



Health Canada and the Public
Health Agency of Canada

Santé Canada et l'Agence
de la Santé publique du Canada

Evaluation of the Consumer Products Activities

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Health Canada and the Public Health Agency of Canada

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List of Acronyms

AMP	Administrative Monetary Penalties
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ASTM	American Society for Testing and Materials
CBPP	Canadian Best Practices Portal
CBSA	Canada Border Services Agency
CCMED	Canadian Coroner and Medical Examiner Database
CCMS	Consumer Product Safety Program (CPSP) Case Management System
CCPSA	<i>Canada Consumer Product Safety Act</i>
CCRPB	Consumer and Clinical Radiation Protection Bureau
CEP	Cyclical Enforcement Program
CEPA	<i>Canadian Environmental Protection Act, 1999</i>
CFIA	Canadian Food Inspection Agency
CFL	Compact fluorescent lamps
CHIRPP	Canadian Hospitals Injury Reporting and Prevention Program
CIB	Consumer Information Bureau
CIHR	Canadian Institutes of Health Research
CLSA	Canadian Longitudinal Study on Aging
CMP	Chemicals Management Plan
CNS	Cosmetic Notification System
CPA	Consumer Products Activities
CPAB	Communications and Public Affairs Branch
CPS	Consumer Product Safety
CPSC	Consumer Product Safety Commission
CPSD	Consumer Product Safety Directorate
CPSP	Consumer Product Safety Program
CRT	Compliance Results Tracking
CSA	Canadian Standards Association
CVMA	Canadian Veterinary Medical Association
DFAIT	Department of Foreign Affairs and International Trade
DM	Deputy Minister
EPA	Environmental Protection Agency
ERHSD	Environmental and Radiation Health Sciences Directorate
FCSAP	Food and Consumer Safety Action Plan
FDA	<i>Food and Drugs Act</i>
HECSB	Healthy Environments and Consumer Safety Branch
HPA	<i>Hazardous Products Act</i>
ICCR	International Cooperation on Cosmetic Regulation
ICPHSO	International Consumer Product Health and Safety Organisation
IEC	International Electrotechnical Commission
ILA	Interdepartmental Letter of Agreement
IRP	Incident Reporting Program
ITF	Investigation Tracking Form

List of Acronyms

MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NCR	National Capital Region
NOV	Notices of Violation
NPSAC	National Public Safety Advisory Committee
NSS	National Standards System
NTP	National Toxicology Program
NTR	National Trauma Registry
OAG	Office of the Auditor General
OAS	Organization of American States
OECD	Organisation of Economic Co-operation and Development
OIS	Organization for International Standardization
OPSI	Office of Strategic Policy and Integration
PAA	Program Activity Architectures
PCO	Pest Control Operator
PCPA	<i>Pest Control Products Act</i>
PDB	Program Development Bureau
PHAC	Public Health Agency of Canada
PMF	Performance Measurement Framework
PMS	Performance Measurement Strategy
PMRA	Pest Management Regulatory Agency
PPID	Policy, Planning and Integration Directorate
PSIS	Product Safety Information System
PSL	Product Safety Lab
PVC	Polyvinyl chloride
RAB	Risk Assessment Bureau
RAPB	Regions and Programs Bureau
RDC	Research Data Centres
REDA	<i>Radiation Emitting Devices Act</i>
RIAS	Regulatory Impact Analysis Statements
RMAF	Results-based Management and Accountability Framework
RMB	Risk Management Bureau
SCC	Standards Council of Canada
SCU	Surveillance and Coordination Unit
SME	Small- to medium-sized enterprises
SOP	Standard Operating Procedures
WHO	World Health Organization

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Executive Summary

The purpose of this evaluation is to examine consumer products activities (CPA)¹, with a particular (but not exclusive) focus on CPA under the Food and Consumer Safety Action Plan (FCSAP). FCSAP CPA are organized into three strategic “pillars”, **active prevention** to avoid product safety incidents; **targeted oversight** to improve product safety checks at various stages of the production process; and **rapid response**, which gives increased authority to government to take action when it identifies a risk related to consumer products. Broadly speaking, CPA within these three pillars include collaboration and communication with government, industry, and consumers; development of standards and regulations; conducting risk assessments of consumer products; and conducting surveillance and enforcement of consumer product regulations.

CPA are delivered by the Consumer Product Safety Directorate (CPSD) and the Environmental and Radiation Health Sciences Directorate (ERHSD) within the Healthy Environments and Consumer Safety Branch (HECSB), the Pest Management Regulatory Agency (PMRA)², the Communications and Public Affairs Branch (CPAB), the Regions and Programs Bureau (RAPB). External to Health Canada, the Public Health Agency of Canada (PHAC) also plays a role in delivering CPA.

The Evaluation of Consumer Products Activities is part of Health Canada’s Five-Year Evaluation Plan. Using the current Treasury Board Policy on Evaluation (TBS, 2009), the evaluation assesses the relevance and performance (effectiveness, efficiency, and economy) of Health Canada’s CPA. The evaluation focuses on the period since the implementation of the FCSAP in 2007. While evaluation coverage of ERHSD, PMRA, CPAB, RAPB, and PHAC only includes activities undertaken under the FCSAP, the evaluation extends to the pre-FCSAP period for activities delivered by CPSD.

The evaluation drew on several lines of evidence, including a literature review, a document review, a review of administrative data, a survey of industry stakeholders and consumers, case studies, and key informant interviews. Data collection took place between April 2012 and February 2013.

Findings

Relevance

The consumer products component of the FCSAP was originally designed to strengthen Health Canada’s regulatory response to the risks posed by the consumer products it regulates, in order to better protect Canadians from unsafe products. The potential for some of the substances used in the manufacture of consumer products, cosmetics, and consumer pesticides to pose risks to human health, as well as the potential safety risks associated with the design and use of these

¹ Included in the scope of this evaluation, is Health Canada and PHAC’s CPA regarding general consumer products, cosmetics, radiation-emitting devices, and consumer pesticides. Unless otherwise specified, “consumer products” refers to consumer products, cosmetics, and radiation-emitting devices. Typically, consumer pesticides are referenced separately.

² PMRA is responsible for pesticide regulation in Canada, including, but not limited to, consumer pesticides. Only PMRA’s work related to consumer pesticides falls within the scope of the consumer products component of the FCSAP.

products suggest an ongoing need for Health Canada's CPA. Moreover, consumer product safety emerged as a major federal priority with the launch of FCSAP in December 2007 and was reaffirmed in the 2010 Speech from the Throne.

Performance – program implementation

Health Canada has made significant progress in establishing and implementing the *Canada Consumer Product Safety Act* (CCPSA) and has conducted a myriad of activities to support the CCPSA and other existing legislation. Health Canada and PHAC have also demonstrated progress in other areas including providing information to industry and Canadians, developing standards, expanding product-related injury surveillance and risk assessment, collaborating with international partners, and enhancing compliance and enforcement activities. Work remains to further develop information technology systems to support the CCPSA, and modernize the *Cosmetics Regulations* and the *Radiation-Emitting Devices Act* (REDA). The following highlights the status of some of the CPAs included in the consumer products component of the FCSAP.

Canada Consumer Product Safety Act (CCPSA)

One of Health Canada's major accomplishments was the coming into force of the CCPSA, which includes new provisions and powers that improve Health Canada's ability to respond to and address potential human health and safety risks associated with consumer products. In support of the CCPSA, Health Canada developed and implemented the Consumer Product Safety Program (CPSP) Case Management System (CCMS). It also centralized its risk assessment and risk management activities, and established dedicated divisions to handle the monitoring and triage of incident reports. *Administrative Monetary Penalties (Consumer Products) Regulations* (AMPS) came into force on May 24, 2013 and were published in *Canada Gazette*, Part II on June 5, 2013.

As of the date of this evaluation, Health Canada had not yet used its powers under the CCPSA to issue any mandatory orders or AMPs, as the Department first works with non-compliant companies to encourage them to implement corrective actions on a voluntary basis. Some of the ongoing, but yet to be completed, CCPSA-related activities include developing departmental policies, guidelines, and procedures associated with the new powers under the CCPSA; developing clear guidance on interpreting and applying the general prohibition against the manufacture, importation, sale, or advertisement of consumer products that are a danger to human health or safety; and for CCMS, establishing business rules for data entry and further developing data extraction/reporting capabilities.

Modernization of the Cosmetic Regulations and the Radiation-Emitting Devices Act

Although Health Canada intended to amend the *Cosmetic Regulations* and propose amendments to existing legislation, or even a new Act, for radiation-emitting devices, the Department has since decided not to pursue legislative/regulatory changes. Instead, for the *Cosmetic Regulations*, the Department is examining opportunities for improvement using non-regulatory approaches. And, for REDA, 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.

Information to Canadians and Industry Understanding its Obligations

Health Canada has conducted a wide range of outreach activities:

- To improve the information that Health Canada provides to Canadians about product safety, the department created the Consumer Information Bureau (CIB). However, it was later disbanded and activities were integrated into the ongoing work of the Public Affairs Directorate whose mandate aligns with this objective.
- To provide consumer products-related information to Canadians, Health Canada re-launched the Healthy Canadians website. According to Health Canada representatives, this was intended to be a one stop consumer-oriented site that combines content from seven federal departments related to health and safety. Social media activities (Twitter, widget, etc.) and a Recalls and Safety Alerts web and mobile application were also launched.
- To inform industry of its new obligations under the CCPSA, Health Canada conducted extensive industry outreach activities, including updating its website and holding cross-Canada information sessions.
- To inform Canadians about the safe use of consumer pesticides, PMRA launched consumer awareness and outreach campaigns, added more information to its compliance and enforcement website, and expanded the consumer pesticides-related content on the Healthy Canadians website.

Product-Related Injury Surveillance and Risk Assessment

PHAC implemented several projects to improve product-related injury surveillance and risk assessment. Examples include modernizing the Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) and expanding the number of participating hospitals; 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 in the Canadian Population Longitudinal Health Survey.

Monitoring and Enforcing Industry Compliance

Health Canada increased the level of resources, including the number of inspectors, it devoted to compliance and enforcement activities. Specifically, for consumer products, Health Canada expanded the coverage of its Cyclical Enforcement Program (CEP) from 23 product categories 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.

PMRA also undertook several initiatives to monitor and enforce industry compliance with the *Pest Control Products Act*. Specifically, it implemented a compliance verification program for consumer product vendors, introduced a compliance verification program targeting vendors of unregistered international pest control products, and it implemented a cyclical compliance monitoring program.

Performance – performance measurement and achievement of outcomes

Health Canada and PHAC have engaged in many activities that should, in theory, contribute to the expected outcomes. Data to support a definitive conclusion regarding the extent to which expected outcomes have been achieved are, however, relatively limited. In part, this reflects the following weaknesses associated with the performance measurement framework (PMF) for the consumer products component of FCSAP: many of the performance indicators are activity-based; in some cases, the same indicators are used to demonstrate progress toward different outcomes; and some critical performance indicators are not being tracked. It also reflects the current limitations of the CCMS, which has constrained the ability to report on some performance indicators.

Immediate outcomes

The intended immediate outcomes of CPA are increased awareness and understanding among external stakeholders of risks related to consumer products, increased awareness and understanding among industry of Health Canada's regulatory framework for consumer products, increased safety of consumer products, and increased industry compliance with Health Canada's regulatory requirements related to consumer products.

Ultimately, the evaluation was not able to determine the extent to which consumers' awareness of the risks related to consumer products had changed. Nonetheless, the survey, conducted as part of this evaluation, of consumers who subscribe to one or more of Health Canada's electronic information services found that the vast majority of respondents were aware of at least some of the consumer products-related information Health Canada has produced. Further, those who had used the information tended to rate it as "very" or "somewhat" useful, understandable, accessible, of high quality, and timely. In summary, about two thirds of consumers agreed that *"overall, Health Canada provides enough information to the general public about the human health safety risks associated with consumer products."*

The evaluation found that Health Canada's outreach activities have raised industry's awareness of its consumer product safety obligations under the CCPSA. However, it is apparent that there is a need for ongoing and continued outreach efforts as industry lacks clarity about the mandatory incident reporting and document retention requirements, 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, the survey of industry, conducted as part of the evaluation, found that, using a scale of 1 to 5, where 1 is poor and 5 is excellent, only half of the industry respondents rated the level of knowledge within their company/organization of the CCPSA as a "4" or "5 — excellent."

For consumer pesticides, based on PMRA reports on completed inspections, it appears there is reasonably high understanding of regulatory requirements in some sectors (e.g., requirement for pest control operators to sell only registered and properly-labelled commercial and domestic class pest control products), but, in other cases, there is low awareness of regulatory requirements (e.g., requirement to sell only registered and properly-labelled pet products).

It is not possible to determine the degree of industry compliance with Health Canada's regulatory requirements for consumer products since compliance and enforcement activities target instances of suspected non-compliance. Nonetheless, the evaluation found that 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 being developed. That being said, the case studies suggest there is ongoing non-compliance with the *Children's Jewellery Regulations* and the *Cribs, Cradles and Bassinets Regulations*. They also found evidence of non-compliance with the *Corded Window Covering Products Regulations*. Enforcement action was taken on 100% of non-compliant products through the CEP, for example, information letters, stop sales and voluntary recalls.

