Health Canada and the Public Health Agency of Canada
Santé Canada et l'Agence de la santé publique du Canada

Evaluation of the Food and Consumer Safety Action Plan 2008-2009 to 2012-2013

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List of Acronyms

AMP	Administrative Monetary Penalties
API	Active pharmaceutical ingredients
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ASTM	American Society for Testing and Materials
CBSA	Canada Border Services Agency
CCCF	Codex Committee on Contaminants in Food
CCMED	Canadian Coroner and Medical Examiner Database
CCMS	Case Management System
CCPSA	*Canada Consumer Product Safety Act*
CEP	Cyclical Enforcement Program
CFIA	Canadian Food Inspection Agency
CHIRPP	Canadian Hospitals Injury Reporting and Prevention Program
CIHR	Canadian Institutes of Health Research
CIPARS	Canadian Integrated Program for Antimicrobial Resistance Surveillance
CLSA	Canadian Longitudinal Study on Aging
CPAB	Communication and Public Affairs Branch
CPSP	Consumer Product Safety Program
CSA	Canadian Standards Association
DEL	Drug Establishment Licenses
DON	Deoxynivalenol
DSEN	Drug Safety and Effectiveness Network
EMA	European Medicines Agency
EMF	Electromagnetic Frequency
EU	European Union
EUND	Extraordinary Use New Drug
FCSAP	Food and Consumer Safety Action Plan
FDA	Food and Drug Administration
FDALO	Food and Drugs Act Liaison Office
FEAC	Food Expert Advisory Committee
FEPN	Food and Environmental Parasitology Network
GVP	Good Pharmacovigilance Practices
GMP	Good Manufacturing Practices
HECSB	Healthy Environments and Consumer Safety Branch
HPCDPB	Health Promotion and Chronic Disease Prevention Branch
HPFB	Health Products and Food Branch
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDPCB	Infectious Disease Prevention and Control Branch
IMA	Interim Marketing Authorizations

List of Acronyms

ISO	International Standards Organization
LRMSC	Legislative and Regulatory Modernization Steering Committee
MAH	Market authorization holders
ML	Maximum level
MLVA	Multi-Locus Variable Number of Tandem Repeat Analysis
MOA	Memorandum of Agreement
MOU	Memoranda of Understanding
MTB	Mechanically tenderized beef
PAAT	Post-authorization activity table
PBRER	Periodic Benefit Risk Evaluation Report
PCPA	*Pest Control Products Act*
PCPP	Patient and Consumer Participation Pool
PHAC	Public Health Agency of Canada
PMDSE	Post-market drug safety and effectiveness
PMRA	Pest Management Regulatory Agency
PSUR	Periodic Safety Update Reports
REDA	*Radiation-Emitting Devices Act*
RMP	Risk management plan
RMSFN	Regulatory Modernization Strategy for Food and Nutrition
RSA	Recalls and Safety Alerts
SBD	Summary Basis of Decision
SME	Small and medium enterprises
SPB	Strategic Policy Branch
VNTR	Variable Number of Tandem Repeat
WHO	World Health Organization

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Executive Summary

The Food and Consumer Safety Action Plan (FCSAP) is a complex horizontal initiative consisting of multiple activities that are organized under three components: Consumer Products, Health Products, and Food Safety. The overall objective of the FCSAP is to modernize and strengthen Canada's safety system for food, health, and consumer products by modernizing regulations and practices in Canada, and using proactive interventions and active oversight to respond as early as possible to potential risks. Partners in the FCSAP include Health Canada, the Public Health Agency of Canada (PHAC), the Canadian Food Inspection Agency (CFIA), and the Canadian Institutes of Health Research (CIHR).

The FCSAP was funded over five years beginning in fiscal year 2008–2009 and ending in 2012–2013, with ongoing resources allocated to the partners. The evaluation of the FCSAP covers the five years of the plan. The evaluation was undertaken to fulfill the requirements of the Treasury Board of Canada's *Policy on Evaluation* (2009). The purpose of the evaluation was to assess the relevance and performance of the FCSAP, in accordance with Treasury Board requirements.

The primary sources of evidence for the overall FCSAP evaluation were evaluation reports recently completed by FCSAP partners, annual reports on the FCSAP for fiscal years 2008–2009 through 2010–2011,[1] and annual reports to Treasury Board Secretariat on plans, spending, and results for fiscal years 2008–2009 through 2012–2013. In some instances, data beyond 2012-2013 was also considered when deemed necessary to clarify particular activities and/or in response to Program requests. In addition, FCSAP partners were invited to identify a small number of key informants to participate in a telephone interview to supplement and update the information contained in these reports. A total of nine individuals were interviewed.

There have been nine evaluation reports completed addressing FCSAP activities. The following Programs, components of FCSAP, were evaluated:

- Consumer Products Activities (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/2013/cpa-pdcfni-eng.php)
- Veterinary Drugs (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/vdp-evaluation-pmv-eng.php)
- Medical Devices (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/medical_devices-materiels_medicaux-eng.php)
- Food Safety and Nutrition Quality (HC) (to be posted by the second week of August 2014)
- Human Drugs (HC) (to be posted on August 29, 2014)
- Biologics (HC) (to be posted on September 24, 2014)
- Drug Safety and Effectiveness Network (CIHR) (posting date to be determined)
- Food Safety Action Plan (CFIA) (http://www.inspection.gc.ca/about-the-cfia/accountability/other-activities/audits-reviews-and-evaluations/fsap/eng/1384540904088/1384540966557)

[1] Annual reports prepared by Programs and available for the evaluation.

These evaluations have provided 34 recommendations with approximately 60 deliverables to be completed by FCSAP partners between 2013 and 2016.

FINDINGS

Relevance

There is a clear ongoing need for government action to protect the health and safety of Canadians. The health and safety risks associated with consumer products, health products, and food necessitate ongoing government oversight in order to help manage these risks. Furthermore, trends such as the globalization of the supply chain and the emergence of new and innovative products that blur traditional product boundaries are creating uncertainties that further support the need for government action to protect the health and safety of Canadians.

Protecting Canadians from health and safety risks associated with food, consumer products, and health products continues to be a priority of the federal government. Furthermore, the activities initiated under the FCSAP are well-aligned with the strategic outcomes of the partners and with federal roles and responsibilities.

Effectiveness

Immediate Outcome #1 – Increased awareness and understanding of product safety and food safety risks by consumers and health professionals

FCSAP partners have undertaken a number of initiatives that are intended to improve consumer and health professional awareness and understanding of product safety and food safety risks. These include developing a one-stop, consumer-oriented website that provides up-to-date information on the risks and benefits associated with food and consumer products, as well as information on recalls, advisories, and warnings. FCSAP partners have also enhanced information products and broadened their dissemination, and have taken steps to make the regulatory system more open to consumer input and involvement.

Despite progress in these areas, evidence of increased awareness and understanding is relatively limited at this time, since FCSAP partners do not regularly collect this information. Available survey data suggests overall consumer satisfaction with information on consumer products and food safety. In the area of consumer products, most consumers surveyed had used at least some of the consumer-products-related information Health Canada has produced, and the vast majority found this information to be useful, understandable, accessible, of high quality, and timely. About two thirds of respondents agreed that “overall, Health Canada provides enough information to the general public about the human health safety risks associated with consumer products.” In the area of food safety, although a large majority of Canadians surveyed were familiar with food safety guidelines and believed that they had sufficient information on food safety, more than half had misconceptions about food handling. Many Canadians continued to express an increased desire for more information on food safety, particularly food recalls, as well as more information about how to protect themselves and their families from food safety risks.

Immediate Outcome #2 – Increased awareness and understanding of regulatory requirements by industry

Since the FCSAP was launched, several new pieces of legislation and regulations have been proposed or have come into force to modernize Canada's legislative and regulatory regime for food, consumer products, and health products. In the area of consumer products, the *Canada Consumer Product Safety Act* (CCPSA) came into force in June 2011. This legislation modernizes Canada's consumer product safety regime and brings it into alignment with those of Canada's international trading partners and competitors. Key provisions include a general prohibition related to the manufacture, importation, sale, or advertisement of consumer products that could pose a danger to human health or safety; the power to order mandatory recalls of consumer products; and increased fines and penalties, including an Administrative Monetary Penalties (AMPs) system, to provide a stronger deterrent against violations of the Act or the regulations that jeopardize the health and safety of the public.

In the area of health products, key developments include a new submission pathway for Extraordinary Use New Drugs (EUND) and new requirements for Good Manufacturing Practices (GMP) and Drug Establishment Licenses (DEL) for active pharmaceutical ingredients (APIs). Most recently, in December 2013, the Government of Canada proposed new patient safety legislation, the *Protecting Canadians from Unsafe Drugs Act* (Bill C-17, Vanessa's Law).[2] The proposed legislation would amend the Food and Drugs Act to give Health Canada the power to recall therapeutic products from the market when they present an imminent or serious risk to health; compel drug companies to revise labels to clearly reflect health risk information; and compel drug companies to provide information for the purpose of assessing serious risks to health, and to compile information, conduct new tests or studies, and/or monitor experience, for the purpose of obtaining additional information. The legislation also includes mandatory serious adverse reaction reporting requirements for healthcare institutions, and increased fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison.

In the area of food safety, the *Safe Food for Canadians Act* was passed in November 2012 and is expected to fully come into force in June 2015. This legislation is intended to protect consumers by targeting food tampering and other unsafe practices; implementing tougher penalties for activities that put health and safety at risk; allowing the CFIA to more effectively track food through all stages of preparation and distribution through enhanced inspections; and providing better controls over food imports.

Health Canada has undertaken extensive outreach to inform the consumer products industry of its obligations under the new CCPSA, and plans to consult with the health products industry as part of the process of developing supporting regulations for the new patient safety legislation. Similarly, the CFIA is currently working with industry to bring the new food safety legislation into force. While, for the most part, it is premature to assess the extent to which industry awareness and understanding of the new requirements has increased, the available data suggest a high level of satisfaction with the information Health Canada makes available to industry. For example, in 2013–2014, between 90% and 100% of consumer product industry stakeholders indicated that they were somewhat or very aware of and understood their legislative obligations

[2] Bill C-17 passed second reading in March 2014.

following attendance at information sessions about the CCPSA. Based on a survey of industry, a large majority of respondents rated Health Canada's information on consumer products as "very" or "somewhat" useful, understandable, accessible, of high quality, and timely. Similarly, based on a limited number of responses to surveys of the health products industry, most respondents indicated having a strong understanding of Health Canada's regulatory requirements for health products and were generally satisfied with the information Health Canada provides to industry.

Immediate Outcomes #3 and #4 – Improved surveillance, information, and knowledge sharing related to products, food, and adverse health incidents

FCSAP partners have taken several important steps to improve surveillance, information, and knowledge sharing (including with international partners) related to health and consumer products, food, and adverse health incidents.

In the area of consumer products, key developments include mandatory industry reporting of consumer product incidents under the CCPSA, along with a new information system, process, and dedicated division for monitoring, triaging, and assessing these reports. In addition, PHAC implemented several projects to improve consumer-product-related injury surveillance and risk assessment. Among others, these projects included modernizing and expanding the Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP); using CHIRPP data in reports on child and youth injuries; collecting, analyzing and disseminating data on select consumer products in order to strengthen the evidence base for action; collaborating with Statistics Canada on the Canadian Coroner and Medical Examiner Database (CCMED); adding a module of questions on injury and consumer product-related falls to the Canadian Longitudinal Study on Aging (CLSA); and conducting risk assessments on patterns and trends of injury using these data sources.

With respect to health products, the proposed patient safety legislation includes two provisions that would increase the information available to Health Canada for the purposes of post-market surveillance, including a provision for mandatory reporting of serious adverse reactions by healthcare institutions and a provision giving Health Canada the authority to require manufacturers to compile information, conduct new tests or studies, and/or monitor experience, for the purpose of obtaining additional information. In addition, Health Canada took steps to implement a more structured, comprehensive, and systematic approach to pharmacovigilance planning and risk management planning, and enhanced its existing program for collecting and reviewing Periodic Safety Update Reports (PSURs). Finally, CIHR established the Drug Safety and Effectiveness Network (DSEN) as Canada's first national post-market drug safety and effectiveness virtual network**.** Research on 36 queries has been prioritized; of these, seven queries have been answered while research is ongoing for 22 and has been planned for the remaining seven queries as of March 31, 2013. Health Canada has used data generated in response to DSEN queries to inform decision making in a few areas.

In the area of food safety, the CFIA, Health Canada, and PHAC took numerous steps to improve their ability to identify, assess, and prioritize potential food safety hazards through improved data collection and risk mapping, with a focus on priority areas of imported food ingredients, produce, mycotoxins, and undeclared allergens. Among other activities, the CFIA carried out targeted surveys in chemistry, microbiology, and allergens, while Health Canada collaboratively updated risk profiles, carried out work in the assessment of options for risk profiling tools, and

updated and published 49 methods to enhance the ability to detect microbiological hazards in the food supply. PHAC used FCSAP funds to maintain and enhance FoodNet Canada and the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS), two important, integrated surveillance systems designed specifically to address food safety issues and examine source attribution. PHAC also continues to expand the capacity of its web-based Outbreak Summary Reporting System, which allows standardized dissemination of the results of disease outbreak investigations. The first report of outbreak summaries data, covering outbreaks reported in the system from 2008 to 2012, will be released to participating provincial public health partners in June 2014.

Immediate Outcome #5 – Improved ability to respond when unsafe products and food are identified

FCSAP partners have undertaken a number of legislative, regulatory, and other initiatives to improve their ability to respond when unsafe products and food are identified. In the area of consumer products, the new CCPSA gives Health Canada the ability to order mandatory recalls of consumer products that pose a danger to health or safety, introduced a requirement for industry to report consumer product-related incidents, and increased fines and penalties to provide a stronger deterrent against non-compliance. Health Canada also increased resources for compliance and enforcement activities and expanded the coverage of its Cyclical Enforcement Program (CEP) from 23 to 35 product categories. FCSAP partners have also implemented a cyclical enforcement strategy and a cyclical compliance monitoring program for radiation-emitting devices and consumer pesticides, respectively.

In the area of health products, through the establishment of the National Border Integrity Program, Health Canada strengthened its ability to make and support admissibility decisions at the border as they relate to health products. The proposed Bill C-17 would give Health Canada several new authorities to improve its ability to respond when unsafe health products are identified, including the power to recall therapeutic products from the market when they present an imminent or serious risk to health; the power to compel drug companies to revise labels to clearly reflect health risk information; and increased fines and penalties, such as a fine of up to $5 million and/or imprisonment for no more than two years on indictment for a violation of the *Food and Drugs Act* or *Food and Drug Regulations*.

In the area of food safety, the CFIA increased its oversight of high-risk sectors by increasing inspections in the imported and manufactured foods and fresh fruits and vegetables sectors and increasing its capacity to respond to a growing number of food safety investigations and food recalls due to enhanced surveillance testing. The CFIA also enhanced its oversight of imported products by increasing the number of port-of-entry or border blitzes undertaken each year.

Intermediate Outcome #1 – Increased appropriate selection and safe use of products and food

There is no information on which to base conclusions about the extent to which this outcome may have been achieved. Furthermore, none of the FCSAP partners have assessed the extent to which their activities may have contributed to this outcome.

Intermediate Outcome #2 – Increased industry compliance with regulatory requirements

Based on completed inspections and compliance monitoring activities, industry compliance with established regulations is reasonably high, although some product categories and industry sectors are exceptions.

In the area of consumer products, industry compliance ranges between 90% and 100% for most product categories subject to inspections, although low rates of compliance (ranging from 0% to 33%) have been found for some product categories, including utility lighters; matches; carriages and strollers; children's jewellery; cribs, cradles, and bassinets; and corded window coverings. With respect to consumer pesticides, industry compliance ranges from 52% among vendors, importers, and distributors of international pest control products to 82% among pest control operators selling commercial and domestic class pest control products. It is not possible, however, to determine the overall industry compliance rate with Health Canada's regulatory requirements for consumer products since compliance and enforcement activities intentionally target higher risk instances of suspected non-compliance. For the product categories examined in the Consumer Products activities evaluation, enforcement action was taken on 100% of non-compliant products, which included information letters, stop sales, and voluntary recalls.

Similarly, the available information generally suggests a high level of industry compliance with existing regulatory requirements for health products. Of the inspections conducted, the compliance rate generally exceeds 90% for Good Clinical Practices (GCP), GMP, and Good Pharmacovigilance Practices (GVP) inspections. With respect to health products referred to Health Canada by the Canada Border Services Agency (CBSA) during the period of 2010–2011 and 2011–2012, Health Canada recommended that approximately 72% of all shipments referred be refused entry into Canada. This percentage reflects the non-compliance rate for shipments referred to Health Canada by the CBSA due to suspected non-compliance. It does not reflect the compliance rate for all shipments received at the border.

In the area of food safety, as already mentioned, in 2012–2013 and 2013–2014, the CFIA's enhanced inspection program found non-conformity rates of 14% and 24% for the imported and manufactured foods and fresh fruits and vegetables sectors, respectively.

For legislative and regulatory changes that have very recently come into force, it is premature to draw conclusions about industry compliance.

Intermediate Outcome #3 – Improved risk assessment and risk mitigation

In all product areas, FCSAP partners have undertaken new initiatives that will enhance the information available to them for the purpose of assessing product risks and identifying safety issues requiring risk mitigation or corrective action.

For consumer products, relevant initiatives include new requirements for mandatory industry reporting of consumer product-related incidents, expansion of the CEP to additional product categories, and enhancement of product-related injury surveillance.

For health products, relevant initiatives include the introduction of GMP and DEL requirements for APIs; enhancements to the existing risk management plan (RMP) and PSUR programs; the proposed provisions in Bill C-17 to compel drug companies to conduct post-market safety studies and to introduce mandatory serious adverse reaction reporting for healthcare institutions; and the establishment of the DSEN as Canada's first national post-market drug safety and effectiveness virtual network, which is intended to generate and promote the use of research evidence to enable healthcare decision makers to better determine safety and effectiveness profiles for drugs and implement measures that will promote their optimal use.

In the area of food safety, the most important initiatives include improved identification, assessment, and prioritization of potential food safety hazards through improved data collection and risk mapping; ongoing health risk assessments; updates to risk profiles of various foodborne pathogens; updates to methods used to enhance the ability to detect microbiological hazards in the food supply; and ongoing surveillance, risk profiling, laboratory method development, and knowledge synthesis and dissemination activities.

Intermediate Outcome #4 – Improved early response to unsafe products

In all product areas, FCSAP partners have undertaken new initiatives that will enhance their ability to respond early through taking action when unsafe products are identified.

