the development of food safety policies and standards.</li> <li>• Review (2004-2005) of BMH's revised Guideline # 12 (Fermented Sausage) and recommendation on a separate food safety control guideline for beef jerky.</li> <li>• Recommendation (2005-2006) on the issue of interim guidelines for the control of Verotoxigenic E. coli in dried beef products (policy on E. coli 0157.H7).</li> <li>• Advice (2008-2009) on the identification of food safety risks and strengthening of Health Canada policy (update on Salmonella policy).</li> </ul>
FCSAP (food additives, allergens; natural toxins; foodborne pathogens, and bioactives)	2008 an on-going	FCSAP-related initiatives to establish instruments (regulatory and non-regulatory)	<ul style="list-style-type: none"> <li>• Regulations related to enhancing labelling for food allergens, gluten sources and added sulphites.</li> <li>• Amendments to the Food Additive Tables, including nine IMA notices.</li> <li>• Amendments (three) for food additives for a total of 13 submissions.</li> <li>• Amendment for the approval of the additive Carnobacterium maltaromaticum CB1 or "Micocin," a food additive aimed to prevent Listeria growth in Ready-to-Eat (RTE) meat/poultry products.</li> <li>• Amendments enabling 14 food additives.</li> <li>• Publication of 11 IMAs.</li> <li>• Health Canada's Policy Direction with respect to revising Canada's gluten-free labelling regulations.</li> <li>• Guidance (13) and standards/frameworks/ policies (four).</li> <li>• Guidance on caffeine, allergens, fresh produce and powdered infant formula.</li> <li>• Risk communication material on the microbial safety of fresh produce.</li> <li>• Risk/exposure assessment of the natural toxin DON to develop a guideline its presence in Canadian foods.</li> </ul>
Food fortification	1998 to 2005	Consultation on food industry submission for discretionary fortification	<ul style="list-style-type: none"> <li>• <i>Addition of Vitamins and Minerals to Foods: Proposed Policy Recommendations</i> (2000) and implementation plans.</li> </ul>
Listeriosis	2008 an on-going	HRAs in relation to the 2008 national Listeriosis outbreak and following investigation	<ul style="list-style-type: none"> <li>• Method updates.</li> <li>• Update of the 2004 policy on Listeria monocytogenes in RTE foods (2011).</li> <li>• <i>Weight of Evidence: Factors to Consider for Appropriate and Timely Action in a Foodborne Illness Outbreak Investigation</i> (2011).<sup>lxxv</sup></li> </ul>
Mercury in fish	2007	Human HRA of mercury in fish and health benefits of fish consumption	<ul style="list-style-type: none"> <li>• Updating the existing risk management strategy of mercury in retail fish (2007).</li> <li>• <i>Consumption Advice: Making Informed Choices about Fish</i> (2008).</li> </ul>

<sup>lxxv</sup> A guidance document to assess the quality and strength of evidence accumulated during foodborne outbreak investigations.<sup>133,140,269</sup>

Area	Time period	Trigger	Impact
Raw milk cheese	2000 and on-going	Multi-year project to collate data for a risk assessment on the safety of domestic and imported raw milk cheese in Canada  Multiple HRAs	<ul style="list-style-type: none"> <li>Quantitative assessment of Salmonella, Listeria and Verotoxigenic E. coli in raw milk cheese (2003).</li> <li>Policy on raw milk cheese (2005).</li> <li>Draft raw milk cheese federal code of practice (2006).</li> <li>Issue Analysis Summary (2010).</li> <li><i>Discussion Document on Soft and Semi-Soft Cheese made from Raw or Unpasteurized Milk</i> (2011).</li> <li><i>Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada</i> (2012).</li> </ul>
Sprouted seeds and beans	2001 to 2006	Qualitative Risk Assessment of Seeds/Beans and Sprouted Seeds/Beans	<ul style="list-style-type: none"> <li><i>Policy on Managing Health Risk Associated with the Consumption of Sprouted Seeds and Beans</i> (2006).</li> <li><i>Guidance for Industry: Sample Collection and Testing for Sprouts and Spent Irrigation Water</i> (2006).</li> <li>CFIA's <i>Code of Practice for the Hygienic Production of Sprouted Seeds</i> (2007).</li> <li><i>Health Canada reminds Canadians about the risks in eating sprouts</i> – information update.</li> <li>IYH – <i>Risks Associated with Sprouts</i>.</li> </ul>
Trans fats	2002 and on-going	Regulatory impact analysis statement on mandatory nutrition labelling, including declaration of trans fatty acids  Proposed amendments to the F&DR on reduction of Trans Fat Content in the Canadian food supply	<ul style="list-style-type: none"> <li>Regulatory amendments requiring manufacturers to list calories and the content of 13 core nutrients, including trans fat, on the labels of most pre-packaged foods (2007).</li> <li>Health Canada's Trans Fat Monitoring Program (2007).</li> <li>IYH – <i>Trans Fat</i>.</li> <li><i>Health Canada, Cost-Benefit Analysis of Reducing the Trans Fat Content of the Canadian Food Supply</i> (2009).</li> </ul>
Unpasteurized fruit juice/cider	2000	Qualitative risk assessment of unpasteurized fruit juice/cider	<ul style="list-style-type: none"> <li>CFIA's <i>Code of Practice for the Production and Distribution of Unpasteurized Apple and Other Fruit Juice/Cider in Canada</i>.</li> <li>IYH – <i>Unpasteurized Fruit Juice and Cider</i>.</li> <li><i>Unpasteurized Fruit Juices and Cider – Know What You Are Drinking</i> – pamphlet.</li> <li><i>Unpasteurized Fruit Juice/Cider</i> – fact sheet.</li> </ul>

While knowledge improvement and its use are evident from the above examples, interviewees during the evaluation expressed concerns related to the need for increased laboratory capacity to satisfy current and emerging demands, to remain abreast of scientific advances, and to increase internal expertise in a number of fields (e.g., biostatistics, epidemiology, electro-microscopy, bioinformatics, etc.). Some of these concerns are being addressed by the Program as part of broader efforts following the 2008 Listeriosis outbreak, for example:

- FD hired additional staff between 2009 and 2011 to strengthen its capacity to respond to HRAs 24/7, provide policy interpretations, and build surge-capacity in the case of a national foodborne illness event; however, over half of the completed hires were not



permanent, including five dedicated to develop and/or improve microbiological and chemical methods.<sup>272</sup>

- Federal surge capacity is being upgraded through hiring, training, laboratory certification, and partnerships among Health Canada, the Public Health Agency of Canada and CFIA.<sup>133</sup>
- FD has completed the development of a high intensity computing structure to support statistical and surveillance activities (Stat Lab).<sup>269</sup>
- Work is being done by Health Canada, CFIA and the Public Health Agency of Canada to create an inventory of the capabilities of federal laboratories (e.g., staffing levels, scientific expertise and available equipment/technologies) and to identify what partnerships have been established to increase the capacity for rapid detection of, and response to, potential foodborne illness outbreaks.<sup>133</sup>

### Immediate Outcome # 5: Improved Collaboration with F/P/T Partners and Stakeholders

To what extent has collaboration with F/P/T partners and stakeholders improved?

**The Program coordinates priorities and risk management approaches within Canada’s FSNQ system and contributes to improved collaboration through a number of committees and initiatives that include key Program participants, partners and stakeholders. While there is some satisfaction with Program efforts in this area, issues remain to be addressed with respect to communications and procedures related to Food Safety Assessments (FSAs) and HRAs.**

#### COLLABORATION EFFORTS

##### Engagement through Committees

Committees play an important role in collaborative initiatives by bringing together key Program participants, partners and stakeholders. **Table 14** provides a list of some of the committees identified during the evaluation that facilitate engagement and discussion on relevant areas.

**Table 14 Food Safety and Nutritional Quality Committees**

Committee	Participants	Meetings	Objectives
Agri-Subcommittee on Food Safety	AAFC, Health Canada, CFIA, Public Health Agency of Canada, industry representatives	4/year initially (2003), as needed thereafter	Strengthen relationships among Federal food safety partners and industry to ensure roles and responsibilities are understood and to contribute to the improvement of food safety policies and standards.
Canadian Inter-Departmental/ Inter-Agency DRI Steering Committee	Health Canada (FD, ONPP, Natural Health Products Directorate, FNIHB), Public Health Agency of Canada, CIHR, AAFC, CFIA, Department of National Defence, Correctional Services Canada	As needed (~2/year)	Coordinate participation of the federal government in DRI review activities and application of the DRIs in policies and programs.

Committee	Participants	Meetings	Objectives
F/P/T Food Safety Committee <sup>lxxvi</sup> (FPTFSC)	Health and Agriculture Ministries across Canada (e.g., Health Canada and CFIA), P/T representatives	2/year or as needed, additional meetings as required	Coordinate the development of national food safety policy options to implement initiatives to achieve national food safety goals and priorities and to enhance accountability.
F/P/T Group on Nutrition (FPTGN)	Health Canada (FD, ONPP, FNIHB), P/T health representatives	1/year, teleconferences as needed	Provide leadership to encourage actions to achieve Canadians' nutritional well-being by sharing information on food and nutrition technical issues, programs, policies and human resources.
Food and Nutrition Surveillance System Working Group	Health Canada, other government departments and agencies, P/T governments through FPTGN	As needed	Develop a description of a national food and nutrition surveillance system, seek departmental commitment and financial support to ensure its implementation, and serve as an advisory body to the operation of the national Food and Nutrition Surveillance System.
Food Security Reference Group	Inuit Tapiriit Kanatami, Assembly of First Nations, Health Canada, Aboriginal Affairs and Northern Development Canada (AANDC), experts	4/year (maximum), teleconferences as needed within sub-groups	Aid in focussing collective efforts towards improved food security for First Nations and Inuit and help inform the work of FNIHB.
Health Canada/CFIA Committee on Food Safety and Nutrition	Health Canada, CFIA	As needed	Provide guidance and leadership on policies and strategic directions to the federal food safety and nutrition regulatory system.
Health Canada/CFIA Science and Policy Advisory Committee on Food Safety and Nutrition	Health Canada, CFIA	3-4/year	Support the Health Canada/CFIA Steering Committee on Food Safety and Nutrition and contribute to the coordination of relevant activities between Health Canada and CFIA.
Health Canada/CFIA Research and Surveillance Subcommittee on Food Safety and Nutrition	Health Canada, CFIA	3-4/year	Support the Science and Policy Advisory Committee and be the forum for joint planning, coordination strategies in the areas of research and surveillance and information exchange.
Health Canada/CFIA Steering Committee on Food Safety and Nutrition	Health Canada, CFIA	2/year	Support the Health Canada/CFIA Committee on Food Safety and Nutrition through strategic advice, problem resolution, and oversight of federal food safety and nutrition regulatory activities.

<sup>lxxvi</sup> FPTFSC amalgamated three F/P/T Government committees that facilitated FD's communication with its F/P/T partners on food safety issues: the F/P/T Committee on Food Safety Policy, the Canadian Food Inspection System Implementation Group, and the F/P/T Agri-Food Inspection Committee.

Committee	Participants	Meetings	Objectives
Health Canada/Public Health Agency of Canada/CFIA Committees on Food Safety (CFS) at the Director General (DG CFS), Assistant Deputy Minister (ADM CFS) and Deputy Minister (DM CFS) level	Health Canada, Public Health Agency of Canada and CFIA. Other partners are invited as required: AAFC (a standing participant), Environment Canada (EC), Fisheries and Oceans Canada, DFATD and others contribute on issues of relevance to their mandate	1/biweekly (DG CFS) 1/month (ADM CFS) 1/year (DM CFS)	Coordinate and support concerted efforts related to food safety programs developed and implemented+by federal partners.
Outbreak Investigation Coordination Committee	Health Canada, Public Health Agency of Canada, CFIA, P/T representatives	As needed	Allow the partners to use the FIORP as a guide to share information and to formulate and coordinate the outbreak investigation and response strategies in order to mitigate or contain the effects of multi-jurisdictional foodborne illness outbreaks in a timely and effective manner, thereby protecting the health of Canadians.
National Nutrition Advisory	FNIHB and territorial nutritionists	2/year, scheduled teleconferences throughout the year	Serve as a forum for discussions on food and nutrition issues specific to First Nations and Inuit populations to inform national policies and programming; enable sharing of regional and territorial food and nutrition information related to First Nations and Inuit populations.

In 2009, FD created its Food Policy and Science Integration Committee as “the principal intra-Directorate advisory body to discuss and recommend options to address key food safety and nutrition issues.”<sup>217</sup> Regular members include FD and PPIAD within HPPFB, while additional participants can be informed of “agenda items that may be of interest to them, and [would be welcomed]... to attend and participate in discussions on those agenda items should they choose to do so.” Additional participants include VDD, ONPP, the Public Health Agency of Canada and CFIA.<sup>217</sup> The purpose of the committee is to serve as a forum for discussion and advice on risk management and emerging risks, regulatory decision-making, horizontal science and policy files, and international and interagency international meeting issues; oversee a coordinated response to food risk issues and ensure that food policies are based on science; determine FD’s recommended options for action; identify issues for decision-making at HPPFB, senior departmental management and/or ministerial level; provide updates to senior management on major science and surveillance projects and review the alignment of laboratory-based work to support food policy development and standard-setting; ensure transparency of process and decision-making through on-going documentation, status reports and follow-up of risk management issues and initiatives.

In 2009, FD also embarked on the creation of a Food Regulatory Advisory Committee aimed at gathering members with expertise in scientific fields relevant to the mandate of the Directorate from research/academia, health professional/regulatory, industry, and patient and consumer groups. The Committee held its inaugural meeting in September 2010. Later in 2011, the Food Regulatory Advisory Committee was renamed as the Food Expert Advisory Committee (FEAC) to capture areas of its mandate that went beyond food regulatory questions.

As part of the government response to the 2008 Listeriosis outbreak, the Special Committee of Deputy Heads (SCDH) was formed to improve coordination and collaboration among federal departments and agencies that have responsibilities in Canada's food safety system to better position partners to share information and collaborate in response to potential foodborne illness outbreaks. The Committee includes representation from AAFC, Health Canada, the Public Health Agency of Canada and CFIA and Agri-Subcommittee on Food Safety as needed.

Subsequent to the review of the federal governance structure for food safety and nutrition, and the implementation of lessons learned resulting from the 2008 Listeriosis outbreak, structures were updated and are now based on the DM CFS, ADM CFS and DG CFS. The DM CFS was identified as the on-going structure taking over for SCDH.

### Collaboration through Initiatives

Key Program participants, partners and stakeholders also collaborate in the development of policies, protocols and MoUs to address relevant regulatory areas such as:

- Governance:
  - o MoU between Health Canada, the Public Health Agency of Canada and CFIA on the roles and responsibilities of each organization with respect to common issues that impact human health, including food safety and nutrition, infectious disease outbreak management and emerging zoonotic diseases.<sup>363</sup>
- HRAs:
  - o MoUs (1999 and 2007) with CFIA and FNIHB delineating roles and responsibilities for the development of HRAs.<sup>179,190</sup>
  - o HRAs (2010 and 2011 [second part in 2012]) developed as part of on-going policy work to update the F&DR requirements around soft and semi-soft cheese made from raw milk.
- Foodborne outbreaks:
  - o The *Canada Foodborne Illness Outbreak Response Protocol (FIORP) to Guide a Multi-Jurisdictional Response*<sup>141</sup> and its recent revision<sup>142</sup> led by the Public Health Agency of Canada in consultation with Health Canada, CFIA and P/T counterparts “to enhance collaboration and overall effectiveness of the response to multi-jurisdictional food-borne illness outbreaks”.<sup>133</sup>
  - o MoU between Health Canada and the Public Health Agency of Canada (2008) to ensure that both organizations would be appropriately prepared to provide for the continued delivery of the analysis of samples of *L. monocytogenes* (in support of LRS) in the event of a major food safety event and to clarify their respective roles and responsibilities as a result of lessons learned during 2008 Listeriosis outbreak.<sup>364</sup>
  - o The *Foodborne Illness Emergency Response Plan*, developed by the Public Health Agency of Canada and Health Canada “for those occasions when a food-borne illness outbreak requires a response beyond the scope of the FIORP.”<sup>133</sup>

- o Guidance provided by FD, the Public Health Agency of Canada and CFIA in the *Weight of Evidence: Factors to Consider for Appropriate and Timely Action in a Foodborne Illness Outbreak Investigation* to assess the quality and strength of evidence accumulated during foodborne outbreak investigations.<sup>140</sup>

Other initiatives carried out by the Program that contribute to collaboration include:<sup>173,476,133,135</sup>

- Pre-submission meetings in preparation for industry food submissions.
- Partner initiatives such as the NCP and the First Nations Environmental Contaminants Program involving the Assembly of First Nations, FNIHB and the First Nations University of Canada; the First Nations Food, Nutrition and Environment Study involving the University of Northern British Columbia, the Université de Montréal, the Assembly of First Nations and FNIHB;; Lifeline;<sup>lxxvii</sup> and, the Food Mail Program, which was replaced by Nutrition North Canada in April 2011.
- Key Program participant initiatives such as work by FNIHB and the Public Health Agency of Canada on the Food Security Knowledge Initiative (2009-2012) to demonstrate the value of community-driven approaches for informing action and programming at the community level.<sup>lxxviii</sup>
- Workshops such as *Towards a National Food Safety Strategy* involving federal government departments and agencies related to food safety, provincial governments, industry, academia, and trade, producer and consumer associations.
- Work through advisory bodies, e.g., the Trans Fat Task Force (TFTF) involving Health Canada, CFIA, the Public Health Agency of Canada, AAFC, academia, industry and consumer associations.
- Work through expert advisory bodies, e.g., Advisory Committee on Management and Advisory Committee on AMR Risk Assessment.
- Bilateral stakeholder meetings, e.g., HPFB's ADM stakeholder meetings, and le Forum d'échanges avec les intervenants québécois sur les aliments.<sup>lxxix</sup>
- Bilateral P/T meetings, e.g., Health Canada-British Columbia Quarterly Conference Calls,<sup>lxxx</sup> and meetings to address specific issues (e.g., raw milk cheese).<sup>250,317,318,323,325,326,327,440,441,312</sup>

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<sup>lxxvii</sup> FNIHB and PMRA work with the LifeLine Group (a US non-profit organization) to address issues of environmental health research, risk assessments of traditional foods and nutritional concerns related to First Nations and Inuit communities in Canada.

<sup>lxxviii</sup> One of the projects within this initiative included the testing of a solutions-oriented community food assessment model in both a First Nations and an Inuit community. Community food assessments showed promise in helping improve local food access, build partnerships between key sectors, and inform action in neighbouring communities. This knowledge has been integrated into FNIHB policy and community-based programming such as the Aboriginal Diabetes Initiative.

<sup>lxxix</sup> Engagement of selected consumer groups and health professional organizations piloted at the provincial level, specifically in Québec.

<sup>lxxx</sup> Bilateral meetings to discuss files of common interest related to food safety and nutrition as well as to share and discuss regulatory updates. Health Canada-BC meetings occur on a quarterly basis.

- Consultations with stakeholders such as those on the issue of updating the existing requirements to enhance the protection of the health of Canadians who consume soft and semi-soft cheese made from raw milk.<sup>250,317,321,442,318,323,324,325,326,327,440,441,312</sup>
  - o Health Canada implemented a three-phase consultation strategy: 1) provincial health and agriculture agencies were engaged in 2010 and 2011 to develop a shared understanding of the issue; 2) a consultation process with a broader range of stakeholders (experts, interested and affected stakeholders, including the public) on options to manage the risks of soft and semi-soft cheese made from raw milk was scheduled to occur in 2012; 3) Health Canada anticipated publishing its proposed policy intent on its Web site to obtain comments on proposed regulatory amendments in winter/spring 2013 followed by pre-publication in the Canada Gazette Part I in spring 2014.<sup>lxxxi</sup>
- Multi-agency meetings, e.g., the Ontario Multi-Agency Foodborne Outbreak/Food Recall Working Group.<sup>lxxxii 380,382</sup>
- Broad industry engagement, e.g., regular Food Supply Chain Stakeholders meetings.
- Targeted industry engagement, e.g., proposed risk management strategies to reduce exposure of the natural toxin Ochratoxin A in food.
- International engagement, e.g., evaluation of options for risk profiling tools and information exchange with the US Department of Agriculture and USFDA.

## SATISFACTION WITH COLLABORATION

Evaluation interviewees expressed some satisfaction with Program efforts on collaboration and consultation, in particular with P/T governments and regional offices (e.g., through FPTGN, TTF and FPTFSC), with industry and consumer associations (e.g., through FPTGN and TTF), with other federal partners (e.g., through FPTGN, TTF, FPTFSC and federal Food Safety Senior Management meetings involving Health Canada, the Public Health Agency of Canada and CFIA), and with First Nations and Inuit (e.g., through FPTGN, the National Nutrition Advisory, and the Food Security Reference Group).

While some interviewees mentioned that there was a lack of integrated strategic planning and engagement with AAFC, recent efforts to increase collaboration between food safety partners (e.g., through SCDH and CFS, the Food Safety Health Risk Assessment Consortium, and the recent integration of CFIA into the Health Portfolio) may already be addressing this concern.

The evaluation also examined the interaction between Health Canada and CFIA in the case of FSAs and HRAs as presented in the following sub-sections.

<sup>lxxxi</sup> As of the third quarter of 2013, Health Canada had not yet published its proposed policy intent.<sup>417</sup>

<sup>lxxxii</sup> The WG seeks to improve the effectiveness of the multi-agency response to foodborne outbreak/food recall events in Ontario. Its membership consists of the Association of Supervisors of Public Health Inspectors (Ontario), CFIA, the Canadian Institute of Public Health Inspectors (Ontario Branch), Health Canada, the Ontario Ministry of Agriculture – Food and Rural Affairs, the Ontario Ministry of the Environment, the Ontario Ministry of Health and Long-Term Care, the Ontario Ministry of Natural Resources, the Public Health Agency of Canada, and Public Health Ontario.

## Food Safety Assessments

Subsection 11(4) of the CFIA Act states that the “... Minister of Health is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada and assessing the effectiveness of the Agency’s activities related to food safety.”<sup>35</sup> An *Appendix to Memorandum of Understanding between Health Canada and the Canadian Food Inspection Agency on the Food Safety Assessment Provision contained in Subsection 11(4) of the CFIA Act* outlines the general principles and operating procedures to carry out FSAs.<sup>13</sup> The *Assessment Policy – Food Safety Assessment Program (FSAP)* identifies its coverage as assessing “the rationale and design of CFIA’s activities; their implementation; and their success in meeting objectives and achieving results including compliance with health and safety standards.”<sup>154</sup> To facilitate interaction between Health Canada and CFIA, a FSA Advisory Committee was created to provide corporate guidance for the FSAs of CFIA activities, including overseeing the FSAP planning process, providing advice as needed throughout the conduct of individual FSAs, and reviewing the final assessment reports.

The evaluation identified a number of issues affecting collaboration and level of satisfaction with this activity:

- Poor FSA timeliness due to a number of factors, including conflicting operational demands within CFIA, a long multi-stakeholder review and acceptance process, and CFIA’s perceived burden of being audited or evaluated by multiple organizations.<sup>lxxxiii</sup> BFSAs had completed seven FSAs, two assessment frameworks and one paper (partial assessment) in a 10-year period<sup>lxxxiv</sup> and estimated its coverage of CFIA’s inspection programs at 57% over this same period.<sup>372</sup>
- Difficulty in planning and priority setting due to a lack of agreement on a risk-based approach to assessment selection and a lack of engagement through the FSA Advisory Committee. While a food safety risk ranking was carried out by the joint Health Canada-CFIA Food Safety Science Committee in 2008 and a list of proposed assessments for the period 2010 to 2015 was identified,<sup>184,187,167,177,178,183,208,37,219,233</sup> only six meetings of the FSA Advisory Committee took place during the period 2001 to 2007 with no other formal meetings held since the end of 2007.<sup>261,247,372</sup>
- Challenges to the approach and methodology used for FSAs due to lack of clarity regarding alignment with evaluation or audit practices. According to the Assessment Policy and the MoU between BFSAs and CFIA “the words ‘assessing the effectiveness’ in the CFIA Act were deliberately chosen to reflect an evaluation approach as described in the Treasury Board Evaluation Policy.”<sup>154,13</sup>
- Inconsistent implementation of recommendations due to insufficient monitoring of Management Response and Action Plans before 2007.<sup>lxxxv</sup><sup>187</sup> CFIA increased its follow

<sup>lxxxiii</sup> “... CFIA is audited or evaluated by the OAG [Office of the Auditor General of Canada], by its own internal audit and evaluation teams, occasionally by the OCG [Office of the Comptroller General of Canada], by major trading partners (U.S. and EU) and by BFSAs.”<sup>372</sup>

<sup>lxxxiv</sup> Not included are the Hatchery and Shell Eggs reports; MRAPs for these assessments were approved by CFIA’s Evaluation Committee in 2011.