For consumer pesticides, the evaluation found that PMRA has developed a compliance and enforcement policy guideline, held a National Pesticide Compliance Workshop, and developed a database to track compliance activities. According to PMRA's compliance monitoring activities, depending on the types of products involved, compliance ranged 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.

Intermediate outcomes

The intended intermediate outcomes of CPA are external stakeholders' adoption of safe behaviours associated with consumer products, increased use of scientific evidence and risk-benefit analysis by Health Canada to inform decision-making, timely regulatory response to identified risks, harmonization of Canada's regulatory framework for consumer products with international approaches, and reduced exposure to identified risks associated with the use of consumer products.

It is reasonable to assume that Health Canada's efforts to increase consumer and industry awareness and understanding of the health and safety risks associated with consumer products and the regulatory framework for these products will lead to some degree of adoption of safe behaviours. It appears that although industry may require additional information about specific aspects of the mandatory incident reporting and document retention requirements under the CCPSA, the majority seem to know the requirements exist. Additionally, the results of the survey of consumers (who have had previous contact with Health Canada), which was conducted as part of this evaluation, suggest that the information that Health Canada provides has increased consumers' knowledge of human health or safety risks associated with consumer products, influenced their decisions about the consumer products that they purchase, and has influenced how they use consumer products.

The evaluation relied on qualitative evidence to assess the extent to which Health Canada uses scientific evidence and risk analysis to inform decision-making. Although the evaluation confirmed that Health Canada uses this type of information in decision-making, it was not possible to determine if use of this information has increased.

The program aims to provide timely regulatory responses to identified risks. Regulatory responses in the form of new regulations can be lengthy, frequently due to factors beyond the Department's control. Based on the case studies, it has taken about four years to enact regulations for children's jewellery and corded window covering products, from the time that the department had announced its intent to regulate. In November 2009, Stork Craft voluntarily recalled drop-side cribs in collaboration with Health Canada and the US CPSC. The US prohibited drop side cribs effective June 28, 2011. The process of drafting an amendment to the Canadian *Cribs, Cradles and Bassinets Regulations* to address the safety risk posed by drop-side cribs is underway. According to Health Canada representatives, the proposed changes will also improve the general safety of cribs, cradles and bassinets and further align Canadian and U.S. requirements. This has required additional time in amending the regulations.

The coming into force of the CCPSA will provide the department with a broadened suite of instrument choice to address human health and safety risks associated with consumer products. The CCPSA introduces a "general prohibition" which reduces the need to rely on Governor in Council regulations to address health or safety issues, resulting in an enhanced capacity for Health Canada to respond.

The evaluation relied on qualitative evidence to assess the extent to which Canada's regulatory framework for consumer products has been harmonized with international approaches. The evaluation found that enactment of the CCPSA has helped better align Canada's legislation with other countries. It also noted that Health Canada is participating in a variety of standards committees, collaborating with a range of international institutions/organizations, and issuing joint recalls with the US CPSC.

Long-term outcomes

The intended long-term outcomes of CPA are reduced adverse events and/or incidents associated with the use of consumer products and increased public confidence in consumer products and the related regulatory system. Concrete data to support conclusions on these outcomes has not been collected.

In theory, Health Canada's CPA should contribute to reducing adverse events associated with the use of consumer products. It seems that, given the mandatory incident reporting requirement for industry and Health Canada's efforts to raise public awareness of the ability for consumers to voluntarily report incidents, the Department is beginning to receive an increased number of reported incidents. Given the information provided to the evaluation, it was not possible to determine trends in consumer product-related injuries and deaths. Nonetheless, based on the case studies, there has been little change over time in the annual number of crib-related injuries, although the annual number of deaths has decreased since 1986. Further, there does not appear to be a clear trend in the child fatality rate associated with corded window coverings.

Aside from key informant opinion and the results of a survey of industry and consumers who have had contact with Health Canada, there is no data upon which to assess whether public confidence in consumer products and the related regulatory system has increased. Generally speaking, Health Canada representatives and external stakeholders indicated that Health Canada is beginning to be viewed as a leading regulator of consumer products. However, only 38% of survey respondents agree that “Health Canada does enough to monitor the safety of consumer products on the market.” Further, only 31% agree that “Health Canada does enough to enforce its consumer products regulations.”

Performance – 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 systems link information about program costs to specific inputs, activities, outputs and expected results. Although Health Canada tracks planned and actual spending by FCSAP pillar and strategy, there was a lack of departmental financial data linked to the quantity and type of outputs, and since several CPA apply to more than one FCSAP strategy and/or pillar, the amount of financial and human resources reported as being used for each component does not accurately reflect the actual level of resources required to implement them.

According to internal key informants, CPA have been implemented efficiently and similar results could not have been achieved at a lower cost. Examples of operational approaches that created efficiencies included new approaches to information dissemination (webinars rather than information sessions in every city), working with other jurisdictions to learn from their experiences, and developing consistent templates and standards to facilitate processes

According to information provided by Health Canada and PHAC, overall, over the period of 2008–09 to 2011–12, actual spending (\$65.6 million) for the consumer products component of FCSAP was 96% of planned spending (\$68.54 million).

RECOMMENDATIONS

The following are the recommendations stemming from the evaluation.

Recommendation 1.

Health Canada (CPSD, RAPB) should take further steps to enable the use of new powers granted through the CCPSA.

Recommendation 2.

Health Canada (CPSD, RAPB, PMRA) should implement service standards for risk assessment and risk management.

Recommendation 3.

Health Canada (all participants) and PHAC should take steps to improve the Performance Measurement Strategy (PMS) for the consumer products component of FCSAP.

Recommendation 4.

Health Canada (CPSD, RAPB) should implement measures to improve the quality of CCMS data.

Recommendation 5.

Health Canada (CPSD, RAPB, CPAB) should continue to inform and educate industry about their obligations under the CCPSA.

Recommendation 6.

Health Canada (CPSD, ERHSD, RAPB) should ensure that the risk-based Cyclical Enforcement Program aligns with the broader scope of relevant products regulated under the CCPSA, REDA and FDA.

Management Response and Action Plan (MRAP) Evaluation of the Consumer Products Activities

This Management Response and Action Plan (MRAP) has been developed by participating organizations [i.e., Consumer Product Safety Directorate (CPSD) and Environmental Radiation and Health Sciences Directorate (ERHSD) of the Healthy Environments and Consumer Safety Branch (HECSB); the Regions and Programs Bureau (RAPB); the Communications and Public Affairs Branch (CPAB); the Pest Management Regulatory Agency (PMRA); and the Public Health Agency of Canada (PHAC)] in response to the recommendations made in the Evaluation of the Consumer Products Activities Report. *All responsibility for reporting on key activities rests at the Director General level.*

Draft Recommendations *	Partner	Response	Key Activities	Responsible Manager	Time Frame
R1. Health Canada (CPSD, RAPB) should take further steps to enable the use of new powers granted through the CCPSA.	CPSD	Agree	<p>The Consumer Product Safety Directorate has completed a number of initiatives in support of this recommendation, specifically:</p> <ul style="list-style-type: none"> • AMPs regulations were pre-published in the <i>Canada Gazette</i>, Part I in 2012. The regulations were approved by the Governor in Council on May 23, 2013, came into force on May 24, 2013 and were published in the <i>Canada Gazette</i>, Part II on June 5, 2013. • CPSD has developed a full suite of materials in support of the Review of Orders process pursuant to s.35 of the Act. As well, review officers have been designated and trained. • Guidance materials for industry have been developed and posted to the HC website on the Mandatory Incident Reporting and Preparing and Maintaining Documents provisions of the CCPSA. <p>CPSD will further develop protocols and guidance in support of staff training on the use of new powers granted through the CCPSA, which will include the development of self-training modules and delivery of national training related to the General Prohibition, Review of Orders and AMPs, as new policy work is completed.</p>	Director General, CPSD	All deliverables and activities planned to be completed by March 2014.
	RAPB	Agree	RAPB will collaborate on the development of policies, guidelines, and provide employees with appropriate training.	RDG Executive File Lead RAPB	Appropriate training will be completed by March 2014, and as required afterwards.

Draft Recommendations *	Partner	Response	Key Activities	Responsible Manager	Time Frame
R2. Health Canada (CPSD, RAPB, PMRA) should implement service standards for risk assessment and risk management.	CPSD	Agree	The Program will continue to monitor service standards for triage of incident reports. Service standards have been developed and will be finalized for first-level risk assessments and for selected risk management activities, including compliance and enforcement activities.	Director General, CPSD	The Program will continue to monitor service standards for triage of incident reports on an ongoing basis. Service standards for first-level risk assessment and selected risk management activities will be finalized by March 2014, followed by ongoing performance monitoring.
	RAPB	Agree	RAPB will participate in the development and tracking of RAPB-related performance service standards (risk management and compliance and enforcement activities).	RDG Executive File Lead RAPB	Service standards will be developed by March 2014, and as required afterwards.
	PMRA	Agree	Though PMRA's performance standards have evolved as a result of the DM Dashboard, the PMRA will review and, where necessary and feasible, refine risk-based performance standards related to compliance and enforcement activities.	Director General, Compliance, Lab Services and Regional Operations, PMRA	Risk-based performance standards related to compliance and enforcement activities will continue to be reviewed and will be updated by March 2014.
R3. Health Canada (all participants) and PHAC should take steps to improve the Performance Measurement Strategy (PMS) for the consumer products component of FCSAP.	CPSD	Agree	A Consumer Products Component PM Strategy Working Group (CPC PMS WG) will be created, and will work to build upon and strengthen recently updated performance indicators and outcomes, which were developed at the time of the commencement of the Evaluation of Consumer Products Activities. It should be recognized, however, that it is a common challenge to measure true outcome-related performance indicators given attribution issues and limited opportunities for cost-effective data collection and analysis.	Director General, CPSD	Refinement and DG approval of the CPC PMS will be completed by March 2015.
	RAPB	Agree		RDG Executive File Lead RAPB	
	ERHSD	Agree		Director General, ERHSD	
	PMRA	Agree		Director General, Compliance, Lab Services and Regional Operations, PMRA	
	CPAB	Agree		Director General, Public Affairs Directorate, CPAB	
	PHAC	Agree		Director General, Centre for Chronic Disease Prevention, Health Promotion and Chronic Disease Prevention Branch, Public Health Agency of Canada (PHAC)	

Draft Recommendations *	Partner	Response	Key Activities	Responsible Manager	Time Frame
<p>R4. Health Canada (CPSD, RAPB) should implement measures to improve the quality of CCMS data.</p>	CPSD	Agree	<p>To improve the quality of CCMS data, CPSD has developed business procedures for the different aspects of the CCMS, which are being refined and aligned across the Program on an ongoing basis, and staff are being trained and informed as required.</p> <p>CPSD will work internally to further develop data analysis templates and reports, to continue facilitating monitoring of current performance indicators, as well as newly created performance indicators (see R3).</p>	Director General, CPSD	<p>CPSD will continue to define and implement business procedures for the CPSP Case Management System (CCMS) on an ongoing basis.</p> <p>Following the refinement of the PMS (see R3), CPSD will incorporate new performance indicators in the CCMS where applicable, with implementation for tracking beginning by March 2015.</p> <p>Following the finalization of service standards for first-level risk assessment, and selected risk management activities in by March 2014 (see R2), CPSD will integrate these service standards for tracking purposes into the CCMS with implementation beginning in 2014-2015.</p>
	RAPB	Agree	RAPB will collaborate with CPSD to identify performance indicators to be tracked in RADAR. RAPB will ensure that regional operational procedures are in place for proper data entry related to the tracking of performance in RADAR.	RDG Executive File Lead RAPB	RAPB timelines for these activities will be aligned with CPSD timelines for R4.
<p>R5. Health Canada (CPSD, RAPB, CPAB) should continue to inform and educate industry about their obligations under the CCPSA.</p>	CPSD	Agree	CPSD has developed and disseminated information about industry's obligations under the <i>CCPSA</i> . This work has included publications, information sessions, webinars, web content, and collaboration with stakeholders. CPSD will continue to conduct targeted outreach with high priority industry sectors/players through a variety of appropriate means.	Director General, CPSD	CPSD will continue to conduct targeted outreach in 2013-2014, and as planned/required afterwards.
	RAPB	Agree	<p>RAPB will continue to work with CPSD on industry outreach products, and continue to inform and educate industry.</p> <p>RAPB will continue to meet with industry individually and through various other mechanisms.</p>	RDG Executive File Lead RAPB	March 2015, and as required afterwards.
	CPAB	Agree	E-Communications will provide web support, ensure content is written in a web friendly format and publish in a timely manner.	Director General, Public Affairs Directorate, CPAB	Specific details to be identified based on Program requests.