For consumer products, these initiatives include Health Canada's new authority under the *CCPSA* to order mandatory recalls of consumer products that pose a danger to health or safety; the increase in the level of resources devoted to consumer-product-related compliance and enforcement activities; the expansion of the CEP from 23 to 35 product categories; and the development and implementation of a cyclical enforcement strategy and a cyclical compliance monitoring program for radiation-emitting devices and consumer pesticides, respectively.

For health products, these initiatives include proposed amendments to the *Food and Drugs Act* that would give Health Canada the power to recall therapeutic products from the market when they present an imminent or serious risk to health and compel drug companies to revise labels to clearly reflect health risk information; proposed amendments that would increase fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison; and increased resources for regulatory oversight of imported health products under the National Border Integrity program.

In the area of food safety, relevant initiatives include the new *Safe Food for Canadians Act,* which will target food tampering and other unsafe practices, implement tougher penalties for activities that put health and safety at risk, allow the CFIA to more effectively track food through all stages of preparation and distribution through enhanced inspections, and provide better controls over food imports; enhanced inspection of high-risk sectors; improved tracking of imported foods; and increased capacity to respond to an increase in the number of food safety investigations and food recalls due to enhanced surveillance testing.

Long-term outcome – Reduced adverse health incidents related to health and consumer products

While FCSAP activities have certainly contributed to reducing adverse events associated with these products, finding concrete evidence of this outcome is challenging.

In the area of consumer products, FCSAP activities such as mandatory incident reporting for industry, efforts to raise public awareness of the ability for consumers to voluntarily report incidents, and the introduction of new legislation giving Health Canada the power to issue mandatory recalls of consumer products should lead to a reduction in adverse health incidents associated with these products. While the data show that the number of reported incidents has been increasing, this may simply reflect an increase in reporting due to the mandatory incident reporting provision in the CCPSA, and not necessarily an increase in adverse health incidents.

Similarly, in the area of health products, FCSAP activities such as removing unsafe products from the market through recalls and recommending the refusal of entry into Canada of products deemed non-compliant with the legislative and/or regulatory requirements should reduce the availability of non-compliant health products, thereby contributing to health risk mitigation. Although the number of domestic adverse reaction reports submitted to Health Canada has been increasing steadily over time, the proportion that are classified as "serious" — i.e., that require in patient hospitalization or prolongation of existing hospitalization, that cause congenital malformation, result in persistent or significant disability or incapacity, are life threatening or result in death — has remained stable since 2001, accounting for just over two thirds of all reports submitted each year.

Finally, in the area of food safety, FCSAP activities such as improved identification of potential food safety risks and enhanced inspection of high-risk sectors should contribute to a reduction in adverse health incidents associated with food. While the available evidence, from PHAC's FoodNet Canada and Notifiable Disease On-Line, shows a small decrease in the number of reported enteric diseases over the past decade, which is matched by a small decrease in the number of food safety investigations and recalls carried out by the CFIA over the same period, it is not possible to infer a relationship between these two trends.

Efficiency and economy

The proposed governance structure for the FCSAP, consisting of three task forces with oversight for Health Products, Consumer Products, and Food, was implemented with limited success due in part to the prior existence of committees with overlapping mandates and membership. At the end of the five-year lifespan of the FCSAP, oversight of Health Products activities was transitioned to Health Canada's Health Products and Food Branch Executive Committee and oversight of Food activities was transitioned to the Interdepartmental Director General Committee on Food Safety. The Consumer Products Task Force, led by the Healthy Environments and Consumer Safety Branch of Health Canada, remains active.

Over the period of time covered by this evaluation, performance measurement and financial reporting systems necessary to support analysis of efficiency and economy were not in place within the FCSAP departments and agencies, although progress is being made to improve performance measurement and financial reporting to inform the assessment of efficiency and economy in future. For the purpose of this evaluation, the assessment of efficiency and economy is limited to a comparison of planned and actual expenditures. Actual spending on the FCSAP was approximately 83% of planned ($405.3 million compared to $489.7 million) between 2008–2009 and 2012–2013. Variances in spending are related to challenges with staffing, found efficiencies, and changes to some of the activities.

Since this is a roll up evaluation report, recommendations relevant to each component Program have been provided in each component evaluation report. Evidence analyzed during this evaluation did not lead to any roll up recommendations.

1.0 Evaluation Purpose and Scope

The evaluation of the Food and Consumer Safety Action Plan (FCSAP) covered the five years of the plan from 2008–2009 to 2012–2013. The evaluation was undertaken to fulfill the requirements of the Treasury Board of Canada's *Policy on Evaluation* (2009). The purpose of the evaluation was to assess the relevance and performance of the FCSAP, in accordance with Treasury Board requirements.

2.0 Description

2.1 Context

The FCSAP was announced by the Government of Canada in December 2007 in response to a growing number of food, health product, and consumer product safety incidents, recalls, and concerns. Incidents such as confirmed cases of high lead levels in some imported children's jewellery, a global withdrawal of Vioxx after thousands of people suffered heart attacks, and numerous high profile food safety incidents and recalls (involving, for example, spinach, carrot juice, seafood, and lettuce) highlighted the need for national action to strengthen and modernize Canada's safety system for health and consumer products and food. The vast number of products and producers and the complexity of the global marketplace further underscored the need for a modernized approach in the context of a changing risk environment. The FCSAP was also expected to align Canada's approach to regulating health and consumer products and food more closely with approaches taken internationally.

2.2 Profile

The FCSAP is a complex horizontal initiative consisting of multiple activities that are organized into three components: Consumer Products, Health Products, and Food Safety. The overall goal of the FCSAP is to modernize and strengthen Canada's safety system for food, health products, and consumer products by modernizing regulations and practices in Canada, and using proactive interventions and active oversight to respond as early as possible to potential risks. Under the FCSAP, some activities were enhancements to existing activities, while others were new.

Partners in the FCSAP include Health Canada, the Public Health Agency of Canada (PHAC), the Canadian Food Inspection Agency (CFIA), and the Canadian Institutes of Health Research (CIHR). Within Health Canada, several entities have responsibilities under the FCSAP, including the Health Products and Food Branch (HPFB) for health products and food safety; the Healthy Environments and Consumer Safety Branch (HECSB) for consumer products, excluding consumer pesticides; and the Pest Management Regulatory Agency (PMRA) for consumer pesticides. Other Health Canada entities with responsibilities under the FCSAP include the Communication and Public Affairs Branch (CPAB) and the Strategic Policy Branch (SPB).

Within PHAC, the Infectious Disease Prevention and Control Branch (IDPCB) has responsibility for activities related to food safety, and the Health Promotion and Chronic Disease Prevention Branch (HPCDPB) has responsibility for activities related to consumer products.

The three components of the FCSAP — Consumer Products, Health Products, and Food Safety — consist of 31 strategies organized under three strategic "pillars:"

Active prevention involves preventing food and product safety incidents through systematic risk assessment, increased scientific knowledge, improved standards, improved traceability, early identification of safety issues, increased consumer awareness, and larger penalties for industry violation of relevant regulations.

Targeted oversight works to improve product safety checks at various stages of the production process. This is achieved through new mandatory reporting legislation for suppliers, enhanced inspection and import control, improved border security, and improved audits of domestic industry and importers.

Rapid response gives increased authority to government to take action when it identifies a risk related to health, consumer, and food products. "Appropriate action" may include mandatory recalls and fines that the government was previously not able to enforce.

2.3 Description of the Logic Model[3]

An overview of the FCSAP is presented in a one-page logic model on the next page. This logic model describes the inputs, activities, outputs, reach, and anticipated outcomes for the FCSAP as a whole. This evaluation uses the overall FCSAP logic model to report on outcomes achieved.

More specifically, the Food and Consumer Safety Action Plan (FCSAP) has as its foundation the three pillars of active prevention, targeted oversight and rapid response. In order to carry out activities related to these three pillars, FCSAP partners use a number of inputs such as acts and regulations (i.e., the new Consumer Product Safety Act, including Administrative Monetary Penalties; the modernized Food and Drugs Act and Cosmetics Regulations; the modernized Radiation Emitting Devices Act; and, the new regulatory framework for Active Pharmaceutical Ingredients [APIs]) as well as human and financial resources.

FCSAP activities are organized under five main activity themes, namely:

- Consumer involvement and information:
  - consult stakeholders;
  - develop and disseminate consumer information; and,
  - respond to inquiries and complaints.

[3] To obtain a copy of the Logic Model graphic please use the following e-mail "Evaluation Reports HC - Rapports Evaluation@hc-sc.gc.ca".

- Industry involvement and information:
  - collaborate/engage with industry and other stakeholders;
  - develop and provide guidance information and tools; and,
  - develop risk control systems.

- Research, risk-assessments and reviews:
  - undertake risk assessments;
  - review data;
  - develop implementation plans;
  - analyse registries, trials and surveillance, and epidemiological studies;
  - develop and implement risk management/mitigation plans;
  - review pre-market API submissions; and,
  - fund research.

- Surveillance and monitoring:
  - implement mandatory reporting of incidents and adverse reactions;
  - collect, analyze and disseminate data;
  - conduct inspections;
  - review Periodic Safety Update Reports (PSURs);
  - participate in the establishment of international systems/agreements for the global market;
  - identify and monitor imported products; and,
  - provide import/border services support.

- Compliance and enforcement:
  - conduct inspections, investigations, compliance and enforcement activities.

As a result of each activity, partners in the FCSAP generate a number of products and/or services, namely:

- Consumer involvement and information:
  - product/food safety information;
  - educational information/for a; and,
  - products registry and complaints system.

- Industry involvement and information:
  - best practices agreements, guides, standards, protocols, codes of practice, regulatory frameworks; and,
  - pre-submission meetings (health products industry).

- Research, risk-assessments and reviews:
  - risk assessments;
  - pharmacovigilance plans;
  - guidance documents;
  - risk management tools;
  - API submission reviews; and,
  - research knowledge.

- Surveillance and monitoring (also contribute to products and services under research, risk-assessments and reviews):
  - mandatory reporting systems;
  - data and inspection reports;
  - PSURs;
  - partnerships/agreements;
  - global product safety data;
  - tracking system for imported products; and,
  - Import Service Centre.

- Compliance and enforcement:
  - recalls;
  - fines;
  - surveillance reports;
  - inspection reports; and,
  - monetary penalties.

These outputs are targeted at different groups, namely:

- Outputs related to consumer involvement and information are targeted at consumers and health professionals.
- Outputs related to industry involvement and information are targeted at health and consumer product and food industries.
- Outputs related to research, risk-assessments and reviews are targeted at HC, CFIA, PHAC, health and consumer product and food industries, and drug plan managers.
- Outputs related to surveillance and monitoring are targeted at health and consumer product and food industries as well as provincial/territorial and international partners.
- Outputs related to compliance and enforcement are targeted at health and consumer product and food industries.

Carrying out activities under the FCSAP and producing outputs is expected to contribute to the achievement of specific immediate, intermediate and final outcomes. In the immediate term, each FCSAP main activity theme corresponds with one immediate outcome, namely:

- Consumer involvement and information: increased awareness and understanding of product safety and food safety risks by consumers and health professionals.
- Industry involvement and information: increased awareness and understanding of regulatory requirements by industry.
- Research, risk-assessments and reviews: improved information, data and knowledge sharing related to products, food and associated adverse health incidents.
- Surveillance and monitoring: improved monitoring of products, food and associated adverse health incidents.
- Compliance and enforcement: improved ability to respond when unsafe products and food are identified.

The achievement of these immediate outcomes is expected to lead to intermediate outcomes. In this way, the achievement of immediate outcomes related to research, risk-assessment and reviews, surveillance and monitoring, and compliance and enforcement (i.e., improved information, data and knowledge sharing related to products, food and associated adverse health incidents; improved monitoring of products, food and associated adverse health incidents; and, improved ability to respond when unsafe products and food are identified) will lead to:

- increased appropriate selection and safe use of products and food (as long as there is increased awareness and understanding of product safety and food safety risks by consumers and health professionals);
- increased industry compliance with regulatory requirements (as long as there is increased awareness and understanding of regulatory requirements by industry); and,
- improved risk-assessment and mitigation.

Finally, achieving improved monitoring of products, food and associated adverse health incidents, together with the improved ability to respond when unsafe products and food are identified will lead to the intermediate outcome of improved early response to unsafe products.

In the long term, FCSAP partners expect to see reduced adverse health incidents related to health and consumer products (including cosmetics, pesticides, and radiation emitting devices) and food.

Since the FCSAP is a complex initiative, separate and more detailed logic models for each component product area were also developed. Each of the component logic models describe the specific activities to be undertaken by the FCSAP partners and links these activities to outputs and outcomes. The component logic models were aligned, to the extent possible, with the overall logic model to facilitate evaluation reporting. The component logic models are in Appendix A.

2.4 Resources

Planned spending for the FCSAP totalled $489.7 million for 2008–2009 to 2012–2013.

3.0 Evaluation Description

The evaluation of the FCSAP covered the five years from 2008–2009 to 2012–2013 and assessed the relevance and performance (effectiveness, efficiency and economy) of the FCSAP in accordance with the Treasury Board *Policy on Evaluation* (2009).

The primary sources of evidence for the overall FCSAP evaluation were evaluation reports recently completed by FCSAP partners,[4] annual reports on the FCSAP for fiscal years 2008–2009 through 2010–2011,[5] and annual reports to the Treasury Board Secretariat on plans, spending, and results for fiscal years 2008–2009 through 2012–2013. In some instances, data beyond 2012-2013 was also considered when deemed necessary to clarify particular activities

[4] A diagram identifying the different component evaluations is provided in Appendix B.
[5] Annual reports prepared by Programs and available for the evaluation.

and/or in response to Program requests. A bibliography is provided in Appendix C. In addition, FCSAP partners (HPFB, HECSB, PMRA, PHAC, CFIA, and CIHR) were invited to identify a small number of key informants to participate in a telephone interview to supplement and update the information contained in these reports. A total of nine individuals were interviewed. Some program areas also provided additional information in writing.

There have been nine evaluation reports completed addressing FCSAP activities. The following Programs, components of FCSAP, were evaluated:

- Consumer Products Activities (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/2013/cpa-pdcfni-eng.php)
- Veterinary Drugs (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/vdp-evaluation-pmv-eng.php)
- Medical Devices (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/medical_devices-materiels_medicaux-eng.php)
- Food Safety and Nutrition Quality (HC) (to be posted by the second week of August 2014)
- Human Drugs (HC) (to be posted on August 29, 2014)
- Biologics (HC) (to be posted on September 24, 2014)
- Drug Safety and Effectiveness Network (CIHR) (posting date to be determined)
- Food Safety Action Plan (CFIA) (http://www.inspection.gc.ca/about-the-cfia/accountability/other-activities/audits-reviews-and-evaluations/fsap/eng/1384540904088/1384540966557)

These evaluations have provided 34 recommendations with approximately 60 deliverables to be completed by FCSAP partners between 2013 and 2016.

The overall FCSAP evaluation has the same methodological limitations that applied to and were described in the component evaluations. These included a general lack of administrative and performance measurement data to assess progress against outcomes; poor response rates to surveys designed to address gaps in information; and limited financial and human resource information to assess efficiency and economy. To the extent possible, gaps in information were mitigated through the use of multiple lines of evidence to respond to the evaluation questions. Nevertheless, for some outcomes, evidence is limited.

4.0 Findings

This section of the report presents the evaluation findings.

4.1 Relevance: Issue #1 – Continued need

There is a clear, ongoing need for government action to protect the health and safety of Canadians. The health and safety risks associated with consumer products, health products, and food necessitate government oversight in order to manage these risks. Furthermore, trends such as the globalization of the supply chain and the emergence of new and innovative products that blur traditional product boundaries are creating uncertainties that further support the need for government action to protect the health and safety of Canadians.

Consumer products

Canadians may be exposed to a variety of health and safety risks associated with consumer products and consumer pesticides through various avenues. Some of the substances used in consumer products and/or consumer pesticides, such as Bisphenol A (BPA), phthalates, and heavy metals, can pose risks to human health.[6] Additionally, health and safety risks may be inherent in the design of products, or may arise based on the manner in which products are used. Cribs and corded window coverings are two consumer products that pose both types of risks. Using corded window coverings as an example, strangulation is the main safety risk related to product design. However, many of the incidents associated with corded window coverings take place in spite of safety devices and warnings intended to reduce strangulation risks. Common scenarios surrounding corded window covering incidents include placing babies' cribs too close to a window, thereby allowing access to outer pull-cords and resulting in entanglement; placing furniture near a window or patio door, which children can climb on, and then become entangled in a nearby window covering cord; and the forming of knots in the cords, which defeats the safety device. These risks are examples of risks related to product use.

Finally, there are risks associated with radiation emission from consumer products, including sleep disturbance, communication interference and annoyance resulting from noise pollution, and exposure to ultraviolet radiation and radiofrequency energy.

[6] BPA in polycarbonate baby bottles is prohibited under the new *Canada Consumer Product Safety Act*, which was developed and implemented under the FCSAP. The *Phthalates Regulations* under the *CCPSA* limit the use of these substances in children's toys and child care products. Health Canada has had regulations limiting the use of lead in various consumer products since the 1970s (e.g., kettles; consumer paints and other surface coatings; glazed ceramic and glass foodware; applied paints and other surface coatings on toys, children's furniture, and other articles; and pencils and artists' brushes).

Health products

Similarly, a variety of risks to human health and safety are associated with the use of health products. For example, risks to health and safety may arise as a result of incomplete understanding of a product's effect on health at the time of market approval; from off-label use of approved products; from abuse or misuse of prescription drugs; from mistakes made in drug compounding; and from drug shortages, which can lead to increased reliance on inappropriate alternatives, delayed medical procedures, and higher likelihood of medication errors. Risks may also arise from deficiencies in the manufacturing and distribution of health products. Indeed, globalization of the supply chain for active ingredients and finished products is contributing to the potential for counterfeiting, tampering, adulteration, contamination, and other risks that could harm the products' end users.

Unique risks are associated with biologic products. For example, biologic drugs incorporating monoclonal antibodies have been linked to serum sickness, tumour lysis syndrome, cytokine release syndrome, heighted risk of infection, platelet and thrombotic disorders, autoimmune diseases, cancer, dermatitis, and cardiac dysfunction. Similarly, developing biologic therapies, such as cell and gene therapies, also carry certain risks, such as autoimmune responses, transmission of infectious diseases, introduction of adventitious agents, and alteration of cells' biological characteristics, causing malignant transformations in cells that result in the formation of tumours. Some biologic products, including blood and blood components and cells, tissues, and organs for transplantation, present a risk of infectious disease transmission.