<sup>lxxxv</sup> CFIA, personal communications, e-mail, September 1<sup>st</sup> and 6<sup>th</sup>, 2011.

up efforts after this time and all recommendations have been addressed for the assessments completed.<sup>lxxxvi</sup>

In order to address these issues, the FSAP began a review in 2010 to assess its relevance, governance, processes, and performance based on an examination by Health Canada of the FSA experience (1999 to 2009) and a consideration of FSAP's future strategic direction in the broader context of food policy development and implementation.<sup>226,266</sup> As a result, the launch of the next cycle of assessments as well as finalization of a draft multi-year risk-based assessment plan were put on hold pending the external review outcome.<sup>226,266,285</sup> Health Canada also began a Food Safety Meta-Review project with the objective of identifying broad themes for food safety improvement, best practices and/or lessons learned. The project was based on a document review that included BFSAs' FSA reports, CFIA evaluation reports as well as relevant domestic (e.g., Office of the Auditor General of Canada) and international (e.g., Australia, the EU, New Zealand, the UK and the US) food safety reports published between 1999 and 2010.<sup>226,266,285</sup>

A number of events, including the change in the reporting relationship of CFIA to the Minister of Health<sup>381</sup> and the discontinuation of the FSAP Advisory Committee, are also likely to affect the conduct of FSAs.

### Health Risk Assessments

Following the 2008 Listeriosis outbreak, FD committed to make improvements to enhance the efficiency and reliability of CFIA investigations and associated decision-making. The updated SOP *Food Directorate Standard Operating Procedures for Providing Health Risk Assessments to the CFIA in the Context of Food Safety Investigations* (2011) included confirmed service standard times, procedures for raising awareness of HRA decisions within the ADM Office at HPFB, HRA templates specific to BCS, BMH and BNS, and 24/7 emergency contact numbers to respond to after-hours CFIA requests. Although CFIA-specific, these SOPs are also intended as a guide for responding to HRA requests from other governmental organizations (e.g., P/Ts).<sup>273,133,255</sup> The same year, Health Canada, the Public Health Agency of Canada and CFIA created a national Food Safety Health Risk Assessment Consortium to perform collaborative risk assessments. The goal of this Consortium is to change the relatively independent approach to risk assessment, which has led to the creation of data gaps and effort duplication, by bringing together F/P/T, academia and industry expertise. This is expected to allow the development of an operational platform through which priority issues can be selected for collaborative studies, including joint Health Canada-Public Health Agency of Canada work.<sup>279,249,260</sup>

While interviewees viewed the working relationship between CFIA and FD as well as the timeliness of responses to enquiries from CFIA as satisfactory, a HRA analysis performed by FD in 2011 identified three areas where communications and procedures specific to CFIA requests could be improved, namely:<sup>267</sup>

- E-mail HRA communications:
  - o E-mail "bounce back" due to large file attachments.<sup>lxxxvii</sup>

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<sup>lxxxvi</sup> CFIA, personal communications, e-mail, November 8<sup>th</sup>, 2013.



- Business continuity:
  - Bureau Web Office outage.<sup>lxxxviii</sup>
  - 24/7 access to the Sir Frederick G. Banting Building, which hosts FD's main installations.
  - Secured eMail and file transfers.
  - Solution PosteCS™.<sup>lxxxix</sup>
- HRA communication protocols and point of contact:<sup>xc</sup>
  - Bilateral meetings held between FD and CFIA's Office of Food Safety and Recall in 2011 to maintain dialogue on:
    - exchange of information;
    - agreement on communication protocols on HRA issues; and,
    - agreement on single point of contact on HRA issues.

It should be noted that some of these improvements are related to FD/Health Canada IT infrastructure and the fact that Health Canada and CFIA do not share the same IT platform.

## 4.4.2 To what extent have the intermediate outcomes been achieved?

### Intermediate Outcome # 1: Healthier Food Choices made by Consumers

**To what extent have consumers made healthier food choices based on Program activities?**

**It is not known if consumers have made healthier food choices as a result of Program efforts. Available information points to issues of concern related to the dietary intake of the general population (e.g., high calories from fat, sodium intakes exceeding recommended limits) and First Nations and Inuit communities (e.g., consumption of certain food groups below recommended levels). While food labels are viewed as an important tool in helping consumers make informed food choices, the success of this tool is unclear.**

The evaluation was unable to identify conclusive evidence linking changes in consumer food choices to Program contributions (e.g., information products). While increased awareness and understanding of food safety and nutrition related risks and health benefits are expected to contribute to the achievement of this outcome, the Program has not assessed its contributions to this outcome. The evaluation has identified, however, areas where consumers lack awareness or

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<sup>lxxxvii</sup> According to CFIA, the pending restrictions on e-mail box sizes as a result of the Email Transformation Initiative will likely contribute to increased issues with communications.

<sup>lxxxviii</sup> Bureau Web Office is a Web-based service that allows employee access to Health Canada's resources from a remote desktop at any time. This service hosts Health Canada's standard and business applications and grants file access to an employee's data.<sup>25</sup>

<sup>lxxxix</sup> PosteCS™ is an Internet-based document delivery service offered by Canada Post that allows electronic documents to be sent securely, speedily and conveniently to anyone with an Internet e-mail address and a Web browser.<sup>401</sup>

<sup>xc</sup> One of the conclusions in the source states "fostering better communications and consistent procedures in line with draft FD SOP."<sup>267</sup>

understanding (e.g., nutrition and healthy eating, nutrition labelling, trans fats and GM foods; see immediate outcome # 2).

Data from several sources examined provides only a partial picture of current food choices, while acknowledging differing views, for example:

- “Canadians are generally within acceptable ranges for the number of servings from the four major food groups and the percentage of calories from fat, protein and carbohydrates and is generally true for both sexes, all age groups, by region, and by household income.”<sup>114</sup>
- “...the majority of Canadians do not eat the recommended daily minimum of five servings of vegetables and fruit.”<sup>114</sup>
- “More than a quarter of men and women in their thirties and forties get more than 35% of their calories from fat,” the threshold beyond which health risks increase.<sup>114</sup>
- Snacks<sup>xci</sup> account for more calories than breakfast and about the same as lunch for most Canadians.<sup>114</sup>
- “More than one-third of children aged 4 to 9 do not have the recommended two servings of milk products a day, and among seniors aged 71 or older, the proportion surpasses 70%.”<sup>114</sup>
- For children below the age of nine, many do not consume the recommended minimum daily levels of vegetables and fruits (70% for children aged 4 to 8).<sup>114</sup>
- “Canadians of all ages get more than a fifth of their calories from ‘other foods,’ and on a given day, a quarter of Canadians, adults and children alike, eat something that was prepared in a fast-food outlet.”<sup>114</sup>
- “Among Canadians aged 19-70, over 85% of men and 60% of women have sodium intakes exceeding the recommended Upper Limit (UL).”<sup>xcii 47</sup>
- “... among people aged 9 to 70, over 85% of men and between 63% and 83% of women had sodium intakes exceeding the UL. Similarly, in young children, 77% of those aged 1 to 3 and 93% of those aged 4 to 8 years had intakes exceeding the UL. Among males in their teen years, 97% exceed the UL, and for females in that age group 82% exceed the UL.”<sup>229</sup>
- “The major contributors to dietary sodium intake are commercially prepared foods, including those from restaurants and food service establishments. ...In total, it is estimated that commercially processed foods account for 77% of the sodium intake.”<sup>229</sup>

In the case of First Nations on-reserve and Inuit communities, evaluation interviewees believed that knowing something about *Eating Well with Canada’s Food Guide – First Nations, Inuit and Métis*,<sup>196</sup> while positive, did not necessarily translate into changing dietary behaviour. These interviewees also believed that First Nations and Inuit individuals, in particular, find it difficult to make healthy dietary choices. Some interviewees also believed that food safety guidelines, health risks and nutrition labels are not well understood. It should also be noted that some food decisions by First Nations on-reserve and Inuit communities may be affected by food insecurity

<sup>xci</sup> Food and drink consumed between meals.

<sup>xcii</sup> 2,300 mg per day.<sup>229</sup>

and its influencing factors, including poverty, high food costs, environmental changes and government restrictions:

- For Aboriginal children, adolescents and adults alike, consumption of fruit and vegetables as well as milk and alternatives are below the recommendations found in *Canada's Food Guide*.<sup>96,341,304,448,336,56,55,97,23</sup>
- Children and adults alike are not adequately limiting low-nutrient “snack” foods and sugar-sweetened beverages, resulting in most commonly 10% to 20% and up to 35% of energy coming from such foods.<sup>341,342,23,448,336,55,56,383</sup>
- Traditional food contributes less energy to the diet than in years past, although the number of traditional food consumers remains high in many First Nations and Inuit communities.<sup>448,56,55</sup> Possible reasons for the decrease in the consumption of traditional foods include lack of abundance of traditional foods, concerns over pollution and a changing way of life.<sup>464,149</sup> Some communities report a reduction in the consumption of specific foods (e.g., specific types of fish) in response to public health advisories to limit consumption of potentially harmful contaminants (mercury, cadmium, etc.).<sup>143,334,113</sup>
- According to public opinion research conducted in 2008, First Nations people on-reserve identify fast food (24%) and poor diet (12%) as two of the leading causes of obesity in their communities.<sup>196</sup>

One of the ways in which the Program can aid the consumer in making healthier food choices is through food labels; however, data on the success of this tool is inconsistent. According to *Tracking Nutrition Trends VII* (2008), 95% of Canadians who use food labels are able to find the information they need and use it to determine the nutrient and calorie contents of foods, to make comparisons among foods and to determine if the food contains a specific ingredient. The report also states that 68% of Canadians get nutrition information from product labels and identifies the most influential drivers of food choice as low trans fat content (80%), made with whole grains (78%), low in sugar content (72%) and low in salt or sodium content (71%).<sup>34</sup> Other sources provide different information:

- The nutrition facts panel on product labels is “always or usually” read by only 61% of women and 52% of men. One of the main weaknesses in Canada’s nutrition facts panel is that there is no standard serving size, which makes it difficult for consumers to compare the nutritional quality of similar food products.<sup>47</sup>
- “Canadians lack knowledge about calories and nutrients, which compromises their ability to select nutritious foods” (e.g., little understanding of the % DV and what would be considered “high” or “low” content of a nutrient).<sup>229</sup>
- Food product labels present challenges to consumers, including interpretation of the % DV and the specific amount of food presented on labels.<sup>229</sup> Portion size is a significant contributor to the obesity problem.<sup>344</sup>
- Understanding of trans fats changes according to the cohort being interviewed, e.g., a survey conducted in 2004 (n=1,423) reported that 36% of Canadians did not know what “trans fats” signified and that only 46% had high awareness of trans fatty acids;<sup>153</sup> another survey (n=over 12,000 Canadian households) that same year reported that 79% of Canadian households were aware of health risks associated with trans fatty acids.<sup>159</sup>

A lack of continuous information has presented challenges. According to the 2005 *Food and Nutrition Surveillance System Business Case*, no national population-based data on food consumption, and related physical and biological measures, had been collected in the previous three decades. It also identified the lack of a viable, effective, comprehensive national food and nutrition surveillance system in Canada as well as the lack of Health Canada infrastructure to support it. This gap includes the ability to manage data coming from the investment in the *Canadian Community Health Survey (CCHS) 2.2*,<sup>xciii</sup> while such systems are widely in place internationally.<sup>155</sup> Similarly, data collection on Canadians' dietary intakes has been uneven (prior to 2004, comprehensive food consumption data was collected in 1970-1972) and while the CNF contains valuable information, its food classification system does not align with *Canada's Food Guide* (which has impeded the analysis of CCHS 2.2 data in relation to the 2007 *Canada's Food Guide*).<sup>xciv,xcv</sup> While recent efforts by Statistics Canada (StatCan) and Health Canada may be addressing some data collection issues by repeating CCHS on a continuous basis, the next national nutrition survey is planned to take place in 2015 and the ability to manipulate CCHS data by interested parties (e.g., F/P/T governments, health groups, research institutions and industry) appears restricted due to confidentiality issues. These issues may affect policy and Program development.

## **Intermediate Outcome # 2: Reduced Exposure to Microbial, Chemical and Physical Hazards and Nutritional Risks**

**To what extent has exposure to microbial, chemical and physical hazards and risks been reduced and nutrition benefits been increased?**

**The number of cases of reported enteric diseases appears to have declined over the past decade (from 793 to 409 or 48% according to C-EnterNet data, and from 36,544 to 21,132 or 42% according to Notifiable Diseases Online), while compliance rates for chemical residue testing have remained overall high (at or above 95%). Program efforts to address emerging issues (e.g., Listeriosis, acrylamide) as well as initiatives to re-assess products already on the market (e.g., pesticide re-evaluation) may be playing a role in reducing exposure to microbial and chemical hazards. While the change in exposure to nutritional risks could not be ascertained due to insufficient data, some Program initiatives, such as awareness campaigns, trans fat reduction, and food fortification, appear to be contributing to risk reduction in certain areas.**

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<sup>xciii</sup> CCHS 2.2 data collection took place in 2004.

<sup>xciv</sup> Changes involving multiple internal partners were required to the food classification system in the CNF to align foods with the Food Guide. That process was expected to be finalized in spring 2012.

<sup>xcv</sup> Data interpretation is limited by different data collection methods employed by each survey or report: data collection for the *1970-1972 Nutrition Canada National Survey* was done manually by dietitians/nutritionists, whereas for CCHS 2.2 trained interviewers used an automated system; the response rate for the former (47%) was much lower than that for the latter (77%); etc.).<sup>114</sup>

Changes in the exposure to microbial and chemical hazards can be the result of several factors, among them:

- Improved Program assessment and detection mechanisms (e.g., HRAs or laboratory methods).
- New and/or modified policies that reflect Program learning such as improved surveillance, monitoring, compliance and enforcement activities.
- Proactive changes by industry (e.g., producers, manufacturers and distributors) such as the implementation of new detection methods.
- Changes in food handling by consumers due to, for example, increased awareness and understanding of food safety risks.
- Proactive changes by consumers to address emerging issues (e.g., dietary changes).

Similarly, changes in the exposure to nutritional risks can be the result of multiple factors linked to consumer behaviour, industry actions and Program initiatives.

### CHANGE IN EXPOSURE TO MICROBIAL HAZARDS

C-EnterNet data on enteric diseases collected by the Public Health Agency of Canada's Sentinel Site 1 reported an overall decline of 48%<sup>xcvi</sup> in the number of reported cases of 11 enteric diseases between 1990 and 2011.<sup>407,408,410,415,416</sup> A similar trend is reported by the Agency's Notifiable Diseases On-Line database, which points to a national decline on 42%<sup>xcvii</sup> in all the nine enteric diseases tracked between 1990 and 2004.<sup>406</sup> The largest numbers of cases have been linked to Campylobacteriosis, Salmonellosis, and Giardiasis.

These trends provide an overall positive picture regarding microbial hazards, while some issues of concern remain with specific products. For example, the risks related to the consumption of cheese made from raw or unpasteurized milk (also known as "raw milk cheese") have been investigated by the Program for over a decade.

In 2001, after a review by Health Canada and CFIA determined that the application of the outcomes-based EU Directives on raw milk cheese by the French industry included requirements considered to be equivalent or more stringent to those found in Canada, certain French manufacturers were provided with a "special dispensation" permitting them to import and sell their soft raw milk cheeses in Canada in contravention with the F&DR. Later in 2008, after a review by Health Canada, Québec amended its regulations to permit the sale and production of soft and semi-soft raw cheeses that do not comply with the storage requirements of the F&DR,<sup>xcviii</sup> provided the cheese is produced in compliance with specified standards.<sup>xcix</sup>

250,317,321,318,324,325,326,440,441,312,236,353,354

<sup>xcvi</sup> 51% for the sub-set of diseases for which reporting has been continuous over the 22 years of data collection, namely Amoebiasis, Campylobacteriosis, Giardiasis, Salmonellosis, Shigellosis, Verotoxigenic E. coli, and Yersiniosis.

<sup>xcvii</sup> 41% for the sub-set of diseases for which reporting was kept over the 15 years of data collection, namely Campylobacteriosis, Giardiasis, Hepatitis A, Salmonellosis, Shigellosis, and Verotoxigenic E. coli.

<sup>xcviii</sup> The F&DR storage requirement specifies a 60-day storage period at 2°C.

During this time, Health Canada has conducted a number of HRAs, including a *Joint FDA/Health Canada quantitative assessment of the risk of Listeriosis from soft-ripened cheese consumption in the United States and Canada*,<sup>477</sup> and considered a number of strategies to improve the safety of raw milk cheese (see **Table 13**) due to concerns regarding the efficacy of F&DR requirements. While recent advances in food safety and Good Manufacturing Practices can help to minimize the risks associated with soft and semi-soft raw milk cheese if undertaken by manufacturers of these cheeses, recent research indicates that pathogenic bacteria such as *L. monocytogenes*, *E. coli* O157:H7 and *Salmonella* can survive the production conditions used to make these cheeses and, for some cheese types, the levels of some pathogens such as *L. monocytogenes* may actually increase during the storage requirement specified in the F&DR. Consequently, Health Canada determined that the F&DR's current microbiological criteria for soft and semi-soft cheese made from unpasteurized milk are outdated and do not reflect the current science on mitigating the risk posed by foodborne pathogens such as *L. monocytogenes* or *E. coli* O157:H7. In 2009, Health Canada issued a Temporary Marketing Authorization Letter (TMAL)<sup>c</sup> to a domestic manufacturer permitting the sale of soft raw milk cheese that does not comply with the storage requirement of the F&DR but is produced according to Québec regulations in order to generate information that will be used to amend the F&DR.<sup>ci</sup> Also, as a result of an Issue Analysis Summary conducted in 2010, Health Canada has identified a number of elements to be incorporated into a revised policy to manage the risks associated with the consumption of these cheeses. Since some of these elements would require regulatory amendments, Health Canada began stakeholder and expert consultations in 2011. It is expected that pre-publication of the policy intent in the Canada Gazette Part I will occur in 2014.<sup>250,319,317,321,442,318,323,324,325,326,327,440,441,312,477</sup>

## CHANGE IN EXPOSURE TO CHEMICAL HAZARDS

CFIA tests on various products for chemical residues<sup>cii</sup> have revealed overall high compliance rates as shown in **Table 15** with the possible exception of shell egg and honey.<sup>39,40,41,42,43,44,45,46</sup> CFIA establishes a compliance target of 95% or above to deem the performance status as met.

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**xcix** The regulations emphasize the mitigation of potential microbiological contamination of cheese during production.

**c** The F&DR permit Health Canada to issue a TMAL to a manufacturer or distributor to sell an otherwise prohibited product in order to generate information in support of an amendment to the regulations.

**ci** The TMAL was recently re-issued until 2015.

**cii** The testing usually targets new products or products that may pose health risks.

**Table 15 Domestic and Imported Food Products – Compliance Rates for Chemical Residue Testing by Food Program**

CFIA Food Program	Compliance Rate <sup>ciii</sup>										
	2002-2003	2003-2004	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012	
										Domestic	Imported
Meat	100%	100%	100%	96%	97%	96%	97%	96%	97%	96%	99%
Fish and seafood				98%	96%	95%	96%	95%	95%	98%	84%
Fish, seafood and production (domestic)			98%								
Fish, seafood and production (imports)			86%								
			(non-targeted) <sup>civ</sup>								
			78%								
		(targeted) <sup>cv</sup>									
Fresh fruit and vegetables	98%	99%	100%	99%	97%	95%	97%	97%	97%	97%	95%
Processed products	98%	99%	100%	99%	100%	99%	99%	99%	99%	94%	95%
Shell egg	100%	100%	100%	93%	87%	97%	97%	97%	94%	93%	99%
Dairy	99%	99%	96%	99%	99%	97%	98%	96%	98%	96%	90%
Honey	95%	98%	99%	94%	92%	84%	76%	61%	70%		

The Total Diet Study<sup>cvi</sup> also shows a reduction in chemical food contaminants in certain cases (e.g., trace lead levels in whole milk); however, this observation cannot be extrapolated to support the assumption that chemical contaminants have been reduced in all food as: 1) the available data is not continuous (i.e., data has not been consistently collected for all locations<sup>cvii</sup> across all years),<sup>cviii</sup> and, 2) the data varies greatly according to the food analyzed (e.g., trace zinc levels in whole milk vs. beef steak).

Some targeted Program initiatives may be playing a role in reducing exposure to chemical hazards such as those related to benzene in soft drinks,<sup>19,453,166,192,329</sup> acrylamide in

<sup>ciii</sup> CFIA only reported individual chemical residue testing compliance by domestic and imported products in 2004-2005 for fish and seafood and in 2011-2012 for all products.

<sup>civ</sup> Since most testing of imported fish and seafood products targets products with a poor compliance history, or none at all, separate compliance rates are provided for targeted and non-targeted testing for 2004-05. Past compliance rates were not calculated in the same manner and are, therefore, not comparable to the 2004-05 rates.

<sup>cv</sup> Idem.

<sup>cvi</sup> The study provides estimate levels of exposure to chemicals that Canadians in different age-sex groups accumulate through the food supply. The study has been conducted since 1969 over six separate periods (i.e., 1969 and 1973, 1976 to 1978, 1985 to 1988, 1992 to 1999, 2000 to 2004, and the most recent started in 2005). Each study is conducted in several major Canadian cities over the span of the survey period, normally one city each year, by testing each individual food item (there are approximately 210 individual food items for the current study).

<sup>cvii</sup> Toronto, Montreal, Winnipeg, Halifax, Vancouver, Ottawa, Whitehorse, Calgary, Québec and St. John's.

<sup>cviii</sup> 1993 to 2009.

foods,<sup>138,302,303,7,8</sup> and BPA in food packaging.<sup>197,21,301,296,193</sup> In the specific case of acrylamide, once the potential hazard related to acrylamide was communicated through JECFA in early 2002, Health Canada began research into the potential health risk posed by the presence of acrylamide in the food supply and also into the determination of the mechanisms of formation of acrylamide in food. By September of 2002, Health Canada had isolated the major mechanism for the creation of acrylamide and its contributing factors. Following the investigation into the dietary sources of acrylamide in Canada, the article *Acrylamide in Foods: Occurrence, Sources, and Modelling* was published in the *Journal of Agricultural and Food Chemistry* in 2002;<sup>17</sup> and later in 2004, also in a paper entitled *Acrylamide in French Fries: Influence of Free Amino Acids and Sugars*.<sup>18</sup> In 2007, acrylamide was identified as a Challenge Chemical under the CMP and added to the List of Toxic Substance in Schedule 1 of the *Canadian Environmental Protection Act 1999*.<sup>92</sup> This classification of acrylamide into the CMP resulted in funding to FD for further determination of acrylamide residues in foods that are sold in Canada.<sup>209</sup> Canada has consequently updated its action response and risk management approach (2009) to acrylamide, which will help reduce Canadians' exposure to acrylamide from food sources, is proposing to add acrylamide to Health Canada's Cosmetic Ingredient Hotlist,<sup>60</sup> and has provided recommendations for Canadians on how to reduce acrylamide in foods. During 2009 and 2010, Health Canada held consultations on its proposal to amend the F&DR to permit the use of Asparaginase in certain food products as a processing aid to reduce the formation of acrylamide.<sup>210,424,452</sup> In March 2012, Health Canada amended the F&DR as a result of the consultations<sup>432</sup> and revised its exposure assessment of acrylamide in food.<sup>303</sup>

Evidence on the extent of potential exposure to chemical hazards among First Nations who consume traditional foods is being developed for the first time through FNIHB's FSNQ funding. Under FNFNES, a 10-year collaborative initiative started in 2008, a baseline of the modern diets of First Nations as well as the residue in traditional foods is being established for the first time; it is expected that this study will enable the assessment of changes in exposure. Study results to date have helped guide risk assessment and risk communication activities for First Nation communities. FNFNES is the First Nations equivalent to the Total Diet Studies conducted over the past four decades among the general Canadian population but not in First Nation Communities.

### Pesticide Re-evaluation Activities

PMRA's pesticide re-evaluation program applies to technical active ingredients as well as to active ingredients in end-use products registered prior to December 31<sup>st</sup>, 1994. The re-evaluation process takes into consideration current scientific assessment methods, regulatory criteria, use patterns of the active ingredients (including incident reports), the diversity of the end-use products, and market penetration. This process also assesses exposure risks to sensitive groups such as children; aggregate exposure from combined dietary, residential and drinking water sources; and, risk of cumulative exposure to chemicals with a common mechanism of toxicity.