Draft Recommendations *	Partner	Response	Key Activities	Responsible Manager	Time Frame
<p>R6. Health Canada (CPSD, ERHSD, RAPB) should ensure that the risk-based Cyclical Enforcement Program aligns with the broader scope of relevant products regulated under the CCPSA, REDA and FDA.</p>	CPSD	Agree	<p>CPSD has completed Cyclical Enforcement related to cosmetics, and in areas related to the General Prohibition, including cadmium in children’s jewellery.</p> <p>In addition, implementation of a pilot to address the General Prohibition is scheduled this year, and this work will be expanded during next fiscal year.</p> <p>CPSD will implement the work plan to incorporate General Prohibition (GP) into the Cyclical Enforcement Plan, for consumer products and cosmetics.</p>	Director General, CPSD	<p>CPSD will implement the pilot related to the General Prohibition by March 2014, with this work being expanded upon in 2014-2015. Planning for this expanded work will be completed by end of March 2014.</p> <p>CPSD will complete this implementation by March 2015.</p>
	RAPB	Agree	<p>RAPB will collaborate with CPSD to develop Cyclical Enforcement Programs for cosmetics and consumer products that are not covered by product-specific regulations and will deliver on all nationally agreed-upon Cyclical Enforcement Programs.</p>	RDG Executive File Lead RAPB	<p>RAPB timelines for these activities will be aligned with CPSD timelines for R7.</p>
	ERHSD	Agree	<p>ERHSD is developing a cyclical enforcement plan for existing and emerging radiation- emitting devices regulated under the <i>Radiation Emitting Devices Act (REDA)</i>. The cyclical enforcement plan will assess these devices based on level of risk or other information received such as complaints or requests.</p>	Director General, ERHSD	<p>A cyclical enforcement plan for radiation-emitting devices will be completed by March 2014.</p>

1.0 Introduction

Consumer Products Activities (CPA) are delivered by the Consumer Product Safety Directorate (CPSD) and the Environmental and Radiation Health Sciences Directorate (ERHSD) within the Healthy Environments and Consumer Safety Branch (HECSB) of Health Canada; the Pest Management Regulatory Agency (PMRA); the Communications and Public Affairs Branch (CPAB); and the Regions and Programs Bureau (RAPB). External to Health Canada, the Public Health Agency of Canada (PHAC) also plays a role in delivering CPA.

The Evaluation of the Consumer Products Activities is part of Health Canada and the Public Health Agency of Canada's Five-Year Evaluation Plan. Using the current Treasury Board Policy on Evaluation (TBS, 2009), the evaluation assesses the relevance and performance (effectiveness, efficiency, and economy) of Health Canada's and PHAC's consumer products activities. The evaluation focuses on the period since the implementation of the Food and Consumer Safety Action Plan (FCSAP) in 2007. While evaluation coverage of ERHSD, PMRA, CPAB, RAPB, and PHAC only includes activities undertaken under the FCSAP, the evaluation extends to the pre-FCSAP period for activities delivered by CPSD.

PRA Inc., an independent evaluation consulting firm, conducted the evaluation on behalf of Health Canada. The evaluation drew on several lines of evidence, including a literature review, a document review, a review of administrative data, a survey of industry stakeholders and consumers, case studies, and key informant interviews. Data collection took place between April 2012 and February 2013. This report presents the evaluation findings, draws conclusions, and makes recommendations.

1.1 Guide to the report

The report is organized in several sections. Section 2 provides a brief profile of CPA, and Section 3 describes the methodology. Section 4 contains the evaluation findings pertaining to relevance, and Section 5 contains the evaluation findings on performance. Section 6 concludes the report and makes recommendations.

The following appendices accompany the main report:

- Appendix A provides the list of references
- Appendix B presents the FCSAP logic model
- Appendix C contains the evaluation matrix

2.0 Profile of Consumer Products Activities

The purpose of this evaluation is to examine CPA, with a particular (but not exclusive) focus on consumer products activities under the FCSAP, which is a horizontal initiative involving Health Canada, the Canadian Food Inspection Agency (CFIA), the Canadian Institutes of Health Research (CIHR), and PHAC. Launched by the Government of Canada in December 2007 in

response to a growing number of food safety incidents, recalls, and concerns, FCSAP consists of a series of initiatives to “modernize and strengthen Canada’s safety system for food, health and consumer products” (Health Canada, 2012a). FCSAP has the overall goal of “strengthening and modernizing Canada’s safety system for health, consumer, and food products to protect the health of Canadians, through program investments and legislative amendments” (GoC, 2008). FCSAP funding totals \$489.4 million over five years and \$126.7 million ongoing (Health Canada, 2012b).

The long-term outcome of the consumer products component of FCSAP is reduced adverse health incidents related to consumer products (including cosmetics, pest management products, and radiation-emitting devices).

FCSAP CPA are organized into three strategic “pillars” (GoC, 2008, p. 20):

- **Active prevention** involves avoiding product safety incidents through systematic risk assessment, increased scientific knowledge, improved standards, early identification of safety issues, and increased consumer awareness.
- **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, establishment of systems for surveillance and risk assessment, and modernization of regulatory oversight.
- **Rapid response** gives increased authority to government to take action when it identifies a risk related to consumer products. Actions include mandatory recalls and fines that the government was previously not able to enforce and recordkeeping requirements to facilitate product tracing.

Broadly speaking, CPA within these three pillars include collaboration and communication with government, industry, and consumers; development of standards and regulations; conducting risk assessments of consumer products; and conducting surveillance and enforcement of consumer product requirements. It is important to note that Health Canada’s CPA do not include a pre-market approval process for consumer products or cosmetics for sale.³

2.1 Roles and responsibilities

Implementation and delivery of the consumer products component of FCSAP is a shared responsibility of several federal participants. The roles and responsibilities of these participants are described below.

³ However, Health Canada must be notified of all cosmetics sold in Canada within 10 days of entering the marketplace. Additionally, pesticides must be registered for sale in Canada, and they are subject to re-evaluation every 15 years.

Consumer Products Safety Directorate

CPSD, in partnership with RAPB, is responsible for delivering Health Canada's Consumer Product Safety Program (CPSP).⁴ The CPSP "helps protect the Canadian public by researching, assessing, and collaborating in the management of the health risks and safety hazards associated with the many consumer products that Canadians use every day" (CPSD, 2011a). It administers and enforces the *Canada Consumer Product Safety Act* (CCPSA), and cosmetic-related provisions of the *Food and Drugs Act* (FDA), as well as the *Cosmetic Regulations*.

The goal of CPSD is to identify, assess, manage, and communicate to Canadians the health and safety hazards and health risks associated with consumer products and cosmetics. It consists of three bureaus located in the National Capital Region (NCR):

- **Program Development Bureau (PDB)**, responsible for the integration of shared accountabilities across the directorate, provides an ongoing challenge function to the existing body of Regulations; integrated planning and performance measurement; legislative, regulatory, and policy guidance and development; and integrated/coordinated international and intergovernmental relations. PDB is also accountable for effective external relations, including the development and implementation of consumer and industry outreach activities.
- **Risk Assessment Bureau (RAB)** develops, implements, and maintains an integrated framework and processes to support the provision of centralized scientific risk assessment and hazard analysis services, which are designed to support minimizing Canadians' exposure to potentially hazardous products. RAB includes the Product Safety Lab (PSL), which provides support for standards development; testing services for compliance and enforcement work; and training and advice to manufacturers, importers, and private laboratories interested in testing consumer products. Additionally, other product-related activities are undertaken, such as novel test method development.
- **Risk Management Bureau (RMB)** develops, implements, and maintains an integrated framework and processes to support the provision of centralized scientific risk management services designed to minimize the exposure of Canadians to potentially hazardous products. Related to this are accountabilities for operational policy, training, development of regulations and standards, and oversight and coordination of compliance and enforcement. RMB is also responsible for recall monitoring activities, including the oversight of cyclical enforcement projects, compliance and enforcement actions, recall monitoring, and complaint follow-up.

Environmental and Radiation Health Sciences Directorate

ERHSD's role includes environmental health and radiation regulation, health research and surveillance, chemical surveillance and monitoring, and science policy. Its activities include surveillance, hazard and risk identification, assessment and management, research, epidemiological investigations and emergency planning, policy coordination, and administration

⁴ CPSP refers to activities delivered by CPSD, in collaboration with RAPB (i.e., the Regions). CPSD refers to activities delivered out of the National Capital Region (NCR).

of the *Radiation Emitting Devices Act* (REDA). The Consumer and Clinical Radiation Protection Bureau (CCRPB), a bureau within the ERHSD, is responsible for the administration of the REDA, which addresses radiation safety issues for X-ray and non-ionizing radiation devices, including devices used in consumer and industrial applications, as well as medical devices.

Pest Management Regulatory Agency

PMRA is responsible for pesticide regulation in Canada, including, but not limited to, consumer pesticides. Specifically, PMRA is responsible for administering the *Pest Control Products Act* (PCPA) and its Regulations. Its main activities⁵ include registering pesticides for sale in Canada; monitoring the use of pesticides through enforcement, compliance, and education mechanisms; re-evaluating existing pesticides every 15 years to confirm that they continue to meet modern scientific standards; and managing legislated incident reporting from companies (PMRA, 2011a). Only PMRA's work related to consumer pesticides falls within the scope of the consumer products component of the FCSAP.

Communications and Public Affairs Branch

CPAB⁶ is the communications organization that supports both Health Canada and the Public Health Agency of Canada. It delivers social marketing campaigns, manages the Health Canada, Public Health Agency of Canada and Healthy Canadians websites and digital channels, manages public engagement (public opinion research and consultations) and operates the Department's distribution centre in order to provide Canadians with accessible, relevant and up-to-date health and safety information.

Regions and Programs Bureau

RAPB provides a regional⁷ perspective in the development of Health Canada policies and programs and helps to build relationships with partners and stakeholders. It helps to deliver Health Canada programs and implement Health Canada policies. With respect to consumer products and consumer pesticides, RAPB's specific activities include implementing compliance and enforcement programs; working with industry to address non-compliance (e.g., information letters, consumer advisories, stop sales, product seizures, and/or recalls); communicating with the consumer product/consumer pesticide industry to promote and clarify their responsibilities under the CCPSA, the PCPA, the REDA and the FDA (including the *Cosmetic Regulations*); providing on-the-ground information and education to consumers about product safety; and participating in committees that examine legislative updates.

⁵ All of PMRA's activities relate to all categories of pesticides, including consumer pesticides. PMRA's activities under the consumer products component of FCSAP only relate to consumer pesticides, which only represents a portion of PMRA's overall activities.

⁶ CPAB was formally called the Public Affairs, Consultation and Communications Branch (PACCB).

⁷ There are six regions, including British Columbia, Prairie (Alberta, Saskatchewan, and Manitoba), Ontario, Quebec, Atlantic, and Northern. Five of the regions participate in service delivery, with the Prairie region having responsibility for service delivery for all programs related to the FCSAP activities (i.e., product safety and pesticides).

Public Health Agency of Canada

PHAC is the main Government of Canada agency responsible for public health in Canada. The agency's goal is "to strengthen Canada's capacity to protect and improve the health of Canadians and to help reduce pressures on the health-care system" (PHAC, 2011a). In the context of CPA under FCSAP, PHAC provides information on injuries related to consumer products and the risks and circumstances in which such injuries occur; conducts surveillance and related research to obtain more detailed information on consumer product-related injuries, risks, and contributing factors; disseminates information to those able to take action in the areas of product design and use, injury prevention, public awareness, and policy development (e.g., provides information to injury prevention/safety promotion organizations); and conducts risk assessments, such as post-market consumer product reviews for Health Canada.

2.2 Program logic

A logic model for CPA (see Appendix B) was developed as part of the FCSAP Results-based Management and Accountability Framework (RMAF). For the purposes of the evaluation, the expected outcomes laid out in the FCSAP logic model were subsumed within a set of expected outcomes developed for use in evaluations across Health Canada's regulatory programs.

In the immediate term, CPA are expected to lead to increased awareness and understanding among external stakeholders of risks related to consumer products, increased awareness and understanding among industry of Health Canada's regulatory framework for consumer products, and increased industry compliance with the regulatory framework.

The achievement of these immediate outcomes is expected to lead to intermediate outcomes of adoption of safe behaviours associated with consumer products by external stakeholders; increased use of scientific evidence and risk analysis by Health Canada to inform decision-making; timely regulatory response to identified risks; reduced exposure to health risks associated with the use of consumer products; and harmonization of Canada's regulatory framework for consumer products with international approaches.

In the long term, Health Canada hopes to reduce health risks and adverse events associated with the use of consumer products; increase public confidence in consumer products and the related regulatory system; and produce a sustainable, cost-efficient, responsive, and science-based regulatory system for consumer products in Canada. These outcomes are expected to contribute to Health Canada's ultimate goal of improving the health and well-being of Canadians.

3.0 Methodology

This section of the report provides a detailed description of the evaluation methodology.

3.1 Evaluation questions

The evaluation addresses 10 key questions and a number of sub-questions. Appendix C contains a detailed evaluation matrix that links each question to a set of indicators, data sources, and collection methods. Relevant indicators pertaining to CPA from FCSAP were incorporated into the matrix. The evaluation questions and the matrix are based on the results of an evaluability assessment and conform to the Treasury Board of Canada's Policy on Evaluation.

Although much of the focus of this evaluation is on FCSAP, evaluation coverage of CPSD's CPA is not restricted to FCSAP. Therefore, the evaluation questions and indicators are not identical to those developed to support FCSAP, although FCSAP indicators have been incorporated into the evaluation matrix where appropriate. Evaluation coverage of ERHSD, PMRA, CPAB, RAPB, and PHAC is limited to FCSAP activities and outcomes.