Food

As with consumer and health products, various health and safety risks may arise with respect to food. These include traditional microbial hazards (e.g., bacteria such as Salmonella and Listeria monocytogenes) and chemical food safety hazards (e.g., food-processing-induced chemicals), as well as emergent and re-emergent pathogens arising from multiple factors. These factors include food manufacturing and agricultural processes that may allow for the introduction of food-related pathogens; microbial adaptation/antimicrobial resistance to interventions; and globalization of the food supply.

In addition, new technologies such as genetically modified organisms and their derivatives, biotechnology, nanotechnology, irradiation, and food additives present potential risks to health and safety, as does the use of food as a health delivery agent. Some examples of the latter are functional foods such as nutraceuticals and non-traditional micronutrients such as lycopenes, beta-carotenes, and isoflavones. Finally, there is an ongoing need to develop new detection methodologies and determine acceptable risk (tolerance) levels for pesticides, heavy metals, growth hormones, antibiotics, and fertilizers in food.

Overall, the range of health and safety risks associated with food, consumer products, and health products warrant an ongoing role for government in order to help manage these risks.

4.2 Relevance: Issue #2 – Alignment with government priorities

Protecting Canadians from health and safety risks associated with food, consumer products, and health products continues to be a priority of the federal government. FCSAP activities are also well-aligned with the strategic outcomes of the partners.

The FCSAP was a five-year initiative covering the period from 2008–2009 to 2012–2013, aimed at modernizing and strengthening Canada's safety system for food, health products, and consumer products. The federal government has committed $125 million on an ongoing basis to activities initiated under the FCSAP, beginning in 2013–2014.

In its most recent Speech from the Throne in October 2013, the federal government reaffirmed its commitment to making further progress in modernizing the regulatory systems for food and health and consumer products. For example, the Speech referred to the *Safe Food for Canadians Act*, which was developed and implemented under the FCSAP, as a "significant milestone in strengthening Canada's world class food safety system," and committed the federal government to working with the provinces and territories to further strengthen the food inspection regime. In the same Speech from the Throne, the Government of Canada also made commitments to protect Canadians from the health and safety risks associated with health products by ensuring that drug labels are written in plain language and that the potential side effects of medication are accurately indicated on drug labels. It also indicated its intent to introduce new patient safety legislation to help identify potentially dangerous drugs, to ensure the quick recall of unsafe drugs, and to introduce new powers to require reporting of adverse drug reactions. This legislation — the *Protecting Canadians from Unsafe Drugs Act* — was subsequently introduced in the House of Commons in December 2013, and passed second reading in March 2014.

Finally, FCSAP activities to protect Canadians from health and safety risks associated with food and consumer products are well-aligned with the strategic outcomes of the partners, as expressed in their most recent (2014–2015) Reports on Plans and Priorities:

- PHAC's FCSAP activities are consistent with its strategic outcome of "protecting Canadians and empowering them to improve their health."
- Health Canada's FCSAP activities are consistent with its Strategic Outcome #2, namely, that "health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians."
- CFIA's FCSAP activities are consistent with its strategic outcome of "a safe and accessible food supply and plant and animal resource base."
- CIHR's role in the FCSAP through the Drug Safety and Effectiveness Network (DSEN) is consistent with its strategic outcome that "Canada is a world leader in the creation, dissemination and application of health research knowledge."

4.3 Relevance: Issue #3 – Alignment with federal roles and responsibilities

The initiatives under the FCSAP are well-aligned with federal roles and responsibilities.

The federal government's role and responsibilities in protecting Canadians from the health and safety risks related to food and consumer products are articulated in several federal statutes. Prior to implementation of the FCSAP, the main relevant pieces of legislation were the *Hazardous Products Act*, the *Radiation-Emitting Devices Act* (REDA), the *Canadian Food Inspection Agency Act*, the *Food and Drugs Act*, and the *Pest Control Products Act* (PCPA).

A main objective of the FCSAP was to adapt this legislative framework to accommodate a changing risk environment. As a result, a major planned element of the FCSAP was updating these Acts and their accompanying Regulations (with the exception of the PCPA). This was to be accomplished through development of the *Canada Consumer Product Safety Act* (CCPSA), modernization of the *Food and Drugs Act* and the REDA, and modernization of the *Cosmetic Regulations*. As a result of the FCSAP, the CCPSA has been implemented and several regulatory amendments have been made under the *Food and Drugs Act*. In addition, new patient safety legislation — the *Protecting Canadians from Unsafe Drugs Act* — has been introduced. These and other relevant legislative and regulatory changes are described in the sections that follow.

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 awareness and understanding of product safety and food safety risks by consumers and health professionals

While FCSAP partners have made efforts to inform consumers on the risks and benefits associated with consumer products and food (i.e., one-stop website), evidence of increased awareness and understanding is relatively limited. According to survey data, while there appears to be overall satisfaction with information on consumer products and food safety, there remain misconceptions and a desire to obtain more information on food safety risks.

Initiatives relevant to consumer products, health products, and food

Under the FCSAP, Health Canada implemented plans for a comprehensive consumer information and outreach strategy applicable to consumer products, health products, and food in order to increase awareness and understanding of product safety and food safety risks among health professionals and the general public. The strategy aimed to make more information available to consumers; make consumer information more accessible and consumer friendly; and make the regulatory system more open to consumer input and involvement.

The Consumer Information Secretariat and the Consumer Information Bureau[7] were created within Health Canada to coordinate these efforts and provide a standardized approach to consumer communications, centralized development of policies and tools, and ongoing communications guidance. Health Canada also established a central contact centre for consumer phone and email requests for information on food and product safety issues, with data tracking done by the Public Enquiries Centre.

To increase the amount of information available to consumers and to make consumer information more accessible and consumer friendly, Health Canada re-launched the Healthy Canadians website as a one-stop, consumer-oriented site that combines content from seven federal departments related to health and safety. The single-window website provides access to up-to-date information on risks and benefits, as well as information on recalls, advisories, and warnings. Between 2008–2009 and 2012–2013, there were a total of 2,952 recalls and safety alerts posted for consumer products, 5,305 for health products, and 2,130 for food.[8]

In 2010, Health Canada launched the Healthy Canadians and Canadiens en santé fan pages on Facebook. As of March 31, 2013, these pages had 14,073 fans. Since their creation, there have been regular posts on both pages, including online polls, health and safety tips, and health facts, resulting in comments and sharing of links.

In December 2010, a Recalls and Safety Alerts (RSA) mobile application was launched to provide Canadians with easy, "on-the-go" access to the latest recalls and safety alerts from the Government of Canada. In October 2012, Health Canada launched the RSA Database, a revised system that amalgamated recall and safety alert information that was previously scattered across the Health Canada website into one common and public interface on the healthycanadians.gc.ca website. The new presence has advanced search features, and in addition to Health Canada issued recalls and advisories, also incorporated food recall information from the CFIA and vehicle recalls issued by Transport Canada. An updated and enhanced version of the mobile application was also launched, to align with the web presence.

In addition to the broad consumer information strategy, FCSAP partners also undertook education and awareness-raising activities related to specific product lines, as described below.

Consumer products

In the area of consumer products, the Consumer Safety Portal of Health Canada's website was expanded to provide access to 50 consumer product bulletins and information about the new *CCPSA*. Health Canada also launched a consumer incident report form, along with information for consumers on how to report an incident and what to do in the event of a recall. Survey data from the evaluation of Consumer Products Activities indicate that most consumers surveyed had used at least some of the consumer products-related information Health Canada has produced, such as consumer product advisories, warnings, and recalls (92%), the Health Canada Consumer Product Safety website (76%), and product safety fact sheets (55%). The vast majority of those

[7] The Consumer Information Bureau was disbanded in late 2012, and activities were integrated into the ongoing work of the Public Affairs Directorate whose mandate aligns with this objective.

[8] These figures include recalls and safety alerts posted in both English and French.

who had used this information found it to be "very" or "somewhat" useful, understandable, accessible, of high quality, and timely. About two thirds of respondents agreed that "overall, Health Canada provides enough information to the general public about the human health safety risks associated with consumer products." The survey did not test consumers' understanding of consumer product safety risks.

PHAC collected, analyzed, and disseminated data on select consumer products (e.g., magnets, small button batteries, trampolines, detergent packages, and baby products, including strollers and carriages) in addition to poisonings in order to strengthen the evidence base for action. The Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) was modernized and expanded, and a real-time secure surveillance system to identify emerging hazards, injury trends, illnesses and deaths related to consumer products and other risk factors was launched. The Agency developed and offered training webinars for the new real-time surveillance system to familiarize participating hospital staff with the data collection system and to help improve quality and integrity of the data collected, particularly those injuries related to consumer products. The Agency, together with its partners and stakeholders, published peer-reviewed journal articles using data from the CHIRPP for many injuries, including those related to consumer products. Data collected from CHIRPP was made available to the public through the Government of Canada's Open Data Initiative.

To inform Canadians about the safe use of consumer pesticides, PMRA launched consumer awareness and outreach campaigns that focus on safe use practices for topical flea and tick control products and home and garden pest control products; added more information to its compliance and enforcement website; and expanded the consumer pesticides-related content on the Healthy Canadians website.

Finally, consistent with the objective of making the regulatory system more open to stakeholder input and involvement, Health Canada conducted numerous public consultations regarding proposed regulatory and policy changes for consumer products. For example, the public was consulted on potential regulatory amendments to the *Playpens Regulations*; a proposal for cadmium guidelines in children's jewellery; legislative action on 2-(2-methoxyethoxy) ethanol under the CCPSA; proposed Group 2 Regulations under the Lead Risk Reduction Strategy for consumer products; and proposed changes to the Cosmetic Ingredient Hotlist, among other topics.

Health products

In the area of health products, HPFB undertook several initiatives to make more information available to consumers and health professionals. Key initiatives included the following:

- publishing Summary Basis of Decision (SBD) documents, which are intended to increase the transparency of the review process by providing Canadians with improved access to information about approved products; between 2008–2009 and 2013–2014, Health Canada published 210 SBDs for pharmaceuticals, biologics, and medical devices
- introducing the post-authorization activity table (PAAT) as part of SBDs beginning in September 2012 to provide ongoing (i.e., post-market) information about approved products, such as information related to submissions for a new use of the product

(whether Health Canada's decision was positive or negative), submissions filed in order to meet conditions (for products that received a Notice of Compliance with Conditions), and regulatory decisions such as the cancellation of the Drug Identification Number
- publishing the consumer portion of drug product monographs for new drug submissions, and conducting consultations on enhancements to the consumer, health professional, and scientific sections of the product monograph
- under the Plain Language Labelling Initiative, implementing regulations requiring manufacturers to list non-medicinal ingredients on non-prescription drug labels, and developing regulatory amendments that would introduce a general requirement for drug labels to use plain language and a format or presentation that does not impede comprehension
- launching the Safety Labelling Stakeholder Notification System on the Health Canada website in February 2013, which provides monthly information updates and/or new safety information for brand name pharmaceutical products

There is no current, direct evidence of the extent to which consumers and health professionals use the available sources of information, or the extent to which these may have contributed to increased awareness and understanding of health product safety risks.[9] Health Canada has recently completed an evaluation of its risk communications products relating to pharmaceuticals, biologics, and medical devices, which may provide some insight into the extent to which consumers and health professionals are using these sources of information, as well as the effectiveness of these products at improving stakeholder awareness and understanding of product safety risks.

To improve the internal consultation process within HPFB, the Branch launched the Patient and Consumer Participation Pool (PCPP) in 2011. The PCPP was identified as an efficient way to utilise a group of engaged and informed patients and consumers to participate in decision making. A total of 87 participants were recruited. As of 2013, two consultations were undertaken that drew on the PCPP.

Health Canada also established the *Food and Drugs Act* Liaison Office (FDALO) to improve relations between external stakeholders and representatives of Health Canada and increase the openness and transparency in the regulatory process. The FDALO acts as an impartial and confidential resource for receiving complaints, concerns, or enquires from individuals, businesses, and organizations.

9 The available information predates the FCSAP. A series of studies conducted between 2003 and 2007 found opportunities to improve awareness and use among both consumers and health professionals of drug safety information available from Health Canada. For example, in both 2003 and 2006, about one third of consumers were aware that new drug safety information was available through Health Canada's website. However, only about 10% had accessed this information within the last six months. Conversely, about two thirds were aware of advisories and warnings issued through the media. Similarly, in 2003, only a minority of health professionals were familiar with Health Canada-issued online drug safety advisories and identified Health Canada as a source for new drug safety information. The Human Drugs, Biologics, and Medical Devices evaluations included surveys of consumers and health professionals but achieved too low a response rate to support conclusions.

Finally, external experts provide advice and recommendations to HPFB through participation in a variety of scientific and expert advisory bodies.

Food safety

In the area of food safety, Health Canada developed guidance/educational tools and documents with respect to allergens, toxins, emerging foodborne pathogens, and bioactives. A three-year food safety campaign, with funding from FCSAP and other initiatives, was carried out to increase awareness and knowledge of the health risks associated with unsafe food handling practices and foodborne illnesses among the general public and at-risk groups. The campaign included information in annual publications, mail inserts, print media, a radio campaign, and a strategic alliance. The campaign also included a survey (2010) regarding Canadians' knowledge and behaviours related to food safety. Health Canada also launched and/or contributed to other initiatives (Nutrition Facts Education Campaign, Children's Health and Safety, Safe and Informed Consumers, Hazardcheck).

In addition, Health Canada and the CFIA developed and/or published several guidance documents, videos, and an online game providing Canadians with better information on what they are eating and how to handle food safely. The CFIA implemented a number of outreach initiatives and marketing campaigns, including partnerships, email, video, newspaper, radio, and print ads to raise awareness of food safety (imported products, safe handling of produce, recalls) and direct consumers to the CFIA food recall and allergy alert email notification service, as well as the CFIA website and the new Food Safety Portal (a single access point for consumer information on the web). The CFIA completed the "Canada's 10 Least Wanted Food-borne Pathogens" publication series and the "Common Food Allergies – A Consumer's Guide to Managing the Risks" booklet, which provides information to consumers on the nature of the microorganisms that can cause foodborne illness and the most common food allergens, respectively.

The CFIA revised food recall warnings to make them clearer and easier to understand. In addition, the Agency enhanced its web presence by developing a more user-friendly consumer centre and adding interactive tools on the food safety investigation and recall process, and the beef processing and inspection process. The Agency posts the results of targeted surveys on its website to help raise consumer awareness about food safety risks and issues.

Most recently, the CFIA developed and implemented a Food Safety Risk Communications Strategy in 2012–2013 to provide consumers, media, and parliamentarians with relevant, easy-to-understand information in multiple formats. The Strategy is also intended to integrate risk communication principles and practices into core CFIA food safety messages, and enhance the effectiveness of recall communication products and activities.

PHAC publishes reports on its surveillance activities under FoodNet Canada and the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) on its website. Although aimed primarily at individuals working in food safety and public health, these reports are accessible to the public.

To enhance consumer involvement in food safety decisions, CFIA consulted stakeholders on revisions to its *Product of Canada* policy. The revised policy was announced in 2008.[10] Through the Consumer Association Roundtable, the CFIA meets with consumer organizations to ensure that consumers have an opportunity to discuss, and provide input to, food safety and other topics related to CFIA priorities, policies, programs, and services that benefit from consumer input.

Health Canada conducted consumer consultations on a number of food safety issues: allergen regulations (precautionary labelling), proposed policy intent for revising Canada's gluten-free labelling requirements, and proposed definition of dietary fibre. Health Canada also held two technical consultations: to permit the use of the enzyme asparigenese, and on the proposed maximum level (ML) for the presence of the natural toxin Ochratoxin A in foods. Finally, Health Canada established the Food Expert Advisory Committee (FEAC), which includes representatives from patient/consumer groups, health professional/regulatory sectors, and research/academia, as well as industry, and consulted it on several topics.

Survey data from 2010 and 2011 cited in the Food Safety and Nutrition Quality evaluation suggested opportunities at that time to further improve the food safety information made available to the public. In 2010, only 60% of Canadians were aware of foodborne illnesses. The following year, a large proportion of Canadians (64%) believed that the federal government "has done a good job of keeping Canadians informed of all relevant food safety issues" but a similar proportion (63%) "still wish[ed] they had more information about food safety and how to protect themselves from foods that pose a health risk." In the same year, 94% were familiar with food safety guidelines, and 76% said they had sufficient information on food safety. However, more than half mistakenly believed that most preventable contamination occurs outside of the kitchen. Misconceptions about food handling were most prevalent among at-risk groups such as pregnant women, people with compromised immune systems, and seniors.

Public opinion research conducted in early 2013 shows that 90% of Canadians were moderately to extremely confident in Canada's food safety system. Three quarters had heard about food safety or recalls in Canada in the last six months, and those who had heard of CFIA were much more likely to have heard about food safety or recalls (78%) than those who were unaware of CFIA (48%). However, Canadians continued to express an increased desire for more information on food safety, particularly food recalls.

Immediate Outcome #2: Increased awareness and understanding of regulatory requirements by industry

Since the FCSAP was launched in 2008–2009, several new pieces of legislation and regulations have been proposed or have come into force to modernize Canada's legislative and regulatory regime for food, consumer products, and health products. While it is, for the most part, premature to assess the extent to which industry awareness and understanding of the new requirements has increased, survey data suggest a high level of satisfaction with the information Health Canada makes available to industry.

[10] The revised policy raised the threshold from 51% total direct costs to require "all or virtually all" Canadian content in a food product when making a "Product of Canada" claim. It also introduced criteria for distinct "Made in Canada" claims for foods that contain imported ingredients. Compliance monitoring is now taking place through label reviews and inspections.

Consumer products

In the area of consumer products, the CCPSA was developed and came into force in June 2011. This legislation modernizes Canada's consumer product safety regime and brings it into alignment with those of Canada's international trading partners and competitors.

A key provision of the CCPSA is a general prohibition related to the manufacture, importation, sale, or advertisement of consumer products that could pose a danger to human health or safety. In the evaluation of Consumer Products Activities, Health Canada representatives noted that although the general prohibition requires industry to ensure their products do not pose a danger to human health or safety, it can be challenging for industry to understand what this means concretely. Therefore, regulations may be used in cases where it is necessary to define explicitly the requirements that industry must meet. Further, Health Canada representatives mentioned that other approaches, such as standards, may also be used to define safety requirements. In the context of the safety net afforded by the general prohibition, the Department is currently in the process of developing guidelines for use in determining under what circumstances regulations should be established. The Department is also developing a Risk Management Framework that will provide an overall view of the principles and process that support risk management and compliance and enforcement decision making, and is exploring opportunities to provide guidance to industry stakeholders on the application of voluntary industry standards to help identify products that pose a danger to human health or safety.