The purpose of the re-evaluation program is to determine if these products remain acceptable for use when assessed against modern scientific standards.<sup>387</sup> According to *Regulatory Directive DIR2001-03*, the program intended to review the continued acceptability of 405 active ingredients and their associated end-use products under Section 19 of the *Pest Control Products*



*Regulations.* This number was later reduced to 401 as four of these active ingredients were disinfectants no longer regulated under the PCPA.<sup>391,388</sup> The new PCPA (2006) requires that all pesticides be re-evaluated on a 15-year cycle using current scientific and risk assessment standards.<sup>393</sup>

In order to complete<sup>cix</sup> the re-evaluations of these active ingredients in a timely manner, make efficient use of the Agency’s re-evaluation resources, and maintain a level playing field for trade products treated with pesticides in Canada and the United States, PMRA decided to incorporate foreign reviews into re-evaluations, particularly those conducted by the USEPA, where available and suitable. In particular, because some pesticides are used throughout North America, PMRA worked with USEPA on the re-evaluation of these pesticides through a work sharing and joint review approach. Based on this approach, PMRA had originally intended to complete all re-evaluations by 2006; however, holdups related to changes in the USEPA schedule for conducting re-evaluations and the availability of its reviews led to several delays. Moreover, PMRA experienced other challenges related to the complexity of some assessments, reduced number of alternative products, need for risk management, and transition strategies. According to PMRA, there were 18 pending re-evaluations at the end of March 31<sup>st</sup>, 2012 as shown in **Table 16**.<sup>338,395,388,389,390,392,393,396,397,398</sup> However, the proportion of food-related pesticides from the total numbers provided in the table was not available.

**Table 16 PMRA Re-evaluation Activities as of March 31<sup>st</sup>, 2012**

Final Decision Outcomes <sup>cx</sup>	Number of decisions								
	2003-2004	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012
Discontinued/withdrawn by registrant	58	72	79	79	83	83	84	85	106
Phase-out requested by PMRA	6	6	5	5	5	7	7	10	12
Registration continued – label modifications	14	31	48	61	104	153	169	190	207
Registration continued – no label changes	2	4	4	6	8	9	10	10	18
Cumulative number of final decisions	80	113	136	151	200	252	270	295	343
Proposed and Pending Decisions at Year-end <sup>cx</sup>	55	69	97	93	74	78	90	78	40
Total – Final, Proposed and Pending Decisions	135	182	233	244	274	330	360	373	383

**CHANGE IN EXPOSURE TO NUTRITIONAL RISKS**

<sup>cix</sup> PMRA defines completion as the issuance of a final re-evaluation decision, a proposed re-evaluation decision, or a re-evaluation note for an active ingredient.<sup>338</sup>

<sup>cx</sup> PMRA has finalized the re-evaluation decisions for these products (usually published in a Re-evaluation Decision Document or Re-evaluation Note) or registrants have indicated their intent to discontinue all products with that pesticide.

<sup>cx</sup> Proposed: PMRA has published the proposed decisions (usually a Proposed Acceptability for Continuing Registration document or Proposed Re-evaluation Decisions). Pending: Assessments have been completed, and decisions proposed, but PMRA has not yet published the proposed decisions.

The evaluation was unable to identify conclusive evidence in relation to changes in exposure to nutritional risks (refer to intermediate outcome # 1 for an identification of challenges encountered with available data). Nonetheless, the evaluation was able to identify some initiatives that have effected and may yet effect changes in the exposure to certain nutritional benefits, namely:

- Trans fats:
  - o Canada became the first country in 2003 to require mandatory declaration of trans fatty acid content on the labels of most pre-packaged foods.<sup>176</sup>
  - o According to data collected by Health Canada’s two-year Trans Fat Monitoring Program, nutrition labelling regulations were considered an effective motivator for industry to reformulate their products since many had reduced the trans fat content in their products and were meeting the 5% trans fat of total fat content limit, including various ethnic foods.<sup>cxii 465,467,468,466</sup>
  - o A Canadian study showed that trans fatty acid levels in human milk in Canada have decreased and attributed this trend to Health Canada’s labelling requirements leading to reduced exposure to trans fatty acids derived from partial dehydrogenization of vegetable oils.<sup>112</sup>
  - o A cost-benefit analysis commissioned by Health Canada reported a reduction in the average trans fat intake in Canada across all persons between 2004 and 2008, from approximately 4.9 g/day to 3.4 g/day, respectively.<sup>137</sup>
  - o The same analysis showed that, over a 20-year study period, nutrition labelling regulations would result “in a significant net benefit to Canadian society.”<sup>137</sup>
- Food fortification:
  - o Canada introduced a policy of mandatory fortification of white flour, enriched pasta and cornmeal with folic acid in 1998. Several papers conclude that food fortification with folic acid was associated with a significant reduction in the rate of neural tube defects in Canada.<sup>77,426,62</sup>

While these initiatives provide examples of positive changes in exposure to nutritional risk, other risks remain, for example:

- Trans fats:
  - o According to the aforementioned cost-benefit analysis, while nutrition labelling regulations met with some success, 20% to 25% of foods (e.g., pre-packaged baked goods) still contain high trans fat levels and there is a risk of regression, especially in unlabelled products.<sup>137</sup>
  - o While FEAC members have expressed support for “continuing to encourage voluntary reduction efforts and reinstate monitoring of trans fat levels in the Canadian food supply through data gathering, exposure assessment and publication of the findings” to meet the trans fat maximum intake limit recommended by the WHO (1% of total energy intake),<sup>251,257,258,256</sup> Health

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<sup>cxii</sup> The data is only relevant to a specific sub-set of foods identified by Health Canada as being the most commonly consumed foods with potential high trans fat content.

Canada has decided to continue pursuing the voluntary reduction approach and rely on alternative methods of data collection, in collaboration with industry, to monitor progress on the reduction of trans fats in Canadians' diets.

- Sodium:
  - o According to previously reported data (see intermediate outcome # 1), Canadians' sodium intakes exceed the recommended UL.
  - o During FEAC discussions on the Sodium Reduction Strategy, members have stated that "a tool is needed that will help consumers make informed food choices and address both general and population-specific needs..."<sup>259</sup>
  - o Canada's health ministers endorsed in 2010 the 2016 interim intake goal of 2,300 mg per day.<sup>251,256</sup> Health Canada decided in 2010 to rely on FEAC for advice on the government's sodium-reduction plans with the addition of expert members dedicated to this issue.

### **Intermediate Outcome # 3: Increased Adoption of International Standards by Canada and Other Countries**

**To what extent have international standards been adopted by Canada and other countries?**

**The Program has processes in place to consider the adoption of international standards. While it was not possible to identify a change in the level of adoption, there is evidence of adherence by Canada to international standards. With respect to adherence by other countries, while this could not be determined it is assumed that membership in international standard setting organizations denotes an interest in harmonization.**

The Program's processes to consider international standards are based on international cooperation approaches and objectives established at the departmental, agency and branch levels (see 0) that focus on:<sup>161,162,170</sup>

- Exchanging information and conducting collaborative work through bilateral or multilateral working relationships with international regulatory counterparts.
- Collaborating with international organizations to set standards and work towards harmonization.
- Engaging with countries in the process of developing regulatory systems by building capacity and providing technical assistance to improve harmonization.

As discussed under immediate outcome # 3, the Program has established a number of international MoUs, agreements, and commitments to strengthen the exchange of knowledge and expertise in order to increase organizational knowledge and enable proper response mechanisms to current and emerging issues. These arrangements address food regulatory matters of mutual interest with the partner organizations with a focus on a collaborative approach to, among others, policy development and regulatory approaches; surveillance and monitoring systems; emergency response mechanisms; aboriginal health; food safety (chemical and microbial); novel foods and health claims; and, nutrition and food fortification.

The Program is also active in international fora (e.g., Codex, FAO/WHO, etc.) as well as in direct engagement with international regulatory counterparts (e.g., QUAD meetings, International Microbial Food Safety Liaison Group) to encourage the systematic exchange of information on research, risk assessment, policy development, standard setting, and regulatory and enforcement activities. This is done to address current and emerging food safety issues and facilitate the harmonization of food safety standards, surveillance, monitoring and inspection and certification systems.

As a result of all these activities, the evaluation identified several examples of adherence by Canada to international standards, namely:

- Nutritional labelling:
  - o Increasing compatibility with the US nutritional labelling system was one of the objectives of the nutrition labelling regulations amending the F&DR in 2003. As a result, the Canadian and US Nutrition Facts labels have a similar look and format and display the same list of core nutrients.<sup>431,188</sup>
- Microbial safety:
  - o Canada is in line with a July 2009 Codex decision related to tolerable levels of *L. monocytogenes* in RTE foods where a ML (100 cfu/g<sup>cxiii</sup>) was set for certain foods where the bacteria cannot grow. In RTE products where growth is possible (e.g., raw milk cheese), no *L. monocytogenes* will be allowed (zero tolerance).<sup>463</sup>
- Chemical safety:
  - o Health Canada agreed with JECFA's recommendations to reduce exposure to acrylamide. Health Canada has decided to coordinate its risk management efforts for acrylamide in food with key food regulatory partners in Australia, Europe, Japan, New Zealand and the US.<sup>138</sup>
  - o Health Canada continues to work with the international community in the study of acrylamide through participation in JECFA.<sup>490</sup>
  - o Health Canada's scientific assessments of food additive and packaging material submissions align with the risk analysis principles developed by the WHO/FAO.<sup>101</sup>

The evaluation identified cases when Canada has been unable to adhere to international standards due to issues related to the lengthy regulatory approval process or concerns with international approaches that may not fully reflect the Program's position (emanating from scientific and policy considerations). An example of this has been the approval of asparaginase as a food processing aid to reduce the formation of acrylamide in food. While Canada identified the major mechanism for the creation of acrylamide and its contributing factors in 2002, Health Canada only concluded the public consultation process relating to the proposal to amend the F&DR to permit the use of asparaginase in certain foods in 2010,<sup>210</sup> and amended the F&DR as a result of these consultations.<sup>432</sup> Health Canada then revised its exposure assessment of acrylamide in food in 2012.<sup>cxiv 303</sup> Conversely, asparaginase was permitted for use in foods years

<sup>cxiii</sup> Colony forming unit by gram: a count of living organisms in food.

<sup>cxiv</sup> Changes in legislative requirements have been made easier since then to approve food additives.

earlier in the US, Australia, New Zealand and Denmark while also receiving a favourable evaluation by JECFA.

On the issue of adherence to international standards by other countries, membership in international standard setting organizations (e.g., Codex) denotes an interest in international collaborative work and eventual harmonization, albeit the presence of similar limitations as those experienced by Canada. It is expected that the adoption of Codex standards and related texts, especially by developing countries, will lead to improved food safety worldwide and greater assurance by Canadian regulators that foods imported into Canada from these countries will comply with regulatory requirements.

#### **Intermediate Outcome # 4: More Integrated Approach to F/P/T Food Safety and Nutrition Priorities and Activities**

**To what extent has the Program increased the integration of FSNQ priorities and activities?**

**The Program collaborates with F/P/T partners and stakeholders through a number of committees and initiatives. While there is some satisfaction with this approach, there are some concerns related to communications among key Program participants and between the Program and its P/T partners (e.g., on HRAs, FSAs, roles and responsibilities) and its stakeholders (e.g., information consolidation and transparency).**

As discussed under immediate outcome # 5, key Program participants collaborate with one another as well as with F/P/T partners and stakeholders through a large number of committees and numerous initiatives. The Program uses this multipronged approach to exchange information, foster dialogue, consult, and coordinate priorities and risk management approaches.

Some evaluation interviewees viewed this approach as appropriate as they indicated that there were no areas of duplication at the federal level with roles and responsibilities clearly defined. The existence of MoUs (e.g., between Health Canada, the Public Health Agency of Canada and CFIA<sup>362,363</sup>) was seen as an effective way of providing a clear definition of roles and responsibilities. With respect to F/P/T interaction, some evaluation interviewees saw no duplication or overlap since, while some responsibilities were shared, roles were viewed as complementary. This was aided by the existence of protocols, fora and systems used to ensure coordination among jurisdictions and to provide a consistent approach to common issues.

Nonetheless, some evaluation interviewees also identified specific concerns related to the effectiveness of communications among key Program participants and between the Program and its P/T partners, namely:

- Lingering uncertainty among P/T government representatives on the roles of Health Canada and CFIA as they relate to HRA preparation.
- Inadequate communications and agreement on priority settings between BFSA and CFIA on the issue of FSAs.
- Limited integrated strategic planning and engagement with AAFC.

- Need for improved understanding by P/T partners of the functions, and their limits, between federal and P/T governments as well as the lead role played by each organization (e.g., on food regulation related to additives, labelling, nutritional quality and trans fats).
- Lack of clarity among emergency response partners and stakeholders on the role of systems (e.g., PulseNet), the role of F/P/T parties (especially in communications with the public), and the role of laboratories (NML and BMH laboratories).

It is expected that some of these concerns will be addressed through recent developments, namely:

- F/P/T health ministers have identified the need for the Health and Agriculture portfolios to collaborate in order to have a more integrated Canadian food safety system.<sup>133</sup>
- “deputy ministers of health have agreed to move forward on three priorities: enhanced and integrated food and human illness surveillance, prevention of food-borne risks through targeted interventions, and outbreak preparedness response.”<sup>133</sup>
- F/P/T ministers of agriculture are working to advance three food safety priorities, including “...better linkages among food safety and human health surveillance information sources to improve targeted interventions and manage food-borne illness outbreaks more effectively.”<sup>133</sup>
- The Public Health Agency of Canada is leading discussions within the Pan-Canadian Public Health Network with regard to food safety.<sup>cxv,cxvi</sup>
- Recent integration of CFIA into the Health Portfolio.

Other interviewees identified areas of concern related to stakeholder communications (the issue of stakeholder communications has been discussed earlier, see immediate outcome # 2 and immediate outcome # 5), namely:

- Seemingly uncoordinated approach to the production and dissemination of consumer information by key Program participants.
- Need for improved, more structured public communications regarding Program information on areas being addressed, on work being conducted (e.g., on relevant issues such as sodium) and on primary roles (i.e., Health Canada, the Public Health Agency of Canada and CFIA).

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<sup>cxv</sup> PHAC, personal communications, September 22<sup>nd</sup>, 2011.

<sup>cxvi</sup> The Network was created in 2005 by F/P/T health ministers as an intergovernmental mechanism to enhance Canada’s public health capacity and day-to-day work, and to enhance response to public health events and threats.

### 4.4.3 To what extent have the long-term outcomes been achieved?

#### Long-Term Outcome # 1: Improved Nutritional Status of Canadians

To what extent has the nutritional status of Canadians improved based on Program activities?

According to available evidence, the nutritional status of Canadians does not appear to have improved over the period of the evaluation. Among the general population, there are a number of concerns related to high energy intake, high fat intake, nutrient insufficiency, sodium intakes associated with an increased risk of adverse health effects, and rising BMI. While information on First Nations on-reserve and Inuit communities has been limited, evidence points to low intake of some important vitamins and minerals, high sodium intakes and obesity prevalence.

#### OVERALL NUTRITIONAL STATUS

According to the WHO, “nutrition is the intake of food, considered in relation to the body’s dietary needs.”<sup>cxvii</sup> The state of the body in response to this intake can be used to describe nutritional status. Based on the sources examined, Canadian nutritional data appears to be limited and inconsistent (see intermediate outcome # 1); moreover, trend analyses needed to analyze changes over time were limited. According to data previously presented under intermediate outcome # 1 and other recent data from Health Canada presented here below<sup>287,288,289</sup> it appears that there are a number of nutritional concerns among the Canadian population in general:

- Children (aged 1 to 8 years):
  - o 20% of children have energy intakes that exceed their energy needs.
  - o A notable proportion of the diets of 1-3 year-old children contain total fat in quantities below the recommended range.
  - o Children’s diets provide adequate amounts of most vitamins and minerals, with the exception of vitamin D and calcium (4 - 8 years only).
  - o For nutrients with an Adequate Intake (AI),<sup>cxviii</sup> there is concern that children may not be meeting their needs for potassium and fibre.
  - o Children's sodium intakes are associated with an increased risk of adverse health effects.
- Adolescents (aged 9 to 18 years):
  - o 30% of adolescents have energy intakes that exceed their energy needs.
  - o Adolescents’ saturated fat intakes could be further decreased.

<sup>cxvii</sup> <http://www.who.int/topics/nutrition/en/>

<sup>cxviii</sup> The recommended average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group of apparently healthy people who are assumed to be maintaining adequate nutritional status. An AI is fixed when there is insufficient evidence to establish the distribution of requirements and, subsequently, to determine the Estimated Average Requirement (EAR).<sup>287,288,289</sup>

- o Many adolescents have inadequate intakes of magnesium, vitamin A, vitamin D, calcium and phosphorous.
- o For nutrients with an AI, there is concern that adolescents may not be meeting their needs for potassium and fibre.
- o Adolescents' sodium intakes are associated with an increased risk of adverse health effects.
- Adults (aged 19 years and over):
  - o 70% of males and 50% of females have energy intakes that exceed their energy needs.
  - o 25% of males and 23% of females have fat intakes above the Acceptable Macronutrient Distribution Range.<sup>cxix</sup>
  - o 32% of males and 21% of females have carbohydrate intakes below the Acceptable Macronutrient Distribution Range.
  - o Many adults have inadequate intakes of magnesium, calcium, vitamin A and vitamin D.
  - o For nutrients with an AI, there is concern that adults may not be meeting their needs for potassium and fibre.
  - o Adults' sodium intakes are associated with an increased risk of adverse health effects.

A study on the adaptation of the American Healthy Eating Index to the recommendations in *Canada's Food Guide* and analysis of data from CCHS 2.2 to determine a measure of overall Canadian diet quality rendered the following results:<sup>cxx 116</sup>

- Average score of 65+: children aged 2 to 8 years (highest average scores).
- Average score of 59: population aged 2 years and over. Almost 17% of the population scored below 50 and less than 1% scored more than 80.
- Average score below 50: less than 3% of children aged 2 to 8 years, more than 25% of adolescents aged 14 to 18 years of both sexes and of men aged 19 to 30 years, and 16% of men and 7% of women aged 71 years and over.

Overall, women's scores at all ages exceeded those of men. In general, average scores decreased (i.e., diet quality deteriorated) towards early adolescence and stabilized at around 55 at ages 14 to 30 years. Average scores then increased (i.e., diet quality improved) after this age group up to approximately 60 at age 71 years and over. Scores were positively impacted by the consumption of grain products, meats and alternatives, and unsaturated fats. Scores were negatively impacted by the low consumption of dark green and orange vegetables, whole fruits and whole grains, and the percentage of calories derived from "other foods."

The same study also concluded that CCHS questions about the frequency of vegetable and fruit consumption could be used as an approximation of diet quality.<sup>116</sup> According to recent data,<sup>449</sup>

<sup>cxix</sup> The range of intake of an energy source (i.e., fat, protein, carbohydrate) that is associated with a reduced risk of chronic disease while providing adequate amount of essential nutrients.<sup>287,288,289</sup>

<sup>cxx</sup> The 1995 Healthy Eating Index diet quality categories (more than 80 points = a good quality diet; 50 to 80 points = a diet that requires improvement; and, less than 50 points = a poor diet) were used in the study to define low, average and high scores in the Canadian adaptation.



the percentage of Canadians aged 12 years and over that reported consuming fruits and vegetables five times or more per day increased between 2003 and 2009 but has decreased since then. A lower consumption frequency has been reported for males across all age groups.

A common way to identify changes in nutritional status is to examine Body Mass Index (BMI)<sup>cxxi</sup> differences over time. Changes in BMI (underweight, overweight and obesity<sup>cxxii</sup>) can be the result of poor nutrition among other factors such as health behaviours (eating habits and daily physical activity), and broader social, environmental and biological determinants that influence these behaviours. According to CCHS data,<sup>449</sup> the number of overweight Canadians aged 18 years and over has remained relatively consistent over the last 10 years. Obesity, however, has been slowly increasing for both sexes during this period, this is part of a global trend that the WHO has described as an epidemic.<sup>115</sup>

According to *Obesity in Canada*, both measured and self-reported<sup>cxxiii</sup> data indicate that the prevalence of adult obesity increased between 1978/79 and 2004, which has led to one-quarter of Canadians being obese (obese class I: increased from 11% to 15%; obese class II: increased from 2% to 5%; and, obese class III: increased from 1% to 3%).<sup>405</sup> During this same time period:

- Children and youth (aged 2 to 17 years): the prevalence of measured obesity rose by 2.5 times.<sup>405</sup> According to the report *Healthy Weights for Healthy Kids* (2007), “Canada has one of the highest rates of childhood obesity in the developed world” (fifth out of 34 OECD countries) with “26% of young Canadians aged 2 to 17 years being overweight or obese.”<sup>29</sup> The report *Building a Heart Healthy Canada* (2009) states that “at least one of every four children in Canada... is overweight or obese.”<sup>47</sup>
- Adolescents (aged 12 to 17 years): obesity tripled from 3% to 9%.<sup>405</sup>
- While measured obesity has increased in the last decades, between 2000 and 2008 self-reported obesity among those aged 12 to 17 has been relatively stable. As is the case with adults, self-reported obesity prevalence tends to be lower than measured estimates.<sup>405</sup>
- Older age groups: obesity is more prevalent, up to approximately 65 years of age and, while it tends to be more prevalent among males than females, this observation is affected by the age group and reporting method (self-reported vs. measured). Also, females are more likely than males to fall into obese classes II and III.<sup>405</sup>

<sup>cxxi</sup> BMI is calculated by dividing the respondent's body weight (in kilograms) by their height (in metres) squared. BMI is a method of classifying body weight according to health risk. According to the WHO and Health Canada guidelines, health risk levels are associated with each of the following BMI categories: normal weight = least health risk; underweight and overweight = increased health risk; obese, class I = high health risk; obese, class II = very high health risk; obese, class III = extremely high health risk. A definition change was implemented in 2004 to conform to the WHO and Health Canada guidelines for body weight classification. The index is calculated for the population aged 18 and over, excluding pregnant females and persons less than 3 feet (0.914 metres) tall or greater than 6 feet 11 inches (2.108 metres).<sup>449</sup>

<sup>cxxii</sup> According to the WHO and Health Canada guidelines, the index for body weight classification is: less than 18.50 (underweight); 18.50 to 24.99 (normal weight); 25.00 to 29.99 (overweight); 30.00 to 34.99 (obese, class I); 35.00 to 39.99 (obese, class II); 40.00 or greater (obese, class III).<sup>449</sup>

<sup>cxxiii</sup> The report indicates that self-reported obesity is lower (17%) than measured estimates.

## NUTRITIONAL STATUS OF FIRST NATIONS AND INUIT POPULATIONS

The evaluation encountered considerably more difficulties in trying to identify changes in nutritional status among First Nations on-reserve and Inuit communities (see intermediate outcome # 1). Food insecurity and its influencing factors (e.g., poverty, high food costs, environmental changes, government restrictions) have been identified as affecting food choices among First Nations and Inuit populations and, thus, nutritional status.<sup>cxxiv</sup> Data points to a low intake of some important vitamins and minerals as well as high sodium intakes; this is consistent with consumption of fruit and vegetables as well as milk and alternatives below the level recommended in *Canada's Food Guide* and increased consumption of “foods to limit:”

- Based on the available data, many adults have inadequate intakes of calcium, vitamin A and vitamin D.<sup>448,56,55</sup>
- There is concern that adults may not be meeting their needs for potassium and fibre.<sup>55</sup>
- Adults' sodium intakes are associated with an increased risk of adverse health effects.<sup>55</sup>

With respect to BMI, the sources examined identify a number of concerns:

- Analyses of the 2002/03 First Nations Regional Longitudinal Health Survey estimated 37% of adults aged 18 years and older to be overweight and 36% obese, 28% of youth ages 12 to 17 to be overweight and 14% obese, 29% of children ages 9 to 11 to be overweight and 26% obese, and 13% of children ages 3 to 5 to be overweight and 49% obese.<sup>96</sup>
- According to the 2008/10 First Nations Regional Health Survey, 34% of adults were overweight and 35% obese, 30% of youth were overweight and 13% obese, and 20% of children aged 2 to 11 were overweight and 42% obese.<sup>97</sup>
- According to public opinion research conducted in 2008, First Nations people on-reserve identify lack of exercise (30%), fast food (24%) and poor diet (12%) as the leading causes of obesity in their communities.<sup>196</sup>
- According to the 2006 Aboriginal Peoples Survey, 24% of Inuit adults and 26% of children ages 6 to 14 were obese.<sup>405</sup>
- Results from the 2007-08 Inuit Health Survey for Adults, conducted in five Inuit regions show that 28% of Inuit in the regions surveyed were overweight, and 35% were obese.<sup>88</sup> In the Nunavik Inuit Health Survey, prevalence of overweight was 30%, and obesity was 28%.<sup>376</sup>
- Results from the 2007/08 Nunavut Inuit Child Health Survey have estimated the prevalence of overweight to be 39% and of obesity to be 28% among children ages 3 to 5.<sup>89</sup> Thirty five percent of energy in the children's diet came from low nutrient dense foods such as powder drinks, fruit juices and drinks, high sugar baked goods and high fat or salty snacks; 15% of the energy came from high-sugar beverages.<sup>336</sup>

<sup>cxxiv</sup> The dietary patterns found among Aboriginal people may be strongly linked to a lack of food security and lower socioeconomic status, which generally affect Aboriginal populations to a much greater degree than non-Aboriginal populations in Canada. Depending on the study and Aboriginal sub-population, food insecurity ranges from 3-6 times higher among Aboriginal households than non-Aboriginal households, and is especially pronounced in northern and isolated communities.<sup>55,56,89,304</sup>

## Long-Term Outcome # 2: Reduced Food- and Nutrition-Related Illnesses

To what extent have Program activities contributed to the reduction of food- and nutrition-related illnesses?