3.2 Evaluation design and data collection methods

The evaluation design was developed based on the findings of an evaluability assessment completed as a first step in the evaluation. As part of the evaluability assessment, PRA conducted a preliminary review and assessment of available documents and administrative data to determine their usefulness and relevance to the evaluation. PRA also completed 7 preliminary interviews with a total of 19 program representatives.⁸ The evaluation matrix in Appendix C was developed on the basis of the evaluability assessment.

The evaluation consisted of the following data collection methods:

- **Literature review.** The literature review addressed evaluation questions related to relevance, harmonization of Canada's regulatory framework with international approaches, reduction of adverse events associated with the use of consumer products, and alternate approaches.
- **Document and administrative data review.** The document review addressed all the evaluation questions, to the extent that supporting documents were available. The review encompassed several hundred documents, primarily produced by Health Canada, related to CPA planning, management, and ongoing operations. It also considered FCSAP annual reports, CPSD databases (the CPSP Case Management System [CCMS] and the Product Safety Information System [PSIS]), PMRA databases (Investigation Tracking Form [ITF] and Compliance Results Tracking [CRT]⁹), and information on Health Canada's website.

⁸ Each of the federal departments/directorates/agencies involved in delivering CPA participated in the preliminary interviews.

⁹ As described in Section 5.3, the ITF has been replaced by the CRT.

- **Case studies.** Three in-depth case studies were conducted. The case studies examined Health Canada's response to the human health and safety risks associated with the following consumer products, which are regulated and have been high-profile in the media: children's jewellery; cribs, cradles, and bassinets; and corded window coverings. The case studies consisted of a document review, a group interview with Health Canada representatives, and an interview with an external stakeholder.
- **Survey of industry representatives and consumers.** The bilingual survey of industry representatives and consumers used a web-based approach and focussed on evaluation questions related to implementation and outcomes. The survey targeted participants in CCPSA information sessions and subscribers to Health Canada's Consumer Product Safety electronic newsletter and/or the CCPSA electronic newsletter. The final sample consisted of 12,626 email addresses. The contact lists for the survey did not contain information about the type of stakeholder; therefore, it was not possible to determine how many stakeholders belong to the industry or consumer group prior to the start of the survey. The first question in the survey asked respondents to indicate the nature of their involvement with consumer products, and based on their responses to this question, directed them to the relevant survey questions. A total of 1,117 respondents, including 343 industry representatives and 774 consumers completed the questionnaire. The refusal rate for the survey was 5.9%, and the completion rate was 9.3%. The margin of error¹⁰ for the survey overall is $\pm 2.8\%$, 19 times out of 20. Given that the population of industry stakeholders and consumers is unknown, the estimated margin of error for the industry survey is $\pm 5.3\%$, 19 times out of 20, and for the consumer survey is $\pm 3.5\%$, 19 times out of 20.
- **External key informant interviews.** The key informant interviews addressed all of the evaluation questions. Key informants, identified by Health Canada and PRA, were selected for the information and specific perspectives they could bring to the selected evaluation questions. A total of 19 interviews were conducted with representatives of the following groups: industry associations (n=12); consumer, health, and other associations (n=5); and other external stakeholders (n=2). Additionally, five interviews were conducted with PMRA's external stakeholders, who were asked about the adequacy and effectiveness of PMRA's consumer pesticides activities.
- **Internal key informant interviews.** In addition to the preliminary interviews with 16 Health Canada representatives completed at the project outset, a second round of interviews with 31 Health Canada representatives was conducted following the conclusion of the other data collection activities. This round of interviews was intended to give program personnel the opportunity to respond to some of the preliminary evaluation findings, and to provide additional information, as necessary.

¹⁰ Broadly speaking, the results of surveys achieving a margin of error equal to or less than $\pm 5\%$, regardless of the completion rate achieved, can be considered representative of the general population. However, as mentioned in Section 3.4., given that the surveys conducted as part of this evaluation targeted individuals with previous contact with Health Canada, it is possible that some bias has been introduced, as these individuals may be more aware of CPA than industry and consumers in the general population.

3.3 Approach to data analysis

For final reporting, data from all lines of evidence was integrated or triangulated in order to arrive at the overall evaluation findings. Triangulation is a process through which answers to research questions generated by different data collection methods are compared. Where different methods produced similar findings, those findings were assumed to have greater validity and therefore greater confidence in the results is warranted. Program representatives were provided the opportunity to review and comment on the draft evaluation report.

3.4 Limitations and mitigation strategies

The following methodological limitations, and associated mitigation strategies, are important to note:

1. The survey conducted as part of this evaluation was intended to gather information on outcomes such as industry/consumer awareness and understanding. The survey used existing databases of individuals and industry representatives who had previously been in contact with Health Canada for reasons related to CPA (e.g., by subscribing to listservs). Therefore, when reviewing the survey results, it is important to recognize that, because survey respondents have had at least some level of engagement with Health Canada, it is possible that some bias has been introduced, as these individuals may be more aware of CPA than industry and consumers in the general population. To mitigate this limitation, where possible, the evaluation placed the findings of the survey in context of previous public opinion research, related to consumer products, conducted for Health Canada.
2. Health Canada's CCMS was identified as one of the key sources of performance data. CCMS was implemented in 2011 when the CCPSA was brought into force. Although CCMS replaced the former PSIS database, the two data systems do not collect analogous information. Further, CCMS is still in development and, as such, provides limited performance analysis support at this time. Two reasons for this are: 1) business rules have not been fully established to ensure consistent data entry; and 2) data extract/analysis capabilities have not been fully developed. Consequently, the evaluation had to rely on other lines of evidence to assess the extent to which Health Canada has achieved its intended outcomes. Ultimately, limited data were available to support assessment of achievement of outcomes.
3. Given the limitations of the Departmental financial system, including a lack of a time reporting component for accurate FTE utilization data, the evaluation was not able to conduct a robust assessment of program efficiency and economy. The evaluation attempted to use key informant interviews with representatives of Health Canada to mitigate this limitation.

4.0 Findings: relevance

This section of the report presents the evaluation findings on relevance, organized by evaluation question.

4.1 Continued Need

Health Canada has regulated consumer products since the 1950s. The consumer products component of the FCSAP was originally designed to strengthen Health Canada's regulatory response to the risks posed by the consumer products it regulates, in order to better protect Canadians from unsafe products. Government planning documents from 2007 identified three main drivers behind the FCSAP initiative:

- Health Canada's regulatory system was perceived as inadequate to deal with a rapidly growing and complex global market place.
- A number of high profile incidents in food and consumer safety had demonstrated critical gaps and inconsistencies in how these products are regulated.
- A 2006 report by the Office of the Auditor General raised questions about the adequacy of Health Canada's resources, tools, and risk-based approaches for regulation to protect the health and safety of Canadians (OAG, 2006).

The evaluation found there is a continued need for CPA. Canadians may be exposed to health and safety risks associated with consumer products and consumer pesticides through various avenues. As indicated in the scientific literature, some of the substances¹¹ used in consumer products and/or consumer pesticides can pose risks to human health. Additionally, as illustrated through the case studies, health and safety risks may be inherent in the design of products, or risks may arise based on the manner in which products are used.

There are also risks associated with radiation emission from consumer products (e.g., acoustics, noise pollution).¹² The World Health Organization (WHO) considers sleep disturbance, communication interference, and annoyance resulting from noise to be adverse health impacts, since "health" is defined as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (Michaud, Keith, & McMurchy, 2008).

¹¹ Examples include Bisphenol A (BPA), phthalates, and heavy metals. BPA in polycarbonate baby bottles is prohibited under the CCPSA. 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).

¹² Other risks relate to exposure to ultraviolet (UV) radiation and radiofrequency energy.

Case study examples: illustrations of risks associated with consumer products

Cribs, cradles, and bassinets

Risks related to product design: Crib-related injuries can occur if children's limbs become entrapped between the crib slats; the child becomes wedged between the crib and the mattress; the crib malfunctions or collapses; or the child in the crib gains access to a hazardous substance or object (PHAC, 2008).

Risks related to product use: In Canada, the main cause of crib-related injuries is falls out of the crib (GoC, 2010a). However, some of the deaths in Canada and the US associated with drop-side cribs occurred as a result of the caregivers trying to repair the drop-side portion of the crib on their own, sometimes with parts or hardware not supplied by the manufacturer (Health Canada, 2010a).

Case study examples continued

Corded window coverings

Risks related to product design: The *Corded Window Covering Products Regulations* define a corded window covering as "an interior window covering that incorporates a bead chain, cord, or any type of flexible looped device in its operation" (GoC, 2012a, sec. 1). Examples of corded window coverings are horizontal and vertical blinds, roll-up blinds, roller shades, and roman shades (CSA, 2008). The primary safety risk associated with corded window coverings is strangulation, particularly for children aged ten months to four years (Health Canada, 2008a). The two main strangulation hazards include a cord forming a loop, which can entangle the child, or a long cord wrapping around the child's neck (Health Canada, 2010b). Safety risks are also associated with other features of corded window coverings such as, but not limited to, inner cord loops and cords on the back of roman shades.

Risks related to product use: 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 the following: 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 (Health Canada, 2007).

4.2 Alignment with government priorities

CPA are well-aligned with the priorities of the Government of Canada. With the launch of FCSAP in December 1997, consumer product safety emerged as a major federal priority. Further, CPA conducted by Health Canada and PHAC support the strategic outcomes/objectives of their respective Program Activity Architectures (PAA).

As discussed above, the consumer products component of FCSAP was designed to address weaknesses and gaps in Health Canada's regulatory framework for consumer products. In response to the OAG report, Health Canada undertook a variety of comprehensive reviews of its regulatory programs, including risk assessments and gap analyses. Overall, the main conclusion of a series of capacity assessments conducted in 2007 for consumer product safety¹³ was that the existing approach to regulating consumer products was inadequate to keep pace with recent significant changes in the consumer product market, including globalization; the emergence of new products and technologies (e.g., nanotechnology); the emergence of counterfeit products; and the growing prevalence of electronic stores, dollar stores, and second-hand stores

¹³ Note that this capacity assessment did not cover activities related to consumer pesticides

(KellySears Consulting Group, 2007, pp. 2, 8). In all areas, the capacity assessments identified a need to build capacity through improving processing, increasing resource levels, and/or improving information management systems. Many of the issues identified through capacity assessments were subsequently included in FCSAP.

The federal government reaffirmed its commitment to consumer product safety in the 2010 Speech from the Throne, which vowed to “reintroduce legislation to protect Canadian families from unsafe food, drug and consumer products” (GoC, 2010b). Following through on this commitment, and as promised as part of FCSAP, new consumer product safety legislation, namely the CCPSA, came into force in June 2011 (GoC, 2011a). More recently, however, the 2011 and 2012 Budgets did not specifically mention consumer products or consumer product safety, and neither did the 2011 Speech from the Throne (GoC, 2011b, 2011c, 2012b).¹⁴

CPA are also well-aligned with Health Canada’s current PAA. Of the three Health Canada strategic outcomes, CPA align most closely with the outcome of ensuring that Canadians “are informed of and protected from health risks associated with food, products, substances and environments, and are informed of the benefits of healthy eating” (Health Canada, 2012c). This strategic priority links to the operational priority to “modernize health protection legislation and programs” (Health Canada, 2012c).

There is also evidence of alignment of CPA with the PAA of PHAC, which is based around the three strategic directions of strengthening health promotion and disease prevention leadership; strengthening public health capacity and science leadership; enhancing public health security and excelling in innovation and management (PHAC, 2013). CPA align with the second strategic direction, which includes enhancing public health surveillance of non-communicable disease risk factors, maternal and child health, injuries and infectious diseases as well as fostering, promoting and strategically managing surveillance, science and research to support public health decisions and actions.

4.3 Alignment with federal roles and responsibilities

CPA are consistent with the federal roles and responsibilities set out in the *Department of Health Act* and other federal statutes relevant to health and consumer products. Further, the federal government has a long history of taking action to address consumer product-related issues and risks.

Health Canada’s mandate is set out in the *Department of Health Act*, which defines the Minister’s duties to include the promotion and preservation of Canadians’ health and well-being, and specifically “the establishment and control of safety standards and safety information requirements for consumer products” (GoC, 2006). More broadly, the Minister’s jurisdiction covers all matters related to the health of Canadians that have not otherwise been assigned to a federal department, body or agency of the Government of Canada. The roles of the Department (now known as Health Canada) include promoting the physical, mental, and social well-being of people in Canada; protecting them against health risks; conducting investigations and research in public health, including monitoring diseases; establishing consumer product safety standards or

¹⁴ The 2012 Speech from the Throne was not available online.

limits; and collecting and distributing health-related information (GoC, 2006). These roles align with the objectives of CPA, to the extent that these enable research, monitoring, and surveillance pertinent to consumer products; the development of policies, standards, and regulations guiding their use; communication with, engagement of, and support for partners and stakeholders; and the execution of compliance and enforcement activities.

Case study example: federal role

In 1997, Canada signed the “Declaration of the Environment Leaders of the Eight on Children’s Environmental Health,” which identified lead as a major hazard to children and committed signatories to eliminate the intentional addition of lead to children’s products (Health Canada, n.d.-a). In response to this commitment, Health Canada drafted the “Strategy for Reducing Lead in Children’s and other Consumer Products,” which was later renamed the Lead Risk Reduction Strategy (LRRS). In the late 1990s, in alignment with the LRRS, and in response to two incidents reported to Health Canada, the Department began to address the specific issue of lead in children’s jewellery, and later extended this to also include cadmium. In May 2005, *Children’s Jewellery Regulations* came into force under the HPA, and in July 2011, Health Canada prepared a draft proposal for cadmium guidelines in children’s jewellery.