The new CCPSA gave the Minister of Health the ability to order mandatory recalls of consumer products that pose a danger to health or safety and the ability to require tests and studies, and introduced a requirement for industry to report consumer-product-related incidents. Finally, the Act increased fines and introduced an Administrative Monetary Penalties (AMPs) system to provide a stronger deterrent against violations of the Act or the regulations that jeopardize the health and safety of the public.

To inform industry of its obligations under the new CCPSA, Health Canada has developed a number of guidance documents and has conducted extensive industry outreach activities, including updating its website and holding cross-Canada workshops, information sessions, and webinars with retailers, distributors, and manufacturers from a range of sectors. In 2013–2014, according to participant feedback forms, between 90% and 100% (target 95%) of industry stakeholders indicated that they were somewhat or very aware of and understood their legislative obligations following the sessions. Health Canada also provided training and advice through the Product Safety Laboratory to manufacturers, importers, and private laboratories interested in testing consumer products covered by the CCPSA.

The evaluation of Health Canada's Consumer Products Activities found that Health Canada's outreach activities have raised industry's awareness of its consumer product safety obligations under the CCPSA. However, there is a need for ongoing and continued outreach efforts, since industry lacks clarity about the new mandatory incident reporting and document retention requirements under the legislation, and there is a perception that some small and medium enterprises (SMEs) may not be aware of the CCPSA. Despite the success of the CCPSA industry

information sessions, only half of the respondents to the industry survey conducted as part of the evaluation rated the level of knowledge of the CCPSA within their company/organization as a "4" or "5 — excellent."

The majority of industry representatives were aware of other information about consumer products that Health Canada makes available to them, such as safety standards, guidance documents, information on enforcement actions, and information on post-market surveillance activities, and many have also used these sources of information. Overall, between 85% and 89% of industry representatives rated Health Canada's information on consumer products as "very" or "somewhat" useful, understandable, accessible, of high quality, and timely.

Health Canada also undertook a myriad of activities related to standards development and adoption for consumer products, including signing a Memorandum of Agreement (MOA) with the Standards Council of Canada to support the National Standards System. Other activities included contracting with the Canadian Standards Association (CSA) to support the development of an International Standards Organization (ISO) Guideline on Product Safety and drafting an ISO Recall Guidance Standard; participating in discussions for standard setting with the American Society for Testing and Materials (ASTM) International and the CSA; expanding trilateral collaboration on international standards to include Australia, as well as the United States (US) and the European Union (EU); leading various international standards committees; forming a task force through the National Public Safety Advisory Committee to develop a national approach to electrical product safety; and providing input on five improved ISO standards on determining noise from machinery.

Health Canada also undertook initiatives to increase industry understanding of existing regulations related to cosmetics and pesticides. With respect to cosmetics, although Health Canada intended to amend the *Cosmetic Regulations* and propose amendments to existing legislation, the Department has since decided not to pursue legislative/regulatory changes and is examining opportunities for improvement using non-regulatory approaches. However, Health Canada has updated the Cosmetic Ingredient Hotlist, which is an administrative tool used to communicate to manufacturers and others that certain substances, when present in a cosmetic, may contravene existing regulations, and published and/or updated various guidance documents to increase industry understanding of the existing regulations.

With respect to consumer pesticides, the PMRA undertook a number of activities to enhance industry understanding of its obligations under existing legislation and regulations. These activities included consultations and outreach with industry stakeholders involved in the manufacturing of domestic class products and in the importation and sale of consumer pest control products; conducting a multi-phased initiative focusing on rental property associations' knowledge about the safe use of pesticides in multi-unit buildings and their structural pest control obligations; and conducting outreach to provincial veterinary medical associations and related organizations on the importance of incident reporting. Other key activities included developing the Standard for Pesticide Education, Training and Certification in Canada, drafting a final version of the pesticide compliance and enforcement best practice guidance document, publishing guidelines for the registration of non-conventional pest control products, and developing a compliance and enforcement strategy for the antimicrobial-treated articles policy.

PMRA reporting on completed inspections indicates that industry understanding is reasonably high in some sectors (e.g., requirement for pest control operators to sell only registered and properly-labelled commercial and domestic class pest control products), while in other cases, there is low awareness of regulatory requirements (e.g., requirement to sell only registered and properly-labelled pet products).

Finally, although Health Canada intended to propose amendments to the existing REDA, or even propose new legislation, the Department has since decided not to pursue legislative/regulatory changes. Instead, Health Canada has opted to work in partnership with other federal regulators to make better use of existing resources and to capitalize on other existing legislation in the management of radiation-emitting devices.

Health products

In the area of health products, new regulations came into force in 2011 enabling sponsors to submit an Extraordinary Use New Drug (EUND) submission. EUNDs provide a pathway for the authorization of new drugs under extraordinary circumstances by allowing sponsors to use results of animal studies in conjunction with results from limited data from human safety and efficacy studies to support their drug submission. EUNDs are intended for extraordinary use in response to exposure to a chemical, biological, radiological, or nuclear substance where action is required to treat, mitigate, or prevent a life-threatening or other serious disease or disorder resulting from that exposure, or for preventive use in persons who are at risk of such exposure. The EUND Regulations will apply in situations such as the 2009 H1N1 pandemic, in which Health Canada had to rely on interim orders to approve H1N1 vaccines.

In November 2013, a new regulatory framework for active pharmaceutical ingredients (APIs) was developed and came into force, extending requirements for Good Manufacturing Practices and Drug Establishment Licenses to APIs. These regulations harmonize Health Canada's requirements with those of its counterparts in the US, the EU, Australia, and Japan, where Good Manufacturing Practices (GMP) requirements for APIs have been in place for approximately the past decade. Health Canada has also published several guidance and other documents related to the regulatory amendments.

More recently, in December 2013, the Government of Canada announced the *Protecting Canadians from Unsafe Drugs Act* (Bill C-17, Vanessa's Law).[11] The proposed legislation includes amendments to the *Food and Drugs Act* that would give Health Canada the power to recall therapeutic products from the market when they present an imminent or serious risk to health; compel drug companies to revise labels to clearly reflect health risk information; and compel drug companies to provide information for the purpose of assessing serious risks to health, and to compile information, conduct new tests or studies, and/or monitor experience, for the purpose of obtaining additional information. The amendments also include mandatory adverse reaction reporting requirements for healthcare institutions, and increased fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison. As part of the development of supporting regulations, Health Canada will launch industry outreach activities to inform industry of its obligations under the legislation.

[11] Bill C-17 passed second reading in March 2014.

Finally, Health Canada took a number of steps to improve the pre-submission meeting process with drug sponsors, including developing Standard Operating Procedures and publishing a guidance document for industry**.** The main objective of pre-submission meetings — which are optional at the discretion of drug sponsors — is to provide scientific and regulatory advice to industry at early stages of product development. Between 2008–2009 and 2013–2014, a total of 696 pre-submission meetings were requested by sponsors, and 515 meetings were held.

In the Human Drugs and Biologics program evaluations, most respondents to the industry surveys indicated that their firm has a strong understanding of Health Canada's submission requirements for pre-market approval. That said, industry representatives indicated that greater clarity may be required with respect to combination products, classification of emerging health products, and Health Canada's use of foreign reviews and foreign guidance in the drug review process. The biologics industry also perceives a need for greater clarity with respect to naming of subsequent entry biologics; classification of cell, tissue, and organ products; and regulation of stem cell and other emerging biologic therapies. Industry key informants also identified opportunities to improve the pre-submission meeting process by addressing long waits for meetings and ensuring that the principal submission reviewer is in attendance.

The Human Drugs and Biologics program evaluations found that industry survey respondents and key informants were generally satisfied with the information that Health Canada currently provides to industry. Furthermore, there appears to be a strong understanding of Health Canada's existing mandatory adverse reaction reporting requirements, as well as its requirements relating to GMP, establishment licensing, and regulatory compliance activities and related enforcement actions.

Food safety

In the area of food safety, the *Safe Food for Canadians Act* was passed in November 2012 and is expected to fully come into force in June 2015. This legislation is intended to protect consumers by targeting food tampering and other unsafe practices; implementing tougher penalties for activities that put health and safety at risk; allowing the CFIA to track food more effectively through all stages of preparation and distribution through enhanced inspections; and providing better controls over food imports.

The CFIA is currently working with consumer groups and industry to develop regulations under the *Safe Food for Canadians Act*. In June 2013, CFIA released a discussion paper, *Proposed Regulatory Framework for Federal Food Inspection*, which highlighted key elements of the proposed regulations under development and posed a number of questions to stimulate debate and generate ideas. Proposed regulations would include requirements for licences, food safety preventive controls, and traceability for all food traded inter-provincially, imported, and exported, including the growing and harvesting of fresh fruit and vegetables. The CFIA consulted with close to 2,100 stakeholders in person and through webinars and received 78 written submissions. Draft regulatory provisions for licensing and preventive controls are to be released in May 2014 for stakeholder feedback, along with draft interpretive guidelines for preventive controls that would apply to all food.

In addition, the CFIA is proposing the *Imported Food Sector Product Regulations*, which would require importers to register with CFIA for a licence, have a written recall plan, and keep records. The proposal is currently awaiting approval for publication. Development of industry guidance on the *Imported Food Sector Product Regulations* is contingent on their coming into force.

Since the FCSAP was implemented, the CFIA has published several guidance documents for industry, including the *Guide to Food Safety* and the *General Principles of Food Hygiene, Composition and Labelling*. The former is a voluntary tool that provides the Canadian food industry with generic guidance on how to design, develop, and implement effective preventive food safety control systems, while the latter is an assessment tool to assist food manufacturers in establishing manufacturing practices that maintain food safety and meet regulatory requirements.

Health Canada published its *Regulatory Modernization Strategy for Food and Nutrition* (RMSFN) in 2009, which outlines a plan and vision for modernizing the regulatory system for food. As part of regulatory modernization, Health Canada published 23 food additive regulatory amendments in Canada Gazette Part II and 34 food additive Interim Marketing Authorizations (IMAs) in Canada Gazette Part I. Regulatory amendments related to "Enhancing labelling for food allergens, gluten sources and added sulphites" were published in February 2011 in Canada Gazette Part II. Health Canada also developed or modified a number of policies (e.g., unpasteurized juice/cider products).

Finally, Health Canada worked on increasing its engagement with industry stakeholders. It engaged industry on proposed risk-management strategies to reduce exposure to OTA in food, and consulted industry on guidance documents and microbiological criteria related to E. coli O157 in raw beef and Cronobacter sakazakii in powdered infant formula. Industry stakeholders are also represented on the FEAC.

Immediate Outcome #3 and #4: Improved surveillance, information, and knowledge sharing related to products, food, and adverse health incidents

This section provides a combined discussion of two of the immediate outcomes in the FCSAP logic model, namely: "improved information, data and knowledge sharing related to products, food and associated adverse health incidents" and "improved monitoring of products, food and associated adverse health incidents." These two outcomes were combined into a single immediate outcome ("improved surveillance, information, and knowledge sharing related to products, food and adverse health incidents"), since very similar information was available as evidence in support of both outcomes.

FCSAP partners have taken several important steps to improve surveillance, information, and knowledge sharing (including with international partners) related to health and consumer products, food, and adverse health incidents. Examples include implementing mandatory industry reporting of consumer product incidents, introducing legislation to require healthcare institutions to report adverse drug reactions, improving post-market surveillance for health products, and improving the ability to identify, assess, and prioritize potential food safety hazards.

Consumer products

In the area of consumer products, mandatory industry reporting of consumer product incidents was implemented as part of the CCPSA, which came into force in June 2011. Health Canada developed and implemented the Consumer Product Safety Program (CPSP) Case Management System (CCMS) to improve its ability to track and manage its surveillance activities, including its response to incident reporting. It also implemented a process and dedicated divisions to handle the monitoring and triage of mandatory incident reporting and to conduct assessments of high-priority consumer product incident reports.

Between the introduction of the CCPSA in June 2011 and March 31, 2014, Health Canada received a total of 5,109 incident reports, of which 67% were from industry and 33% were from consumers. In the last year of this period (2013–2014), 88% of 1,460 incident reports received (target 90%) were triaged within service standards. Of the total, 44% were subject to risk management, 24% were subject to risk assessment, and 21% were subject to surveillance.

With respect to cosmetics, Health Canada developed information systems to improve processing of cosmetic notifications submitted by industry and identify non-compliant products.[12] Business process re-engineering has eliminated a backlog in cosmetic notifications, from 31,000 in 2008 to effectively zero in 2010. To further improve the process, work was undertaken on a new chemical products database, which is expected to allow notifications in a more automated fashion; electronic submission of cosmetic notifications has been implemented.

Health Canada undertook a variety of initiatives with international partners related to consumer products. Major initiatives included implementing an action plan in October 2011 with the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of China, with the objective of cooperating to protect consumers' safety and health; creating a joint pilot alignment initiative to explore harmonization of technical requirements on certain consumer products with the US, the EU, and Australia; participating in the first North American Consumer Product Safety Summit in September 2011 with the US and Mexico; participating in the Organisation of Economic Co-operation and Development's Consumer Policy Working Party on Consumer Product Safety; providing input into the Canada–Europe Comprehensive and Economic Trade Agreement negotiations; participating as a member of the Scientific Oversight Committee, which oversees the International Electromagnetic Frequency (EMF) Project, and undertaking several studies as part of the EMF Project; and co-founding and participating in the International Cooperation on Cosmetic Regulation with the US, the EU, and Japan.

[12] While incident reporting is not mandatory for the cosmetics industry, manufacturers and importers of a new cosmetic product must notify Health Canada about it within the first 10 days that it is available for sale in Canada.

PHAC implemented several projects to improve product-related injury surveillance and risk assessment. As already noted, the Agency improved injury data by modernizing the CHIRPP and launching a real-time secure surveillance system to identify emerging hazards, injury trends, illnesses, and deaths related to consumer products and other risk factors. Other examples include expanding the number of hospitals participating in the CHIRPP to 17 by the end of 2012–2013; using CHIRPP data in reports on child and youth injuries; collaborating with Statistics Canada on the Canadian Coroner and Medical Examiner Database (CCMED); adding a module of questions on injury and consumer product-related falls to the Canadian Longitudinal Study on Aging (CLSA); and conducting risk assessments on patterns and trends of injury using these data sources. These resulted in strengthened networks and improved knowledge sharing, as well as improved ability to conduct product-related injury surveillance and risk assessment. In the upcoming year, an eCHIRPP app will be developed and made available to the hospitals to increase efficiency of data capture.

While some collaboration and information sharing takes place between PHAC and Health Canada (primarily the Surveillance and Analysis Division with the Consumer Products Safety Directorate), the evaluation of Consumer Products Activities found that there are opportunities to strengthen relationships and improve data sharing between these parties, as well as with external stakeholders such as fire chiefs, poison control centres, and other regulatory bodies. Such collaboration may help Health Canada and the Agency to integrate additional proactive signal detection activities into their surveillance work.

Health products

In the area of health products, given the increasing costs of the submission review process and substantial backlogs stemming from the increasing complexity and volume of submissions, two-year interim funding under the FCSAP was intended to enable Health Canada to speed up the submission review process, pending implementation of a new cost recovery framework.

Between 2008–2009 and 2010–2011, improvements were made in the timeliness of submission review performance for some submission types, although there were ongoing challenges in meeting performance targets in the case of pharmaceuticals (especially generics). In April 2011, a new cost recovery framework for drugs and medical devices was implemented with the coming into force of the new *Fees in Respect of Drugs and Medical Devices Regulations*, and it is expected to further enhance Health Canada's ability to review drug submissions in a timely manner.[13]

Health Canada undertook several initiatives to address the long-standing problem of under-reporting of adverse drug reactions by healthcare professionals, including publishing a guidance document to assist health professionals in reporting adverse events; providing education activities on adverse reaction reporting to health professionals through employees working in the regions; and engaging Accreditation Canada, the body responsible for accrediting Canadian hospitals and other healthcare institutions, to establish national adverse reaction reporting standards within the existing accreditation system, which were released in January 2013.

[13] Submission review performance under the new cost recovery framework is being monitored as part of the performance measurement strategy for that initiative.

More recently, the proposed Bill C-17 includes an amendment introducing mandatory reporting of adverse reactions by healthcare institutions. Once implemented, this provision will increase the number of Canadian adverse reaction reports submitted to Health Canada, thus increasing the volume of data available for analysis and detection of potential safety signals.

Health Canada has also taken steps to implement a more structured, comprehensive, and systematic approach to pharmacovigilance planning and risk-management planning. In 2009, Health Canada adopted International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2E on pharmacovigilance planning and established interim requirements for risk management plans (RMPS) based on the guidelines of the European Medicines Agency (EMA). Although originally conceived as separate, pharmacovigilance planning is now considered a component of risk-management planning. The number of RMPs submitted by industry has been steadily increasing on an annual basis.

Health Canada has enhanced its existing program for collecting and reviewing Periodic Safety Update Reports (PSURs) by introducing two levels of PSUR review and setting performance standards for review. Most recently, it announced that it was moving toward implementing ICH E2C(R2) guidance and Periodic Benefit Risk Evaluation Report (PBRER) reporting in order to align with international best practices and reduce the reporting burden on industry. Since March 1, 2013, market authorization holders (MAH) may submit a PBRER to satisfy the requirement in C.01.018 of the *Food and Drug Regulations* to prepare an annual summary report of adverse drug reaction data.

While Health Canada intended eventually to propose legislative and regulatory amendments to compel manufacturers to submit RMPs and PSURs, it has not yet pursued this course. However, Bill C-17 gives Health Canada the authority to impose “terms and conditions” on market authorizations, which could include a requirement to submit an RMP. Bill C-17 also includes a provision intended to improve Health Canada’s ability to collect post-market safety information. In particular, the provision gives Health Canada the authority to require persons to provide information within their control for the purpose of assessing serious risks to health, and to require manufacturers to compile information, conduct new tests or studies, and/or monitor experience, for the purpose of obtaining additional information.

Although this initiative was not originally included as a strategy within the Health Products component of the FCSAP, Health Canada also received FCSAP funding for its Post Market Reporting Compliance inspection program — now called the Good Pharmacovigilance Practices (GVP) inspection program. In August 2013, the new guidance document *Good Pharmacovigilance Practices (GVP) Guidelines* (GUI-0102) was implemented. That document provides interpretive guidance to industry on the expectations of inspectors with respect to the adverse drug reaction and post-approval reporting requirements when conducting GVP inspections. These expectations include systems related to the preparation of annual summary reports. In addition, there is a new expectation for MAH and importers to have a self-inspection program in place. In 2013–2014, over 80 GVP inspections were conducted.