Food-related illnesses appear to have decreased over the past decade. Information directly linking nutrition to illnesses was limited. The rates of high blood pressure and diabetes among the general population, two chronic conditions related to nutrition, appear to have increased over the last decade. In the case of First Nations on-reserve, the rates of diabetes are high compared to the overall Canadian population, although these do not appear to have increased for the last several years. Similarly, high blood pressure rates have not increased for the last several years. Rates of diabetes and high blood pressure among Inuit populations approach those of the overall Canadian population.

### FOOD- AND NUTRITION-RELATED ILLNESSES AMONG THE GENERAL POPULATION

As discussed under intermediate outcome # 2, data from the Public Health Agency of Canada's C-EnterNet and Notifiable Diseases On-Line points to a decrease in the number of cases of tracked enteric disease; this trend appears to match a small decrease in the number of food safety investigations and recalls carried out by the CFIA during the same period as shown in **Table 17**.<sup>39,40,41,451,450</sup>

**Table 17** CFIA Food Safety Investigations and Recalls 2000-2001 to 2011-2012

Action	2000-2001	2001-2002	2002-2003	2003-2004	2004-2005	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012	Total	CAGR <sup>cxxv</sup>
Investigations (all types)	3,889	4,462	4,961	4,526	4,223	2,675	3,104 <sup>cxxvi</sup>	3,040	3,439	2,904	2,956	2,808	42,987	-3%
Recalls	353	481	381	343	253	259	246	218	236	212	264	301	3,547	-1%

With respect to nutrition-related illnesses, many of these are chronic conditions such as high blood pressure, diabetes, and heart disease and, while they may be the result of poor nutrition, they can also be linked to many other factors including health behaviours and broader social, environmental and biological determinants. While the evaluation found limited evidence directly linking nutrition to chronic conditions (e.g., fortification of certain foods with folic acid leading to a reduction in neural tube defects in Canada), it is assumed that nutrition plays a role and that underweight, overweight and obese individuals are at an increased health risk and can experience these diseases. As previously stated, one quarter of Canadians were obese in 2004; however, another 36% were overweight, thus approximately 60% of Canadians "...were in a weight range that increased their risk of developing health problems."<sup>47,462,405</sup> While obesity has been discussed under long-term outcome # 1, the prevalence of three chronic conditions for Canadians

<sup>cxxv</sup> Compound Annual Grow Rate.

<sup>cxxvi</sup> There was a discrepancy in the data provided by the sources: 2,915<sup>41</sup> vs. 3,104.<sup>451</sup> The data from *Statistics: Food Safety Investigations* was used.

aged 18 years and over<sup>cxxvii</sup> in 2004 in relation to BMI categories remain a concern.<sup>462</sup> Overall, as BMI has increased so has the prevalence of chronic conditions among both women and men: high blood pressure increased from nearly 10% among normal weight individuals to 28% to 30% for obese individuals (class III); diabetes rose from 2% in normal weight individuals to 11% to 14% for obese individuals (classes II and III); and, heart disease grew from 3% in the case of normal weight individuals to 6% to 8% for obese individuals (classes II and III).

The prevalence of diabetes and high blood pressure for Canadians aged 12 years and over between 2003 and 2012 are also of concern.<sup>449</sup> Both chronic conditions have increased over the time period. Once again, the prevalence of both chronic conditions increased among both women and men during this period: high blood pressure from 14% to 17%, and diabetes from 5% to 7%.

### FOOD- AND NUTRITION-RELATED ILLNESSES AMONG FIRST NATIONS AND INUIT COMMUNITIES

Sources of data on First Nations people living on-reserve and Inuit communities living in the North have been limited. On the other hand, data on off-reserve populations has been more readily available, for example through the CCHS and the Aboriginal Peoples Survey. Recently, sources of data appear to be increasing; however, the levels of coverage and stratification available in these sources have not been assessed by this evaluation.

While issues of obesity have been discussed earlier in this report, other nutrition-related diseases affecting on-reserve First Nations people and Inuit communities include diabetes and high blood pressure.

The 2002-03 First Nations Longitudinal Regional Health Survey identified 20% prevalence for diabetes among First Nations adults living on-reserve;<sup>cxxviii</sup> being diagnosed with diabetes was associated with excess body weight in First Nations adults.<sup>96</sup> In the 2008/10 First Nations Regional Health Survey, the age-standardized prevalence among First Nations adults aged 25 years and over was virtually unchanged from the earlier survey, at 21%.<sup>97</sup> In the case of Inuit populations, the 2007/08 Inuit Health Survey reported a prevalence of 5% overall for Inuit adults in the five Inuit regions, and similar prevalence between Inuit regions.<sup>88</sup>

Hypertension, or high blood pressure, is a risk factor for circulatory diseases such as stroke and for kidney disease, and may be directly influenced by sodium in the diet. According to the 2002-03 First Nations Regional Health Survey, the prevalence of high blood pressure in First Nations adults living on-reserve was 20%.<sup>cxxix</sup><sup>96</sup> Results from the 2008-10 First Nations Regional Health Survey show a similar overall prevalence of 22% of adults with high blood pressure.<sup>97</sup> Among Inuit men aged 18 to 89 years, results from the 2008/10 Inuit Health Survey identified

<sup>cxxvii</sup> Excluding the Territories.

<sup>cxxviii</sup> The prevalence of diabetes was lowest among individuals aged 18 to 29 years (3%) and increased each decade to a high of 36% in those aged 55 to 64 years, with 35% among those aged 65 years and older.

<sup>cxxix</sup> Prevalence increased with age: 8% in adults aged 30 to 39 years (4% in the general Canadian population), 16% in adults aged 40 to 49 years (10% in the general Canadian population), and 31% in adults aged 50 to 59 years group (22% in the general Canadian population).

hypertension in 23% of the individuals.<sup>333</sup> This is similar to the prevalence of hypertension found in both Inuit men and women in northern Québec (17%).<sup>80</sup>

### **Long-Term Outcome # 3: Safer Food Products in International Trade**

**To what extent have Program activities contributed to safer food products in international trade?**

**The Program is engaged with international regulatory partners and participates in international fora as part of efforts to standardize, harmonize and increase food safety. Adoption of international standards by Canada and other countries is expected to contribute to international food safety.**

The level of safety of imported foods has been a topic of increasing concern and recognized in Speeches from the Throne as well as by initiatives (e.g., FCSAP) and studies. Internationally, the Program has actively engaged economic partners (e.g., Australia, Mexico and the US) to address standardization and food safety issues (see immediate outcome # 3 and intermediate outcome # 3). Moreover, the Program is involved in a number of fora intended to exchange knowledge, achieve consensus and develop standards leading to harmonization and increased food safety (e.g., Codex, FAO and the WHO). Among these, Codex acts as the forum for the development of international standards on FSNQ and, while Codex standards are not legally binding, they represent the international consensus on a given subject. The adoption of Codex standards and related texts by other countries, especially developing countries, is expected to lead to improved food safety worldwide and greater assurance by Canadian regulators that foods imported into Canada from these countries will comply with Canadian regulatory requirements.<sup>170</sup>

### **Long-Term Outcome # 4: Canada Viewed as a Responsible Participant and Scientific Expert in an International Context**

**To what extent is Canada viewed as an active participant and scientific expert in an international context?**

**The Program's expertise and contribution to the international community are recognized through the Program's involvement in standard development, as a host of international collaborating centres and laboratories, and as a partner in international capacity development.**

As previously discussed (see immediate outcome # 3 and intermediate outcome # 3), the Program actively participates in several international fora (e.g., Codex, the WHO and FAO) and collaborates with international regulatory counterparts through bilateral and multilateral initiatives (e.g., QUAD and the Regulatory Cooperation Council). As part of this work, the Program seeks to further international standard setting, equivalency and harmonization efforts.

The Program's expertise and contribution to the international community have been recognized through the Program's participation in the joint development of standards in areas related to microbial and chemical safety as well as nutrition, for example:

- Codex:
  - o Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants.<sup>163</sup>
  - o Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.<sup>168</sup>
  - o Standards to control levels of melamine in food and feed worldwide.<sup>225</sup>
  - o MLs for DON and its acetylated derivatives in cereals and cereal-based products.<sup>135,66</sup>
  - o Risk Assessment Guidance regarding Foodborne Antimicrobial Resistant Organisms.
- WHO and FAO:
  - o Work on the toxicology of and dietary exposure to acrylamide (e.g., isolation of the mechanism for the creation of acrylamide and contributing factors).
  - o Monographs for Furan and Cyanogenic Glycosides.<sup>285</sup>
  - o Expert consultation to review the toxicological and health aspects of BPA (including food packaging materials).<sup>488</sup>
  - o Work with FERG on estimate reporting, epidemiological reviews, estimate and cause attribution models.<sup>491</sup>
- OECD:
  - o Work with the OECD Task Force for the Safety of Novel Foods and Feeds on a harmonized guidance on the assessment of products and processes resulting from modern and innovative technologies.<sup>378</sup>
- AOAC acceptance of FD's method for the measurement of trans fatty acids in foods.<sup>339</sup>
- Work with the Institute of Medicine's Food and Nutrition Board on establishing updated DRIs for Canada and the US.<sup>473</sup>
- EU reference to Canadian studies and guidelines to provide useful insights for the proposed European plan on harmonizing micronutrient requirement standards.<sup>16</sup>
- USFDA reference to joint funding by the US and Health Canada regarding the development of harmonized reference standards for food labelling.<sup>24</sup>
- FNIHB's Research Laboratory coordination of an International Mercury in Hair Quality Assurance Program.

The Program hosts a number of international collaborating centres and reference laboratories in the following areas:

- WHO Collaborating Centres:<sup>486</sup>
  - o Food Contamination Monitoring (Health Canada).
  - o Foodborne viruses (Health Canada).<sup>cxxx</sup>
  - o Non Communicable Disease Policy (Public Health Agency of Canada).

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<sup>cxxx</sup> This collaborating centre is in the process of being transferred to Health Canada.

- o Emerging and Zoonotic Diseases Detection, Diagnostics, Reference and Research (Public Health Agency of Canada).
- o Preparedness and Response to Enteric Pathogens and their AMR (Public Health Agency of Canada).
- World Organisation for Animal Health (OIE) Reference Laboratory:<sup>492</sup>
  - o LFZ – Salmonellosis (Public Health Agency of Canada).

The Program conducts laboratory personnel exchanges (e.g., with Korea and China) and provides technical assistance and capacity building initiatives to developing countries on food safety (e.g., as part of Canada's duties under the World Trade Organization [WTO] Agreement on the Application of Sanitary and Phytosanitary Measures, the WTO Agreement on Technical Barriers to Trade and in support of WHO initiatives to help countries establish laboratory-based networks for AMR surveillance).

Some evaluation interviewees (including key Program participants, partners and stakeholders) believed that Canada was well perceived, respected and recognized at the international level. They also believed that Canada was viewed as a good team player that acted as a moderator and consensus builder. However, some interviewees expressed concerns with Canada's diminishing international presence due to a lack of financial resources.

### **Long-Term Outcome # 5: A Sustainable and Integrated System for FSNQ in Canada**

**To what extent has the Program contributed to a sustainable and integrated system for FSNQ in Canada?**

**The Program's approach to consultation and collaboration seeks to engage all partners and stakeholders and is expected to continue to enhance system integration. Government Directives are in place to guarantee a consultative, coordinated and cooperative approach to regulatory development. There are challenges to the responsiveness of the regulatory framework, which recent legislative amendments and Program strategic plans are expected to address.**

#### **CONSULTATION AND COLLABORATION WITH KEY PROGRAM PARTICIPANTS, PARTNERS AND STAKEHOLDERS**

The evaluation identified numerous approaches used by the Program to engage partners and stakeholders in an effort to communicate, collaborate and integrate multiple perspectives (see immediate outcome # 5 and intermediate outcome # 4); these include committees integrated by F/P/T representatives as well as stakeholders, policy and regulatory development initiatives, workshops, bilateral/multi-agency meetings, and consultations to name a few.

Evaluation interviewees expressed some satisfaction with Program efforts on collaboration and consultation, and it is expected that ongoing efforts to engage food safety partners will continue to enhance opportunities for consultation and collaboration (e.g., through SCDH and CFS, FEAC and Food Supply Chain Stakeholder meetings as well as ongoing consultations on regulatory modernization). It is also expected that FCSAP, through its focus on consultation and

communication with industry and Canadians as part of its active prevention strategies, will contribute to these efforts. Nonetheless, the results of all these initiatives will have to be assessed to determine their level of success.

The evaluation identified a number of issues affecting collaboration in the FSA process leading to delays and difficulties in planning and priority setting. FSAP began a reassessment process in 2010. As of October 2013, CFIA has joined the Health Portfolio. A recent Order in Council has designated the Minister of Health as the appropriate Minister with respect to CFIA for the purposes of the Financial Administration Act.<sup>381</sup>

On the issue of collaboration and consultation on HRA development as a response to CFIA requests, evaluation interviewees saw the working relationship between Health Canada and CFIA as being satisfactory.

#### **LEVEL OF INCLUSION OF THE RESULTS FROM CONSULTATION INTO POLICIES, STANDARDS AND REGULATORY DECISIONS**

The *Cabinet Directive on Streamlining Regulation* (2007)<sup>27</sup> as well as the more recent *Cabinet Directive on Regulatory Management* (2012)<sup>26</sup> state that, when regulating, the federal government will “create accessible, understandable, and responsive regulation through ... transparency, accountability, and public scrutiny” and “require timeliness, policy coherence, and minimal duplication throughout the regulatory process by consulting, coordinating, and cooperating across the federal government, with other governments [and jurisdictions] in Canada and abroad, and with businesses and Canadians.” The evaluation identified a number of guidelines, standards, frameworks and policies in high priority areas that had been impacted or developed as a result of advancement in scientific and regulatory research as well as consultation (see immediate outcome # 4).

#### **LEVEL OF RESPONSIVENESS OF THE REGULATORY FRAMEWORK**

The level of responsiveness of the regulatory framework for FSNQ has been challenged for a number of years:

- As early as 1999, an industry opinion article in a Canadian food trade journal indicated the need for a fast track approval process to introduce products into the marketplace claiming that Europe, Japan and the US were well ahead of Canada in product introduction procedural rules.<sup>87</sup>
- *A review of Canadian food safety policy and its effectiveness in addressing health risks for Canadians* (2002) found that food safety regulations were having difficulties keeping pace with many of the new developments, especially because the risk assessment approach cannot properly identify and address non-acute hazards. The approach was found to not properly weigh the benefits of new technologies or compare their performance to other approaches in an effort to mitigate hazards.<sup>356</sup>



- A 2006 Food and Consumer Products of Canada report identified four key challenges with the regulatory environment in Canada:<sup>99</sup>
  - o “Approval times routinely take three to five years because of a cumbersome system for regulatory change. Some approvals never happen at all.
  - o Small regulatory differences between Canada and our largest trading partner prevent Canadian-based companies from competing for North American product mandates.
  - o Lack of capacity and responsiveness within Health Canada means that proactive policies, such as food fortification and health claims, take years to be addressed.
  - o Regulation is a very significant determinant of economic performance and competitiveness. The food industry’s key economic indicators show some troubling trends.”
- A trade journal article on novel fibre development in 2007 indicated the need for a shorter lag time for marketplace introduction. The article cited examples where Canadian new fibre products were accepted by and introduced into the US 10 years before Canadian approval was given. The trade article suggested that Health Canada needed to keep pace with the rest of the world in its regulatory approval process.<sup>98</sup>
- A 2008 Food and Consumer Products of Canada report on Canada’s regulatory system concluded that:<sup>100</sup>
  - o Canada was not competitive and that its food regulatory system was behind those of world leading nations.
  - o Canada’s lagging system had very high costs.
  - o Canada’s regulatory system needed to be modernized.
  - o Lack of commercialization opportunity was fuelling the decline of the sector.
  - o There was no evidence to link the lags to measures to help improve the health and safety of Canadians.
- A 2008 report on 12 case studies estimated the costs incurred by food companies (i.e., “direct costs, opportunity costs to the food manufacturing companies looking to develop new food products and/or market products with health claims, potential lost sales for retailers because of lack of product availability and potential lost sales for primary producers”) at more than \$440 million in view of lags stemming from the current regulatory regime and linked to “poor administrative processes and lack of a framework for decision-making.”<sup>100</sup>
- The report *Canadian food regulatory outlook 2008 – 2009* (2009) comments on the lack of progress on allergen labelling and organics and identifies policies on food fortification as too rigid.<sup>121</sup>
- A 2011 survey on Canadians’ awareness, attitudes and behaviours with respect to food safety (n<sub>1</sub>=1,003, n<sub>2</sub>=1,001, n<sub>focus groups</sub>~36) reported that while 89% of Canadians were at a minimum moderately confident in the food system, there were concerns that it was over-burdened.<sup>343</sup>
- According to FCSAP, “food-borne illness outbreaks, major food recalls and increased consumer and media interest in import product safety have raised questions around the integrity of food safety systems in Canada and abroad.”<sup>cxxxii</sup>

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cxxxii Official Government documents.

Many evaluation interviewees considered the F&DA and F&DR as non-responsive and outdated. They saw the F&DR as either too prescriptive or unclear, which sometimes required legal interpretation that led to many exceptions and exemptions as well as to a lack of coherence among key Program participants (e.g., between Health Canada and CFIA). Interviewees also believed that the F&DR did not reflect market advances due, in part, to a lengthy amendment process (e.g., publishing in Canada Gazette Parts I and II may take two or five years) that precluded regulations from keeping up with scientific progress, thus making them obsolete.

On the regulatory amendment process, interviewees further clarified that some regulatory proposals do not move forward or the amendment process takes too long (e.g., food fortification, pasteurized fruit juices, food irradiation, allergens, labelling, health claims, additives and IMAs to mention a few) due to several factors:

- Resource issues, especially lack of legal resources.
- Legislative renewal no longer being active causing many proposals to be re-started.
- A lack of internal understanding of the regulatory process (i.e., one project may lead to many amendments).
- A focus on low-impact issues, which compete for resources with larger-impact issues.
- Political concerns.

Interviewees also believed that the lengthy regulatory modernization was perpetuating a lack of clarity in the regulatory framework. In some cases, this situation seemed to be leading industry to find other ways to move their concerns forward (e.g., food industry submissions being submitted or re-submitted for pre-market assessment as a Natural Health Product [NHP]). This was not only affecting industry but was causing enforcement challenges.

For its part, the Program has committed to address several of the above challenges through a number of strategies, initiatives and regulatory changes aimed at modernizing the system, for example:

- One of the objectives of the Blueprint for Renewal was: “Health Canada will design and implement a modern, efficient and responsive food regulatory framework that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace.”<sup>175</sup>
- One of the strategies in HPFB’s 2007-2008 Business Plan and HPFB’s Roadmap for 2007-2012 was identified as: “Promote health through a modernized food regulatory system and a proactive approach to nutrition.”<sup>174,172</sup>
- Health Canada’s Regulatory Modernization Strategy for Food and Nutrition identified five goals, namely:<sup>191</sup>
  - o “Improving predictability, effectiveness, efficiency, and transparency in Health Canada’s food regulatory system.
  - o Promoting regulatory responsiveness to food innovation and promoting consumer access to foods with assessed health benefits.

- o Modernizing the regulatory toolkit to address ‘food contributors’ to chronic disease.
- o Improving Health Canada’s responsiveness to acute food safety health risks – responding to new threats while managing on-going risks.”
- FCSAP is “...composed of a series of initiatives to modernize and strengthen Canada’s safety system for food, health and consumer products.” With respect to food safety system modernization, FCSAP notes that the system “...needs to provide ‘new and better information on food risks in the Canadian marketplace, and involve industry and Canadians to address those risks.’” Further, the Plan recognizes the need to enhance policies, standards and processes as well as collaborate with international partners, to strengthen the prevention of food safety issues.”<sup>191</sup>
  - o However, FCSAP’s Results-Based Management and Accountability Framework is not exhaustive on measures related to efficiency, transparency and predictability. It identifies only the following two indicators under the outcome “improved potential for more timely availability of food that meets expected standards:” “% and range of new submissions addressed within time standards” and “research in policy and [regulatory impact analysis statements].”<sup>127</sup>
  - o It is expected that recent amendments (2012) to the F&DA introducing a new Marketing Authorization framework and a new Incorporation by Reference authority will grant Health Canada the ability to address some of these concerns. The new Marketing Authorization framework will allow faster regulatory approval of substances (e.g., food additives) and claims used in or on food and food labels, while Incorporation by Reference will permit broader referencing of internally and externally generated documents on a static or ambulatory basis as part of the regulations in order to shorten the regulatory amendment process involved in updating lists included in the F&DR (e.g., food additives, maximum limits for chemical contaminants, etc.).<sup>12,425</sup>
- Recent approval (2012) of Bill S-11: *Safe Food for Canadians Act*, with its focus on prevention, increased traceability and imported foods, will address some of the concerns related to surveillance and monitoring measures.<sup>31</sup>

## 4.5 Performance: Issue # 5 – Demonstration of Efficiency and Economy

**Have alternate delivery structures been considered as part of Program implementation and delivery? Has the Program designed and implemented a Performance Measurement Strategy? Has the budget allocated to the Program and its expenditures been suitable for the Program to achieve its outcomes?**

**Program performance and financial information was insufficient to properly demonstrate efficiency and economy. There are a number of Program areas where performance issues may be affecting efficiency. Potential alternative delivery structures focussed on resource sharing (e.g., partnerships, outsourcing, and cost recovery) may contribute to efficiency improvement if fully implemented.**

The Treasury Board of Canada's *Directive on the Evaluation Function* (2009) and guidance regarding *Assessing Program Resource Utilization When Evaluating Federal Programs* (2013) define the demonstration of economy and efficiency as "an assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes."<sup>81,53</sup> This assessment is based on the assumption that departments and agencies have standardized performance measurement systems and that financial systems link information about Program costs to specific inputs, activities, outputs and expected results.

The data structure of the detailed financial information provided for the Program did not facilitate the assessment of whether Program outputs were produced efficiently, or whether expected outcomes were produced economically. Specifically, the lack of output/outcome-specific costing data limited the ability to use cost-comparative approaches. In terms of assessing economy, challenges in tracking funding within the broader Program envelope limited the assessment. Considering these issues, the evaluation provides observations on economy and efficiency based on findings from the document review, a case study on similar FSNQ programs in other countries, interviews and available financial data.

## OBSERVATIONS ON EFFICIENCY

Findings previously discussed under each of the evaluation outcomes have identified a number of issues that may impact efficiency in various areas of the Program. Due to insufficient data on inputs (e.g., FTEs and budget) allocated to these areas, it is only possible to assess these areas of concern based on general observations on performance, namely:

- Pre-market submissions:
  - o Submission assessments are not meeting the regulated time standards and available data indicates an increase in the number of submissions awaiting completion. The volumes of some types of submissions have risen considerably (e.g., food packaging material from 2,035 submissions at end of FY 2011-2012 to 3,186 at end of FY 2012-2013). Many submission assessments have been awaiting completion for several years. It is not yet known how recent changes implemented by FD will affect these trends.
- HRAs:
  - o While HRAs conducted in response to CFIA requests are being completed according to established standards, some concerns remain that could affect future efficiency (e.g., IT infrastructure challenges, largely paper-based process).
- Communications:
  - o Communication products and engagement activities lack impact assessments that would allow the Program to determine the success of these efforts and, thus, any efficiency gains or losses. This is particularly relevant in the case of Health Canada's large online presence.