The FCSAP RMAF indicated that the federal statutes with most relevance to health, consumer product, and food issues are the HPA, the REDA, the *Canadian Food Inspection Agency Act*, the FDA, and the PCPA (Health Canada, 2008b). The RMAF also noted the direct role of FCSAP to adapt this legislative framework to accommodate a changing risk environment. As a result, one of the five major elements planned as part of FCSAP was updating these Acts and Regulations (with the exception of the PCPA). This was to be accomplished through the development of the CCPSA, and the modernization of the FDA, the *Cosmetic Regulations*, and the REDA (Health Canada, 2008b).

5.0 Findings: Performance

This section of the report presents the evaluation findings on performance, organized by evaluation question.

5.1 Governance

A number of committees and task forces have been established to manage FCSAP (Health Canada, 2008b, p. 7), including the following examples:

- The Oversight Committee is accountable for key decisions and/or recommendations concerning FCSAP programs and initiatives.
- The Steering Committee is responsible for providing strategic direction, coordination, and managerial oversight of the progress of FCSAP implementation, including assessment of results and resource utilization.

- The Coordinating Committee for FCSAP is responsible for developing collective recommendations, providing horizontal coordination of activities across Task Forces, and providing strategic support and advice to the Steering Committee.
- The Consumer Products Task Force is responsible for management and oversight of the Consumer Product Programs within the FCSAP to better manage horizontal outcomes and share best practices.

With the exception of the Consumer Products Task Force, the evaluation did not have access to meeting minutes or other documentation related to these committees, and could not assess the extent to which they were active in coordinating the delivery of consumer products-related activities under the FCSAP. It was not clear whether the lack of documentation stems from a record-keeping issue or the lack of committee activity. Nevertheless, the evaluation found, through evidence of records of decisions, meeting agendas, and Task Force program updates, that the Consumer Products Task Force has engaged in regular meetings and decision-making related to FCSAP.

The document review found some documented evidence of collaboration of CPA participants with other federal organizations. Key examples of interdepartmental collaboration are the Single Window Initiative, which, through a shared electronic interface, “seeks to deliver a more efficient, effective and integrated approach to collecting and consolidating advance commercial information” (CBSA, 2008; CPSD & CBSA, n.d.); the Improving Together Border Integrity Pilot Project, which involves “developing a single point of contact for all Health Canada programs to facilitate rapid & effective response at-border” (Health Canada, 2011a); and the Chemicals Management Plan (CMP), which, through the *Canadian Environmental Protection Act, 1999* (CEPA), requires industry to provide data about particular high-risk chemical substances used in consumer products, pesticides (including consumer pesticides), and cosmetics, prior to their introduction into Canada. Other examples of interdepartmental collaboration are CCRPB’s MOUs with Industry Canada and the Department of National Defence regarding REDA modernization and an Interdepartmental Letter of Agreement (ILA) between Health Canada and Transport Canada regarding the provision of technical advice on the human health effects of lasers and other directed bright light.

5.2 Performance measurement

A Performance Measurement Framework (PMF) and evaluation plan for the consumer products components of FCSAP are contained in the RMAF. In March 2012, based on the implementation of CPA and experience collecting performance data, program representatives proposed updates to the FCSAP PMF (CPSD, 2012a). Additionally, program representatives said that service standards have been, or are being, developed for CPSD/RAPB activities such as triage of mandatory incident reports; risk assessment; and for response times for risk management actions (e.g., sampling, testing, recalls).

In reviewing the PMF for the consumer products component of FCSAP, it became apparent that many of the performance indicators are activity-based; in some cases, the same indicators are used to demonstrate progress toward different outcomes; for some outcomes, a multitude of weak performance indicators are being tracked, rather than a select number of strong, key

indicators; and some critical performance indicators are not being tracked. Consequently, limited data, upon which achievement of outcomes could be assessed, were available to the evaluation. As such, the evaluation could not make definitive conclusions about the extent to which the consumer products component of the FCSAP has achieved its intended outcomes. With the hindsight of a completed evaluation, it would be beneficial to revise the PMF with a view to clarifying, strengthening, and streamlining expected outcomes and indicators.

Three FCSAP annual reports have been developed to date, each containing a section relating to consumer products that reports on achievements, challenges encountered, and potential risks, and that assesses the strategies selected. A variety of other documents provide performance data relevant to CPA, such as Departmental Performance Reports (DPRs), FCSAP implementation templates, regulation milestone reports, Deputy Minister (DM) dashboards, quarterly reporting on operational plans, and other project status reports. Program representatives said performance reports are used to monitor progress, set priorities, define resource needs, and inform the need for adjustments to processes.

5.3 Implementation

This section describes the activities that were, and were not, completed as planned, as part of the 12 strategies forming the consumer products component of the FCSAP.

Strategy 1: Industry Understanding its Obligations (CPSD, RAPB, CPAB)

Health Canada implemented a stakeholder outreach plan to inform industry of its obligations under the CCPSA.¹⁵ Some of the major initiatives include the following:

- Updating Health Canada's website with a new section on the CCPSA specifically targeting industry.¹⁶ The website currently provides news releases, backgrounders, Frequently Asked Questions, guidance documents, and information on prohibitions and regulations. This website also contains a webinar and educational video for industry on the CCSPA; 450 participants have attended the webinar, and the video has been viewed/downloaded 1,800 times (Health Canada, 2012d). In addition, a subscription service was introduced in 2010–11 allowing industry participants to receive regular updates via email; there were 1,279 subscribers in 2010–11 (Health Canada, 2011b).
- Launching a public notice campaign in 2011 to disseminate information about the CCPSA and outline industry requirements (Health Canada, 2011b). Information was disseminated through emails, trade publications and association e-newsletters, online videos posted on Health Canada's website and YouTube, News Canada articles, an Industry Canada blog, trade commissioners through the Department of Foreign Affairs and International Trade's (DFAIT) consulate offices, and articles in international business papers (Health Canada, 2012e, pp. 5–6).

¹⁵ Note: The funding allotment for this strategy was frozen until the CCPSA received Royal Assent in December 2010. See Strategy 9 (p.28-30) for information on the CCPSA.

¹⁶ As of July 27, 2012, the industry-targeted website was located at: <http://www.hc-sc.gc.ca/cps-spc/legislation/acts-lois/ccpsa-lcspc/indust/index-eng.php>

- Conducting CCPSA workshops and information sessions across Canada. Participants were retailers, distributors, and manufacturers from a range of sectors (Walther, 2011a, 2011b). By the end of fiscal year 2011–12, approximately 130 industry presentations, reaching over 1,500 people, had been made across the country (Health Canada, 2012d).
- Conducting compliance promotion activities with consumer product associations through presentations, trade show exhibitions, and meetings (Health Canada, 2011b, p. 23).
- Providing training and advice through the Product Safety Laboratory (PSL) to manufacturers, importers, and private laboratories interested in testing consumer products covered by the CCPSA.

Strategy 2: Consumer Pesticides Industry Understanding its Obligations (PMRA)

PMRA undertook the following activities to enhance industry understanding of its obligations:

- **Quality control and proficiency testing practices.** To identify current product stewardship practices and barriers to practices pertaining to safety and quality, PMRA conducted consultations with 40 manufacturers, formulators, and registrants involved in the manufacturing of domestic class products (PMRA, 2010a). Although the consultation report noted that “no areas of non-compliance concerns or deficiencies were found,” a sampling and laboratory testing program was planned for 2012–13 to “confirm integrity of end-products on the market” (PMRA, 2010a).
- **Unregistered pest control products.** To address concerns about risks associated with the importation and sale of unregistered consumer pest control products in Canada that have not been evaluated by Health Canada, this initiative focused on informing customs brokers, importers, and distributors of consumer pest control products of their obligations and shared accountabilities under the PCPA and its Regulations (PMRA, 2011b). The initiative involved delivering “engagement activities” to stakeholder groups across Canada, using a consultation questionnaire. A total of 25 outreach activities were conducted in 2011–12, with an additional 46 meetings planned for year two (2012–13) (PMRA, 2012a).
- **Rental property associations.** This multi-phase initiative focused on rental property associations’ knowledge about the safe use of pesticides in multi-unit buildings and their structural pest control obligations.¹⁷ Phase I (2011) involved gathering baseline information with rental property associations; in total, 114 interviews were planned to be conducted across Canada during Phase I, of which 84 were completed (PMRA, 2011c).¹⁸ Phase II (2011) involved the creation and delivery of information materials to associations. Phase III is underway and involves assessing effectiveness of the materials.

¹⁷ Legislation governing structural pest control use in apartment buildings varies depending on the qualifications of the applicator (professional versus non-professional), as well as the province in which the application occurs (PMRA, 2011c).

¹⁸ Fewer consultations were conducted than planned for various reasons, including associations no longer being in operation; being unavailable for contact; or declining to participate (PMRA, 2011c). In some cases, a central organization was contacted rather than individual associations.

- **Incident reporting.** Following a marketplace inspection program¹⁹ that showed a lack of awareness about incident reporting, PMRA initiated a series of outreach activities targeted at provincial veterinary medical associations and other related organizations. In the first year of the program, an information piece on the importance of reporting incidents consistently was published in the Canadian Veterinary Medical Association (CVMA) newsletter (PMRA, 2012b). A total of 81 “engagement activities” were planned for 2012–13²⁰ as part of this program (Health Canada, 2012m).
- **Other activities.** Other activities undertaken by PMRA to increase industry awareness and understanding of its obligations included meeting with Chinese consumer and vendor associations (Health Canada, 2011b, pp. 56, 58); delivering 10 presentations to pest control operators and technicians in Alberta and Quebec (Health Canada, 2011b, p. 56); developing the Standard for Pesticide Education, Training and Certification in Canada (PMRA, 2010b); drafting a final version of the pesticide compliance and enforcement best practice guidance document²¹ (Health Canada, 2011b, p. 67); initiating policy development in the area of non-conventional products (Health Canada, 2010c, p. 21); publishing guidelines for the registration of non-conventional pest control products (PMRA, 2012c); developing a compliance and enforcement strategy for the antimicrobial treated articles policy (PMRA, 2012d); and working to increase industry awareness and understanding of its obligations during the course of inspections and compliance verifications.

Strategy 3: Standards Development and Adoption (CPSD, ERHSD)

Health Canada undertook a myriad of activities related to standards development and adoption. However, the available documents suggest some changes to planned human resources associated with this Strategy. Specifically, Health Canada determined that, given a re-organization of the Directorate, which involved a shift to the use of a functional model, the planned creation of a small unit within CPSD to lead initiatives related to standards development and adoption was not necessary and that staffing in the area could be reduced (Health Canada, 2012e, p. 7). Ultimately, CPSD’s RMB was given responsibility for standards development and adoption initiatives (Health Canada, 2012e, p. 7). Health Canada representatives reported that much of the work on standards remains the responsibility of individual project officers within RMB, where they continue to actively participate on national and international standards writing bodies. They also noted that standards development is now being approached in a manner consistent with the government’s policy direction of regulatory cooperation and harmonization of safety standards. It is unclear, however, what impact organizational and staffing changes had on planned activities related to standards development and adoption.

¹⁹ For more information about the results of the marketplace inspection program, please see Strategy 12 (p.38).

²⁰ Program representatives reported that more than half of these activities were planned for the 4th quarter, 2012–13.

²¹ In 2011, the OECD reported that a Best Practice Guidance on Pesticide Compliance and Enforcement had been developed under the leadership of Canada and that the document is due to be published in spring of 2012 (OECD, 2011, p. 20). At the time of reporting, the guidance document was not available on OECD’s website and was not referred to on PMRA’s website.

Under this Strategy, Health Canada worked to increase federal involvement in standards development and improve federal support to the National Standards System (NSS), which is a network of people and organizations involved in voluntary standards development, promotion, and implementation in Canada. The Standards Council of Canada (SCC) is responsible for coordinating and overseeing the work of the NSS (SCC, 2012a). Health Canada's main activities in this area included the following:

- A Memorandum of Agreement (MOA) was signed with the SCC to support the National Standards System (SCC, 2009). Under this MOA, the SCC analyzed international activities related to the development of consumer product safety standards (SCC, 2010a, p. 21). Additionally, the PSL, which is accredited by the SCC,²² was audited in 2011 (Health Canada, 2012e, p. 9).
- Under an MOA with Health Canada, SCC was hired to provide consulting services to support the participation of consumers and small- to medium-sized enterprises (SMEs) in the NSS (SCC, 2010a, p. 21).

Health Canada's activities aimed at improving engagement in existing standard development bodies included the following:

- contracting with the Canadian Standards Association (CSA) to support the development of an ISO Guideline on Product Safety (Health Canada, 2010d, p. 32),²³ and drafting an ISO Recall Guidance Standard²⁴
- participating in discussions for standard setting with the American Society for Testing and Materials (ASTM) International and the CSA (Health Canada, 2011b, p. 56)
- expanding trilateral collaboration on international standards to include Australia, as well as the US and the EU, and to include corded window coverings, as well as baby slings and booster seats (Health Canada, 2011b, p. 56)
- leading various standards committees, including the International Electrotechnical Commission (IEC) and the Organization for International Standardization (OIS) in areas of acoustics, electromagnetics, X-ray devices, and laser and electro optics (Health Canada, 2010c, p. 42)

²² Part of the accreditation requirements is a biennial audit by the SCC of the PSL's Quality Management System.