Finally, CIHR established the DSEN as Canada's first national post-market drug safety and effectiveness virtual network**.** The DSEN is intended to generate and promote the use of evidence on post-market drug safety and effectiveness (PMDSE) and contribute to increasing the capacity to undertake quality PMDSE research within Canada. The evidence generated by DSEN-supported research is intended to enable key healthcare decision makers to better determine safety and effectiveness profiles for drugs and to implement measures that will promote their optimal use. Management and performance protocols and procedures have been developed, including the establishment of seven research teams, working in five methodological areas, and involving approximately 170 researchers across Canada. Research on 36 queries, out of 53 received, has been prioritized. Of these, seven queries have been answered while research is ongoing for 22 and seven more are awaiting funding for research to start as of March 31, 2013.

To date, while there is limited evidence of the extent to which DSEN research has informed decision-making needs, this should be considered in the context of the relatively recent launch of the DSEN program, the small number of completed queries, and the time required for the response to a query to influence decision making. To date, Health Canada has used data generated in response to a DSEN query to confirm a risk decision and assist in formulating recommendations to strengthen the labelling of second-generation antipsychotics regarding cardio-metabolic adverse reactions in children and adolescents. The research findings also prompted Health Canada to review the extent to which antipsychotics were prescribed to First Nations and Inuit children and whether that number was increasing. Evidence provided in response to another query may have informed policy direction related to drugs prescribed to children and pregnant nursing women. Overall, Health Canada representatives indicated that while the contribution of DSEN-funded research to Health Canada drug regulatory and/or policy decision-making activities has not yet reached its full potential, DSEN research is anticipated to complement Health Canada's strengthened authorities to address uncertainties about the safety and effectiveness of drugs.

Food safety

The CFIA, Health Canada, and PHAC took numerous steps to improve their ability to identify, assess, and prioritize potential food safety hazards through improved data collection and risk mapping, with a focus on priority areas of imported food ingredients, produce, mycotoxins, and undeclared allergens. A Health Canada/CFIA Working Group was established for targeted surveys, risk mapping, and prioritization, and a risk mapping model and tool was developed and implemented. Between 2008–2009 and 2012–2013, the CFIA completed a total of 188 targeted surveys in chemistry, microbiology, and allergens. The CFIA also populated an institutional version of the United States Food and Drug Administration (FDA) iRisk tool, which ranks food hazard and commodity combinations based on their human health risk level, and collaborated with Health Canada, PHAC, the Ontario Ministry of Agriculture and Food, and three universities on the development of a Multi-Factorial Risk Prioritization Framework tool.

The CFIA has pursued international efforts to further food safety mitigation approaches. Formal discussions have been held with China, Guatemala, Mexico, the US, and India, based on anticipated and current trade volumes, and Memoranda of Understanding (MOUs) have been established with China and Guatemala.

During the same period, Health Canada contributed expertise in food chemical safety and food microbial safety to the CFIA's targeted surveys and risk mapping activities and conducted risk assessments of various foodborne pathogens. Health Canada collaboratively updated risk profiles (e.g., Mycobacterium avium subsp. Paratuberculosis), carried out work in the assessment of options for risk profiling tools, and exchanged information with international counterparts (USDA, USFDA). Health Canada established the Food and Environmental Parasitology Network (FEPN) to identify and communicate risks and research/surveillance gaps. The joint Health Canada–PHAC Food Virology Reference Centre for Canada continued to build the ViroNet Canada database and network in an effort to facilitate real-time tracking of viruses in Canada.

In addition, Health Canada updated and published 49 methods to enhance the ability to detect microbiological hazards in the food supply. Health Canada collaborated with several national and international partners, including the CFIA, to validate, develop, disseminate, and exchange advice on laboratory testing methods (allergens, natural toxins, emerging foodborne pathogens, and bioactives), and it finalized a Canada–US risk assessment on raw milk soft and semi-soft cheese that will be used to guide policy development to address safety concerns associated with the consumption of these cheese products. Health Canada made use of international chemical liaison groups on food safety for information sharing and issue identification and completed a risk/exposure assessment of Deoxynivalenol (DON) to develop a Canadian guideline for its presence in Canadian foods.

On the international front, Health Canada entered into a number of formal arrangements with major regulatory counterparts to enhance collaboration, support rapid information sharing, and facilitate work sharing opportunities. As part of Codex work, Health Canada prepared and/or presented a number of documents (e.g., the Canadian summary report from the 42nd session of the Codex Committee on Food Additives, the Melamine Codex Maximum Level [ML] document at the 4th session of the Codex Committee on Contaminants in Food [CCCF], the Codex discussion paper on the management of DON in the food supply at the 5th session of the CCCF). The Executive Board of the World Health Organization (WHO) adopted the resolution Advancing Food Safety Initiatives, led by Health Canada and other Canadian partners, which aims to advance global food safety initiatives and augments the recommendations in earlier resolutions.

PHAC carried out work in risk profiling, laboratory method development, and knowledge synthesis and dissemination. PHAC used FCSAP funds to maintain and enhance two important, integrated surveillance systems designed specifically to address food safety issues and examine source attribution. First, it expanded FoodNet Canada (previously C-EnterNet) to a second location (British Columbia) and expanded FoodNet Canada surveillance activities to include sampling of high-risk imported products (leafy greens, berries, and herbs, with sliced fruit to be added this year). Second, PHAC carried out integrated surveillance of antimicrobial resistance in the food chain through the CIPARS, which continued sampling in seven provinces, including selected imported meats, domestic and imported seafood, and selected imported produce. Both FoodNet Canada and CIPARS contribute valuable population-based information that is not available from other sources.

PHAC developed and rolled out next-generation laboratory fingerprinting for PulseNet Canada (e.g., Multi-Locus Variable Number of Tandem Repeat [VNTR] Analysis or MLVA for E. coli); an ongoing assessment of new molecular characterization methods for differentiation of foodborne pathogens is being carried out to improve accuracy and turnaround time.
PHAC continues to expand the capacity of its web-based Outbreak Summary Reporting System, which allows standardized dissemination of the results of disease outbreak investigations. The application has been implemented in British Columbia, Manitoba, Nova Scotia, Newfoundland and Labrador, and Prince Edward Island. Recently, a contract was completed to upload all available historical data from Manitoba, thus improving the completeness of this provincial dataset. Ontario has expressed its willingness to participate at a provincial level, and PHAC is currently working with the Province to integrate its data into the system. A recently-negotiated memorandum with Quebec for data sharing for a separate application is being reviewed and considered for an amendment to include the sharing of provincial outbreak data with the Outbreak Summary Reporting System.

As of March 31, 2014, there were over 3,300 outbreak summaries in the system. The first report of outbreak summaries data, covering outbreaks reported in the system from 2008 to 2012, will be released to participating provincial public health partners in June 2014. PHAC expects the outbreak summaries report to showcase the utility of the application and data for supporting activities related to outbreak response and source attribution. PHAC also expects the report to be beneficial as a marketing tool for encouraging additional provinces and territories to participate.

A more fulsome data quality, analysis, and reporting plan is being developed and will be implemented in 2014–2015. This plan should improve accessibility to and utility of the data within the application and will also establish a regular reporting and products cycle.

Finally, Health Canada and PHAC collaborated on joint risk-assessment activities. For example, in 2012–13, they updated an existing risk-assessment model to determine risks to Canadians from consumption of E.coli O157 in mechanically tenderized beef (MTB); the model had previously been developed by PHAC to quantify the impact of specific interventions on risk. The risk model developed by PHAC researchers was used to provide scientific input into the decision by Health Canada to implement labelling rules for MTB. The PHAC model was used in collaboration with Health Canada to show a fivefold increase in risk from MTB products when compared to intact cuts of beef. Health Canada has now amended the Food and Drug Regulations by introducing the following elements: a definition of MTB, a requirement that all MTB sold in Canada be labelled clearly with information that it has been mechanically tenderized, and safe cooking instructions.

Immediate Outcome #5: Improved ability to respond when unsafe products and food are identified

FCSAP partners have undertaken a number of legislative, regulatory, and other initiatives to improve their ability to respond when unsafe products and food are identified. Examples relate to the power to order mandatory recalls of products that pose a danger to health or safety, increased fines and penalties for violations, enhanced inspections, and increased resources for compliance and enforcement.

Consumer products

In the area of consumer products, the new CCPSA introduced the new general prohibition, gave the Minister of Health the ability to order mandatory recalls of consumer products that pose a danger to health or safety and the ability to require tests and studies, and introduced a requirement for industry to report consumer product-related incidents. The Act also increased fines and introduced an AMPs system to provide a stronger deterrent against violations that jeopardize the health and safety of the public.

To date, Health Canada has used the authority to order mandatory recalls in two small powerful magnet sets recalls and has issued two orders for tests and studies. To date, Health Canada has not issued fines or penalties under the CCPSA. Health Canada representatives indicated that this is due to success in integrating mandatory recalls and other orders in the CCPSA into the existing "stepwise" enforcement model used in administering and enforcing product safety legislation. Industry stakeholders found to be in non-compliance are in typical cases first informed and educated about their requirements under the CCPSA, and then asked to voluntarily bring their products into compliance. Health Canada representatives indicated that in the vast majority of cases, this is sufficient to achieve rapid compliance.

Health Canada representatives noted that the CPSP is moving toward performance indicators that measure how quickly it responds when non-compliance is identified through the Cyclical Enforcement Program (CEP) or through incident reporting. These performance indicators consist of service standards for select risk-management actions. In 2013–2014, on average, the CPSP responded to non-compliance within service standards 97% of the time.

Health Canada increased the level of resources, including the number of inspectors, it devoted to compliance and enforcement activities related to consumer products. Specifically, Health Canada expanded the coverage of its CEP from 23 to 35 product categories. Additionally, it developed reference manuals for each product category included in CEP, conducted recall monitoring, prepared guidelines for recall effectiveness and conducted recall effectiveness monitoring, and drafted a Compliance and Enforcement Strategy for Consumer Products and Cosmetics. Health Canada is implementing a CEP for consumer products that are subject to product or hazard-specific regulations under the CCPSA, and a cyclical enforcement strategy for radiation-emitting devices is also being developed. The administrative function of the REDA was strengthened through the development of seven Compliance and Enforcement Standard Operating Procedures for nine products under REDA.

PMRA undertook several initiatives to monitor and enforce industry compliance with the PCPA. It implemented a compliance verification program for consumer product vendors, introduced a compliance verification program targeting vendors of unregistered international pest control products, and implemented a cyclical compliance monitoring program. It also developed a compliance and enforcement policy guideline, held a National Pesticide Compliance Workshop, and developed a database to track compliance activities.

Health products

In the area of health products, the proposed Bill C-17 includes amendments to the *Food and Drugs Act* that would give Health Canada several new authorities to improve its ability to respond when unsafe health products are identified, including the power to recall therapeutic products from the market when they present an imminent or serious risk to health; the power to compel drug companies to revise labels to clearly reflect health risk information; and increased fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison.

Additionally, through the National Border Integrity Program, Health Canada strengthened regulatory oversight of imported health products. The objective of the Border Integrity Program is to strengthen Health Canada's ability to make and support admissibility decisions at the border relating to health products. The program engages in compliance and enforcement actions to mitigate potential risks to the health of Canadians. These actions include activating Canada Border Services Agency (CBSA) targets for non-compliant importers, recommending the refusal of non-compliant products, recommending the release of compliant products, contributing to public warnings, and issuing compliance letters to importers. Health Canada works closely with the CBSA to verify that imported health products meet the regulatory requirements for the *Food and Drugs Act* and associated Regulations. The CBSA can refer health products suspected to be in violation of import requirements to Health Canada to undergo an admissibility determination for entry into Canada. Products that are deemed non-compliant with the legislative and/or regulatory requirements are recommended for refusal into Canada. The National Border Integrity Program is engaged in the development of the Single Window Initiative led by the CBSA, which is intended to create an automated, risk-based approach to identifying high-risk goods and accelerating the flow of low-risk goods. In 2010–2011 and 2011–2012, a total of 64,976 shipments of health products were referred by the CBSA to the Health Products and Food Branch Inspectorate of Health Canada to undergo an admissibility determination for entry into Canada.

Food Safety

In the area of food safety, the CFIA took steps to increase its oversight of high-risk sectors through verification of domestic and imported industry food safety control systems. A total of 1,632 inspection activities were conducted in the Imported and Manufactured Food Program and the Fresh Fruit and Vegetables Program between 2008–2009 and 2012–2013, with another 463 the following year. The focus of inspection efforts is evaluation of imported food ingredients, produce safety, evaluation of mycotoxins in cereals, and undeclared allergens.

Additionally, to better prevent unsafe food from entering Canada, the CFIA increased the number of port-of-entry or border blitzes undertaken each year, from 22 in 2008–2009 to 97 in 2013–2014, with an overall total of 356 border blitzes carried out over this period. The CFIA also implemented a more comprehensive import control and tracking program for the non-federally registered sector by aligning its approach to coding products with international codes and standards. As of March 31, 2013, implementation of the revised approach was completed for most food commodities, with the exception of alcoholic beverages.

Finally, the CFIA increased its capacity to respond to an increase in the number of food safety investigations and food recalls due to enhanced surveillance testing. The number of recalls and incidents has increased since 2008–2009, correlating with an increasing number of activities associated with Enhanced Inspection of High Risk Sectors. In total, there were 1,724 recalls conducted within the Imported and Manufactured Food Program and the Fresh Fruit and Vegetables Program between 2008–2009 and 2012–2013.

4.4.2 To what extent have the intermediate outcomes been achieved?

Intermediate Outcome #1: Increased appropriate selection and safe use of products and food

In the intermediate term, FCSAP activities are expected to result in increased appropriate selection and safe use of products and food. There is no information on which to base conclusions about the extent to which this outcome may have been achieved. Furthermore, none of the FCSAP partners have assessed the extent to which their activities may have contributed to this outcome.

Intermediate Outcome #2: Increased industry compliance with regulatory requirements

In the intermediate term, FCSAP activities are expected to result in increased industry compliance with regulatory requirements. Based on completed inspections and compliance monitoring activities, industry compliance with established regulations is reasonably high, although some product categories and industry sectors are exceptions. For legislative and regulatory changes that have very recently come into force, it is premature to draw conclusions about industry compliance.

Consumer products

It is not possible to determine the overall industry compliance rate with Health Canada's regulatory requirements for consumer products since compliance and enforcement activities intentionally target higher risk instances of suspected non-compliance as part of its Cyclical Enforcement Plan (CEP). For the product categories examined in the Consumer Products activities evaluation, enforcement action was taken on 100% of non-compliant products, which included information letters, stop sales, and voluntary recalls.

Compliance data for fiscal years 2008–2009 to 2010–2011 suggest that prior to implementation of the CCPSA, industry compliance with regulatory requirements was generally high (between 90% and 100%) for most product categories. However, some categories had compliance rates under 10%, including utility lighters (7%), carriages and strollers, cribs and cradles, and tents (all 0%). Case studies completed as part of the evaluation of Consumer Products Activities suggest there is ongoing non-compliance in relation to several product categories, including children's jewellery; cribs, cradles, and bassinets; and corded window coverings.

More recent data from Health Canada's CEP, which targeted 16 regulated products with identified hazards in 2011–2012 and 2012–2013, suggest that compliance continues to be an issue in the cribs, cradles, and bassinets (0%) and children's jewellery (26%) categories. Low rates of compliance were also found for matches (27%) and lighters (33%). For most other products, compliance rates were generally over 90%.

With respect to consumer pesticides, reporting on PMRA's compliance monitoring activities indicates that depending on the types of products involved, industry compliance ranges from 52% among vendors, importers, and distributors of international pest control products to 82% among pest control operators selling commercial and domestic class pest control products.

Health products

For health products, the available information suggests a high level of industry compliance with regulatory requirements for health products. Of the inspections conducted, the compliance rate generally exceeds 90% for clinical trial inspections, GMP inspections, and GVP inspections. For example, in 2012–2013, compliance rates were 96% for Good Clinical Practices (GCP), 95% for GMP, and 100% for GVP. That said, GCP inspections were not explicitly targeted by the FCSAP, and it is premature to assess the extent of industry compliance with GMP requirements for APIs, since these regulations came into effect very recently, in November 2013.

For imported health products, data from the National Border Integrity Program show that in 2010–2011 and 2011–2012, a total of 64,976 shipments of health products were referred by the CBSA to the Health Products and Food Branch Inspectorate of Health Canada to undergo an admissibility determination for entry into Canada. Of these, Health Canada recommended to the CBSA that 46,850 shipments (72%) be refused entry due to non-compliance with Canadian regulations, including some that were refused because they were suspected of or confirmed to contain counterfeit product. While this may seem like a high rate of non-compliance, shipments are specifically targeted for inspection on a risk basis. The risk-based approach is applied to achieve the greatest impact and efficiency of resources by expediting border processing of compliant health products while systematically assessing the compliance of health products that are suspected to be in violation of the *Food and Drugs Act* and associated Regulations. Most border refusals — both in absolute and percentage terms — involve prescription drugs (as per the Prescription Drug List, Products for Human Use). Prescription drugs are also most likely to be refused due to being suspected or confirmed as counterfeit product.

Food safety

In the area of food safety, as already mentioned, the CFIA took steps to increase its oversight of high-risk sectors through enhancements to its inspection program and an increase in the annual number of border blitzes. In 2012–2013 and 2013–2014, the inspection program found non-conformity rates (i.e., non-technical violations associated with a potential health risk) of 14% and 24%, respectively. Compliance information related to the border blitzes exists at the regional level but is non-standardized, making it difficult to compile a national report on these activities.

Intermediate Outcome #3: Improved risk assessment and mitigation

In the intermediate term, FCSAP activities are intended to improve risk assessment and risk mitigation by the partners. In all product areas, FCSAP partners have undertaken new initiatives, such as enhanced surveillance and new requirements for incident and adverse reaction reporting, that will enhance the information available to them for the purpose of assessing product risks and identifying safety issues requiring risk mitigation or corrective action.

Consumer products

For consumer products, relevant initiatives include the following:

- the new requirement under the CCPSA for mandatory industry reporting of consumer-product-related incidents;
- the implementation of a new information system to improve Health Canada's ability to track and manage its surveillance activities, including its response to incident reporting;
- the implementation of a process and dedicated divisions to handle the monitoring and triage of mandatory incident reporting and to conduct assessments of high-priority consumer product incident reports;
- the expansion of the CEP to additional product categories; and,
- enhanced product-related injury surveillance.