- Regulations:
  - o The lengthy regulatory amendment process may be affecting Program and industry performance (e.g., regulatory amendments on food processing aids) and may be exacerbated by a lack of human resources.
  - o Evaluation interviewees noted that some regulatory proposals do not move forward or the amendment process takes too long (e.g., food fortification, pasteurized fruit juices, food irradiation, allergens, labelling, health claims, additives and IMAs to mention a few) due to several factors (e.g., limited human resources).

The evaluation examined alternate delivery structures through consultation with Program personnel as well as a comparative case study on similar programs in other jurisdictions. The following sub-sections identify lessons learned in this area.

### Organizational Restructuring

Among the countries examined as part of the case study on FSNQ programs in selected countries (i.e., Canada, Australia, New Zealand, the UK and the US), all except the US had undergone a restructuring of their food safety systems during the period of this evaluation. The reasons for re-organization varied by country and included various combinations of the following factors: streamlining inefficient systems, reducing activity duplication/overlap, lowering costs, and/or restoring public confidence. These restructuring processes resulted in two approaches to program implementation: 1) a plural approach with multiple organizations playing specific and complementary roles such as that of Canada, the UK (e.g., UKFSA, the UK Department for Environment, Food and Rural Affairs [UKDEFRA] and the UK Health and Safety Executive [UKHSE]) and the US (e.g., USFDA, the US Centers for Disease Control and Prevention [USCDC] and USEPA); and, 2) a consolidated approach where most or all functions are concentrated in a single organization or agency (e.g., FSANZ and the New Zealand Food Safety Authority). In all cases, except for New Zealand, pesticides are administered by separate agencies or authorities (i.e., PMRA, the Australian Pesticides and Veterinary Medicines Authority, UKHSE, and USEPA).

In the case of all countries involved in system restructuring (including Canada), the restructuring processes were mirrored in changes to regulatory systems, which led to a division of risk assessment and risk management functions. However, there is little documented evidence on how this separation has affected the efficiency of policy development, risk assessment and risk management groups; specifically, how these groups have adjusted and maintained connections with each other and with frontline events. A report by the US Government Accountability Office entitled *Experiences of Seven Countries in Consolidating Their Food Safety Systems* (2005) (including Canada, New Zealand and the UK), stated that “none of the countries has conducted an analysis to compare the effectiveness and efficiency of its consolidated food safety system with that of the previous system.”<sup>482</sup>

### Public-Private Partnerships

Generally, research partnerships between key Program participants and other sectors, such as academia or industry, are limited or non-existent. The Program does not use grants to encourage research in areas of interest as done by other regulatory counterparts.<sup>cxxxii</sup> Some FD interviewees stated that there were no partnerships due to the different purposes between government and academic or industry research. They also viewed collaboration with academia as costly while limiting the uses of the results, probably due to intellectual property rights. Some FNIHB interviewees identified opportunities where partnership had been sought and delivered successful results (e.g., work related to the Food Mail Program, and the Nutrition North Canada Program that replaced it, and LifeLine). Finally, a few Public Health Agency of Canada interviewees stated that there was a push for partnerships in research but that it was hard to implement and there were also concerns with losing scientific expertise in the Agency.

### In-House vs. External Research

The level of research outsourcing varies among key Program participants. FD conducts little outsourcing since there is a lack of financial resources allocated to outsourcing work and associated expenses (e.g., Request for Proposal preparation, proposal review, and travel time as expertise tends to be found outside the National Capital Region); there is a perceived lack of viability since the necessary multidisciplinary expertise for certain projects cannot be found among academia or industry; and, there are apparent risks related to credibility (competency of contractor) and confidentiality.

### Cost Recovery

The majority of Program activities are not cost recovered. An examination of similar programs in other countries identified the following:

- Australia, New Zealand, the UK and the US charge fees for assessing certain pre-market food submissions from the food industry. The reasons for cost recovery are linked to submission complexity (e.g., food additives, novel foods), potential commercial gain by the applicant upon submission approval, or desire by the applicant to fast track the submission process.
- Food safety activities related to surveillance and outbreaks are not cost recovered by any country.
- Pesticide-related activities (e.g., assessment of submissions, granting licences and annual renewal) are cost recovered by all countries.

A comparison of cost-recovered activities between Canada's FSNQP and its counterparts in Australia, New Zealand, the UK and the US is provided in **0**.

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<sup>cxxxii</sup> Some of the international organizations examined have access to grants and partnership programs, for example USFDA offers a variety of awards and grants (e.g., on food safety and security monitoring in areas related to microbiology, chemistry and radiological).<sup>481</sup> Moreover, CFSAN has on-going structured collaboration with various universities and centres of excellence.<sup>54</sup>

According to some evaluation interviewees, there have been discussions on implementing cost recovery for pre-market food submission assessments; however, the process has not moved forward as a result of several concerns. One concern is related to the lack of market exclusivity (via patents) for the majority of food submissions, which is considered to be a significant difference between foods and health products or pesticides. In this case, it is believed that cost recovery could represent a significant disincentive for industry to file submissions; however, several of the submissions are mandatory, thus giving the applicant no option but to file. Further, the use of patents in the food industry to protect innovation and, thus, differentiate foods or packages based on technological advantages that could benignly affect human health is not uncommon (there are a number of food process and packaging patents in the US addressing antimicrobial protection and improved food texturing<sup>472</sup>).

A 2011 report assessing food packaging innovation found that companies are continuously innovating to address consumer concerns (e.g., tamper-evident packaging and interactive packages that use radio frequency identification technology to track food from source to destination).<sup>76</sup> A 2009 report on patents and health claims related to functional foods<sup>cxxxiii</sup> found that “patenting a formulation or a process for creating a functional food may exclude others from selling the formulation, or from using the process. The technology can also be licensed out, enabling the inventor(s) to make money from it.”<sup>470</sup> A 2009 article on functional foods conducted a search of patent collections in Europe, Japan, the US and the World, or Patent Cooperative Treaty offices; the article identified “approximately 3,900 patents and applications pertaining to health foods, functional foods or ‘foods for wellness’” with approximately half of these patents classified as A23L: “foods...not covered by other subclasses: their preparation or treatment.”<sup>471</sup>

## OBSERVATIONS ON THE ADEQUACY AND USE OF PERFORMANCE MEASUREMENT DATA

Overall, the performance measurement data available for the evaluation was of limited use in addressing the achievement of the identified outcomes. The collection of performance data does not appear to be consistent, there are a variety of measures and formats used, there is no Program approach to data collection and analysis, and efforts tend to focus on tracking mainly Program outputs. Examples include:

- A Performance and Accountability Framework for the Program was developed in 1999.<sup>cxxxiv</sup> This framework described activities, outputs, reach as well as short- and long-term outcomes related to FD, FNIHB, PMRA and the Public Health Agency of Canada together with a short list of general indicators. A second framework was developed in 2000<sup>cxxxv</sup> that described activities, outputs, reach as well as short- and long-term outcomes related to FD and the Public Health Agency of Canada only. Each key Program participant has also developed its own Performance Measurement Strategy but these strategies have not been developed with a Program view.

<sup>cxxxiii</sup> A functional food is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.

<sup>cxxxiv</sup> Official Government documents.

<sup>cxxxv</sup> Idem.

- As of 2005, departmental and Agency data used for preparing RPPs and Departmental Performance Reports (DPRs) was to originate through a more structured approach through the development of Management, Resources and Results Structures (MRRS),<sup>cxxxvi</sup> which provide a template to capture performance information according to PAA level. While Health Canada had developed its MRRS, the systematic creation, collection, capture and use of information only began in FY 2007-2008.<sup>310</sup> The Public Health Agency of Canada had a MRRS approved by Treasury Board in 2009.<sup>414</sup> The indicators used are too high level to address evaluation needs.
- Departments, branches and agencies have also developed a series of annual, operational and business plans that provide performance information. Some key Program participants (e.g., FD) have produced performance reports but not on a regular basis. FD reports examined covering FY 2009-2010 to 2012-2013 show a variety of performance measures and reporting formats used on a quarterly and annual basis making temporal comparisons difficult if not impossible.<sup>205,221,222,270,262,297,292,290,225,226,227,266,269,285,228</sup>
- FD uses the Program Management Reporting System (PMRS) as a tool for managing project work (e.g., planning and resource allocation). PMRS is used to support quarterly reporting on priorities to the ADM and provides information for RPPs, DPRs and other operational reviews. However, while some projects contain performance indicators, this is not a common approach; thus, the usefulness of PMRS as a performance measurement tool is limited by lack of performance data.
- FD has also developed a performance measurement best practices manual<sup>308</sup> and a *Food Directorate Performance Measurement System* based on a logic model approach.<sup>164</sup> The system contains project-based logic models and associated activities and performance indicators on specific topic areas such as special purpose foods, allergens, and novel foods. However, although prototyped in 2002 and launched in 2005-2006, with an intention to link it to PMRS, the system is not being used due to decisions associated with changes in reporting processes at HPFB and departmental levels.

Some FD interviewees believed that, although some of these tools were available and useful as planning tools, measuring policy effectiveness needed to be addressed. They elaborated that monitoring the impacts of policy (e.g., behaviour change) was complicated by the inability to conduct public opinion research, which was deemed essential to assess the impacts on the health of Canadians and measure progress on Program outcomes. Some FD interviewees also believed that performance measurement activity was seen as a lower priority and that FD had no clear strategic plan for this activity. They mentioned that although data elements were identified, data was not regularly collected. Moreover, some interviewees mentioned that performance measurement responsibility was given to FD Bureaux whose staff lacked performance measurement expertise.

FD interviewees stated that indicators used in PMRS were mostly focused on outputs, which, while useful for planning purposes, provided an insufficient measure of level of quality (e.g., quality of the reviews vs. number of pre-market submissions processed). This sentiment was

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<sup>cxxxvi</sup> A MRRS links PAA strategic outcomes with expected results. It also identifies performance indicators, data sources, targets and date to achieve targets, among other measures.



echoed by other Program interviewees, who believed that it was not possible to assess the effectiveness of the Program as this was not monitored through performance measurement indicators (e.g., indicators seeking to measure the impact of decisions made, actions taken and concomitant changes, level of integration of all activities, level of reporting according to key commitments and achievements, level of transparency/communication, etc.).

Recent efforts to employ a Program approach to reporting, such as the response to the *Weatherill Report* (2009), and efforts to link key commitments to performance indicators to outcomes, as proposed by Health Canada's Food and Nutrition Safety Program strategic plans,<sup>305,291</sup> may help to improve performance measurement data collection and analysis.

## OBSERVATIONS ON ECONOMY

Budgetary and expenditure data available was insufficient to permit an economic assessment of the Program. The evaluation identified a number of issues affecting the quality and availability of data:

- As noted earlier, the Program experienced several organizational changes during the 2000-2004 period (and some beyond) that led to a transfer of funds between organizations. These changes included:
  - o The creation of three new branches, namely HPFB, FNIHB and RAPB,<sup>cxxxvii</sup> through realignment of the Health Protection Branch (HPB), the Medical Services Branch, and the Health Promotion and Programs Branch.
  - o The creation of the Public Health Agency of Canada with the concomitant transfer of functions from HPB/HPFB (i.e., the Laboratory Centre for Disease Control, the functions of which now reside within CFEZID) and the Population and Public Health Branch (i.e., the Centre for Surveillance Coordination, now the Surveillance Coordination Unit within the Office of Public Health Practice) to this new Agency.
- PAAs examined changed considerably over the evaluation period. For example, in the case of Health Canada, PAAs developed for FY 2007-2008 and earlier were designed to report on sub-Activities and sub-sub-Activities that reflected Program functional activities (e.g., sub-Activity: pre-market regulatory evaluation & process improvement, sub-sub-Activity: approval times). Conversely, PAAs used since FY 2008-2009 have been designed to report on sub-Activities and sub-sub-Activities that reflect Programs and their component Directorates (e.g., sub-Activity: food safety and nutrition, sub-sub-activity: food-borne pathogens). It was not possible to link financial data between these two periods or to align it with the logic model developed for the evaluation.
- In the case of Health Canada, departmental government-wide reduction exercises of previous years were cash-managed at the branch level and funded by branch surpluses at year end. These transactions were not attributed to any specific sub-Program according to the PAA. Also, interpretative information that would explain decisions made in annual budget derivations and reasons for transactions was not available.

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<sup>cxxxvii</sup> Created in 2008.

- SAP data examined was inconsistently coded or had missing information in some fields. For example, an examination of FD functional area codes showed inconsistencies across FYs and in grouping structures (PAA-based). An analysis of SAP internal order (IO) numbers covering FY 1999-2000 to 2007-2008 to link with data reported in PMRS showed 32% of records missing an IO/project number.<sup>cxxxviii</sup> Although the IO field exists in SAP, HPFB has stated that it is not a mandatory field in the coding block and, therefore, not required when incurring expenditures and commitments.
- While the Program is financed through dedicated funding requests (i.e., resources requested to address specific objectives) and through core funding (i.e., funding allocated by departments, branches and agencies to allow the Program to carry out its everyday activities), these sources were difficult to identify and track in the available data (e.g., derivations). The level of detail available from dedicated funding requests varies and is inconsistent across all the documents examined (e.g., in many cases, while multiple activities are identified in the documents, funding tables do not allocate monies on an activity basis). Funding received through these dedicated requests is presented in **Table 18**.<sup>cxxxix</sup> According to this data, the Program was granted approximately \$553 million in dedicated funding during FY 1999-2000 to 2011-2012. According to HPFB, “funding source” is not a mandatory field in the coding structures; however, cost centre (organization), G/L (type of expenditure) and Functional Area (FA, which is the lowest level of the PAA structure) related to activity/Program area are tracked.

Moving forward, HPFB plans to make use of IO numbers to capture financial information on Program delivery, which will enable a better separation of reporting elements/components to link sources of funding with Program expenditures. According to HPFB, separate IO numbers have been created for all funding earmarked through dedicated funding requests; however, the majority of IO numbers are related to A-base funding and other initiatives, which the Directorates or the Program may want to track for various reasons. Once the requirement to track the earmarked funds is lifted, the funds/expenditures may be combined with A-base as deemed appropriate by HPFB. HPFB has also recently introduced financial management controls, including an improved time tracking system, to help validate costing. The plans of other key Program participants to address financial tracking deficiencies are unknown.

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<sup>cxxxviii</sup> Total of 88,315 records of which 28,606 had missing order number data.

<sup>cxxxix</sup> Official Government documents.

**Table 18 Funding allocated through Dedicated Funding Requests by Key Program Participant**

FY	1999-2000		2000-2001		2001-2002		2002-2003		2003-2004		2004-2005		2005-2006		2006-2007		2007-2008		2008-2009		2009-2010		2010-2011		2011-2012		Total
	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M	FTE	\$M
HPFB	\$7.7	25	\$20.2	75	\$23.2	92	\$23.2	93	\$27.1	93	\$27.3	93	\$27.6	93	\$27.6	93	\$27.6	93	\$24.7	100	\$28.2	118	\$32.2	131	\$32.1	125	\$328.6
FNIHB	\$0.5	0	\$1.1	0	\$2.2	0	\$2.6	1	\$2.4	1	\$2.4	1	\$2.4	1	\$2.4	1	\$2.4	1	\$2.4	1	\$2.4	1	\$2.4	1	\$2.4	1	\$27.9
HC (sub)	\$8.3	25	\$21.3	75	\$25.3	92	\$25.8	94	\$29.5	94	\$29.7	94	\$30.0	94	\$30.0	94	\$30.0	94	\$27.1	101	\$30.6	119	\$34.5	132	\$34.5	126	\$356.5
PMRA	\$1.0	12	\$2.4	30	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$3.8	48	\$44.7
PHAC	\$3.2	26	\$8.9	49	\$10.2	58	\$14.6	68	\$13.2	68	\$13.2	68	\$13.4	68	\$13.4	68	\$13.4	68	\$12.0	68	\$12.0	68	\$12.0	68	\$12.0	68	\$151.7
Total	\$12.5	63	\$32.6	154	\$39.3	198	\$44.2	210	\$46.4	210	\$46.7	210	\$47.1	210	\$47.1	210	\$47.1	210	\$42.9	217	\$46.4	235	\$50.3	248	\$50.3	242	\$552.9

Notes:

- All dollar amounts exclude 13% Public Works and Government Services accommodation charge.
- All dollar amounts include salaries and wages, Employee Benefit Plan, communications and Operations & Maintenance.
- Funding and FTEs originally allocated under the Laboratory Centre for Disease Control, the Centre for Surveillance Coordination, and Winnipeg Laboratory are reported under the Public Health Agency of Canada.
- Funding and FTEs originally allocated under the Medical Services Branch are reported as part of FNIHB. It could not be determined if the dollar amount and FTEs allocated to FNIHB in this manner addressed only the activities of the evaluated Directorate (i.e., IAPSD).
- Funding and FTEs originally allocated under the Health Promotion and Programs Branch and that now correspond to activities conducted by ONPP (part of a separate evaluation) have been excluded to the extent possible (i.e., only reported when documents did not provide a breakdown of funding by organization by Program objective).
- Some Program objectives (e.g., community surveillance and emergency response, Winnipeg Laboratory/NML, Biosafety Level 3 Laboratory infrastructure, etc.) addressed more than just FSNQ; however, it could not be determined what proportion of the dollar amount allocated to these objectives addressed only food-related activities.
- \$3.5 million for FY 1999-2000 and 2000-2001 as well as \$3.0 million in on-going funding is not included as it was provided for NHPs (part of a separate evaluation).
- Funding and FTEs allocated to HPFB under FCSAP are included.
- Funding and FTEs for the Chemical Management Plan are not included as they are part of a separate evaluation.

## **5.0 Conclusions**

### **5.1 Relevance Conclusions**

#### **5.1.1 Continued Need**

**The Program continues to address a demonstrable need.**

The activities carried out by the Program are designed to address known and emerging issues related to FSNQ (e.g., microbial and chemical food safety hazards, emergent and re-emergent pathogens, new technologies, dietary needs). On-going scientific developments, market changes, and evolving consumer preferences, among others, will continue to present FSNQ challenges, which the Program is in the best position to address.

#### **5.1.2 Alignment with Government Priorities**

**The Program is aligned with government priorities.**

Speeches from the Throne over the years have recognized the importance of FSNQ and identified federal priorities aimed at strengthening Canada's food safety system and ensuring nutrition quality. The Program seeks to address these federal priorities through an inclusive approach reflected in relevant Program planning documents, which has as its goal the risk-based identification and prioritization of issues. Program objectives are aligned with relevant strategic outcomes from Health Canada and the Public Health Agency of Canada.

#### **5.1.3 Alignment with Federal Roles and Responsibilities**

**The Program is aligned with federal roles and responsibilities.**

The Program operates within a legislative framework designed to address priorities through policy development and standard setting, health promotion activities, risk and disease prevention, disease investigation, research and monitoring as well as national and international cooperation, among others. Relevant Acts identify roles and responsibilities that enable key Program participants to operate within the established federal parameters. The Program acts as the umbrella under which federal activities related to the FSNQ are managed. These activities are not duplicated by any other federal program.

## 5.2 Performance Conclusions

### 5.2.1 Achievement of Expected Outcomes (Effectiveness)

#### Immediate Outcomes

#### **Immediate Outcome # 1: Increased Availability of Safe and Nutritious Foods for Canadians**

**While Canadian food safety performance is high, issues of timeliness, in particular with respect to pre-market submission reviews, may be delaying the entry of foods into the market.**

FD assesses pre-market submissions according to regulatory requirements to help ensure that the food product is safe. Overall, pre-market submission assessments are not meeting the regulated time standards (61% increase between FY 2007-2008 and 2012-2013) while some volumes (novel food and food additive) declined between FY 2011-2012 and the third quarter of 2012-2013. During this last period, submissions without regulated time standards saw an increase in some volumes (food packaging and food processing aids) and a decrease in others (incidental additive). FD uses a collaborative approach to submission assessment; however, the evaluation identified several issues contributing to the submission review backlog. Among these, outstanding petitioner information as well as timeliness and communications with respect to the submissions review process are of particular concern to industry stakeholders and contribute to delays.

Some of the delays experienced may be linked to the lengthy regulatory approval/amendment process, while others may be linked to industry's desire to obtain FD's LONOs (documents issued by Health Canada which can be used by the food seller to assure its customers that the products have been evaluated by FD and deemed acceptable). LONOs may be issued by Health Canada for those submissions that do not require a pre-market assessment (e.g., food packaging materials and food processing aids). While FD has been taking steps since 2007 to address the submission review backlog (e.g., establishment of a Submission Management Unit and an Internal Committee on Submission Governance to move forward the authorization of food applications where regulatory amendments were pending), the level of success of these initiatives appears limited as the backlog has continued to increase. Without further evidence, an accurate assessment on the level of success of these initiatives is not possible.

HRAs are developed to determine if the presence of a certain substance or micro-organism in food poses a health risk to consumers. FD reports 100% compliance with delivering HRAs within service standards to CFIA; however, the number of completed HRAs reported by FD in different documents is inconsistent. According to trend analysis data, *L. monocytogenes* and "meat and poultry" were involved in approximately half of

the microbial HRAs conducted during FYs 2008-2009 and 2010-2011. The same analysis points to an increase in CFIA requests for technical advice, which combined with existing FD challenges related to HRA preparation (e.g., lack of suitable IT infrastructure, absence of a single repository of information across the Directorate) may put pressure on future performance. Efforts by FD are underway to better track and analyze data stemming from HRA activity (e.g., trends in HRA requests, linking food safety incidents to HRAs) and to expand capacity (e.g., additional hires, training/cross-training, facility enhancements) in an effort to maintain performance.

### **Immediate Outcome # 2: Increased Awareness and Understanding of Food Safety- and Nutrition-Related Risks and Health Benefits**

**Changes in awareness and understanding were difficult to assess since the Program does not measure uptake of the information it produces. There are areas where further information or education is needed to improve consumer understanding. Some information delivery mechanisms may not be as effective in relaying information to the intended targets/populations.**

The impact of the Program's products and activities on public awareness and understanding cannot be determined since the Program does not measure or track uptake by audience and time period. An exception and best practice was the Listeria social marketing strategy, which included targeted communications, multiple delivery mechanism, and a survey to collect impact data. A key challenge to understanding impact is a lack of alignment between delivery mechanism and target population preferences. For example, while some sub-populations may be more inclined to access food safety information online (e.g., pregnant women and parents in general), others may be more comfortable with traditional print media (e.g., seniors); still others may experience limited access to online resources or access to the required peripherals (e.g., First Nations and Inuit communities in remote locations). This limited "information tailoring" may negatively impact awareness and understanding by reducing communication effectiveness and contributing to uneven public awareness and understanding. In particular, the Program's focus on a large online presence may be challenged based on current Web statistics (e.g., low volume of visits and views of Health Canada's food safety Web pages according to FD Web statistics). Some of the areas where further information or education is needed include food safety, nutrition and healthy eating, nutrition labelling, trans fats, and GM foods. In general, being aware of the information may not be translating into changing dietary behaviour.

**Immediate Outcome # 3: Enhanced Contribution to International Standards that are supported by Scientific Evidence**

**The Program actively engages in international standard development. Its scientific and regulatory research has made important contributions to the international community.**

The Program is active in international collaboration. The Program's contributions to the development of international standards (e.g., on food fortification, chemical contaminants) are widely recognized. Most international work is conducted through Codex and, to a lesser degree, through bilateral and QUAD partnership meetings. The Program is also involved in activities with other international organizations (e.g., FAO, US National Academies, and WHO) and has played a leading role in the creation of the International Food Chemical Safety and Microbial Food Safety Liaison Groups.

**Immediate Outcome # 4: Improved Knowledge and its Use to Support Policies, Guidelines, Standards, Regulations, Strategies, CFIA Inspections and Assessments**

**There are some examples of knowledge development by the Program such as research for the enhancement of methods of analysis and testing as well as the development of guidelines and standards. The Program uses this improved knowledge to support regulatory and policy development as well as collaborative work.**

Scientific method development and validation is an activity that contributes to improved knowledge and safety among key Program participants, partners, and stakeholders. The evaluation identified a number of guidelines, standards, frameworks and policies in high priority areas that have been impacted or developed as a result of advancement in scientific and regulatory research (e.g., work on acrylamide-asparaginase interaction, BPA, Listeriosis). The Program has also used this knowledge to inform consultation efforts. Collaboration among key Program participants and Program partners has led to the development of novel technology (e.g., lab on a chip) as well as enhanced surveillance work. Lessons learned and funding received following the 2008 Listeriosis outbreak have contributed to maintaining the currency of microbiological methods, to greater collaboration (e.g., between Health Canada and CFIA) on method development (Health Canada, Public Health Agency of Canada, and CFIA), and to reduce method response turn-around times (e.g., an enhanced method for the confirmation of Listeria provides results in three to five days instead of the former seven to 10). Nonetheless, there are concerns related to the need for increased laboratory capacity to satisfy current and emerging demands, to remain abreast of scientific advances, and to increase internal expertise in a number of fields (e.g., biostatistics, epidemiology, electro-microscopy, bioinformatics, etc.).