²³ In May 2011, the ISO project committee (for which CSA serves as secretariat) released a draft consumer product safety guidance standard referred to as ISO 10377, which provides practical guidance to designers, manufacturers, importers, distributors, and retailers of consumer products. The standard is anticipated to be completed in 2012 (CSA, 2011; Ross, 2011, p. 15). At the time of reporting, ISO 10377 was not yet published on the ISO website (ISO, 2012a).

²⁴ This standard, referred to as ISO 10393, will not be finished until late 2012 or 2013 (Ross, 2011, p. 17).

- forming a Task Force through the National Public Safety Advisory Committee (NPSAC) to develop a national approach to electrical product safety (Health Canada, 2010d, p. 32)²⁵
- provided input on five improved ISO standards on determining noise from machinery (ISO, 2010a, 2010b, 2011a, 2011b, 2012b)

Strategy 4: Information to Canadians (CPAB, CPSD, ERHSD, PMRA, RAPB)

Health Canada has undertaken a series of interrelated initiatives aimed at providing information to Canadians.

CPAB/CPSD/ERHSD/RAPB

A Consumer Information Strategy was developed in 2009 with the overall objective of providing “relevant, timely, consumer-friendly, accessible, and trustworthy information to Canadians so that they can make informed decisions about the products they buy and use” (Health Canada, 2009a, p. 6). Although a Consumer Information Bureau was set up within CPAB to “develop a consistent departmental approach to consumer communications,” it was disbanded in late 2012 and activities were integrated into the ongoing work of the Public Affairs Directorate whose mandate aligns with this objective (Health Canada, 2009a, p. 8).

In October 2009, Health Canada launched the Consumer Safety Portal, with the goal of providing easy access to consumer, food, and health product information (Health Canada, 2010c). Further, in 2011, the Consumer Safety Portal was integrated into the Healthy Canadians website. According to Health Canada representatives, the Healthy Canadians website is a consumer-centric thematic Government of Canada website with a strong digital presence.

- The Health Canada website currently includes, among other things, a variety of consumer education publications; information on recalls, advisories, and warnings; and information on how to report consumer product-related incidents. There are 50 bulletins on the website, most of which relate to children’s health and safety (38%), and home and garden products (34%) (CPSD, 2012b).
- To support implementation of the CCPSA, Health Canada updated the Health Canada website to include CCPSA information (Health Canada, 2011b, p. 23). An updated consumer incident report form²⁶ was launched (Health Canada, 2011c), and information was provided to consumers on how to report an incident and what to do in the event of a recall.

²⁵ A Request for Proposal was posted in late 2008 requesting services to research and report on the management of electrical product safety issues amongst the various provincial and territorial authorities in Canada (Electrical Safety Authority, 2008). The SCC, which facilitated work on the national approach on product safety for the electrical sector, indicates the study was to be facilitated and completed in 2010 (SCC, 2010a, p. 14, 2010b, p. 26). SCC’s most recent annual report (2010–11) and corporate planning document do not mention the study (SCC, 2011, 2012b). The document review found no further information on the status of these materials.

²⁶ Health Canada representatives said that, as the onus is on industry to assess whether there is an “incident,” in the future, the form for consumers will be referred to as the “consumer product report.”

Health Canada also undertook a variety of other initiatives to provide information to Canadians, as summarized below:

- Developing a new template for advisories, warnings, and recalls (Health Canada, 2010c, p. 21) and revising the Consumer Products Recall Database²⁷ website (Health Canada, 2010d, p. 33).
- Launching, in 2012, a new Recalls and Safety Alerts web application²⁸ in collaboration with Transport Canada and the CFIA. Health Canada representatives said that this new web application streamlines six different sources of advisories, recalls, and safety alerts into a single web interface for information on health and consumer products, food, and vehicles. This web application replaces the Consumer Products Recall Database.
- Launching the Healthy Canadians website²⁹ and beginning to migrate consumer product safety content for consumers to the site (e.g., cosmetics, pests and pest management, home and garden, recalls, injury prevention, toy safety, and safe sleep).
- Implementing a Canadian Health and Safety campaign³⁰ to advertise the new Recalls and Safety Alerts web application and direct Canadians to the main page of the Healthy Canadians website. Health Canada representatives reported that, prior to the November 2012 launch of the campaign, the main page of the Healthy Canadians website received an average of 32,722 visits per month. Since the launching of the campaign, they said the main page receives an average of 12,000 visits per day and the Recalls and Safety Alerts page receives an average of 4,850 visits per day.
- Sending updates and news releases to consumers via a subscription service when “new information, consumer advisories and warnings, consumer product recalls, and consultation documents regarding consumer product safety are posted on the Health Canada web site” (CPSD, 2006). Subscriptions to the Consumer Products Recall website have increased steadily over time, from 800 in 2006 to over 8,000 in 2011 (Health Canada, 2011b).
- Launching a Recalls and Safety Alerts mobile application, which allows users to get the latest recalls and safety alerts from the Government of Canada (Health Canada, Transport Canada, and the CFIA). According to the third annual FCSAP report for 2010–11, there were 5,500 downloads of the recalls and safety alert mobile application since its launch in December 2010 (Health Canada, 2011b). Health Canada representatives reported that a new version of the mobile application was released in 2013, and, as of March 31, had been downloaded 34,391 times.

²⁷ The Consumer Products Recall Database website enables users to search for information about consumer product recalls from 1995 to present, by year and product category.

²⁸ FCSAP funding contributed to this project.

²⁹ Development of the Healthy Canadians website was partially funded through FCSAP.

³⁰ This marketing campaign was not funded under FCSAP. However, it also assisted in providing consumer products information to Canadians.

- Launching, in 2010, a Recalls and Safety Alerts widget that allows users to attach a self-updating feed of Government of Canada (i.e., Health Canada, Transport Canada, and the CFIA) advisories, warnings, and recalls to their own websites (Health Canada, 2010c).
- Expanding online dissemination of information on advisories, warnings, and recalls through the use of social media, including social bookmarking (share), Twitter, Facebook, and YouTube videos (Health Canada, 2010c, pp. 21, 42, 2011b, p. 58). Health Canada's YouTube channel has more than 2,000 subscribers (Health Canada, 2012e) and its Twitter feed has approximately 70,000 followers (Health Canada, 2013).
- Launching the Healthy Canadians and Canadiens en santé fan pages on Facebook,³¹ which are used to disseminate consumer product safety messages and encourage conversations among Canadian parents (Health Canada, 2011b). Health Canada representatives said that, as of March 31, 2013, these pages had 14,073 fans. Since their creation on November 26, 2009, 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 (GoC, 2012c).
- Presenting at consumer events such as fairs, conventions, and exhibitions on topics such as the CCPSA, consumer product safety in general, safety and children, children's sleepwear, industry guides, education bulletins, and cribs/playpens (CPSD, 2012c). Between December 2010 and March 2012, CPSD conducted over 600 outreach activities (e.g., presentations and booths at consumer events), which have reached at least 65,000 people (CPSD, 2012c).
- Responding to consumer inquiries about consumer products. In 2009, Health Canada's Call Centre received over 22,000 calls and 28,500 emails with general inquiries related to consumer products (Health Canada, 2012e).
- Running, in March 2010, a "Report an Unsafe Product" outreach initiative.
- Ensuring that consumers are able to access the web-based incident reporting form from the Healthy Canadians website and the Recalls and Safety Alerts Database easily.
- Developing the use of the 1-800-O-Canada phone number for radiation-emitting devices to assist in triaging the calls from the public. This enhanced the efficiency of responses provided and the best use of resources in Health Canada, and went live on May 2, 2012 (HECSB, 2012a).
- Undertaking public opinion research to gauge public awareness of consumer product safety issues (Health Canada, 2010d, pp. 14, 32, 2011b, p. 56; Phoenix Strategic Perspectives Inc., 2011, pp. iv–v) (see Section 4.3.1 for a summary of the findings).
- Conducting 16 public consultations³² regarding proposed regulatory and policy changes for consumer products since 2009 (Health Canada, 2011d).

³¹ Health Canada representatives noted that this activity was not funded through FCSAP.

³² This figure is based on the public consultations listed on Health Canada's website and is not intended to be a comprehensive list of all consultations undertaken by the Department in relation to consumer products.

Additionally, various consumer education publications on radiation-emitting devices are available on Health Canada's website. Fifteen publications are available on sun safety and preventing skin cancer, safety of cell phones and cell phone towers, radiofrequency energy and safety of Wi-Fi equipment, smart meters, electromagnetic hypersensitivity, and lasers (Health Canada, 2012d).

PMRA

PMRA undertook a number of initiatives to inform Canadians about the safe use of consumer pesticides, including creating and staffing an outreach advisor position (Health Canada, 2010d, p. 15). Additionally, PMRA expanded content on the Healthy Canadians website, such as information on consumer pesticides and Pest Notes, which provide information on common pests and pest control measures. In total, there are 26 Pest Notes available online, each covering a different household or garden pest (CPSD, 2011b).

A particular focus of PMRA's activities was to promote consumer awareness of safe use practices for topical flea and tick control products, as well as home and garden pest control products.

- The focus on topical flea and tick control products was informed by incident reports and complaints received by PMRA indicating adverse reactions in cats and dogs stemming from reported use of these products (PMRA, 2011d).
 - In 2009, PMRA issued an advisory to the public and the veterinary community about concerns related to use of flea and tick spot-on products (PMRA, 2009a, p. 13).
 - In 2010, PMRA issued a public information update (PMRA, 2011d) and introduced a regulatory directive³³ for flea and tick spot-on products (PMRA, 2010c).
 - In 2011, PMRA launched a consumer outreach program aimed at informing consumers of the importance of following the revised label directions on these products (PMRA, 2011d).
 - In 2011, PMRA introduced a consumer awareness campaign to educate consumers in the safe use practices of pest control products used in and around homes and gardens and in public spaces (PMRA, 2011e).

For 2012–13, the consumer awareness and outreach campaigns for topical flea and tick products and home and garden pest control products were combined “to ensure more effective and efficient delivery,” since the programs “had similar objectives and were delivered to the same audiences in various venues” (PMRA, 2011e). A variety of publications describing guidelines for the safe use of pest control products were disseminated to consumers at venues such as home and garden shows, pet shows, pet association meetings, and associated trade shows, as well as through outreach activities delivered to community groups and associations.

³³ DIR2010-02 was a preliminary step to strengthen the labels of spot-on pesticides used on companion animals for flea and tick control.

Finally, PMRA undertook an initiative to increase transparency and consumer knowledge of regulatory decisions for consumer pesticides. More specifically, it introduced a strategy to increase consumer knowledge about changes to the registration status, allowable uses, and labelling of consumer pesticides, primarily by updating its compliance and enforcement web page with additional information such as enforcement bulletins (Health Canada, 2011e). PMRA has also exhibited at various events across Canada to raise consumer awareness of pesticide regulation (Health Canada, 2011b, p. 58).

Strategy 5: Mandatory Reporting of Consumer Product Incidents and Risk Assessment/Risk Mitigation Strategies (CPSD)

Mandatory reporting of consumer product incidents³⁴ was implemented under Section 14 of the CCPSA, which defines a consumer product “incident” as:

- (a) an occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual’s death or in serious adverse effects on their health, including a serious injury;
- (b) a defect or characteristic that may reasonably be expected to result in an individual’s death or in serious adverse effects on their health, including a serious injury;
- (c) incorrect or insufficient information on a label or in instructions — or the lack of a label or instructions — that may reasonably be expected to result in an individual’s death or in serious adverse effects on their health, including a serious injury; or
- (d) a recall or measure that is initiated for human health or safety reasons by a foreign entity or by another jurisdiction in Canada (GoC, 2011a, sec. 14(1)).

Under this provision, manufacturers and importers of consumer products are required to provide Health Canada with a written report about any consumer product incident within 10 days after they become aware of the incident.³⁵ Consumers may report incidents voluntarily to Health Canada.

The coming into force of the CCPSA occurred later than planned (see Strategy 9 on pages 28–30) and, as a result, implementation of mandatory reporting of product safety incidents by industry was delayed. In response to this challenge, as an interim solution, Health Canada implemented a web-based incident reporting form for consumers and industry, to be used on a voluntary basis (Health Canada, 2010c, p. 22); this has since been replaced by a mandatory incident reporting form for industry (Health Canada, 2011f).³⁶

To improve its ability to track and manage its surveillance activities, including its response to incident reporting, Health Canada developed and implemented the CCMS in June 2011. CCMS replaced the PSIS system, which had previously been used to manage complaints, inspections, communications, and decisions (Health Canada, 2012e, p. 24; NCISD, n.d.). CPSD records

³⁴ This requirement does not apply to cosmetics, which are excluded from the definition of a consumer product under the CCPSA, but are regulated under the FDA.

³⁵ Health Canada has prepared a guidance document for industry on mandatory incident reporting (CPSD, 2011c).