Health products

For health products, relevant initiatives include the following:

- the introduction of GMP and Drug Establishment Licenses (DEL) requirements for APIs
- enhancements to the existing RMP and PSUR programs;
- the proposed provisions in Bill C-17 to compel drug companies to conduct post-market safety studies and to introduce mandatory serious adverse reaction reporting for healthcare institutions; and,
- the establishment of the DSEN as Canada's first national PMDSE virtual network, which is intended to generate and promote the use of research evidence to enable healthcare decision makers to better determine safety and effectiveness profiles for drugs and implement measures that will promote their optimal use.

Food safety

In the area of food safety, the most important initiatives include the following:

- improved identification, assessment, and prioritization of potential food safety hazards through improved data collection and risk mapping;
- ongoing health risk assessments, updates to risk profiles of various foodborne pathogens, and updates to methods to enhance the ability to detect microbiological hazards in the food supply; and,
- ongoing surveillance, risk profiling, laboratory method development and knowledge synthesis, and dissemination activities.

Intermediate Outcome #4: Improved early response to unsafe products

In the intermediate term, FCSAP activities are intended to improve the ability of the FCSAP partners to respond early when unsafe products are identified. In all product areas, FCSAP partners have undertaken new initiatives, such as the power to order recalls of unsafe products, enhanced inspections and compliance monitoring activities, and increased fines and penalties for violations, that will enhance their ability to respond early through taking action when unsafe products are identified.

Consumer products

For consumer products, these initiatives include the following:

- Health Canada's new authority under the CCPSA to order mandatory recalls of consumer products that pose a danger to health or safety, as well as the authority to require tests and studies;
- the increase in the level of resources devoted to consumer-product-related compliance and enforcement activities, and the expansion of the CEP from 23 to 35 product categories;
- the development and implementation of new service standards for select risk-management actions to measure response performance when non-compliance is identified; and,
- the development and implementation of a cyclical enforcement strategy and a cyclical compliance monitoring program for radiation-emitting devices and consumer pesticides, respectively.

Health products

For health products, these initiatives include the following:

- proposed amendments to the *Food and Drugs Act* that would give Health Canada the power to recall therapeutic products from the market when they present an imminent or serious risk to health and compel drug companies to revise labels to clearly reflect health risk information;
- proposed amendments to the *Food and Drugs Act* that would increase fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison; and,
- increased resources for regulatory oversight of imported health products under the National Border Integrity Program.

Food safety

In the area of food safety, relevant initiatives include the following:

- the new *Safe Food for Canadians Act,* which will target food tampering and other unsafe practices; implement tougher penalties for activities that put health and safety at risk; allow the CFIA to track food more effectively through all stages of preparation and distribution through enhanced inspections; and provide better controls over food imports; and,

- enhanced inspection of high-risk sectors, improved tracking of imported foods, and increased capacity to respond to an increase in the number of food safety investigations and food recalls due to enhanced surveillance testing.

4.4.3 To what extent has the longer term outcome been achieved?

In the longer term, FCSAP activities are intended to lead to reduced adverse health incidents related to health and consumer products (including cosmetics, pesticides, and radiation-emitting devices) and food. While FCSAP activities have certainly contributed to reducing adverse events associated with these products, finding concrete evidence of this outcome is challenging.

Consumer products

In the area of consumer products, FCSAP activities such as mandatory incident reporting for industry, efforts to raise public awareness of the ability for consumers to voluntarily report incidents, and the power to issue mandatory recalls of consumer products should lead to a reduction in adverse health incidents associated with these products. While the data show that the number of reported incidents has been increasing, this may simply reflect an increase in reporting due to the mandatory incident reporting provision in the CCPSA, and not necessarily an increase in adverse health incidents.

Health products

Similarly, in the area of health products, FCSAP activities such as removing unsafe products from the market through recalls and recommending the refusal of entry into Canada of products deemed non-compliant with the legislative and/or regulatory requirements should reduce the availability of non-compliant health products, thereby contributing to health risk mitigation. Data show that the number of domestic adverse reaction reports submitted to Health Canada has been increasing steadily over time, including since the FCSAP was implemented. However, this is likely due to the greater number and variety of products on the market, along with increased recognition of the need or obligation to report adverse reactions, and is not necessarily indicative of an increase in unsafe products. In fact, the proportion of adverse reaction reports that are classified as “serious” — i.e., that require in patient hospitalization or prolongation of existing hospitalization, that cause congenital malformation, result in persistent or significant disability or incapacity, are life threatening or result in death — has remained stable since 2001, accounting for just over two thirds of all reports submitted each year.

Food safety

Finally, in the area of food safety, FCSAP activities such as improved identification of potential food safety risks and enhanced inspection of high-risk sectors should contribute to a reduction in adverse health incidents associated with food. While the available evidence, from PHAC’s FoodNet Canada and Notifiable Disease On-Line, shows a small decrease in the number of reported enteric diseases over the past decade, which is matched by a small decrease in the number of food safety investigations and recalls carried out by the CFIA over the same period, it is not possible to infer a relationship between these two trends.

4.4.4 Performance: Issue #5 — Demonstration of economy and efficiency

The proposed governance structure for the FCSAP, consisting of three task forces with oversight for Health Products, Consumer Products, and Food, was implemented with limited success due in part to the prior existence of committees with overlapping mandates and membership. At the end of the five-year lifespan of the FCSAP, oversight of Health Products activities was transitioned to the HPFB Executive Committee, and oversight of Food activities was transitioned to the Interdepartmental Director General Committee on Food Safety. The Consumer Products Task Force, led by the HECSB, remains active.

Over the period of time covered by this evaluation, performance measurement and financial reporting systems necessary to support analysis of efficiency and economy were not in place within the FCSAP departments and agencies, although progress is being made to improve performance measurement and financial reporting in order to inform the assessment of efficiency and economy in future. For the purpose of this evaluation, the assessment of efficiency and economy is limited to a comparison of planned and actual expenditures. Actual spending on the FCSAP was approximately 83% of planned ($405.3 million compared to $489.7 million) between 2008–2009 and 2012–2013.

4.4.5 Governance

Governance is largely concerned with allocating resources within a program or initiative, monitoring the achievement of results, and using this information to inform future decision making. As such, the way in which a program or initiative is governed has implications for the efficiency and economy with which program activities are delivered.

The FCSAP Governance Accountability Framework laid out a proposed governance structure for the interdepartmental oversight of FCSAP consisting of task forces for each of the Health Products, Consumer Products, and Food Safety components. This governance structure was implemented with limited success. This was due, in part, to the prior existence of committees with overlapping mandates and membership. In the case of Health Products, the role of the task force was integrated with the existing Legislative and Regulatory Modernization Steering Committee (LRMSC). In the case of Food Safety, trilateral discussions continued within pre-existing fora — as per the Food Safety and Nutrition Committees established by the 1999 Health Canada–CFIA MOU — as well as through semi-annual Task Force meetings focusing on FCSAP objectives. A Consumer Products Task Force was established.

Over the time frame of the FCSAP, various branches within Health Canada provided planning and reporting oversight and led the FCSAP Coordinating Committee with representation from the Health Products, Consumer Products, and Food Safety components of the FCSAP. At the end of the five-year lifespan of the FCSAP, oversight of Health Products activities was transitioned to the HPFB Executive Committee, and oversight of Food activities was transitioned to the Interdepartmental Director General Committee on Food Safety, which reports to the Deputy Head Committee on Food Safety, as per the April 2008 CFIA–Health Canada–PHAC *MOU for common issues related to Human Health*. The Consumer Products Task Force, led by the HECSB, remains active.

Regarding overall oversight and reporting for the FCSAP, since 2012, HPFB has taken on the role at the portfolio level to coordinate the activities and financial reporting from all the partners engaged in the FCSAP. This reporting takes place through annual reports to Treasury Board on plans, spending, and results, as well as through Reports on Plans and Priorities and Departmental Performance Reports, which are tabled in Parliament each year.

4.4.6 Demonstration of efficiency and economy

The demonstration of efficiency and economy, according to the Treasury Board *Policy on Evaluation* (2009), is based on the assumption that departments have standardized performance measurement systems and that financial reporting systems link information about program costs to specific inputs, activities, outputs, and expected results. Over the period of time covered by this evaluation, performance measurement and financial reporting systems necessary to support analysis of efficiency and economy were not in place within the FCSAP departments and agencies. However, some progress is being made to improve performance measurement and/or financial reporting in order to inform the assessment of efficiency and economy in future. For example:

- HPFB recently restructured its financial reporting to comply with Treasury Board requirements, which should improve the accuracy of this information and facilitate future analysis of efficiency and economy.
- The Consumer Products Task Force approved an updated Consumer Products Logic Model in April 2014. The logic model will be used to form the basis for standardizing inputs, activities, outputs, and expected results to support future evaluations of the Consumer Products program activity within Health Canada's Program Alignment Architecture.

For the purpose of this evaluation, the assessment of efficiency and economy is limited to a comparison of planned and actual expenditures. Table 1 below summarizes planned and actual spending on the FCSAP, as this information appears in the annual reports to Treasury Board Secretariat on plans, spending, and results for fiscal years 2008–2009 through 2012–2013. Beginning in 2013–2014, ongoing spending of $125.0 million was planned.

Overall, actual spending over the five-year period was approximately 83% of planned ($405.3 million in actual spending compared to $489.7 million planned).[14] Reporting indicates that variances in spending were related to challenges with staffing, found efficiencies, and changes to some of the activities.

[14] It is important to note that the reports to Treasury Board for 2010–2011, 2011–2012, and 2012–2013 do not report the total planned and actual expenditures for those years, and these amounts were calculated by the evaluator in order to arrive at the overall totals. These calculations were complicated by various discrepancies in the financial data, as identified in the table notes. In addition, it should be noted that, in some years, the figures for Health Canada and the CFIA include funding related to nutrition, although the FCSAP did not address nutrition issues.

Table 1: Summary of FCSAP spending by partner, product, pillar, and fiscal year

Partner	Product/area	Pillar	Spending ($ millions)						
			Spending	2008–2009	2009–2010	2010–2011	2011–2012	2012–2013	2013–2014
Health Canada	Health products	Active prevention	Planned	13.9	10.8	9.7	11.5	10.9	10.2
			Actual	14.0	10.9	7.0	9.1	9.4	-
		Targeted oversight	Planned	2.1	3.9	9.2*	10.2	10.2	10.2
			Actual	1.8	2.1	4.3	6.0	6.4	-
		Rapid response	Planned	(ER)	(ER)	(ER)	(ER)	(ER)	(ER)
			Actual	(ER)	(ER)	(ER)	(ER)	(ER)	(ER)
	Consumer products	Active prevention	Planned	1.5	4.2	9.3	12.5	13.7	13.7
			Actual	0.8	2.5	6.8	7.5	9.7	-
		Targeted oversight	Planned	0.6	2.1	3.8	4.3	4.9	4.9
			Actual	0.2	1.2	5.4	5.7	6.4	-
		Rapid response	Planned	0.9	3.4	4.6	4.6	4.4	4.4
			Actual	1.1	4.0	6.2	6.4	7.5	-
	Pesticide regulation	Active prevention	Planned	0.6	1.3	1.6	1.6	1.6	1.6
			Actual	0.3	1.2	1.4	1.6	1.6	-
		Rapid response	Planned	0.7	1.0	2.1	2.1	2.1	2.1
			Actual	0.7	0.8	1.8	2.1	2.1	-
	Food nutrition (& safety as of 2011-2012)	Active prevention	Planned	3.3	4.9	6.7	7.1	7.6	7.6
			Actual	3.2	4.8	6.5	7.1	6.2	-
		Rapid response	Planned	0.2	0.2	0.3	0.3	0.3	0.3
			Actual	0.2	0.2	0.2	0.3	0.2	-
CFIA	Food safety (& nutrition risks 2011-12, and internal services 2012-13)	Active prevention	Planned	14.3	20.1	25.8	26.6	27.3	27.2
			Actual	8.4	16.4	23.1	21.8	25.5	-
		Targeted oversight	Planned	4.2	13.2	19.2	18.6	21.9	20.4
			Actual	3.0	8.3	13.2	10.3	15.1	-
		Rapid response	Planned	4.4	6.0	7.4	7.2	7.2	7.3
			Actual	3.0	8.6	5.7	8.2	7.7	-

Partner	Product/area	Pillar	Spending ($ millions)						
			Spending	2008–2009	2009–2010	2010–2011	2011–2012	2012–2013	2013–2014
PHAC	Health promotion / Chronic disease prevention and control	Active prevention	Planned	-	-	-	-	-	0.2
			Actual	-	-	-	-	-	-
		Targeted oversight	Planned	0.4**	1.0	2.0	2.3	2.3	2.3
			Actual	0.4	0.5	1.1	2.2	2.3	-
	Infectious disease and injury prevention and control/mitigation / surveillance and population health assessment / infrastructure	Active prevention	Planned	2.1	4.0	4.1	4.1	4.0	3.8
			Actual	1.1	3.2	3.5	3.7	3.6	-
CIHR	Strategic Priority Research	Targeted oversight	Planned	0	2.3	6.9	8.9	9.0	9.0
			Actual	0	1.9	2.1***	7.2***	9.8	-
All partners	Reported	Overall	Planned	49.2	78.4	Not reported	Not reported	Not reported	125.2
			Actual	38.2	66.2****	Not reported	Not reported	Not reported	-
	Calculated	Overall	Planned	49.2	78.4	112.8	121.9	127.4	125.2
			Actual	38.2	66.3****	88.2	99.2	113.5	0.0

* This figure includes Health Canada's reported spending on the DSEN. In the report to Treasury Board, under Health Canada, Health Products, Targeted Oversight, there is $1.0M spent on the DSEN, but the table mentions "included in the CIHR DSEN" and says to also refer to the Strategic Priority Research under CIHR, Targeted Oversight, which has $2.13M spent on the DSEN. It is not clear whether the Health Canada $1.0M is included in the CIHR reported spending, or whether this is a separate amount (i.e., in total $3.13M was provided for the DSEN in 2010-2011, with some coming from Health Canada and some through CIHR)

** These numbers do not match the online tables for 2008-2007 because this table combines the numbers for Health Promotion and Chronic Disease prevention and Control, which are reported as two separate categories in 2007-2008, but in no other year.

*** In order to focus strategically on developing the DSEN network of collaborating researchers, CIHR/DSEN focused efforts on the establishment of the key pan-Canadian network of research centres that delivers the core research capacity for the DSEN initiative. The time and effort required to reach the desired outcome suggested that, to be prudent, DSEN should manage funding between the implementation years to best target the DSEN Grants budget to research that aligns long term with the DSEN mandate and objectives. Thus, in January 2011, CIHR's Chief Operating Officer approved to internally reprofile $4,366,732 and $1,200,000 from 2010–2011 and 2011–2012, respectively, to be returned to the program in subsequent years starting in 2012–2013.

**** The total actual spending amount in the TB report differs from the total actual spending amount calculated by the evaluator.

5.0 Conclusions

This section of the report summarizes the evaluation findings and draws conclusions.

Relevance

There is a clear ongoing need for government action to protect the health and safety of Canadians. The health and safety risks associated with consumer products, health products, and food necessitate ongoing government oversight to manage these risks. Furthermore, trends such as the globalization of the supply chain and the emergence of new and innovative products that blur traditional product boundaries are creating uncertainties that further support the need for government action to protect the health and safety of Canadians.

Protecting Canadians from health and safety risks associated with food, consumer products, and health products continues to be a priority of the federal government. Furthermore, FCSAP activities are well-aligned with the strategic outcomes of the partners and with federal roles and responsibilities.

Effectiveness

Immediate Outcome #1 — Increased awareness and understanding of product safety and food safety risks by consumers and health professionals

FCSAP partners have undertaken a number of initiatives that are intended to improve consumer and health professional awareness and understanding of product safety and food safety risks. These include developing a one-stop consumer-oriented website that provides up-to-date information on risks and benefits associated with food and consumer products, as well as information on recalls, advisories, and warnings. FCSAP partners have also enhanced information products and broadened their dissemination, and have taken steps to make the regulatory system more open to consumer input and involvement.

Despite progress in these areas, evidence of increased awareness and understanding is relatively limited at this time, since FCSAP partners do not regularly collect this information. Available survey data suggests overall consumer satisfaction with information on consumer products and food safety. In the area of consumer products, most consumers surveyed had used at least some of the consumer-products-related information Health Canada has produced, and the vast majority found this information to be useful, understandable, accessible, of high quality, and timely. About two thirds of respondents agreed that “overall, Health Canada provides enough information to the general public about the human health safety risks associated with consumer products.” In the area of food safety, although a large majority of Canadians surveyed were familiar with food safety guidelines and believed that they had sufficient information on food safety, more than half had misconceptions about food handling. Many Canadians continued to express an increased desire for more information on food safety, particularly food recalls, as well as more information about how to protect themselves and their families from food safety risks.

Immediate Outcome #2 — Increased awareness and understanding of regulatory requirements by industry

Since the FCSAP was launched, several new pieces of legislation and regulations have been proposed or have come into force to modernize Canada's legislative and regulatory regime for food, consumer products, and health products. In the area of consumer products, the CCPSA came into force in June 2011. This legislation modernizes Canada's consumer product safety regime and brings it into alignment with those of Canada's international trading partners and competitors. Key provisions include a general prohibition related to the manufacture, importation, sale, or advertisement of consumer products that could pose a danger to human health or safety; the power to order mandatory recalls of consumer products; and increased fines and penalties, including an AMPs system, to provide a stronger deterrent against violations of the Act or the regulations that jeopardize the health and safety of the public.

In the area of health products, key developments include a new submission pathway for EUNDs and new requirements for GMP and DEL for APIs. Most recently, in December 2013, the Government of Canada proposed new patient safety legislation, the *Protecting Canadians from Unsafe Drugs Act* (Bill C-17, Vanessa's Law). The proposed legislation would amend the *Food and Drugs Act* to give Health Canada the power to recall therapeutic products from the market when they present an imminent or serious risk to health; compel drug companies to revise labels to clearly reflect health risk information; and compel drug companies to provide information for the purpose of assessing serious risks to health, and to compile information, conduct new tests or studies, and/or monitor experience, for the purpose of obtaining additional information. The legislation also includes mandatory serious adverse reaction reporting requirements for healthcare institutions and increased fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison.

In the area of food safety, the *Safe Food for Canadians Act* was passed in November 2012 and is expected to fully come into force in June 2015. This legislation is intended to protect consumers by targeting food tampering and other unsafe practices; implementing tougher penalties for activities that put health and safety at risk; allowing the CFIA to track food more effectively through all stages of preparation and distribution through enhanced inspections; and providing better controls over food imports.