## **Immediate Outcome # 5: Improved Collaboration with F/P/T Partners and Stakeholders**

**The Program coordinates priorities and risk management approaches within Canada's FSNQ system and contributes to improved collaboration with partners and stakeholders. There are some issues to be addressed with respect to communications and procedures related to FSAs and HRAs.**

The Program engages in coordination and collaboration through a large number of committees and initiatives that include key Program participants, partners and stakeholders (e.g., FPTSC, FPTGN, the Food Policy and Science Integration Committee, the Food Regulatory Advisory Committee, FIORP). While Health Canada has enhanced the efficiency and reliability of its HRA process to respond to CFIA requests, there are some opportunities to enhance communications and information exchange between Health Canada and CFIA (e.g., e-mail communications, IT tools outages, IT platform differences).

In the case of FSAs (which are intended to assess the rationale and design of CFIA's activities, their implementation, and their level of success including compliance with health safety standards), Health Canada/CFIA collaboration has experienced a number of procedural, planning and operational challenges (e.g., difficulties in priority setting, lengthy review and acceptance process, lack of clarity on FSA approach and methodology). In response, in 2010 Health Canada began a review of the FSAP to assess relevance, governance processes and performance and a consideration of FSAP future strategic direction. Health Canada has also begun a project to identify broad themes for food safety improvements and lessons learned. The results of these studies are not yet available. A number of events, including the change in the reporting relationship of CFIA to the Minister of Health and the discontinuation of the FSAP Advisory Committee, are also likely to have an impact on the conduct of FSAs.

## **Intermediate Outcomes**

### **Intermediate Outcome # 1: Healthier Food Choices made by Consumers**

**While it is not known if consumers have made healthier food choices as a result of Program efforts, evidence points to issues of concern related to the dietary intake of the general population and of First Nations and Inuit communities.**

Available evidence sheds some light on consumer food choices such as high calorie intake from fat and snacks, vegetable and fruit consumption below the recommended daily minimum, a tendency towards fast food and commercially prepared food consumption, and sodium intakes in excess of UL, among others. In the case of First



Nations on-reserve and Inuit communities, sodium intakes exceed recommended limits and the consumption of certain food groups is below recommended levels; some food decisions may be affected by food insecurity and its influencing factors, including environmental changes, poverty and high food costs.

One of the ways in which the Program can aid the consumer in making healthier food choices is through food labels. Data on the success of this tool is inconsistent as some sources point to high consumer uptake, understanding, and use while others report lower use and lack of needed information to make healthy food choices. A lack of standard serving sizes on labels and little understanding of % DV among consumers may be making it difficult for the consumer to make healthier food choices. These are areas in which the Program may be able to influence consumer behaviour.

### **Intermediate Outcome # 2: Reduced Exposure to Microbial, Chemical and Physical Hazards and Nutritional Risks**

**The number of cases of reported enteric diseases appears to have declined over the past decade, while compliance rates for chemical residue testing have remained overall high. While the change in exposure to nutritional risks could not be ascertained, some Program initiatives appear to be contributing to risk reduction in certain areas.**

The number of cases of reported enteric diseases appears to have declined over the past decade (from 793 to 409 or 48% according to C-EnterNet data, and from 36,544 to 21,132 or 42% according to Notifiable Diseases Online), while compliance rates for chemical residue testing have remained overall high (at or above 95%). Program initiatives, such as awareness campaigns, efforts on trans fat reduction and food fortification, have, in theory, effected changes in the exposure to certain nutritional benefits.

### **Intermediate Outcome # 3: Increased Adoption of International Standards by Canada and Other Countries**

**While it was not possible to identify a change in the level of adoption, there is evidence of adherence by Canada to international standards. Other countries' membership in international standard setting organizations denotes an interest in harmonization.**

Canadian adherence to international standards is evidenced, for example, by alignment with regulatory counterparts on nutritional labelling, microbial and chemical safety, and pesticides. Some delays in adhering to international standards have been linked to lengthy regulatory approval processes (e.g., delays in the approval of asparaginase as a food additive) or to concerns with international approaches that may not reflect the Program's position.

#### **Intermediate Outcome # 4: More Integrated Approach to F/P/T Food Safety and Nutrition Priorities and Activities**

**The Program seeks a more integrated approach to F/P/T food safety and nutrition priorities and activities by collaborating with F/P/T partners and stakeholders.**

The Program actively collaborates, both internally with key Program participants and externally with partners and stakeholders by exchanging information, fostering dialogue, consulting, and coordinating priorities and risk management approaches. While identified concerns related to the effectiveness of communications among key Program participants (e.g., FSAs) and between the Program and its P/T partners (e.g., clarification of roles and functions as well as the role of systems and laboratories in emergency response), are expected to be addressed through recent efforts by F/P/T health and agriculture ministers, more structured stakeholder communications and improved transparency regarding Program activities are needed, for example, to clarify roles and responsibilities between the Program and its P/T partners.

#### **Long-Term Outcomes**

##### **Long-Term Outcome # 1: Improved Nutritional Status of Canadians**

**According to available evidence, the nutritional status of Canadians does not appear to have improved over the period of the evaluation.**

Among the general population, there are a number of concerns related to high energy intake (energy intake for 20% of children aged 1 to 8 years exceeds their energy needs), high fat intake, nutrient insufficiency (e.g., many adolescents have inadequate intakes of magnesium, vitamin A, vitamin D, calcium and phosphorous), sodium intakes associated with an increased risk of adverse health effects (across all ages), and rising BMI (e.g., one quarter of Canadians are considered obese). While information on First Nations on-reserve and Inuit communities has been limited, evidence points to low intake of some important vitamins and minerals, high sodium intakes and obesity prevalence.

##### **Long-Term Outcome # 2: Reduced Food- and Nutrition-Related Illnesses**

**Food-related illnesses appear to have decreased over the past decade. Nutrition-related illnesses among the general Canadian population appear to have increased during the same period. The rates of diabetes among First Nations on-reserve are higher than those of the overall Canadian population but seem not to have increased for the last several years (high blood pressure rates have also remained relatively stable).**

### **Rates of diabetes and high blood pressure among Inuit populations approach those of the overall Canadian population.**

The number of cases of reported enteric diseases appears to have declined over the past decade, while compliance rates for chemical residue testing have remained overall high. Information directly linking nutrition to illnesses is limited. The rates of high blood pressure, diabetes and heart disease among the general population, three chronic conditions related to nutrition, have increased over the last decade. In the case of First Nations on-reserve, the rates of diabetes are high compared to the overall Canadian population, although these do not appear to have increased for the last several years (similar to high blood pressure rates). Rates of diabetes and high blood pressure among Inuit populations approach those of the overall Canadian population.

### **Long-Term Outcome # 3: Safer Food Products in International Trade**

#### **The Program contributes to safer food products in international trade. Adoption of international standards by other countries is expected to contribute to international food safety.**

The Program is engaged with international regulatory partners and participates in international fora as part of efforts to standardize, harmonize and increase food safety. Adoption of international standards by other countries is expected to contribute to maintaining and improving food safety.

### **Long-Term Outcome # 4: Canada Viewed as a Responsible Participant and Scientific Expert in an International Context**

#### **Through the activities/contribution of the Program, Canada is viewed as a responsible participant and scientific expert in an international context.**

The Program's expertise and contribution to the international community are recognized through its involvement in standard development, as a host of international collaborating centres and laboratories, and as a partner in international capacity development.

### **Long-Term Outcome # 5: A Sustainable and Integrated System for FSNQ in Canada**

#### **The Program seeks to maintain an integrated system for FSNQ in Canada through consultation and collaboration with partners and stakeholders. There are challenges to the responsiveness of the regulatory framework, which recent legislative amendments and Program strategic plans are expected to address.**

The Program's approach to consultation and collaboration seeks to engage all partners and stakeholders and is expected to continue to enhance system integration. Government Directives are in place to guarantee a consultative, coordinated and cooperative approach to regulatory development. Nonetheless, the level of responsiveness of the regulatory framework is challenged by a lengthy amendment process, the level of resources to carry out regulatory work, the suitability of surveillance and monitoring measures, emergency response mechanisms, and the authority to act on non-compliance. Recent amendments to the F&DA (e.g., the new Marketing Authorization framework and Incorporation by Reference) are expected to address a number of these concerns.

## **5.2.2 Demonstration of Economy and Efficiency**

### **Program performance and financial information was insufficient to properly demonstrate efficiency and economy.**

Financial data available for the evaluation was insufficient to support an analysis of efficiency and economy. As a result, the evaluation could not assess the extent to which Program resources were used as planned, whether Program outputs were produced efficiently, or whether expected outcomes were produced economically. HPFB has recently introduced financial management controls, including an improved time tracking system, to help validate costing.

The collection of performance data does not appear to be consistent or follow a Program approach to its analysis; there are a variety of measures and formats used and efforts tend to focus on tracking mainly Program outputs.

There are a number of Program areas where process performance may be affecting efficiency, namely: the pre-market submission assessment process, the HRA process and its infrastructure, stakeholder communication effectiveness, laboratory research capacity, the FSA process, and regulatory modernization. The Program makes limited use of public-private partnerships and outsourcing, which could contribute to efficiency improvement, while it lacks a cost recovery framework to better manage the costs of its pre-market processes.

## 6.0 Recommendations

### **Recommendation 1. FD should examine options to enhance the efficiency and transparency of its food pre-market submission activities.**

Overall, pre-market submission assessments are not meeting the regulated time standards (61% increase between FY 2007-2008 and 2012-2013) while some volumes (novel food and food additive) declined between FY 2011-2012 and the third quarter of 2012-2013. During this last period, submissions without regulated time standards saw an increase in some volumes (food packaging and food processing aids) and a decrease in others (incidental additive). FD uses a collaborative approach to submission assessment; however, the evaluation identified several issues contributing to the submission review backlog. Among these, outstanding petitioner information as well as timeliness and communications with respect to the submissions review process are of particular concern to industry stakeholders and contribute to delays.

### **Recommendation 2. FD should examine and improve its HRA tracking processes.**

Trend analysis data points to an increase in CFIA requests for technical advice, which combined with existing FD challenges related to HRA preparation may put pressure on future performance.

### **Recommendation 3. Health Canada should conduct impact assessments of its public outreach initiatives to determine uptake.**

The impact of the Program's products and activities on public awareness and understanding cannot be determined as uptake by audience and time period is not measured. A key challenge to understanding impact is a lack of alignment between delivery mechanism and target population preferences.

### **Recommendation 4. Health Canada should develop a coordinated Program approach to performance measurement with a Health Portfolio perspective.**

The collection of performance data does not appear to be consistent or follow a Program approach to its analysis; there are a variety of measures and formats used and efforts tend to focus on tracking mainly Program outputs.

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## Appendix 1 - Program Partners and Stakeholders

The FSNQP operates with a wide range of partners and stakeholders that complement the activities of the key Program participants in the following areas:

- Within Health Canada:
  - o The Strategic Policy Branch co-ordinates overall health and science policy for the department.
  - o The Healthy Environments and Consumer Safety Branch (HECSB) provides guidance and frameworks to manage chemicals and their effects on the environment and human health.
  - o OCAPI provides information and opportunities for Canadians to become involved in HPFB's decision-making processes regarding priorities, policies and programs.
- Within the Health Portfolio:
  - o CIHR fund health research, build research capacity in underdeveloped areas (e.g., population health and health services research) and carry out knowledge translation so that research results may be integrated into the Program's policies, practices, procedures, products and services.
- Across the federal government:
  - o AAFC and the Department of Fisheries and Oceans work with FSNQP as it develops policies and regulations that impact these important economic sectors.
  - o StatCan supports the program in acquiring consumption survey data (for intake estimation of nutrients and contaminants) with financial support from the Program...
  - o EC and AANDC contribute with guidance to further inform Program decisions.
  - o AAFC and DFATD work together with the Program and CFIA to develop Canada's positions on food standards set internationally.
- Nationally:
  - o P/T governments play a key role in the protection and promotion of the health of Canadians and provide consistent, credible evidence-based policies and messages. Health Canada participates in a variety of F/P/T governance bodies.
  - o The Program works in close collaboration with various stakeholders such as food and nutrition advocacy groups, NGOs, producer associations, consumer action groups, health professionals, patient associations as well as the food industry.
- Internationally:
  - o International organizations such as the WHO, FAO, OIE, the Pan-American Health Organization and, in particular, Codex, play a key role in the Program's efforts to ensure Canada is well represented in international policy development and standards setting fora.

- o Health Canada maintains close collaborations with USFDA, EFSA, FSANZ as well as several EU member states' food regulatory agencies. Health Canada also participates in the Asia-Pacific Economic Cooperation Forum's Food Safety Cooperation Forum and actively collaborates with the Chinese government and Food Safety organizations.
- Academia (nationally and internationally):
  - o Several Program personnel have cross appointments with Canadian universities. Health Canada has established collaboration with other research and academic centres nationally and internationally (e.g., the US National Institute of Medicine).

## Appendix 2 - Details on Data Collection and Analysis Methods

The evaluation relied on multiple lines of evidence reflected in the data collection methods chosen for the evaluation. These methods included:

- Literature review;
- File review;
- Interviews; and,
- Case studies.

Inclusion/exclusion criteria were used for each of the reviews and case studies to ensure the most appropriate, credible, reliable and relevant information needed to address specific evaluation questions was selected and reviewed. These criteria included:

- Time of publication: while mostly data generated between April 1<sup>st</sup>, 1999 and March 31<sup>st</sup>, 2012 was used to address the core issues, data from other years was also considered for baseline and trend analysis purposes.
- Coverage of publication: document content relevant to evaluation issues (e.g., performance measurement and monitoring).
- Credibility of source: government publication, peer-reviewed journal articles, grey literature.
- Relevancy of information to each indicator and evaluation question.

For the demonstration of economy and efficiency, an allocative approach was attempted as this is a long-established Program that should have achieved long-term outcomes.

### 1.1 Literature Review

This method consisted of reviewing a number of pre-selected food safety and nutrition literature pieces, many of which were scientific in nature, to answer questions related to Program functioning, gaps, challenges and emerging issues.

Evaluators employed Health Canada's Science Library to conduct a general search of documents related to Food Safety and Nutrition Quality (FSNQ). The purpose was to identify and collect relevant articles by scouring any and all sources of information (e.g., databases such as Food Science and Technology Abstracts and AGRICOLA). The search was based on a list of key words and terms used in combination through a set of Boolean operations producing multiple runs. The result from each run was then further refined through a preliminary review process.

The resulting documents (96) were then analyzed in successive stages: 1) non-relevant documents were first removed; 2) the remaining documents were then analyzed and

summarized according to document topic (food safety or nutrition quality), relevance to evaluation question, article citation, objectives, methods, limitations and findings; and, 3) the documents were summarized into key themes within each topic.

## 1.2 File Review

This method focussed on reviewing documents and databases identified by the Program as relevant to the evaluation. Evidence was compiled according to evaluation indicators and summarized by each evaluation question in order to merge it with information stemming from other methodologies.

Evaluators collected documents (soft and hard copies) from each key Program participant. These documents (over 2,000 in total) were then allocated by indicator in a “one-to-many” correspondence matrix in order to facilitate initial analysis (i.e., since most documents contained information relevant to multiple indicators, the database allowed for a preliminary assessment of gaps). The bulk of the documents covered the period from 1999 to 2012; documents from 1990 to 1998 were used as baselines while documents from later years, including 2013, were used to reflect recent Program changes or achievements linked to ongoing initiatives. Documents were analyzed in successive steps and summarized by indicator. Each document was then categorized into key themes, by indicator and evaluation question.

This process was aided by interviews with key stakeholders, conducted between February and May 2009, to obtain a clear understanding of the Program and the context/scope of the evaluation.

Evaluators also documented information on a number of internal databases and external data files (e.g., survey data) used by the Program. A short list of key databases was then selected to review either the database itself or, in cases where reports existed, reports summarizing the purpose and available data from each application. A number of interviews were then conducted to obtain facts on those databases for which information was not readily available. The relevant information from each database was then incorporated into the analysis.

A further appraisal and classification of the evidence was accompanied by a secondary review of specific Program sources. Any gaps identified through the review were then addressed through a request for new or extended information from key Program participants. The information obtained through these exercises was then incorporated into the existing evidence.

### 1.3 Interviews

This method was used to collect and summarize information from a number of key informants, partners and stakeholders addressing Program performance and, in particular, areas identified for further exploration as a result of the literature and file review. The information also served to inform the case study identification and development process.

Key informants are employees from key Program participants who are knowledgeable about the Program and include staff from FD, BFSa, ONPP, VDD, RAPB, FNIHB, PMRA and Public Health Agency of Canada. Domestic and international partners are organizations that assist in the implementation of the Program (e.g., NGOs), or who have parallel regulatory programs that deal with FSNQ (e.g., F/P/T and international government organizations). Stakeholders receive the benefits or the effects of the Program and include:

- Academia;
- Food and food product importers and exporters;
- Food and farm industry representatives; and,
- Consumer associations.

Due to the large number of individuals involved with the Program, drawing a sample that would produce statistically significant results was financially and time prohibitive. Therefore, evaluators used a stratified purposive sampling<sup>cxl</sup> approach and engaged key Program participants to generate a list of individuals knowledgeable<sup>cxli</sup> about the Program across all identified organizations. In this way, although the sample would not be representative of the population or produce statistically significant results, interviews could still elicit valuable information to provide context for the formulation of findings and conclusions, to delve in areas requiring clarification, or to obtain information where documented evidence was not available. By using the interview information in this manner, the potential for bias was reduced to a minimum. A list of 241 knowledgeable individuals, segmented according to the above groups and sub-groups, was used as the knowledgeable population for the interviews.

As a next step, a master set of interview questions was developed based on the findings elicited from other methodologies. Areas covered by the questions included:

- Program relevance and need;
- Risk assessment processes;

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<sup>cxl</sup> Purposive sampling is a type of non-probability sampling in which the sample is hand-picked to address areas of interest relevant to the research in question. The sampling can be stratified (e.g., key Program participants, partners and stakeholders) to reflect groups that vary according a key dimension (e.g., level of participation with or contribution to the Program).

<sup>cxli</sup> Key Program participants provided names of individuals that were or had been involved with the Program or were knowledgeable about it as a result of organizational interactions.

- Consumer perceptions of the Program;
- Outcomes from international Program activities;
- Development of laboratory methods and results from regulatory research;
- Results from domestic collaboration and consultation activities;
- Level of integration of Canada's food safety system;
- Progress on Program performance measurement activities;
- Challenges related to Program resource levels;
- Identification of alternative Program delivery structures; and,
- Other issues or challenges.

This master list was then used to develop semi-structured interview guides, which were customized for each group and sub-group. To limit the time impact of the interview process on Program personnel and to encourage participation, interview guides were limited to 20 questions for government interviewees and 12 questions for external interviewees. Where the maximum number of questions was exceeded in the semi-structured interview guides, the questions were divided into high and low priority. Interviewees were given the options of extending the interview, scheduling a second interview, or providing written responses at a later date to questions not covered during the initial interview.

Individuals were contacted by e-mail and/or telephone to schedule an interview. The semi-structured interview guides were provided to each interviewee (either in English or French) prior to the interview to allow him/her sufficient time to prepare for the dialogue. Interviewer guides contained a series of probes to elicit further information when required; these probes were used at the discretion of the interviewer.

Individuals were interviewed by applying three interview methods:

- One-on-one, in-person interviews;
- Group, in-person interviews; and,
- Telephone interviews, one-on-one or group (mostly used for interviews outside the National Capital Region).

Interviews were conducted in the interviewee's preferred official language. All interviewees were assured that the data would be kept confidential and guaranteed that said data would be non-attributable to encourage candid responses.

A total of 152 individuals were interviewed across multiple organizations. **Table 19** summarizes the number of interviews by group and sub-group. Interviews were conducted between October and December 2009.

**Table 19 Key Informant, Partner and Stakeholder Interviews**

Group	Sub-groups		Interviews	
Key informants	HPFB	FD	Director General's Office	2
			Bureau of Chemical Safety (BCS)	14
			Bureau of Microbial Hazards (BMH)	8
			Bureau of Nutritional Sciences (BNS)	6
			Bureau of Food Regulatory, International and Inter-Agency Affairs (BFRIIA) <sup>cxlii</sup>	6
			Animal Research Division <sup>cxliii</sup>	3
			Office of Management Services and Planning	3
	PPIAD	International, Federal-Provincial-Territorial and Portfolio Affairs Division	1	
		BFSA	2	
	VDD ONPP		9	
	RAPB	Regional offices and laboratories	12	
	FNIHB	CPD PHCPHD	9	
	PMRA	Re-Evaluation Management Directorate Health Evaluation Directorate	4	
Public Health Agency of Canada	CFEZID NML LFZ	6		
CFIA	Operations Branch Programs Branch Science Branch Audit, Evaluation and Risk Oversight Branch (AERO)	23		
Domestic partners	HPFB	OCAPI	2	
	HECSB		1	
	AAFC		4	
	AANDC <sup>cxliv</sup>		2	
	P/T governments	P/T food/agriculture departments/ministries	10	
International partners	Other Country Food and Regulatory Organizations		1	
	WHO		1	

<sup>cxlii</sup> The Bureau was amalgamated with BFPI and became BPIIGA during Fiscal Year 2011/12.

<sup>cxliii</sup> The Division has been amalgamated with BCS.

<sup>cxliv</sup> During the evaluation period, interviewees were identified as belonging to Indian Affairs and Northern Development Canada.



Group	Sub-groups	Interviews
Stakeholders	<ul style="list-style-type: none"> <li>• Industry Associations:                             <ul style="list-style-type: none"> <li>○ Farm</li> <li>○ Manufacturing</li> <li>○ Import, Export</li> <li>○ Transportation</li> <li>○ Pesticides</li> </ul> </li> </ul>	12
	Environmental Groups	1
	Consumer Associations	3
	First Nations and Inuit Groups	4
	Academia	3
Total		152

Estimated times for interviews were 90 minutes for government employees and 60 minutes for external stakeholders. Small interview groups (two to three individuals) were scheduled for two hours. Interviews with several individuals or those with senior Program managers were conducted by two interviewers; all others were conducted by a single interviewer. Evaluators monitored a sample of interviews to ensure acceptable performance and data collection. Interview notes were recorded for each interview, by interview question. Additional documents for review identified during the interview process were noted and a copy requested from the interviewee.

Interview results were compiled in a matrix by evaluation question and group. Comments were codified in order to allow the identification of top issues and facilitate reporting. Each group was analyzed and non-attributable, summary-level information was reported. Due to the open-ended nature of the questions posed to interviewees, percentages documented in this report reflect multiple responses. Results have been reported as % out of n respondents to a particular question; the top three percentages for a question have normally been reported. In some instances, single mentions have been used to focus on particular areas of interest or to provide background to the answers given by respondents.

## 1.4 Case Studies

Consultations with key Program participants during the Evaluation Framework development process identified a list (14) of case studies. As a result of the evidence gathered through the previous technical reports, six case studies were selected from this list and completed to inform particular areas of interest. An additional case study on Health Canada’s response to the 2008 Listeriosis outbreak was later added to this list to ensure full coverage of Health Canada’s Response to the 2008 Listeriosis Outbreak as well as to report on commitments made through a dedicated funding request related to the 2008 Listeriosis outbreak.

These case studies provided an in-depth understanding of how the various mandated and supporting activities of the Program translated into practice as well as how specific

initiatives led to the demonstrable achievement of the Program’s expected outcomes. **Table 20** provides a list of the case studies and their purpose.