³⁶ Consumers still have the ability to report on a voluntary basis; the web-based incident reporting form is available on the Healthy Canadians website and from the Recalls and Safety Alerts web and mobile application.

incident reports in the CCMS database and then sends the incidents through a triage system to determine the relevance and level of priority of the case (whether the case involves a consumer product or cosmetic and is within mandate) (CPSD, 2012d).

Health Canada also implemented dedicated divisions to handle the monitoring and triage of mandatory incident reporting, and to conduct assessments of high-priority consumer product incident reports (Health Canada, 2011b, pp. 28, 59). Using a risk assessment tool comprised of six questions, triage staff route consumer product incident reports to one of the following sections within CPSD (CPSD, 2012e):

- RMB: consumer products subject to a specific regulation under the CCPSA or reports identifying a proposed corrective action
- Risk Assessment Division of the RAB: consumer products not subject to a specific regulation under the CCPSA where the report is identified as a “high priority”
- Surveillance Unit of the RAB: all other reports regarding consumer products not subject to a specific regulation and not identified as a “high priority”

Health Canada representatives indicated that incident reports from industry and consumers are routinely analyzed to identify consumer product-related injury and hazard trends for the purpose of informing CPSD’s risk-based decision-making processes and policies. They also said that other available data sources are routinely monitored to identify emerging consumer product-related injuries and hazards that otherwise may not be identified from consumer product reports.

Monthly dashboard reports are used to provide senior management with performance information related to CPSD’s triage of the consumer product incident reports. The dashboard reports summarize the number of incident reports received from industry and consumers, the number of cases in triage, and the outcomes of the triage, as well as the number of triage outcomes within the performance standard. Additionally, Health Canada representatives indicated that dashboard reports are being developed to track performance information on cases referred to the RMB and the RAB, or RAPB.

Health Canada representatives reported that, since the CCPSA came into force, CPSD has made a number of high-level presentations about what has been “working well” and where there have been some “challenges”; they said that this information is used to identify the need for industry awareness and/or education activities, as well as to refine and/or update guidance documents. For example, according to a recent Health Canada presentation given at an Organization of American States (OAS) conference in Washington, DC in May 2012 (CPSD, 2012d), Health Canada identified a number of challenges associated with mandatory incident reporting, including the following:

- uncertainty around the level of industry compliance with the requirement
 - Health Canada representatives said that, when CPSD becomes aware of an incident for which it should have received a report from industry, staff contact the company in question to inform and/or remind it of industry’s reporting obligations.

- provision of incomplete information on incident reports (e.g., poor product descriptions, omission of information about where the product was obtained)
 - Health Canada representatives said that, to respond to this challenge, CPSD is updating its guidance to industry. Additionally, they indicated that, when incomplete incident reports are received from industry, CPSD follows up with companies to obtain the required information.
- incorrect identification of the level of trade by industry (e.g., company reports as a retailer when it is actually an importer)
 - Health Canada representatives said that CPSD is responding to this challenge by educating companies on a case-by-case basis, as needed.
- insufficient information in Section 14(3) reports to support risk management (e.g., lack of information on mitigation measures or actions proposed by industry)
 - Health Canada representatives said that, in response to this challenge, CPSD added examples relating to the Section 14(3) information requirements to the guidance for industry. They also indicated that CPSD is educating companies on a case-by-case basis, as needed.

Strategy 6: Modernized *Cosmetic Regulations* and Enhanced Risk Assessment/Risk Management Activities (CPSD – Cosmetics Division)

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. Instead, for the *Cosmetic Regulations*, the Department is examining opportunities for improvement using non-regulatory approaches.

While the amendments to the *Cosmetic Regulations* were not pursued, Health Canada undertook various other initiatives related to risk assessment and risk management, including the following:

- updating the *Cosmetic Ingredient Hotlist* which is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances, when present in a cosmetic, may contravene (a) the general prohibition found in section 16 of the *Food and Drugs Act* or (b) a provision of the *Cosmetic Regulations*.
- publishing a guidance document on heavy metal impurities in cosmetics (Health Canada, 2012q)
- publishing a guidance document on classification of products that share drug and cosmetic characteristics (HECSB, 2008), and creating a Personal Care Working Group to classify these products (Health Canada, 2011b, p. 59)
- updating an existing guide on cosmetic ingredient labelling (CPSD, 2009a)

Further, Health Canada representatives indicated that business process re-engineering eliminated a backlog in notifications, from 31,000 in 2008 to effectively zero in 2010.

Health Canada also worked on developing information systems to improve processing of cosmetic notifications submitted by industry and identifying non-compliant products. While incident reporting is not mandatory for the cosmetics industry, under Section 30 of the *Cosmetic Regulations*, 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 (GoC, 2007, sec. 30). To do this, the manufacturer and importer must submit a Cosmetic Notification Form to Health Canada (Health Canada, 2011g). The manufacturer or importer who has provided the notification form must also inform Health Canada whenever a change is made that affects the information provided on the Cosmetic Notification Form, within 10 days after that change had been made.

According to the 2008–09 FCSAP annual report, initial work was completed on a new chemical products database, which would allow notifications to be processed in a more automated fashion; the project was to be completed in 2009–10 (Health Canada, 2010d, p. 33). However, the following year, Health Canada reported that work was continuing on systems for processing notifications and flagging cosmetic products of concern for compliance action (Health Canada, 2011b, p. 59). Health Canada representatives said they expect electronic submission of cosmetics notifications to be in place by April 2013.³⁷

Strategy 7: International Collaboration (CPSD)

Health Canada undertook a variety of initiatives with international partners. In addition to the international activities mentioned under Strategy 3 above (see pages 16–18), these activities include the following:

- Signing a planned MOU with the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of China in 2007, with the objective of cooperating to protect consumers' safety and health (Health Canada, 2009b); and a subsequent action plan in October 2011 (Health Canada & AQSIQ, China, 2011). Health Canada representatives reported that, under the action plan, Canada and China have established and maintained frequent and ongoing communication; promoted a better understanding of Canadian, Chinese, and international consumer product regulatory requirements; established an urgent consultation mechanism to enable the AQSIQ to follow up on non-compliant products of Chinese origin that are found in Canada; and promoted safe children's products. Additionally, they indicated that development of a laboratory and inspection recognition mechanism is ongoing.
- Signing, in 2005, an MOU with the US Consumer Product Safety Commission (CPSC) on strengthening and enhancing exchange of information and public health and safety cooperative activities related to safety of consumer products (Health Canada, 2009c).
- Creating a joint pilot alignment initiative to explore harmonization of technical requirements on certain consumer products with the US, the EU, and Australia (Health Canada, 2011b, p. 60).

³⁷ Program representatives reported that the original schedule for online notification was delayed to focus on system support for Consumer Product Incident Reports, which they noted is considered a higher risk activity.

- Participating in the first North American Consumer Product Safety Summit in September 2011 with the US and Mexico; in a Joint Statement, the parties agreed to explore further opportunities for collaboration with respect to:
 - consultations on proposed regulations, voluntary standards, potential joint recalls, or corrective actions;
 - cooperation on risk assessment, imports and market surveillance, training, and outreach (inside and outside North America); and
 - coordinated consumer awareness campaigns (Health Canada, CPSC, & Profeco, 2011).
- Participating in the Organisation of Economic Co-operation and Development's (OECD) Consumer Policy Working Party on Consumer Product Safety (Health Canada, 2011b, p. 60).
- Providing input into the Canada-Europe Comprehensive and Economic Trade Agreement negotiations (Health Canada, 2011b, p. 56).
- Participating as a member of the Scientific Oversight Committee, which oversees the International Electromagnetic Frequency (EMF) Project. This project gathers information on the effects of electromagnetic radiation on human health (Health Canada, 2012e, p. 17). Health Canada undertook several studies as part of the EMF Project; these are described in Section 4.3.6.
- Co-founding and participating in the International Cooperation on Cosmetic Regulation (ICCR), with the US, the EU, and Japan.

Strategy 8: Increased Product-Related Injury Surveillance and Risk Assessment (PHAC)

PHAC implemented several projects to improve product-related injury surveillance and risk assessment.

Injury surveillance

PHAC's main injury surveillance activities relate to CHIRPP and the Canadian Coroner and Medical Examiner Database (CCMED).

- **CHIRPP modernization.** As of 2011, CHIRPP was capturing data from 11 paediatric hospitals and 4 general hospitals from across Canada (PHAC, 2011b, p. 115). Program representatives reported that one hospital was added to CHIRPP and indicated that sentinel hospitals will also start collecting data in the upcoming fiscal year.

The CHIRPP modernization project, underway as of 2011, was intended to improve timeliness, capacity, and quality of data collection by focusing on a web-based system for data entry, and is ultimately expected to allow more hospitals to participate, as data entry workloads are reduced and high-risk or targeted injury types are flagged for early detection (Health Canada, 2011b, p. 24). Program representatives said the new system was piloted at one hospital and will be phased into other hospitals in the upcoming fiscal year.

CHIRPP data are used to conduct targeted studies based upon requests from CPSD. The data were also used in a 2009 PHAC report on child and youth injuries, which focused on injuries associated with consumer products such as bunk beds, magnets, baby walkers, trampolines, bath seats, curtain cords, and large appliances (PHAC, 2009).

- **CCMED.** This database was developed in collaboration with Statistics Canada and provincial/territorial chief coroners and medical examiners, and went into production in March 2008; as of 2012, efforts were underway to solicit participation from two provinces (Manitoba and Newfoundland and Labrador), which, along with Nova Scotia and Nunavut, were initially unable to participate (PHAC, 2012a, p. 6). In early 2012, PHAC and Statistics Canada released an annual report on CCMED data, covering 2006 to 2008 (StatCan & PHAC, 2012), and Statistics Canada's Research Data Centres (RDC) program set an informal target of 2013–14 to pilot a project to redevelop and analyze CCMED data (PHAC, 2012b, p. 11). PHAC representatives noted that injury epidemiologists at PHAC continue to mine and analyze the data for product-related injuries.

Risk assessment activities

In the area of risk assessment, PHAC's activities included the following:

- Initiating data linkage projects between the National Trauma Registry (NTR), the National Ambulatory Care Reporting System, and the Discharge Abstract Database for injury risk assessment analysis (Health Canada, 2011b, p. 24)
 - However, program representatives said the data linkage project will need to be reworked, since the NTR is being terminated.
- Making foundational improvements to the Canadian Longitudinal Study on Aging (CLSA), including enhancing the survey with a module of questions on injury and consumer product-related falls (PHAC, 2011c, p. 31).
 - The CLSA targets Canadians who are between the ages of 45 and 85 at the time of enrolling in the study. Tracking respondents over time, the study is expected to generate information about the factors impacting the ageing process, including chronic conditions. PHAC collaborated with investigators leading the CLSA to add a module on injuries and falls to the study. This module gathers information about what, where, and how injuries and falls were sustained. For falls, it also explores if any of the following were contributing factors: assistive devices, ladders, step stools, beds, chairs, other furniture, rugs/carpeting, flooring, electrical cords, footwear, other clothing, toys, yard tools, bicycles, and other sports equipment (CLSA, 2011).
 - PHAC representatives stated that they support the use of the CLSA as a vehicle for gathering information to support risk assessment of consumer product-related injury.

- Establishing a Sentinel Centre at Kingston General Hospital for consumer product-related injury risk assessment (Health Canada, 2011b, p. 24)
 - Kingston General Hospital was awarded a contract to develop a risk analysis framework on consumer product-related injury data, as well as develop and test four consumer product injury-related questionnaires as data collection instruments to be used by Kingston General Hospital and other sentinel centres (Merx, 2010). Program representatives reported that the data collection instruments are being piloted at three hospitals.
- Conducting a feasibility study with the Newfoundland and Labrador Centre for Health Information to examine potential for an additional sentinel centre at Carbonear (Health Canada, 2011b, p. 61)
- Conducting risk assessments on patterns and trends of injury in the Canadian Population Longitudinal Health Survey; incidence of injury associated with immigration status; incidence of fall injury associated with mental health in immigrants compared to non-immigrants; meta-analysis of epidemiological studies on ATV-related injuries (Health Canada, 2011b, p. 61)
- Developing a plan to disseminate knowledge on injury risk assessment using the Canadian Best Practices Portal (CBPP) (Health Canada, 2010d, p. 15)
 - The CBPP was launched in 2006 and provides an online compendium of best practice review sites, a searchable database of effective interventions, and resources to aide public health planning and health promotion goals (PHAC, 2012c).

PHAC program representatives said their relationship with CPSD, primarily the Surveillance and Information Division within the RAB, involves responding to information requests, collaborating on papers, and providing updates on conferences and briefings. Some Health Canada representatives suggested that there are opportunities to strengthen relationships, and improve data sharing, between PHAC, CPSD, and external stakeholders (e.g., fire chiefs, poison control centres, other regulatory bodies), which may help Health Canada integrate additional proactive signal detection activities into its surveillance work.