Health Canada has undertaken extensive outreach to inform the consumer products industry of its obligations under the new CCPSA, and plans to consult with the health products industry as part of the process of developing supporting regulations for the new patient safety legislation. Similarly, the CFIA is currently working with industry to bring the new food safety legislation into force. While for the most part, it is premature to assess the extent to which industry awareness and understanding of the new requirements has increased, the available data suggest a high level of satisfaction with the information Health Canada makes available to industry. For example, in 2013–2014, between 90% and 100% of consumer product industry stakeholders indicated that they were somewhat or very aware of and understood their legislative obligations following attendance at information sessions about the CCPSA. Based on a survey of industry, a large majority of respondents rated Health Canada's information on consumer products as "very" or "somewhat" useful, understandable, accessible, of high quality, and timely. Similarly, based

on a limited number of responses to surveys of the health products industry, most respondents indicated having a strong understanding of Health Canada's regulatory requirements for health products and were generally satisfied with the information Health Canada provides to industry.

Immediate Outcomes #3 and #4– Improved surveillance, information, and knowledge sharing related to products, food and adverse health incidents

FCSAP partners have taken several important steps to improve surveillance, information, and knowledge sharing (including with international partners) related to health and consumer products, food, and adverse health incidents.

In the area of consumer products, key developments include mandatory industry reporting of consumer product incidents under the CCPSA, along with a new information system, process, and dedicated division for monitoring, triaging and assessing these reports. In addition, PHAC implemented several projects to improve consumer-product-related injury surveillance and risk assessment. Among others, these projects included modernizing and expanding the CHIRPP; using CHIRPP data in reports on child and youth injuries; collecting, analyzing and disseminating data on select consumer products in order to strengthen the evidence base for action; collaborating with Statistics Canada on the CCMED; adding a module of questions on injury and consumer product-related falls to the CLSA; and conducting risk assessments on patterns and trends of injury using these data sources.

With respect to health products, the proposed patient safety legislation includes two provisions that would increase the information available to Health Canada for the purposes of post-market surveillance, including a provision for mandatory reporting of serious adverse reactions by healthcare institutions and a provision giving Health Canada the authority to require manufacturers to compile information, conduct new tests or studies, and/or monitor experience, for the purpose of obtaining additional information. In addition, Health Canada took steps to implement a more structured, comprehensive, and systematic approach to pharmacovigilance planning and risk-management planning, and enhanced its existing program for collecting and reviewing PSURs. Finally, CIHR established the DSEN as Canada's first national PMDSE virtual network**.** Research on 36 queries has been completed prioritized. Of these, seven queries have been answered while research is ongoing for 22 and seven more are awaiting funding for research to start as of March 31, 2013. Health Canada has used data generated in response to DSEN queries to inform decision making in a few areas.

In the area of food safety, the CFIA, Health Canada, and PHAC took numerous steps to improve their ability to identify, assess, and prioritize potential food safety hazards through improved data collection and risk mapping, with a focus on priority areas of imported food ingredients, produce, mycotoxins, and undeclared allergens. Among other activities, the CFIA carried out targeted surveys in chemistry, microbiology, and allergens, while Health Canada updated risk profiles, carried out collaborative work in the assessment of options for risk profiling tools, and updated and published 49 methods to enhance the ability to detect microbiological hazards in the food supply. PHAC used FCSAP funds to maintain and enhance FoodNet Canada and the CIPARS, two important, integrated surveillance systems designed specifically to address food safety issues and examine source attribution. PHAC also continues to expand the capacity of its

web-based Outbreak Summary Reporting System, which allows standardized dissemination of the results of disease outbreak investigations. The first report of outbreak summaries data, covering outbreaks reported in the system from 2008 to 2012, will be released to participating provincial public health partners in June 2014.

Immediate Outcome #5– Improved ability to respond when unsafe products and food are identified

FCSAP partners have undertaken a number of legislative, regulatory, and other initiatives to improve their ability to respond when unsafe products and food are identified. In the area of consumer products, the new CCPSA gives Health Canada the ability to order mandatory recalls of consumer products that pose a danger to health or safety, introduced a requirement for industry to report consumer product-related incidents, and increased fines and penalties to provide a stronger deterrent against non-compliance. Health Canada also increased resources for compliance and enforcement activities and expanded the coverage of its CEP from 23 to 35 product categories. FCSAP partners have also implemented a cyclical enforcement strategy and a cyclical compliance monitoring program for radiation-emitting devices and consumer pesticides, respectively.

In the area of health products, through the establishment of the National Border Integrity Program, Health Canada strengthened its ability to make and support admissibility decisions at the border as they relate to health products. The proposed Bill C-17 would give Health Canada several new authorities to improve its ability to respond when unsafe health products are identified, including the power to recall therapeutic products from the market when they present an imminent or serious risk to health; the power to compel drug companies to revise labels to clearly reflect health risk information; and increased fines and penalties, such as a fine of up to $5 million and/or imprisonment for no more than two years on indictment for a violation of the *Food and Drugs Act* or Regulations.

In the area of food safety, the CFIA increased its oversight of high-risk sectors by increasing inspections in the imported and manufactured foods and fresh fruits and vegetables sectors and increasing its capacity to respond to a growing number of food safety investigations and food recalls due to enhanced surveillance testing. The CFIA also enhanced its oversight of imported products by increasing the number of port-of-entry or border blitzes undertaken each year.

Intermediate Outcome #1 – Increased appropriate selection and safe use of products and food

There is no information on which to base conclusions about the extent to which this outcome may have been achieved. Furthermore, none of the FCSAP partners have assessed the extent to which their activities may have contributed to this outcome.

Intermediate Outcome #2 – Increased industry compliance with regulatory requirements

Based on completed inspections and compliance monitoring activities, industry compliance with established regulations is reasonably high, although some product categories and industry sectors are exceptions. For legislative and regulatory changes that have very recently come into force, it is premature to draw conclusions about industry compliance.

In the area of consumer products, industry compliance ranges between 90% and 100% for most product categories subject to inspections, although low rates of compliance (ranging from 0% to 33%) have been found for some product categories, including utility lighters; matches; carriages and strollers; children's jewellery; cribs, cradles and bassinets; and corded window coverings. With respect to consumer pesticides, industry compliance ranges from 52% among vendors, importers, and distributors of international pest control products to 82% among pest control operators selling commercial and domestic class pest control products. It is not possible, however, to determine the overall industry compliance rate with Health Canada's regulatory requirements for consumer products since compliance and enforcement activities intentionally target higher risk instances of suspected non-compliance. For the product categories examined in the Consumer Products activities evaluation, enforcement action was taken on 100% of non-compliant products, which included information letters, stop sales, and voluntary recalls.

Similarly, the available information generally suggests a high level of industry compliance with existing regulatory requirements for health products. Of the inspections conducted, the compliance rate generally exceeds 90% for GCP, GMP, and GVP inspections. With respect to health products referred to Health Canada by the CBSA during the period of 2010–2011 and 2011–2012, Health Canada recommended that approximately 72% of all shipments referred be refused entry into Canada. This percentage reflects the non-compliance rate for shipments referred to Health Canada by the CBSA due to suspected non-compliance. It does not reflect the compliance rate for all shipments received at the border.

In the area of food safety, as already mentioned, in 2012–2013 and 2013–2014, the CFIA's enhanced inspection program found non-conformity rates of 14% and 24% for the imported and manufactured foods and fresh fruits and vegetables sectors, respectively.

Intermediate Outcome #3 – Improved risk assessment and risk mitigation

In all product areas, FCSAP partners have undertaken new initiatives that will enhance the information available to them for the purpose of assessing product risks and identifying safety issues requiring risk mitigation or corrective action.

For consumer products, relevant initiatives include new requirements for mandatory industry reporting of consumer product-related incidents, expansion of the CEP to additional product categories, and enhancement of product-related injury surveillance.

For health products, relevant initiatives include the introduction of GMP and DEL requirements for APIs; enhancements to the existing RMP and PSUR programs; the proposed provisions in Bill C-17 to compel drug companies to conduct post-market safety studies and to introduce mandatory serious adverse reaction reporting for healthcare institutions; and the establishment of the DSEN as Canada's first national PMDSE virtual network, which is intended to generate and promote the use of research evidence to enable healthcare decision makers to better determine safety and effectiveness profiles for drugs and implement measures that will promote their optimal use.

In the area of food safety, the most important initiatives include improved identification, assessment, and prioritization of potential food safety hazards through improved data collection and risk mapping; ongoing health risk assessments; updates to risk profiles of various foodborne pathogens; updates to methods used to enhance the ability to detect microbiological hazards in the food supply; and ongoing surveillance, risk profiling, laboratory method development, and knowledge synthesis and dissemination activities.

Intermediate Outcome #4 – Improved early response to unsafe products

In all product areas, FCSAP partners have undertaken new initiatives that will enhance their ability to respond early through taking action when unsafe products are identified.

For consumer products, these initiatives include Health Canada's new authority under the CCPSA to order mandatory recalls of consumer products that pose a danger to health or safety; the increase in the level of resources devoted to consumer-product-related compliance and enforcement activities; the expansion of the CEP from 23 to 35 product categories; and the development and implementation of a cyclical enforcement strategy and a cyclical compliance monitoring program for radiation-emitting devices and consumer pesticides, respectively.

For health products, these initiatives include proposed amendments to the *Food and Drugs Act* that would give Health Canada the power to recall therapeutic products from the market when they present an imminent or serious risk to health and compel drug companies to revise labels to clearly reflect health risk information; proposed amendments that would increase fines and penalties for non-compliance up to a maximum of $5,000,000 and/or two years in prison; and increased resources for regulatory oversight of imported health products under the National Border Integrity Program.

In the area of food safety, relevant initiatives include the new *Safe Food for Canadians Act,* which will target food tampering and other unsafe practices, implement tougher penalties for activities that put health and safety at risk, allow the CFIA to more effectively track food through all stages of preparation and distribution through enhanced inspections, and provide better controls over food imports; enhanced inspection of high-risk sectors; improved tracking of imported foods; and increased capacity to respond to an increase in the number of food safety investigations and food recalls due to enhanced surveillance testing.

Long-term outcome – Reduced adverse health incidents related to health and consumer products

While FCSAP activities have certainly contributed to reducing adverse events associated with these products, finding concrete evidence of this outcome is challenging.

In the area of consumer products, FCSAP activities such as mandatory incident reporting for industry, efforts to raise public awareness of the ability for consumers to voluntarily report incidents, and the introduction of new legislation giving Health Canada the power to issue mandatory recalls of consumer products should lead to a reduction in adverse health incidents associated with these products. While the data show that the number of reported incidents has been increasing, this may simply reflect an increase in reporting due to the mandatory incident reporting provision in the CCPSA, and not necessarily an increase in adverse health incidents.

Similarly, in the area of health products, FCSAP activities such as removing unsafe products from the market through recalls and recommending the refusal of entry into Canada of products deemed non-compliant with the legislative and/or regulatory requirements should reduce the availability of non-compliant health products, thereby contributing to health risk mitigation. Although the number of domestic adverse reaction reports submitted to Health Canada has been increasing steadily over time, the proportion that are classified as "serious" — i.e., that require in patient hospitalization or prolongation of existing hospitalization, that cause congenital malformation, result in persistent or significant disability or incapacity, are life threatening or result in death — has remained stable since 2001, accounting for just over two thirds of all reports submitted each year.

Finally, in the area of food safety, FCSAP activities such as improved identification of potential food safety risks and enhanced inspection of high-risk sectors should contribute to a reduction in adverse health incidents associated with food. While the available evidence, from PHAC's FoodNet Canada and Notifiable Disease On-Line, shows a small decrease in the number of reported enteric diseases over the past decade, which is matched by a small decrease in the number of food safety investigations and recalls carried out by the CFIA over the same period, it is not possible to infer a relationship between these two trends.

Efficiency and economy

The proposed governance structure for the FCSAP, consisting of three task forces with oversight for Health Products, Consumer Products and Food, was implemented with limited success due in part to the prior existence of committees with overlapping mandates and membership. At the end of the five-year lifespan of the FCSAP, oversight of Health Products activities was transitioned to the HPFB Executive Committee and oversight of Food activities was transitioned to the Interdepartmental Director General Committee on Food Safety. The Consumer Products Task Force, led by the HECSB, remains active.

Over the period of time covered by this evaluation, performance measurement and financial reporting systems necessary to support analysis of efficiency and economy were not in place within the FCSAP departments and agencies, although progress is being made to improve performance measurement and financial reporting to inform the assessment of efficiency and economy in future. For the purpose of this evaluation, the assessment of efficiency and economy is limited to a comparison of planned and actual expenditures. Actual spending on the FCSAP was approximately 83% of planned ($405.3 million compared to $489.7 million) between 2008–2009 and 2012–2013. Variances in spending are related to challenges with staffing, found efficiencies, and changes to some of the activities.

Since this is a roll up evaluation report, recommendations relevant to each component Program have been provided in each component evaluation report. Evidence analyzed during this evaluation did not lead to any roll up recommendations.

There have been nine evaluation reports completed addressing FCSAP activities. The following Programs, components of FCSAP, were evaluated:

- Consumer Products Activities (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/2013/cpa-pdcfni-eng.php)
- Veterinary Drugs (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/vdp-evaluation-pmv-eng.php)
- Medical Devices (HC) (http://www.hc-sc.gc.ca/ahc-asc/performance/eval/medical_devices-materiels_medicaux-eng.php)
- Food Safety and Nutrition Quality (HC) (to be posted by the second week of August 2014)
- Human Drugs (HC) (to be posted on August 29, 2014)
- Biologics (HC) (to be posted on September 24, 2014)
- Drug Safety and Effectiveness Network (CIHR) (posting date to be determined)
- Food Safety Action Plan (CFIA) (http://www.inspection.gc.ca/about-the-cfia/accountability/other-activities/audits-reviews-and-evaluations/fsap/eng/ 1384540904088/1384540966557)

These evaluations have provided 34 recommendations with approximately 60 deliverables to be completed by FCSAP partners between 2013 and 2016.

Appendix A – Component Logic Models

Consumer Products Logic Model

Active Prevention					Targeted Oversight				Rapid Response			
Strategies	**1: Industry Understanding its Obligations (HECS)**	**2: Consumer Pesticides Industry Understanding its Obligations (PMRA)**	**3: Standards Development and Adoptions (HECS)**	**4: Information to Canadians (HECS,PMRA)**	**5: Mandatory Reporting of Consumer Product Incidents and Risk Assessment/Risk Mitigation (HECS)**	**6: Modernized Cosmetics Regulations & Enhanced Risk Assessment/ Management Activities (HECS)**	**7: International Collaboration (HECS)**	**8: Increased Product-Related Injury Surveillance & Risk Assessment (PHAC**	**9: New Canada Consumer Product Safety Act (HECS)**	**10: Modernizing and Enforcing Radiation Emitting Devices Act (HECS)**	**11: Promote and Enforce Industry Compliance (HECS)**	**12: Monitor and Enforce Industry Compliance - Consumer Pesticides (PMRA)**
PAA Key Results Statements	Adherence to Acts, regulations and other control instruments		Enhanced knowledge of risk and evidence to inform decisions	Increased public/ stakeholder awareness/ knowledge of risks and confidence in regulatory activities	Timely regulatory system response to: -Pre- and post-market reviews -Risks from products, substances and environmental risks to health		Declining trends in levels of risk, mortality, exposures, illnesses and injuries from regulated products, substances and environmental risks to health		Adherence to Acts, regulations and other control instruments			
Long-term Outcomes	Reduced adverse health incidents related to consumer products (including cosmetics, pest management products, and radiation emitting devices)											
Intermediate Outcomes	Increased industry compliance with product safety obligations		Increased effective use of standards by consumer products industry	Better informed consumers properly selecting and safely using consumer products	Improved assessment and mitigation strategies	Improved assessment and mitigation strategies	Improved early detection of unsafe consumer products		Improved ability to respond when unsafe products are identified		Increased industry compliance with product safety obligations	
Immediate Outcomes	Increased awareness and understanding of product safety obligations by consumer products industry	Increased industry (manufacturers and retailers) awareness of risks and related regulatory requirements	Increased awareness and understanding of standards by consumer products industry	Increased awareness and understanding of consumer product safety issues by consumers	Improved timeliness and quality of information on consumer product safety	Improved Cosmetic Regulations of the FDA	Increased sharing of information with international regulators	More and better data on accidents, injuries, illnesses and deaths due to consumer products Engagement of risk assessment stakeholders	Improved legislative authority and regulatory tools for products	Improved monitoring of consumer and cosmetic products	Improved monitoring of pest management products using a risk management approach	

	Active Prevention				Targeted Oversight				Rapid Response			
Strategies	**1: Industry Understanding its Obligations (HECS)**	**2: Consumer Pesticides Industry Understanding its Obligations (PMRA)**	**3: Standards Development and Adoptions (HECS)**	**4: Information to Canadians (HECS,PMRA)**	**5: Mandatory Reporting of Consumer Product Incidents and Risk Assessment/Risk Mitigation (HECS)**	**6: Modernized Cosmetics Regulations & Enhanced Risk Assessment/ Management Activities (HECS)**	**7: International Collaboration (HECS)**	**8: Increased Product-Related Injury Surveillance & Risk Assessment (PHAC**	**9: New Canada Consumer Product Safety Act (HECS)**	**10: Modernizing and Enforcing Radiation Emitting Devices Act (HECS)**	**11: Promote and Enforce Industry Compliance (HECS)**	**12: Monitor and Enforce Industry Compliance - Consumer Pesticides (PMRA)**
Outputs	-Guides -Standards -Protocols -Codes of Practices	-Partnerships agreements -Best Practices (e.g., product QA programs, codes of conduct, guides regarding regulatory requirements, standards)	-Standards and guidelines -Promotional tools	-Consumer Information Strategy (consumer information/ education materials) -Consumer Information Bureau (product information) -Consumer workshops	- Incident Management System -Online forms, guidance documents and policies -Incidence reports -Risk management tools	-Electronic notification/ reporting systems -Adverse reaction reports -Good Manufacturing Practices documents	-Global surveillance and consumer product-related illnesses and injuries data -Formal and active partnerships and agreements -MOUs	-Epidemio-logical data (Coroners/ Medical Examiners Database) -Risk assessments completed and prevention interventions assessed and disseminated	-New Canada Consumer Product Safety Act/ modernized RED Act -Regulations -Policies -Operating procedures	-Surveillance reports -Surveys -Notifications -Reports -Inspections -Administrative Monetary Penalties Scheme	-Inspection program results -Enforcement responses e.g., AMPS -Responses to complaints -Strategies and agreements with foreign manufacturers -Risk management strategies and tools	
Activities	-Collaborate with industry, associations -Provide targeted guidance information and tools -Conduct Workshops	-Collaborate with industry and government to develop best practices -Provide quality assurance initiatives and information -Develop market level programs	-Participate in standards development -Build laboratory capacity	-Develop and disseminate information -Respond to consumer inquiries and complaints -Organize meetings, workshops, etc.	-Develop online forms, guidance documents and policies -Process mandatory reporting of consumer product incidents -Conduct risk assessment and mitigation	-Consult with relevant stakeholders -Update regulations -Assess and manage risks	-Participate in the establishment and coordination of international systems and agreements for global market	-Collaborate with CHIRPP hospitals -Collaborate with Statistics Canada -Collect, analyse and disseminate data -Conduct risk assessments	-Consult with relevant stakeholders -Draft Act, operational reference manuals -Update regulations -Provide training	-Undertake surveillance -Collect survey data -Undertake compliance promotion and enforcement (samples, inspections, enforcement activities)	-Conduct inspections -Collect and analyze information -Coordinate regulatory approaches and adopt international standards -Conduct investigations and apply appropriate enforcement response -Exchange information, reports, intelligence and plans with international regulators	