**Table 20 Case Studies**

Case study	Purpose
Acrylamide in foods	To assess and determine how the Program responds to emerging chemical hazards identified in the food supply.
Food packaging material assessment	To examine the Program’s non-mandated process of food packaging material assessment to determine the value of this activity to industry manufacturers and consumers within Canada.
FSNQ programs in selected countries	To benchmark FSNQP and compare it to international FSNQ programs in four international jurisdictions: Australia, New Zealand, the UK, and the US. <sup>cxlv</sup> In particular, this international comparison examined the scope, legislation and budget of each program while aiding in the identification of emerging issues, gaps and changing priorities not presently covered by FSNQP.
Health Canada’s approach to raw milk cheese	To review and investigate the Program’s policy response to the case of a controversial food product in Canada by examining manufacturing, importation into Canada, consumer awareness, and P/T relationships. This case study focused on the presence of <i>L. monocytogenes</i> in soft and semi-soft raw milk cheeses as it is more likely to cause death than other bacteria that cause food poisoning.
Health Canada’s support for community-based research in regard to Mercury Contamination in the Grassy Narrows Community	To examine the Program’s involvement in supporting community-based research to address environmental health issues concerning the mercury contamination that affected the Grassy Narrows and White Dog communities in the late 1970s. As fish and wildlife constitute a major component of the First Nations peoples’ diets, this contamination posed a major food safety concern.
Trans fatty acids <sup>cxlvi</sup>	To review and investigate the Program’s policy response in the case of an unhealthy product and its manufacturing in, and importation to, Canada, both within industry manufacturers and consumers in Canada and abroad.

<sup>cxlv</sup> These countries were selected as a result of discussions held during the Framework development process with key Program participants. Support from participants for the decision stemmed from the fact that Health Canada has considerable interactions with these countries (e.g., MoUs, regular international meetings, etc.); there are similarities in FSNQ approaches; and, the countries are ranked among the top members in the OECD. Variations in population, geographic spread, levels of support, etc., were addressed during the case study analysis. The selection of national organizations was based on a comparison to the scope of FSNQP.

<sup>cxlvi</sup> Trans fat is the common name for unsaturated fats with trans-isomer fatty acids. Industrially made trans fat comes from adding hydrogen to vegetable oil through a process called hydrogenation. Trans fats are more solid than oil, making them less likely to spoil. Using trans fats in the manufacturing of foods helps foods stay fresh longer, have a longer shelf life and have a less greasy feel.

Case study	Purpose
Health Canada's response to the 2008 Listeriosis outbreak	To examine the Program's response to recommendations provided in Health Canada's Response to the 2008 Listeriosis Outbreak, the <i>Beyond the Listeriosis Crisis Report</i> , and the <i>Report of the independent investigator into the 2008 Listeriosis outbreak</i> (henceforth referred to as the <i>Weatherill Report</i> ) as well as commitments made through a dedicated funding request to address said recommendations.

Evidence for the case studies was gathered from literature and file reviews as well as additional interviews with key informants (20) and, where applicable, with partners (6) and stakeholders (3).

Evidence from each case study was summarized according to relevant indicators and evaluation questions. Where possible, the case studies sought to address key accomplishments and challenges in implementing the Program as well as any lessons learned.

### 1.5 Demonstration of Economy and Efficiency

For the demonstration of economy and efficiency, an allocative approach was attempted as this is a long-established Program that should have achieved long-term outcomes. To this end, the evaluation sought to obtain information on dedicated funding requests, budgets and derivations, expenditures, and FTEs over the period of the evaluation. The goal was to align dedicated funding requests, with budgets, and expenditures to then track financial changes over time while attributing them to activities and outcomes. This information, in combination with FTE data, would then allow evaluators to assess resource allocation, investigate efficiencies, and link the results from this analysis to Program data obtained from other sources. The resulting analysis would then also be used to examine how resource changes influenced outcome achievement and the reasons behind the decisions.

## Appendix 3 - Information Products and Tools

Table 21 presents some of the information products developed by the Program.<sup>49,263,403,74,73</sup>

**Table 21 Program Information Products**

Product	Description	Time Frame	Topics	Target Audience	Information Availability
Involving You	This publication provides information on HPFB's decisions on health priorities, policies and programs. It also includes related information from other branches with similar regulatory responsibilities.	2001-2008	<ul style="list-style-type: none"> <li>Health Canada decision-making information on health priorities, policies and programs</li> </ul>	<ul style="list-style-type: none"> <li>General public</li> <li>Industry</li> </ul>	<ul style="list-style-type: none"> <li>Online</li> </ul>
IYH	A series of fact sheets written by FD in consultation with Health Canada and Public Health Agency of Canada's scientists and experts (may also be reviewed by other national experts) that provide information for the public.	2001-ongoing	<ul style="list-style-type: none"> <li>Diseases</li> <li>Environment</li> <li>Food and nutrition</li> <li>Lifestyles</li> <li>Medical information</li> <li>Products</li> </ul>	<ul style="list-style-type: none"> <li>General public</li> <li>Specific: men, parents and children, seniors, women and young adults</li> </ul>	<ul style="list-style-type: none"> <li>Online</li> <li>Print</li> <li>E-mail notification</li> </ul>
Food Times	FD's quarterly newsletter designed to inform stakeholders on the Directorate's standard setting work, publications, performance on issuing pre-market decisions, progress on selected initiatives to improve processes, stakeholder engagement activities and consultations.	2011-ongoing	<ul style="list-style-type: none"> <li>Regulatory decisions for food safety and nutrition</li> <li>Risk communication material</li> <li>Publications and communications</li> <li>FD Web posting</li> <li>Consultation on a variety of topics</li> </ul>	<ul style="list-style-type: none"> <li>All food stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>E-mail (Direct distribution to stakeholders)</li> </ul>
C-EnterNet Reports <sup>cxlvii</sup>	Annual reports providing a summary of reported infectious enteric disease cases in humans originally in Sentinel Site 1 <sup>cxlviii</sup> and, since 2010, Sentinel Site 2.	2005-ongoing	<ul style="list-style-type: none"> <li>Infectious enteric disease</li> </ul>	<ul style="list-style-type: none"> <li>General public</li> <li>Public health partners</li> </ul>	<ul style="list-style-type: none"> <li>Online</li> </ul>

<sup>cxlvii</sup> C-EnterNet receives funding from multiple sources, including the Agricultural Policy Framework and FCSAP.

<sup>cxlviii</sup> Sentinel Site 1 is located in the Regional Municipality of Waterloo, Ontario. C-EnterNet's sentinel site is a community of approximately 500,000 residents, has a mix of both urban and rural areas and demonstrates innovation in public health and water conservation and treatment. Within this site, active surveillance of enteric pathogens is performed in water, food and on farms, and enhanced human disease surveillance is performed in collaboration with public health partners. Sentinel Site 2 is located in the Fraser Health Region on British Columbia.

Product	Description	Time Frame	Topics	Target Audience	Information Availability
CNF <sup>cxlix</sup>	Online database that allows Canadians to search the nutrient values for specific foods. It reports up to 150 nutrients in over 5,807 foods.	Current version 2007	<ul style="list-style-type: none"> <li>• Values for nutrients such as vitamins, minerals, protein, energy, fat, etc.</li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> </ul>
Brochures <sup>cl</sup>	Safe food handling brochures for vulnerable populations.	2010-ongoing	<ul style="list-style-type: none"> <li>• Food safety</li> </ul>	<ul style="list-style-type: none"> <li>• Adults 60+</li> <li>• People with weakened immune systems</li> <li>• Pregnant women</li> </ul>	<ul style="list-style-type: none"> <li>• Print</li> </ul>
Posters <sup>cli</sup>	Safe food handling posters for vulnerable populations.	2010-ongoing	<ul style="list-style-type: none"> <li>• Food safety</li> </ul>	<ul style="list-style-type: none"> <li>• Adults 60+</li> <li>• People with weakened immune systems</li> <li>• Pregnant women</li> </ul>	<ul style="list-style-type: none"> <li>• Print</li> </ul>
Nutrition Labelling Toolkit for Educators—First Nations and Inuit Focus	Toolkit for First Nations and Inuit educators to help them understand food labels and aid them in transmitting this knowledge to their communities to help individuals make healthier choices in the grocery store.	Various	<ul style="list-style-type: none"> <li>• Nutrition labelling</li> </ul>	<ul style="list-style-type: none"> <li>• First Nations and Inuit communities</li> <li>• First Nations and Inuit educators</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Print</li> </ul>
Eating Well with Canada's Food Guide – First Nations, Inuit and Métis	Culturally relevant healthy eating recommendations to promote health, meet nutrient needs, and help lower the risk of several chronic diseases, through Developed to reflect the values, traditions and food choices of First Nations, Inuit and Métis, and recognizes the importance of traditional and store-bought foods in the diet of Aboriginal people.	2007-ongoing	<ul style="list-style-type: none"> <li>• Dietary guidance/ healthy eating recommendations</li> </ul>	<ul style="list-style-type: none"> <li>• First Nations, Inuit and Métis individuals and communities</li> <li>• Educators working with First Nations, Inuit and Métis</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Print</li> </ul>

<sup>cxlix</sup> <http://www.hc-sc.gc.ca/fn-an/nutrition/fiche-nutri-data/index-eng.php>

<sup>cl</sup> Part of Health Canada's social marketing strategy developed to address recommendations from the reviews of the 2008 Listeriosis Outbreak and the *Weatherill Report*.

<sup>cli</sup> Data for other years was not available.

Product	Description	Time Frame	Topics	Target Audience	Information Availability
FNIHB's EHRD research findings	Series of posters, pamphlets and reports to share the results of research conducted by EHRD.	Various	<ul style="list-style-type: none"> <li>• Multiple related to traditional foods and environmental contaminants, e.g.:                             <ul style="list-style-type: none"> <li>○ Examination of traditional food consumption patterns on the basis of community-based research undertaken by selected First Nations in Canada</li> <li>○ National First Nations Environmental Contaminants Program (NFNECP),<sup>clii</sup> part of the First Nations Environmental Contaminants Program<sup>cliii</sup></li> <li>○ Northern Contaminants Program (NCP)<sup>cliv</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> <li>• First Nations and Inuit</li> </ul>	<ul style="list-style-type: none"> <li>• Print</li> </ul>

Table 22 presents some of the information delivery mechanisms used by the Program.

<sup>clii</sup> As part of FNECP, the key objective of NFNECP is to assist Canada's First Nations people (who reside south of the 60th parallel) to assess the extent of their exposure to environmental contaminants and the potential for associated risk to their health and well-being.<sup>373</sup>

<sup>cliii</sup> FNECP was established in 1999 to meet First Nations' technical data needs. The program, administered jointly by Health Canada and the Assembly of First Nations, offers First Nations an opportunity to undertake community-based research projects. The FNECP consists of two main components: NFNECP and the Regional First Nations Environmental Contaminants Program.<sup>316,373</sup>

<sup>cliv</sup> The NCP, led by AANDC, allocates funds for research and related activities in five main areas: human health research, environmental monitoring and research, community based monitoring and research, communication capacity and outreach, and national/regional coordination and Aboriginal Partnerships.<sup>377</sup>

**Table 22 Program Information Delivery Mechanisms**

Name	Description	Time Frame	Topics	Target Audience	Information Availability
<b>Web-based</b>					
Health Canada's Food Safety <sup>clv</sup>	A Web page providing access to IYH fact sheets, partners' Web sites (e.g., CFIA and Public Health Agency of Canada), advisories (CFIA), etc., with the aim of delivering research-based information on food safety.	Ongoing	<ul style="list-style-type: none"> <li>• Animal health and veterinary drugs</li> <li>• Chemical contaminants</li> <li>• Emergency response</li> <li>• Food additives</li> <li>• Food allergies and intolerances</li> <li>• Food irradiation</li> <li>• Food-related illnesses</li> <li>• FSAs</li> <li>• Packaging materials</li> <li>• Safe food handling tips</li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> <li>• Specific: Adults 60+ for safe food handling tips</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Document download</li> <li>• E-mail notification</li> </ul>
Health Canada's Food Related Illnesses <sup>clvi</sup>	Web page providing information on foodborne illnesses (what they are, how people get sick, symptoms and treatments, the role of the federal government) as well as access to other relevant sites and tools (e.g., warnings, advisories and recalls).	Ongoing	<ul style="list-style-type: none"> <li>• Botulism</li> <li>• Campylobacter</li> <li>• Cronobacter</li> <li>• Cyclospora</li> <li>• E. coli</li> <li>• Hepatitis A and E</li> <li>• Listeria and Listeriosis</li> <li>• Norovirus</li> <li>• Salmonella</li> <li>• Shigella</li> <li>• Vibrio</li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Document download</li> </ul>
Health Canada's Food & Nutrition Surveillance, Food Labelling and Nutrition & Healthy Eating <sup>clvii</sup> <sup>clviii</sup> <sup>clix</sup>	Three Web pages providing access to IYH fact sheets, education materials, surveys, studies, databases, assessment results, etc., with the aim of delivering research-based information on nutrition-related risks and health benefits.	Ongoing	<ul style="list-style-type: none"> <li>• Nutrition and health claims</li> <li>• Nutrition labelling</li> <li>• Nutrition surveillance</li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> <li>• Health professionals and communicators</li> <li>• First Nations, Inuit and Métis</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Document download</li> </ul>

- <sup>clv</sup> <http://www.hc-sc.gc.ca/fn-an/securit/index-eng.php>  
<sup>clvi</sup> <http://www.hc-sc.gc.ca/fn-an/securit/ill-intox/index-eng.php>  
<sup>clvii</sup> <http://www.hc-sc.gc.ca/fn-an/surveill/index-eng.php>  
<sup>clviii</sup> <http://www.hc-sc.gc.ca/fn-an/label-etiquet/index-eng.php>  
<sup>clix</sup> <http://www.hc-sc.gc.ca/fn-an/nutrition/index-eng.php>

Name	Description	Time Frame	Topics	Target Audience	Information Availability
Safe Food Handling Tips <sup>clx</sup>	Web portal providing food safety tips regularly updated by Health Canada and CFIA.	2010 - ongoing	<ul style="list-style-type: none"> <li>• Multiple, e.g.:</li> <li>• Allergies</li> <li>• Barbecuing</li> <li>• Eggs</li> <li>• Halloween</li> <li>• Holiday</li> <li>• Botulism</li> <li>• Internal cooking temperatures</li> <li>• Leftovers</li> <li>• Preparing and handling powdered infant formula</li> <li>• Raw milk</li> <li>• Summer</li> <li>• Unpasteurized juice and cider</li> <li>• Using digital food thermometers</li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> <li>• Specific: Adults 60+, people with weakened immune systems and pregnant women</li> </ul>	<ul style="list-style-type: none"> <li>• Online and interactive</li> <li>• Document download</li> </ul>
Healthy Canadians <sup>clxi</sup>	Web portal providing information on recalls and advisories as well as healthy living initiatives.	2010 - ongoing	<ul style="list-style-type: none"> <li>• Recalls and advisories: consumer products, drugs and medical devices, food, vehicles and travel</li> <li>• Healthy living Initiatives: food allergies, environmental hazards, kids' health and safety, safe consumers, safe food handling, seasonal flu, sodium, the % DV, smoking cessation</li> </ul>	<ul style="list-style-type: none"> <li>• General public</li> <li>• Specific: children, adults 60+, people with weakened immune systems and pregnant women</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Document download</li> <li>• E-mail notification</li> <li>• Social media</li> <li>• Mobile</li> </ul>
Food Safety <sup>clxii</sup>	Web portal providing information on food safety as well as access to other relevant sites.	2010 - ongoing	<ul style="list-style-type: none"> <li>• Recalls, warnings and reporting</li> <li>• Safe food handling and preparation</li> <li>• Food safety and labels</li> <li>• Food allergies</li> <li>• Understanding food safety</li> <li>• Food poisoning</li> <li>• Roles in food safety</li> </ul>	<ul style="list-style-type: none"> <li>• General</li> <li>• Specific: Adults 60+, people with weakened immune systems and pregnant women</li> </ul>	<ul style="list-style-type: none"> <li>• Online</li> <li>• Document download</li> <li>• E-mail notification</li> <li>• Social media</li> <li>• Mobile</li> </ul>

clx <http://www.hc-sc.gc.ca/fn-an/securit/kitchen-cuisine/index-eng.php>

clxi <http://www.healthycanadians.gc.ca/index-eng.php>

clxii <http://www.foodsafety.gc.ca/english/introe.asp>



Name	Description	Time Frame	Topics	Target Audience	Information Availability
<b>Other</b>					
Professional publications <sup>clxiii</sup>	Poster distribution targeted to health professionals through a Canadian Medical Association Journal (CMAJ) mail-out.	2010-2011	<ul style="list-style-type: none"> <li>• Food safety</li> </ul>	<ul style="list-style-type: none"> <li>• Health care professionals and their patients: adults 60+, people with weakened immune systems and pregnant women</li> </ul>	<ul style="list-style-type: none"> <li>• Print</li> </ul>
Radio <sup>clxiv</sup>	A 30-second ad as part of a national radio campaign conducted between March 22nd and 31st, 2010.	2010	<ul style="list-style-type: none"> <li>• Food safety</li> </ul>	<ul style="list-style-type: none"> <li>• Adults 55+</li> </ul>	<ul style="list-style-type: none"> <li>• Radio</li> </ul>
Mail <sup>clxv</sup>	Canada Pension Plan bilingual mail inserts	2010-2011	<ul style="list-style-type: none"> <li>• Food safety</li> </ul>	<ul style="list-style-type: none"> <li>• Adults 60+</li> </ul>	<ul style="list-style-type: none"> <li>• Print</li> </ul>

Table 23 provides some of the engagements identified in these reports.<sup>173,157,152</sup>

**Table 23 Sample Program Engagement Activities**

Type of Delivery	Engagements Topics			
	2002-2003	2003-2004	2004-2005	2005-2007
Advisory bodies				<ul style="list-style-type: none"> <li>• Multi-stakeholder task force, co-chaired by Health Canada and Heart and Stroke Foundation of Canada, on healthier alternatives and strategies to eliminate or reduce processed trans fat.</li> </ul>
Bilateral meeting			<ul style="list-style-type: none"> <li>• FPTGN (4 meetings).</li> </ul>	<ul style="list-style-type: none"> <li>• Meeting with P/T governments on the development of a national strategy on public health outcomes for food safety and nutritional quality.</li> </ul>
Consensus conference				<ul style="list-style-type: none"> <li>• Food allergen issues and solutions.</li> </ul>

<sup>clxiii</sup> Part of Health Canada's social marketing strategy developed to address recommendations from the reviews of the 2008 Listeriosis Outbreak and the *Weatherill Report*.

<sup>clxiv</sup> Idem.

<sup>clxv</sup> Idem.

Type of Delivery	Engagements Topics			
	2002-2003	2003-2004	2004-2005	2005-2007
Focus group			<ul style="list-style-type: none"> <li>Focus groups on food fortification (series of 23).</li> </ul>	
Public meeting	<ul style="list-style-type: none"> <li>Overview of HPFB, overview of OCAPI, citizen engagement, Speech from the Throne and HPFB initiatives (information), and food irradiation.</li> <li>Regulatory process, decision-making framework, nutritional labelling, and regional network of citizens.</li> <li>Western regional office, legislative renewal, risk communication, and biotechnology and health communication plan.</li> <li>Openness and transparency (part one), HPFB integrated planning.</li> </ul>	<ul style="list-style-type: none"> <li>Openness and transparency: openness and transparency, public involvement strategy, legislative renewal: advertising of health products, and dispute resolution.</li> <li>Enabling innovation for better health outcomes: animal biotechnology in food use, Health Canada's framework on biotechnology, and AMR.</li> </ul>	<ul style="list-style-type: none"> <li>Development of Canadian input into the elaboration of world-wide Codex standards for FSNQ.</li> </ul>	<ul style="list-style-type: none"> <li>Development of Canadian input into the elaboration of world-wide Codex standards for FSNQ.</li> </ul>
Technical consultation				<ul style="list-style-type: none"> <li>Multi-stakeholder task force, co-chaired by Health Canada and the Heart and Stroke Foundation of Canada, on healthier alternatives and strategies to eliminate or reduce processed trans fat.</li> <li>Consultation on revised mercury risk management strategy.</li> <li>Five US generic health claims considered for use in Canada.</li> </ul>

Type of Delivery	Engagements Topics			
	2002-2003	2003-2004	2004-2005	2005-2007
Workshop			<ul style="list-style-type: none"> <li>• Third workshop on food allergen methodologies.</li> <li>• Identification of irradiated foods and ingredients in meals served by food service establishments.</li> <li>• FD Stakeholder Forum.</li> </ul>	<ul style="list-style-type: none"> <li>• Information workshop to the food industry on improvement of allergen prevention practices.</li> <li>• Training workshop on the preparation of novel food submissions.</li> </ul>

Engagement activities are also carried out by other key Program participants such as workshops conducted by FNIHB on traditional foods and environmental contaminants during the period 2002 to 2007 (in Kamloops, Nanaimo, Prince George, Thunder Bay, Québec, Whitehorse and Alberta).

**Table 24** presents the approaches used as part of the social marketing strategy. To achieve its intended goals, the strategy employed a targeted and multi-pronged approach to information dissemination that went beyond a Web-only push: it included information in annual publications, mail inserts, print media, a radio campaign and a strategic alliance.<sup>49,263,403,74, 72,73,237,238,239</sup>

**Table 24 Social Marketing Approaches employed during FY 2010-2011**

Approach	Reach
1-800 number	<ul style="list-style-type: none"> <li>• General public (92%):                             <ul style="list-style-type: none"> <li>○ 1,132 enquiries about food safety.</li> <li>○ Source of toll-free number: Brochure/publication (41%)</li> <li>○ Origin of call: Ontario (451%)</li> <li>○ Gender of caller: Female (68%)</li> <li>○ Language of caller: English (85%)</li> <li>○ Most common publications ordered (n=9,534): Common Food Allergies - A Consumer's Guide to Managing the Risks (16%) and Safe Food Handling for Adults 60+ /Guide sur la salubrité, des aliments pour les 60 ans et plus (15%)</li> </ul> </li> </ul>
Canadian Medical Association Journal (CMAJ) poster mail-out	<ul style="list-style-type: none"> <li>• Health care professionals and their patients:                             <ul style="list-style-type: none"> <li>○ Safe Food Handling For Adults 60+ /Guide sur la salubrité des aliments pour les 60 ans et plus: 39,552</li> <li>○ Safe Food Handling For People with Weakened Immune Systems /Guide sur la salubrité des aliments pour les personnes ayant un système immunitaire affaibli: 5,617</li> <li>○ Safe Food Handling For Pregnant Women /Guide sur la salubrité des aliments pour les femmes enceintes: 35,498</li> </ul> </li> </ul>

Approach	Reach
Safe food handling posters	<ul style="list-style-type: none"> <li>• Safe Food Handling For Adults 60+/Guide sur la salubrité des aliments pour les 60 ans et plus: direct orders 30, shipped 41,379</li> <li>• Safe Food Handling For People with Weakened Immune Systems/Guide sur la salubrité des aliments pour les personnes ayant un système immunitaire affaibli: direct orders 26, shipped 7,309</li> <li>• Safe Food Handling For Pregnant Women/Guide sur la salubrité des aliments pour les femmes enceintes: direct orders 32, shipped 37,499</li> </ul>
Safe food handling brochures	<ul style="list-style-type: none"> <li>• Safe Food Handling For Adults 60+/Guide sur la salubrité des aliments pour les 60 ans et plus: direct orders 2,120, shipped 447,945</li> <li>• Safe Food Handling For People with Weakened Immune Systems/Guide sur la salubrité des aliments pour les personnes ayant un système immunitaire affaibli: direct orders 1,343, shipped 46,587</li> <li>• Safe Food Handling For Pregnant Women/Guide sur la salubrité des aliments pour les femmes enceintes: direct orders 1,659, shipped 258,552</li> </ul>
Canada Pension Plan mail inserts	<ul style="list-style-type: none"> <li>• Adults 60+: 630,000</li> </ul>
National radio ad campaign	<ul style="list-style-type: none"> <li>• Expected weekly reach of 30% to 35% by market<sup>clxvi</sup> targeting adults 55+</li> </ul>
Strategic alliance with Reitman's Canada	<ul style="list-style-type: none"> <li>• Safe Food Handling for Pregnant Women booklet at Thyme Maternity retail locations: up to 200,000 copies</li> </ul>
Web banner campaign	<ul style="list-style-type: none"> <li>• People with weakened immune systems and pregnant women               <ul style="list-style-type: none"> <li>○ Reach: 4,727,614                   <ul style="list-style-type: none"> <li>▪ English: 7,864 clicks on Babycentre, UpTrend, Olive, Yahoo, WebMD, Canoe, Transcontinental</li> <li>▪ French: 4,917 clicks on Canoe, Olive, Transcontinental</li> </ul> </li> </ul> </li> </ul>

<sup>clxvi</sup> Some exceptions (due to various reasons, e.g., drop in chosen station ratings, inability of station to air ads) to achieving/over-achieving Gross Rating Point: Red Deer, AB; Kingston, ON; Québec, QC; New Brunswick; Nova Scotia; Prince Edward Island; and, Newfoundland. Gross Rating Point is the sum of ratings achieved by a specific media vehicle or schedule. It measures the total volume of delivery of an advertiser's message to the target audience.<sup>74</sup>