Health Products Logic Model

	Active Prevention						Targeted Oversight				Rapid Response
Strategies	**1: Pre-Submission Meetings (HPFB)**	**2: Pharmacovigilance Planning (HPFB)**	**3: Risk Management and Mitigation Strategy (HPFB)**	**4: Regulatory Framework for Active Pharmaceutical Ingredients (HPFB)**	**5: Interim Funding to Speed-up Drug Approvals (HPFB)**	**6: Consumer Information Strategy for Health Products (HPFB)**	**7: Periodic Safety Update Reports (HPFB)**	**8: Mandatory Reporting of Serious Adverse Reactions by Institutions (HPFB)**	**9: Drug Safety and Effectiveness Network (SPB, HPFB, CIHR)**	**10: Risk-based Border Integrity Initiatives (HPFB)**	**11: Corrective Action/ Fines and Penalties (HPFB)**
PAA Key Results Statements	Timely regulatory system response to: -Pre- and post-market reviews -Risks from products, foods, substances and environmental risks to health	Enhanced knowledge of risk and evidence to inform decisions	Declining trends in levels of risk, mortality, exposures, illnesses and injuries from regulated products, foods, substances and environmental risks to health		Timely regulatory system response to: -Pre- and post-market reviews -Risks from products, foods, substances and environmental risks to health	Increased public/stakeholder awareness/ knowledge of risks and confidence in regulatory activities	Timely regulatory system response to: -Pre- and post-market reviews -Risks from products, foods, substances and environmental risks to health	Enhanced knowledge of risk and evidence to inform decisions	Enhanced knowledge of risk and evidence to inform decisions	Adherence to Acts, regulations and other control instruments	
Long-term Outcomes	Improved safety of health products on the market										
Intermediate Outcomes	Increased industry compliance with regulatory requirements	Increased ability to monitor and identify safety concerns before or as they arise	Increased ability to monitor and identify safety concerns before or as they arise	Improved safety, quality and efficacy of health products imported into and/or manufactured in Canada	Timely access to safe drugs by Canadians	Increased safe use of health products by consumers and health professionals	Increased industry compliance with good pharmacovigilance practices (GPP) for pharmaceuticals and product safety monitoring	Improved knowledge of post-market drug reactions	Use by policy makers of DSEN generated post-market evidence to make informed decisions regarding drug safety and effectiveness	Reduction in prohibited and unapproved health products entering Canada	Improved industry compliance

	Active Prevention						Targeted Oversight				Rapid Response
Strategies	**1: Pre-Submission Meetings (HPFB)**	**2: Pharmacovigilance Planning (HPFB)**	**3: Risk Management and Mitigation Strategy (HPFB)**	**4: Regulatory Framework for Active Pharmaceutical Ingredients (HPFB)**	**5: Interim Funding to Speed-up Drug Approvals (HPFB)**	**6: Consumer Information Strategy for Health Products (HPFB)**	**7: Periodic Safety Update Reports (HPFB)**	**8: Mandatory Reporting of Serious Adverse Reactions by Institutions (HPFB)**	**9: Drug Safety and Effectiveness Network (SPB, HPFB, CIHR)**	**10: Risk-based Border Integrity Initiatives (HPFB)**	**11: Corrective Action/ Fines and Penalties (HPFB)**
Immediate Outcomes	Increased industry awareness and knowledge of regulatory requirements	Enhanced knowledge of post-market health product safety risks to inform decisions	Increased oversight of the risk management and risk mitigation strategies for health products	Increased safety of APIs through industry compliance with the FDA and its regulations	Improved timeliness of pre-market reviews	Increased awareness and understanding of the safe use of health products by consumers and health care professionals	Enhanced capacity of HC and industry to identify and respond to risk issues	Increased capacity to identify safety issues with health products on the market	Increased knowledge of post-market drug safety and effectiveness to inform decisions Increased capacity in Canada to address priority research on post-market drug safety and effectiveness	Improved ability to monitor and control importation of health products	Improved ability to respond with better tools when safety incidents occur

	Active Prevention						Targeted Oversight				Rapid Response
Strategies	**1: Pre-Submission Meetings (HPFB)**	**2: Pharmacovigilance Planning (HPFB)**	**3: Risk Management and Mitigation Strategy (HPFB)**	**4: Regulatory Framework for Active Pharmaceutical Ingredients (HPFB)**	**5: Interim Funding to Speed-up Drug Approvals (HPFB)**	**6: Consumer Information Strategy for Health Products (HPFB)**	**7: Periodic Safety Update Reports (HPFB)**	**8: Mandatory Reporting of Serious Adverse Reactions by Institutions (HPFB)**	**9: Drug Safety and Effectiveness Network (SPB, HPFB, CIHR)**	**10: Risk-based Border Integrity Initiatives (HPFB)**	**11: Corrective Action/ Fines and Penalties (HPFB)**
Outputs	-Pre-submission meetings -Advice	-Pharma-covigilance plans	-Risk Management and Mitigations Plans -Guidance documents	-Framework to regulate the manufacture of active pharmaceutical ingredients - Possible compliance and enforcement action	-Submission reviews -Project management tools and approaches	-Monographs -Summary Basis Decision documents -List of non-medicinal ingredients consumer information products -safety education campaigns -advisory bodies	-Periodic Safety Update Report assessments -Harmonized review process	-Mandatory reporting system	- Funded drug safety and effectiveness research activities (centres and projects) - Linked and collaborating centres of excellence in post market safety and effectiveness research - Post-market drug safety and effectiveness common prioritized research agenda - New post-market safety and effectiveness evidence	-Real time data -National Border Strategy -Training program	-Recalls -Fines

	Active Prevention						Targeted Oversight				Rapid Response
Strategies	**1: Pre-Submission Meetings (HPFB)**	**2: Pharmacovigilance Planning (HPFB)**	**3: Risk Management and Mitigation Strategy (HPFB)**	**4: Regulatory Framework for Active Pharmaceutical Ingredients (HPFB)**	**5: Interim Funding to Speed-up Drug Approvals (HPFB)**	**6: Consumer Information Strategy for Health Products (HPFB)**	**7: Periodic Safety Update Reports (HPFB)**	**8: Mandatory Reporting of Serious Adverse Reactions by Institutions (HPFB)**	**9: Drug Safety and Effectiveness Network (SPB, HPFB, CIHR)**	**10: Risk-based Border Integrity Initiatives (HPFB)**	**11: Corrective Action/ Fines and Penalties (HPFB)**
Activities	-Meet with industry	-Assess Risks -Review data -Develop implementation plan	-Analyze registries, clinical trials, and surveillance and epidemiologic studies -Develop and implement risk management and mitigation plans	-Establish regulatory framework for active pharmaceutical ingredients -Conduct compliance and enforcement activities	-Review submissions (pre-market reviews)	-Consult and partner with stakeholders -Conduct public opinion research -Produce and disseminate consumer information	-Assess Product Safety Update Reports	-Provide training in the reporting system -Process adverse reaction reports	-Administer grant program to fund network research activities - Facilitate collaborative research and knowledge translation - Coordinate common prioritized research agenda -Use evidence for regulatory decision-making	-Provide training -Collect and analyze data -Disseminate information	-Conduct compliance and enforcement activities -Inspector Orders

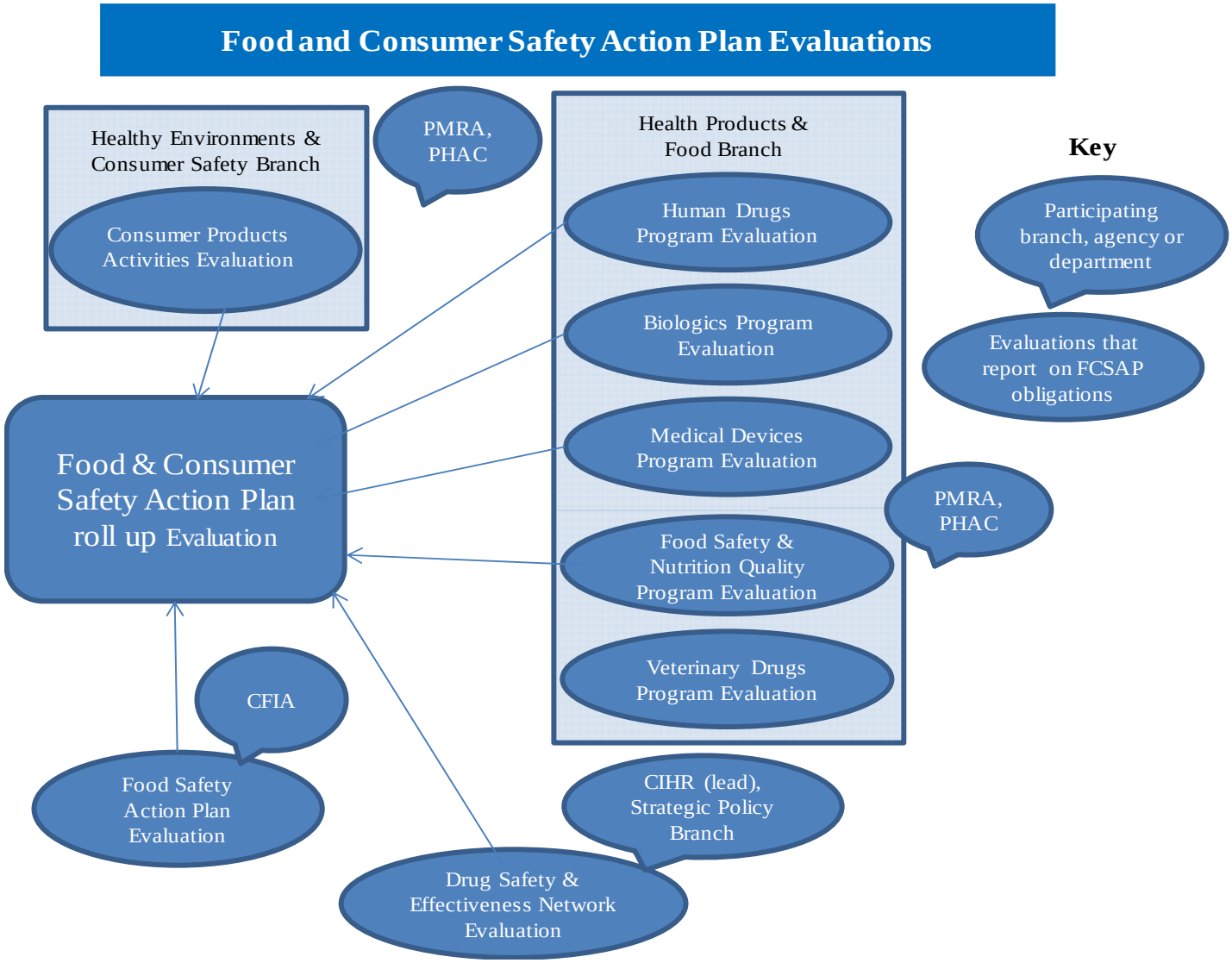
Food Safety Logic Model

	Active Prevention				Targeted Oversight		Rapid Response	
Strategies	**1: Better Understanding of Food Safety Risk (HPFB,CFIA,PHAC)**	**2: Working With Industry to Implement Effective Risk Mitigation (HPFB,CFIA)**	**3: Strengthened Standard Setting and Appropriate Regulatory Backstops (HPFB,CFIA)**	**4: Engage Canadians in Food Safety Decision-Making (HPFB,CFIA)**	**5: Enhanced Inspection of High Risk Sectors (CFIA)**	**6: Targeted Import Control Measures (CFIA)**	**7: Enhanced recall capacity (CFIA)**	**8: Targeted consumer risk communication (HPFB,CFIA)**
PAA Key Results Statements	HC: Enhanced knowledge of risk and evidence to inform decisions PHAC: Reduced incidence and burden of foodborne diseases in Canadians; Communication of disease issues & promotion of health protection activities; Development and transfer of knowledge and tools to support relevant stakeholders in preventing and controlling the spread of infectious disease.	HC: Adherence to Acts, regulations and other control instruments	HC: Adherence to Acts, regulations and other control instruments	HC: Increased public/stakeholder awareness/ knowledge of risks and confidence in regulatory system	HC: Adherence to Acts, regulations and other control instruments		HC: Timely regulatory system response to: -Pre- and post-market reviews -Risks from products, foods, substances and environmental risks to health	HC: Increased public/stakeholder awareness/ knowledge of risks and confidence in regulatory activities
	CFIA: Public health risks associated with the food supply and transmission of animal diseases to humans are minimized and managed Contributes to consumer protection and market access based on the application of science and standards							
Long-term Outcomes	Safer food			-Maintain public/consumer confidence -Safer Food	Safer Food	Safer food in international trade	Safer Food	-Maintain public/consumer confidence -Safer Food
Intermediate Outcomes	Improved assessment and mitigation strategies	-Increased compliance with safety standards by food industry, including risk mitigation processes -Imported food meets Canadian requirements	Improved potential for more timely availability of food that meets expected standards Enhanced Canadian involvement with international standard setting bodies	Food safety policies reflect the needs of Canadians Increased industry compliance with food labelling	Improved compliance by food industry with safety control measures	Targeted import control measures are effective	Effective recalls are maintained	Consumers make informed decisions about food

	Active Prevention				Targeted Oversight		Rapid Response	
Strategies	**1: Better Understanding of Food Safety Risk (HPFB,CFIA,PHAC)**	**2: Working With Industry to Implement Effective Risk Mitigation (HPFB,CFIA)**	**3: Strengthened Standard Setting and Appropriate Regulatory Backstops (HPFB,CFIA)**	**4: Engage Canadians in Food Safety Decision-Making (HPFB,CFIA)**	**5: Enhanced Inspection of High Risk Sectors (CFIA)**	**6: Targeted Import Control Measures (CFIA)**	**7: Enhanced recall capacity (CFIA)**	**8: Targeted consumer risk communication (HPFB,CFIA)**
Immediate Outcomes	Increased understanding of food safety risks by HC, PHAC & CFIA	-Increased industry understanding of and engagement in the development and implementation of food safety risk mitigation processes -Improved international collaboration in addressing common import risks	Establishment of the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures (standards, policies, etc.) to address immediate areas of concern	Increased engagement by Canadians in the regulatory system Increased industry knowledge regarding food labelling	Increased verification of industry food safety measures	Improved ability to monitor and control importation of food	Timely and efficient recall capacity	Increased public understanding of food safety risks, alert systems and safety systems
Outputs	-Targeted surveys -Risk-based studies -Risk mapping -Laboratory methods & validation reports -Outbreak reports, Surveillance reports -Baseline levels and sampling plan reports -Expert consultation reports -Stakeholder workshop	-Rapid screening and detection tools -Registration provisions -Food safety systems -Stakeholder roundtables & engagement & outreach activities -Guidance documents -Tracking system for imported foods -International meetings leading to MOUs, product certifications, etc. -Staff hired	-Labelling standards/regulations/ licensing/registration/ tracking & tracing systems -Policies, standards & regulations -International advice & meetings -Education and compliance tools	-Online consultation tools & associated consultation feedback reports -Stakeholder meetings -Education material -Consumer research - Revised Product of Canada policy -Advertising campaign -Training sessions	-Inspection Reports -Food safety evaluation reports -Staff hired -Training modules	-Data from Imported Foods Tracking System -Inspection Reports -Border blitzes -Training modules -Staff hired -IM/IT business solution implemented	- Recalls issued -Methodology report -Staff hired -Training modules	-Electronic updates -Consumer Hotline service -Targeted risk communication -Technical advice -Consumer education products -Staff hired

	Active Prevention				Targeted Oversight		Rapid Response	
Strategies	**1: Better Understanding of Food Safety Risk (HPFB,CFIA,PHAC)**	**2: Working With Industry to Implement Effective Risk Mitigation (HPFB,CFIA)**	**3: Strengthened Standard Setting and Appropriate Regulatory Backstops (HPFB,CFIA)**	**4: Engage Canadians in Food Safety Decision-Making (HPFB,CFIA)**	**5: Enhanced Inspection of High Risk Sectors (CFIA)**	**6: Targeted Import Control Measures (CFIA)**	**7: Enhanced recall capacity (CFIA)**	**8: Targeted consumer risk communication (HPFB,CFIA)**
Activities	-Collect and analyze data -Conduct stakeholder workshops and expert consultations -Conduct training and marketing to P,T,L public health professionals -Monitor food -Conduct risk modelling and mapping -Conduct surveillance (C-Enternet, CIPARS) -Improve lab methods development & validation	-Assess industry food safety systems -Support industry & stakeholders -Develop educational & compliance tools -Develop guidance documents -Engage with international regulators -Develop education & awareness campaigns -Develop industry consultation plan -Develop importer licensing system and registration system -Hire staff	-Engage international standards bodies -Develop standards, policies, regulations and processes -Develop educational and compliance tools -Develop guidance documents	-Develop & implement consultation tools -Consult stakeholders -Review/revise Product of Canada/Made in Canada policy -Develop advertising campaign -Develop training modules	-Conduct inspections/ testing -Undertake food safety evaluation -Hire & train staff	-Identify & monitor imported food -Conduct inspections -Develop & implement border blitz plan -Develop IM/IT data system -Hire & train staff	-Collect data -Conduct investigations -Validate methodologies -Hire & train staff	-Maintain & update website -Provide targeted consumer information -Provide technical advice -Respond to public inquiries -Develop & implement consumer education products -Hire staff

Appendix B – Component Evaluations



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