## Appendix 4 - International Agreements

The evaluation identified 22 international MoUs, agreements and commitments signed by key Program participants during the period of the evaluation; these are:

- *MoU on Cooperation in Food Safety and Inspection, and Animal and Plant Health between the Secretariat of Agriculture, Livestock and Rural Development of the United Mexican States and the Canadian Food Inspection Agency, responsible to the Minister of Agriculture and Agri-Food, and the Department of Health of Canada (1999). The MoU addresses the exchange of personnel, scientific and technical information, joint research, and organization of meetings related to areas of surveillance and monitoring systems, etc.*<sup>368</sup>
- *Confidentiality Commitment Statement of Legal Authority and Commitment from Health Canada Not to Publicly Disclose Non-Public Information Shared by the U.S. Food and Drug Administration (USFDA), U.S. Department of Health and Human Services (2003).*<sup>69</sup>
- Letter of intent between Health Canada and the Secretariat of Health of the United Mexican States on health sector collaboration (2004). The letter addresses cooperation and exchange between government agencies, health institutions, specialists, scientists and health professionals related to areas of non-communicable diseases, health equity and health care of indigenous people, health policy development, etc.<sup>352</sup>
- *MoU between Food Standards Australia New Zealand and Food Directorate Health Products and Food Branch, Health Canada (2004). The MoU addresses exchange of information and cooperative action related to areas of novel foods, health claims, quantitative microbial risk assessment, food fortification, etc.*<sup>361</sup>
- *Trilateral Cooperation Charter between the Health Products and Food Branch of Health Canada, Canada, the Food and Drug Administration within the U.S. Department of Health and Human Services, and the Federal Commission for the Protection from Sanitary Risks of the Secretaría de Salud of Mexico (2004).*
- MoU between Health Canada and USCDC to enable real-time sharing of information about clinical isolates and their subtypes between NML and USCDC (2005).<sup>454</sup>
- *MoU between the Food Standards Agency of the United Kingdom of Great Britain and Northern Ireland and the Food Directorate Health Products and Food Branch Health Canada (2006). The MoU addresses the exchange of information and cooperative action related to areas of chemical safety, measures to reduce food incidents, emergency response measures, harmonization of risk assessment methods and processes, etc.*<sup>367</sup>
- *Declaration Among the Department of Health and Human Services of the United States of America, the Department of Health of Canada, the Public Health Agency of Canada, and the Ministry of Health of the United Mexican States (2007). The declaration addresses mutual assistance during a public-health*

emergency as well as cooperation to improve public-health emergency preparedness and response efforts.<sup>78</sup>

- MoU between the Public Health Agency of Canada and ECDC (2007).<sup>94</sup>
- *MoU on Indigenous Health between the Department of Health and Human Services of the United States of America and the Department of Health of Canada for the Period 2007 – 2012* (2007). The MoU addresses collaboration and sharing of information related to Aboriginal health, disease-prevention and environmental programs.<sup>369</sup>
- Exchange of letters between HPFB and the USFDA in respect of the amendment of the 2003 MoU to include foods and NHPs (2008).<sup>351</sup>
- *MoU between the Food Directorate of Health Products and Food Branch of the Department of Health of Canada and the Agence Française de Sécurité Sanitaire des Aliments* (2008).<sup>366</sup>
- *Arrangement between the Health Products and Food Branch and the New Zealand Food Safety Authority on Food Safety, Health Product Safety, and Nutrition* (2009).<sup>14</sup>
- Exchange of letters between HPFB and the Medicines and Healthcare products Regulatory Agency of the UK Department of Health in respect of the sharing of confidential information (2009).<sup>349,350</sup>
- Exchange of letters constituting an arrangement between HPFB and HECSB and the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária) in respect of the sharing of confidential information (2009).<sup>345,348</sup>
- *MoU between the Department of Health of Canada and the Ministry of Health of the Federative Republic of Brazil on Health Sector Collaboration* (2009).<sup>365</sup>
- *Trilateral Cooperation Charter between the Secretariat of Health of the Mexican United States, through the Federal Commission for the Protection from Sanitary Risks; the Health Products and Food Branch of the Department of Health of Canada; and the Food and Drugs Administration within the Department of Health and Human Services of the United States of America* (2009).<sup>469</sup>
- *Plan of Action on Cooperation between the Department of Health of Canada, the Public Health Agency of Canada and the Ministry of Health of the People's Republic of China in the Field of Health for the Period 2009-2011* (2009). The plan aims encourage bilateral cooperation in the field of health by promoting exchanges of information, lessons learned and best practices, facilitating the exchange of scientists, and other health professionals, promoting cooperation between health institutions and associations, and encouraging cooperation between research institutions.<sup>460</sup>
- 2009-2011 Work Plan between HPFB, the USFDA and CFIA for health products and for food, NHPs and dietary supplements (2010).<sup>2</sup>
- Exchange of Letters between Health Canada's FD and EFSA in respect of information exchange to support both organizations' efforts to identify, assess and, for Health Canada's FD, manage potential food borne risks to human health.<sup>347,346</sup>

- *Plan of Action on Cooperation between the Department of Health of Canada, the Public Health Agency of Canada, and the Ministry of Health of the People's Republic of China in the Field of Health for the Period 2011-2014* (2011). The plan aims to strengthen bilateral cooperation in the field of health by facilitating exchanges of information, lessons learned and best practices, encouraging cooperation between research and health institutions as well as health associations, and encouraging and facilitating individual contacts and networks between Canadian and Chinese health professionals.<sup>399</sup>
- *International Health Regulations* (2005). A legally-binding agreement that provides a framework for the coordination of the management of events that may constitute a public health emergency of international concern.<sup>489</sup>

## Appendix 5 - Health Canada Compendia

Health Canada publishes three Compendia of methods on its Web site. These methods provide a reference to Health Canada's evaluated methodologies, which may be used by industry and government laboratories to determine compliance, assess quality and support foodborne disease investigation. The Compendia cover the following areas:

- The *Compendium of Food Allergen Methodologies* provides a reference of Health Canada's evaluated allergen methodologies, which may be used for testing by industry and government laboratories. Health Canada and CFIA work through the Allergen Methods Committee to provide "direction and better coordination in the development, delivery and advancement of allergen testing and allergen research programs."<sup>11</sup>
- The *Compendium of Methods for Chemical Analysis of Foods* provides a list of methods classified into Official Methods, HPB Methods, and Laboratory Procedures.<sup>59</sup>
  - o Official Methods (FO-) are those methods of analysis designated as such in the F&RD; HPB Methods (HPB-FC-) are fully validated by inter-laboratory studies and documented analytical methods; and, Laboratory Procedures (LPFC-) are those methods validated by at least one HPB laboratory, but not fully validated by inter-laboratory studies.<sup>59</sup> The Compendium also lists Laboratory Procedures for Surveillance (LPS-).
- The *Compendium of Analytical Methods* is presented in five volumes: Official Methods for the Microbiological Analysis of Foods, HPB Methods for the Microbiological Analysis of Foods, Laboratory Procedures for the Microbiological Analysis of Foods, Methods for the Analysis of Extraneous Material in Foods, and Methods for the Analysis of Parasites, Viruses and Other Food-borne Pathogens.<sup>459</sup> The analytical methods for the microbiological safety and general cleanliness of foods are reviewed by a MMC, which is composed of a Steering Committee and Technical Groups with representation from Health Canada and CFIA.<sup>235</sup>
  - o Official Methods (MFO-) are those methods of analysis designated as such by the Director for use in the administration of the F&DA and F&DR (Section A.01.010). HPB Methods (MFHPB-) are fully validated and documented analytical methods that may be used to determine compliance with various standards and guidelines. Laboratory Procedures (MFLP-) are methods validated by at least one HPB laboratory, but not fully validated by inter-laboratory studies.<sup>200</sup> ExFHPB and ExFLP are HPB Methods and Laboratory Procedures, respectively, for extraneous material in foods while OPFLP are Laboratory Methods for the analysis of parasites, viruses and other foodborne pathogens.



## Appendix 6 - Networks and Web-based Systems for the Collection and Dissemination of Information

**Table 25** identifies some of the networks or Web-based systems used by the Program for information collection and dissemination.

**Table 25 Networks and Web-based Systems for the Collection and Dissemination of Information**

Network or Web-based system	Description
Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS)	CIPARS is a set of surveillance tools that collect information on AMR in enteric pathogens and commensal organisms from the agri-food sector (farm level, abattoir level and retail level), on AMR in enteric pathogens isolated from humans, and on antimicrobial use in humans and animals. <sup>48</sup>
Canadian Listeriosis Reference Service (LRS)	LRS, co-directed by BMH and NML, provides a comprehensive molecular epidemiological database of all isolates in Canada for use as a resource for outbreak investigations, research and other microbiological investigations. <sup>385</sup> The Listeriosis Reference Service holds all strains and characterization data indefinitely, which facilitates the comparison of various strains. <sup>133</sup>
Canadian Network for Public Health Intelligence (CNPHI)	CNPHI, previously the Canadian Integrated Outbreak Surveillance Centre, is a national, secure, Web-based environment that allows for the timely sharing and strategic dissemination (e.g., alerts) of public health intelligence between local/regional and F/P/T public health stakeholders to enhance stakeholder capacity to anticipate, detect, respond, prevent and control health risks associated with communicable disease events. <sup>142</sup>
Canadian Nutrient File (CNF)	CNF is a bilingual, online database of food composition containing average values for nutrients in foods available in Canada. Much of the data has been derived from the US Department of Agriculture Nutrient Database for Standard Reference with removal of foods not sold in Canada and inclusion of Canadian products. As a system for disseminating information, the CNF is accessible, fairly easy to use and has sufficient explanations of terms and the specific nutrients contained.
C-EnterNet	C-EnterNet is a database providing national sentinel site data (Region of Waterloo Public Health and British Columbia Fraser Health Authority) 11 enteric reportable diseases with human risk factors linked to data from food, surface water and animal samples. <sup>52</sup>
First Nations Food, Nutrition and Environment Study (FNFNES)	FNFNES is a Web site that functions as a key mechanism for traditional food knowledge exchange. It contains current information on the modern diets of First Nations people and the chemical safety of traditionally harvested foods on which First Nations rely to ensure good nutrition. In addition to providing information on current knowledge related to food safety and security, the Web site also provides detailed information on protocols and policies, which allow replication of the methodological approaches by First Nations communities.

Network or Web-based system	Description
Global Foodborne Infections Network (GFN)	GFN is a collaborative project of the WHO, the Danish National Food Institute, USCDC, France’s Institut Pasteur, Public Health Agency of Canada, the Netherlands’ Utrecht University, ECDC, Australia’s OzFoodNet, PulseNet International and Japan’s National Institute of Public Health. The objective of the network is to strengthen and enhance the capacities of national and regional laboratories in the surveillance of Salmonella and other major foodborne pathogens as well as AMR in Salmonella and Campylobacter from humans, food and animals. <sup>120</sup>
Global Public Health Intelligence Network (GPHIN)	Managed by Public Health Agency of Canada’s CEPR, and developed in collaboration with the WHO, GPHIN is a secure, Internet-based, multilingual “early warning” system that gathers information of public health significance (e.g., food contamination, disease outbreaks) from around the world on a “real-time,” 24 hours-a-day, seven days-a-week basis. Preliminary reports obtained in this manner are analyzed by a multi-disciplinary and multilingual team of analysts so that relevant information is disseminated to public health and emergency preparedness authorities worldwide for appropriate risk management. Users include the WHO, FAO, OIE, non-governmental agencies and NGOs, and international governments. <sup>185,360</sup>
National Enteric Surveillance Program (NESP)	NESP is a database allowing the analysis of laboratory-based weekly data from all provinces and territories for all reportable enteric pathogens; it provides weekly reports to stakeholders across Canada.
Network for First Nations Environmental Health Research and Communication <sup>clxvii</sup>	This is a virtual network to link First Nations and environmental health researchers to build capacity within First Nations communities, to participate in environmental health research, and to make use of data and knowledge.
Notifiable Diseases On-Line	Notifiable Diseases On-Line is a Web-based application developed by Public Health Agency of Canada’s Centre for Infectious Disease Prevention and Control to enhance dissemination of surveillance data collected on notifiable diseases in Canada. The application contains information on the number of cases reported for several of the notifiable diseases as well as their rate in the population for the years 1989 to 2004.
PulseNet Canada	PulseNet Canada is a virtual, electronic network linking all provincial, and some federal, public health laboratories’ computers and databases. PulseNet is coordinated by NML and tracks Deoxyribonucleic Acid (DNA) fingerprints of all cases of E. coli and most cases of Salmonella. <sup>419</sup> PulseNet has a MoU for surveillance data sharing and the USCDC have access to data in Canadian systems.

<sup>clxvii</sup> Now the First Nations Environmental Health Innovation Network.

## Appendix 7 - Processes to Consider International Standards

Health Canada's international regulatory cooperation approach focuses on:<sup>161</sup>

- Developing agreements/arrangement with international regulatory counterparts (e.g., USFDA) and leading organizations (e.g., Codex).
  - o Canada's strategic objectives for participation in the Joint FAO/WHO Food Standards Program are to enhance Canada's influence on Codex deliberations and outcomes; promote the use of standards as the basis for national policies and regulations; enhance strategic and functional management of Canada's domestic Codex program; and, promote processes to enhance the efficiency of Codex.<sup>212</sup>
- Engaging Canadian stakeholders to improve transparency (e.g., as members of Expert Advisory Committees).
- Establishing information-sharing activities to enhance quality and efficiency of domestic decision-making (e.g., use of foreign reviews to reduce submission backlogs).
- Identifying priorities and accountability measures.
- Approaching technical assistance and capacity building initiatives through cost-effective channels (e.g., country visits, training).

Similarly, HPFB's objectives in engagement in international regulatory cooperation include:<sup>162</sup>

- Developing and strengthening international relations with key regulatory counterparts and other organizations to improve regulatory system performance by adopting best practices, exchanging and integrating scientific knowledge (e.g., developing concurrent and harmonized submissions with other regulators, increasing the use of foreign reviews in decision-making and developing work-sharing mechanisms) and enhancing transparency that would also allow Canada to play an important role in global standard setting.
- Collaborating in international standards setting, equivalency and harmonization initiatives by reviewing existing regulations against international standards; harmonizing and adopting new regulations and policies where beneficial and appropriate; implementing adopted standards and regulations; and, strengthening the branch's role as a leader in certain standard-setting bodies (e.g., Codex).
- Engaging with countries in the process of developing regulatory systems to enable the exchange of knowledge and practices as well as providing assistance in an effort to improve international harmonization, thus reducing food import risks.

These approaches and objectives are reflected in FD's international activities as the regulatory lead for FSNQ:<sup>170</sup>

- Exchanging information and collaborative work with regulatory counterparts from other countries on research, assessment of risks, policy development, standard setting, and other collaborative initiatives in relation to hazards associated with food and the nutritional safety and quality of food. This is done by establishing bilateral or multilateral working relationships through international governmental organizations (e.g., WHO) or regional governmental bodies.
- Developing international food safety standards, including nutritional safety and quality, by engaging with international regulatory counterparts (e.g., through QUAD meetings) and leading organizations (e.g., Codex, FAO/WHO Expert Committees, OECD) to promote the development of international food standards that reflect the level of consumer protection achieved by Canadian policies and standards for food safety.
- Negotiating and implementing international agreements (e.g., MoUs) on food safety regulatory responsibilities. Committees established under these agreements provide a regular forum for consultation and the opportunity to carry out the functions necessary to implement the agreements and the furtherance of their objectives. For example, Sanitary and Phytosanitary measures Committees (SPS Committees) as mandated by the WTO and NAFTA as well as SPS Committees under the Canada-Costa Rica and Canada-Chile Free Trade Agreements; these Committees discuss issues of concern to members such as the conduct of risk assessments, implementation of equivalence, provision of technical assistance, and procedures to improve transparency. Decisions resulting from the SPS Committees would directly affect how FD establishes food safety requirements for Canada.
- Capacity building and technical assistance to developing countries in the areas of food safety; for example, as part of Canada's duties under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures and the WTO Agreement on Technical Barriers to Trade.

Under each of its international activities, FD considers a number of elements for engagement and prioritization, for example: <sup>170</sup>

- Relevance in relation to FD's responsibilities and mandate (e.g., policy development and standard setting).
- Linkage with governmental, departmental and branch priorities as well as Canada's international commitments and objectives.
- Level of regulatory development and "like-mindedness" with international counterpart as well as commonality of issues and potential for synergies.
- Scope of the opportunity both internally (e.g., single or multiple key Program participant involvement) and externally (bilateral or multilateral).

- Degree to which the activity will contribute to enhancing Canada's food safety system (e.g., by improving compliance with international standards leading to safer imports).
- Extent to which agreements may deal with the application of sanitary measures or technical barriers to trade and effects on established WTO Agreements (i.e., Agreement on the Application of Sanitary and Phytosanitary Measures or Agreement on Technical Barriers to Trade).
- Level of impact on Canada's international reputation and influence.
- Willingness of the international counterpart to commit resources (human and capital) to the proposed work as well as level of resources involved (e.g., subject-matter experts).
- Cost and availability of funding.

## Appendix 8 - Comparison of Cost-Recovered Activities

A comparison of cost-recovered activities between Canada’s FSNQP and its counterparts in Australia, New Zealand, the UK and the US is provided in **Table 26**.

**Table 26 Cost Recovery**

Canada	Australia/New Zealand	UK	US
<ul style="list-style-type: none"> <li>• HPFB:                             <ul style="list-style-type: none"> <li>○ There is no cost recovery for activities carried out by FD, e.g., reviewing submissions from the food industry.</li> </ul> </li>   <li>• FNIHB’s PHCPHD and CPD do not charge fees for any of their services, e.g., community programs and food safety monitoring.</li>   <li>• Public Health Agency of Canada’s IDPC does not charge fees for food safety activities, e.g., outbreak surveillance and</li> </ul>	<ul style="list-style-type: none"> <li>• FSANZ does not charge a fee for the assessment of an application unless either:<sup>109</sup> <ul style="list-style-type: none"> <li>○ It “determines that an applicant has an Exclusive Capturable Commercial Benefit <sup>clxviii</sup> (ECCB);” or,</li> <li>○ “An applicant wishes work to start on the assessment immediately, rather than according to the anticipated timeframes established as part of the Administrative Assessment.” <sup>clxix</sup></li> </ul> </li>   <li>• FSANZ, as the central point for the collection of food surveillance data from public health units in Australia and New Zealand,</li> </ul>	<ul style="list-style-type: none"> <li>• UKFSA:                             <ul style="list-style-type: none"> <li>○ Following implementation of the European Council Regulation (EC) 258/97 (1997) concerning Novel Foods and Novel Food Ingredients, a scale of charges is used for the assessment of novel foods and novel food ingredient applications. Fees are set according to:<sup>475,408</sup> <ul style="list-style-type: none"> <li>▪ Applications involving a GM organism for which an environmental risk assessment is required.</li> <li>▪ Any other application; and,</li> <li>▪ A request for an opinion as to substantial equivalence.</li> </ul> </li> </ul> </li>   <li>• UKFSA and UKDEFRA do not charge fees for food safety activities.</li> </ul>	<ul style="list-style-type: none"> <li>• USFDA:                             <ul style="list-style-type: none"> <li>○ There is no cost recovery for activities carried out by CFSAN and the Office of Regulatory Affairs.<sup>479</sup></li> <li>○ Under the <i>Food, Drug and Cosmetic Act</i>, USFDA charges fees for colour certification (batch certification) of colour additives intended for use in USFDA-regulated products.<sup>480</sup></li> </ul> </li>   <li>• USCDC:                             <ul style="list-style-type: none"> <li>○ The National Center for Emerging and Zoonotic Infectious Diseases and the Food Safety office do</li> </ul> </li> </ul>

<sup>clxviii</sup> “Where an application is likely to result in an amendment to the Australia New Zealand Food Standards Code that provides exclusive benefits to the applicant, the application is considered to confer an ECCB and the applicant is required to pay the full cost of processing their application. For example, an application for approval of a novel food that requests an exclusive permission be granted for that particular novel food is likely to be considered to confer an ECCB.”<sup>109</sup>

<sup>clxix</sup> “An Administrative Assessment of an application is made by FSANZ within 15 business days after an application is given to FSANZ. The purpose of the Administrative Assessment stage is to determine whether an application is accepted or rejected under s.26 of the FSANZ Act.”<sup>109</sup>

Canada	Australia/New Zealand	UK	US
<p>epidemiology.</p> <ul style="list-style-type: none"> <li>• Currently, PMRA “charges one-time application fees in accordance with a prescribed fee schedule for the review of applications for the registration of pesticides and an annual maintenance fee per registered product for the right to manufacture or sell a product in Canada. Fee reductions apply to both types of fees. Biopesticides and proposals for User Requested Minor Use Label Expansion are exempt from fees.”<sup>70</sup> PMRA does not charge a fee for pesticide re-evaluation.</li> </ul>	<p>does not charge fees for food safety activities.</p> <ul style="list-style-type: none"> <li>• The Australian Pesticides and Veterinary Medicines Authority charges fees according to agricultural and chemical product application type. The Authority also charges annual fees and levies for registered agricultural and chemical products and the value of product sales in a financial year.<sup>95</sup></li> <li>• The New Zealand Food Safety Authority operates under the following pesticide business model based on a fee schedule:<sup>10</sup> <ul style="list-style-type: none"> <li>○ Pre-screen fees for all applications (non-refundable);</li> <li>○ Application fees provided as an estimate to the applicant based on the schedule of fees at the completion of the pre-screen process (covering new and variation applications, provisional registration, research approval, Smart Track for applications requiring very limited regulatory appraisal and registration renewals);</li> <li>○ Accreditation fees;</li> <li>○ Hourly fees;</li> <li>○ Annual fees;</li> <li>○ Other regulated fees related to approvals, compliance and official information requests; and,</li> <li>○ Discretionary service fees related to certificates, class determinations, data assessment service, deviation from information specified in agricultural compounds</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• UKDEFRA and HSE: <ul style="list-style-type: none"> <li>○ The Chemical Regulations Directorate under UKHSE charges fees to ensure that the full economic costs of assessing and processing applications are recovered. Fees are charged for applications processed by the Registration Branch (product streams) or by the Pesticide Branch (new actives and EU reviews).<sup>75</sup></li> <li>○ The Registration Branch charges fees for activities related to coordination, specialist modules and official recognition.<sup>75</sup></li> <li>○ The Pesticide Branch charges fees for activities related to core data (new substances and European Commission reviews), biological and pheromones, basic substance dossiers and pre-submission meetings.<sup>75</sup></li> <li>○ By implementation of the European Council Directive 91/414/EEC, costs are recovered either by fees charged to applicants or a charge on the UK turnover of pesticides companies.<sup>474</sup></li> <li>○ New fees will be introduced to cover requirements from:<sup>474</sup> <ul style="list-style-type: none"> <li>▪ Regulation 396/2005 (September 2008) that introduced a new regime for the setting and application of MRLs for pesticides in food;</li> <li>▪ Regulation (EC) 1107/2009 (June 2011); and,</li> </ul> </li> </ul> </li> </ul>	<p>not charge fees for food safety activities, e.g., outbreak surveillance and epidemiology.</p> <ul style="list-style-type: none"> <li>• USEPA: <ul style="list-style-type: none"> <li>○ The Office of Pesticide Programs along with the Office of Chemical Safety and Pollution Prevention have the following fees for pesticides:<sup>478</sup> <ul style="list-style-type: none"> <li>▪ Pesticides Maintenance Fee: provides funding for the Registration Review program with a portion supporting the processing of applications involving “me-too” or inert ingredients.</li> <li>▪ Enhanced Registration Services Fee: to accelerate pesticide registration decision service, entities seeking to register pesticides for use in the US pay a fee at the time the registration action request is submitted to the USEPA.</li> <li>▪ Pre-Manufacturing Notification Fee: supports the review and processing of new chemical pre-manufacturing notifications submitted to the USEPA by the chemical industry.</li> </ul> </li> <li>○ The USEPA is proposing to introduce an Accelerated Chemical Risk Reduction Fee: to directly support implementation of a restructured chemicals management program.<sup>478</sup></li> </ul> </li> </ul>

Canada	Australia/New Zealand	UK	US
	and veterinary medicines information requirements, import approvals, premises inspections, setting MRLs, meetings with parties on request and photocopying information.	<ul style="list-style-type: none"> <li>▪ Directive 2009/128/EC establishing a framework for the sustainable use of pesticides (November 2011).</li> </ul>	