Strategy 9: New Canada Consumer Product Safety Act (CPSD, RAPB)

After its third introduction in Parliament, the new CCPSA received Royal Assent and was brought into force. The Act was first introduced as Bill C-52 in the 2nd session of the 39th Parliament on April 8, 2008, but was not passed during that session. The bill was reintroduced as Bill C-6 in the 2nd session of the 40th Parliament on January 29, 2009. However, Parliament was prorogued while the legislation was in the final stages of Senate review. The Act was again reintroduced as Bill C-36 in the 3rd session of the 40th Parliament on June 9, 2010, receiving Royal Assent in December 2010 and ultimately coming into force on June 20, 2011.

The CCPSA was intended to modernize the consumer product safety regime and bring Canada's consumer product safety system in line with international trading partners and competitors. It sought to address numerous perceived limitations of the HPA (e.g., it was largely reactive, requiring a regulatory approach to product safety, and its authority to require corrective action was limited and relied heavily on voluntary actions) (HECSB, 2012b).³⁸ The CCPSA repealed and replaced Part I and Schedule I of the HPA, including the transfer of prohibitions and regulations from the HPA to the CCPSA (CPSD, 2011e).³⁹

As planned, the CCPSA introduced a general prohibition related to the manufacture, importation, sale, or advertisement of consumer products that could pose a danger to human health or safety (Health Canada, 2012f). The general prohibition is found in paragraphs 7(a) and 8(a) of the Act:

“7. No manufacturer or importer shall manufacture, import, advertise or sell a consumer product that

(a) is a danger to human health or safety” (GoC, 2011a, sec. 7)

“8. No person shall advertise or sell a consumer product that they know

(a) is a danger to human health or safety” (GoC, 2011a, sec. 8)

Health Canada representatives reported that the core benefits of the general prohibition are that it allows the regulator to be more proactive and not have to rely on the regulatory process to take action against non-compliance.

However, some Health Canada representatives said the Department has not yet developed internal policies regarding the application of the general prohibition, or provided greater clarity to industry. Additionally, Health Canada representatives reported that the Department is in the process of determining how to integrate the general prohibition into its regular compliance and enforcement activities (e.g., including the general prohibition in cyclical enforcement activities; including, as part of inspections, examination of whether companies have systems and procedures to ensure that they are not violating the general prohibition).

Health Canada representatives reported that the general prohibition is a tool that enables the Department to act quickly to stop the supply or advertising of consumer products believed to pose a danger to human health or safety, without first needing to pass a regulation to do so. They said that, in some cases, there is an ongoing need for product-specific regulations. For example, they suggested that product-specific regulations can be useful for setting protective limits (e.g., setting the maximum allowable level of a chemical/substance in a product at a level that is known to be safe), particularly when there is uncertainty about the margin of risk associated with the product in question.

Health Canada representatives also said 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 concretely understand what this means. Therefore, they stated that regulations may be used in cases where it is necessary to define explicitly the requirements that industry must meet.

³⁸ All of Part II and Part III of the HPA are still in force today.

³⁹ From Part I of Schedule I, regulations were transferred for products that are completely prohibited or prohibited with conditions. From Part II of Schedule I, regulations were transferred for regulated products, i.e., itemized products with particular restrictions.

Further, Health Canada representatives mentioned that other approaches, such as standards, may also be used to define safety requirements. Some Health Canada representatives indicated that, in the context of the safety net afforded by the general prohibition, the Department is in the process of developing guidelines for use in determining under what circumstances regulations should be established.

Some other important new provisions of the CCPSA are described below:

- The Minister of Health may order a recall of a consumer product if it is believed on reasonable grounds that the product poses a danger to health or safety (GoC, 2011a, sec. 31). The Minister can also order other corrective actions, including “stopping the manufacturing, importation, packaging, storing, advertising, selling, labelling, testing or transportation of the consumer product” (GoC, 2011a, sec. 32).
- Industry is required to keep records to enhance traceability in the event of a recall (GoC, 2011a, sec. 13). This includes names and addresses of persons from whom they obtained the product, persons to whom they sold the product, the location where they sold the product, and the period during which they sold the product. Documents must be kept for six years and must be provided to Health Canada upon request.
- Industry is required to report incidents relating to their products (“mandatory incident reporting”) (GoC, 2011a, sec. 14). An “incident” includes an occurrence relating to the product that did or may reasonably be expected to result in death or serious adverse health effects, including serious injury; defects in the product that did or may reasonably be expected to lead to serious adverse health effects, including serious injury; insufficient or incorrect information on a label or package, or the initiation of a recall or other measures for human health or safety by another jurisdiction.
- The Minister of Health can require tests and studies to verify compliance or prevent non-compliance with the Act or regulations (GoC, 2011a, sec. 12).
- 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 (GoC, 2011a, sec. 41–66).

At the time of writing this report, Health Canada had not used its powers under the CCPSA to issue any mandatory orders or AMPs.⁴⁰ Health Canada representatives explained that the Department first works with non-compliant companies to encourage them to implement corrective actions on a voluntary basis; if voluntary compliance cannot be achieved, then Health Canada would consider issuing an order. Health Canada representatives noted that procedures specifying when and how the new powers should be used would be useful.

⁴⁰ Although Health Canada has not issued any mandatory orders or fines under the CCPSA, over the years, it has negotiated various voluntary recalls. Refer to Section 5.3.2 for information about the recalls that the Department has posted to its website since 1995.

Strategy 10: Modernizing and Enforcing the *Radiation Emitting Devices Act* (ERHSD)

First implemented in 1972, REDA regulates the sale, lease, and importation of radiation-emitting devices in Canada. This includes devices emitting electromagnetic energy or acoustical energy. Devices regulated under REDA could be described as consumer products, medical devices, and industrial/commercial products (OSPI-PPID & HECSB, 2011).

Although the original FCSAP documents suggested that Strategy 10 was to focus on potential proposed amendments to REDA, or even a new Act, Health Canada representatives said that the approach to the modernization evolved over time to include opportunities other than legislative amendments (e.g., regulatory amendments, and/or leveraging other statutes, where possible).

The first year of the FCSAP focused on modernizing legislation for the regulation of consumer products (i.e., the CCPSA), as well as food and drugs (i.e., amendments to the FDA). While initial consideration was also being given to the modernization of the legislation governing radiation-emitting devices, Health Canada representatives noted that the Office of Strategic Policy and Integration (OSPI) within the Policy, Planning and Integration Directorate (PPID) of HESCB recognized that policy research and analysis was required in order to do so. They said that this important activity had never been undertaken, and deemed it vital to inform the development of policy options for Cabinet consideration and to fully understand the context and need for modernizing the REDA.

In the second and third year of the FCSAP, Health Canada undertook a comprehensive policy analysis to determine a path forward for the REDA modernization. The analysis involved completing an international legislative comparison (HECSB, 2009a); undertaking an analysis of health and safety considerations for regulatory modernization (Health Canada, 2010e); hosting a workshop to identify program and legislative gaps in the REDA (Health Canada, 2010e); holding an interdepartmental meeting on opportunities to leverage other legislative frameworks to improve radiation-emitting device regulations (Health Canada, 2010e); reviewing stakeholder concerns related to radiation-emitting devices, including a media scan and review of public opinion research on radiation-emitting devices (Health Canada, 2010e); conducting an economic analysis of the Canadian radiation-emitting device industry (Pawlak, 2010); and completing a scan of the Parliamentary context for radiation-emitting devices.

The comprehensive policy analysis in support of REDA modernization was completed in the third year of the FCSAP. The results of the analysis highlighted that legislative change was just one of several policy options that could be used to modernize REDA. Based on the policy analysis phase, Health Canada prepared a REDA “Modernization Storyline” report that summarized the information, presented modernization options, and articulated strategic recommendations (HECSB, 2011). The storyline report outlined three modernization options, as summarized in the list below.

Options outlined in the REDA Modernization Storyline

Option 1 – Status quo plus

“Radiation emitting devices will continue to be regulated by the existing REDA and improvements will be made under the existing framework, where possible.”

“Option 2 – Streamlined REDA for industrial/ commercial products

“Radiation emitting medical devices would be regulated under FDA, radiation emitting consumer products would be regulated under CCPSA, and a new REDA would be drafted for industrial/commercial⁴¹ radiation emitting devices.”

Option 3 – Full modernization of REDA

“REDA would be modernized to include authorities that are in line with legislation regulating similar products (e.g., FDA and CCPSA).”

Source: (HECSB, 2011, pp. 17–18)

The Modernization Storyline analyzed a variety of risks associated with these options and proposed mitigation strategies, ultimately concluding that the preferred option would be to proceed with full legislative modernization of REDA. However, given competing priorities,⁴² it was determined that no legislative changes would be made to REDA at that time. Instead, it was recommended 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 (e.g., CCPSA for consumer products and FDA for medical devices). In addition, existing regulations were to be updated and new regulations proposed to better utilize the authorities under the existing Act. In short, CCRPB would continue to work under the existing framework, while improving the overall implementation of the current REDA (HECSB, 2011, p. 20).

While these alternative mechanisms were initially proposed as interim measures pending more longer-term plans for legislative modernization (HECSB, 2011, p. 20), Health Canada representatives have since noted that the Department has no plans to pursue legislative amendments to REDA in the near future. Without legislative modernization, Health Canada does not have the authority under REDA to order recalls and to require corrective measures (CCRPB & PPID, 2009). However, in addition to the alternative measures identified above, Health Canada continues to pursue various strategies to address these gaps, including: issuing advisories for high risk products; requesting records from the industry to verify compliance with REDA; and posting notices/recommended actions for corrections (CCRPB & PPID, 2009).

Emphasis of REDA modernization also shifted to improving administration and enforcement of the existing legislation and regulations (Health Canada, 2011b). To this end, Health Canada has undertaken the following activities:

⁴¹ Program representatives noted that the CCPSA may also apply to industrial/commercial radiation-emitting devices that can reasonably be obtained by individual consumers.

⁴² Health Canada representatives said the “competing priorities” related to activities associated with the CCPSA and the FDA.

- Efforts to align compliance and enforcement activities with other products regulated by Health Canada through participation in the Single Window Initiative, the Pathfinder43 Project, and the Border Integrity Pilot Project (CCRPB, 2010)
- Developing a draft compliance and enforcement framework for radiation-emitting devices which outlines roles and responsibilities, approaches to compliance and enforcement, reporting and information sharing, training and communication, and risk management (CCRPB, 2011)
- Creating consistent Standard Operating Procedures for compliance and enforcement of regulated products under REDA
- Drafting and updating Safety Codes, guidance documents, and other communication vehicles for radiation-emitting devices on radiation protection
- Updating Safety Code 6, a guide on human exposure guidelines to radiofrequency electromagnetic energy (CCRPB, ERHSD, HECSB, & Health Canada, 2009)

Health Canada representatives also reported that CCRPB is developing a cyclical enforcement strategy for radiation-emitting devices to monitor compliance with the REDA. Its approach to cyclical enforcement will include the use of a risk-management framework that will categorize radiation-emitting devices into risk level based on inherent risk or other information received, such as complaints.

Strategy 11: Monitor and Enforce Industry Compliance (CPSD, RAPB)

Health Canada gradually increased its resources, including the number of inspectors, to enhance existing compliance promotion and enforcement efforts. See Section 5.5 for an overview of resources planned and expended under the various FCSAP strategies.

Since there is no pre-market approval process for consumer products and cosmetics⁴⁴, Health Canada monitors regulatory compliance solely through post-market activities. Main elements of these activities are inspections and product testing, which are carried out in response to consumer complaints, industry incident reports, referrals from the Canada Border Services Agency (CBSA), and recalls in other jurisdictions, as well as being carried out according to a Cyclical Enforcement Program (CEP), described below (CPSD, 2012f, p. 5). In the event of non-compliance, Health Canada may engage in a variety of compliance and enforcement actions, including, but not limited to, requesting a voluntary recall or ordering a recall of the product. Recall monitoring inspections may be conducted after a product has been recalled to confirm the effectiveness and completeness of the recall.

⁴³ Health Canada representatives said that the Pathfinder Project has been put on hold indefinitely as a result of costing scope and level of risk.

⁴⁴ There is, however, a pre-market approval process for pesticides.

Information and training materials

A myriad of information and training materials are available for staff conducting consumer products compliance and enforcement activities.

- Health Canada recently developed a draft Compliance and Enforcement Strategy for Consumer Products and Cosmetics, which outlines “the strategies for a consistent compliance and enforcement approach for consumer products and cosmetics without being prescriptive” (Health Canada, 2012g, p. 2). The document outlines a compliance continuum organized around the three pillars of the FCSAP, namely, active prevention (through compliance promotion and deterring non-compliance), targeted oversight (through compliance monitoring), and rapid response (to address non-compliance, through voluntary and non-voluntary measures). Given that the document is still in draft form, it is not cited more extensively here.
- Policy guides provide staff with information about proper interpretation and enforcement of Acts and Regulations relating to consumer products (e.g., the CCRPB compliance and enforcement policy guide [CCRPB, 2012a] and a guidance document on the classification of products at the cosmetic-drug interface [HECSB, 2008]).
- Reference manuals for each product category covered by the CEP were developed and implemented in response to issues identified through annual CEP reporting, and in order to improve uniformity of enforcement across Canada for similar products. The reference manuals explain the relevant legislation or regulations; categorizing factors that determine the degree of violation as low, medium, or high; and outlining minimum enforcement actions to be taken at each level of violation (CPSD, 2011f, p. 10).
- In 2010, new guidelines for recall effectiveness were introduced that will require product safety officers to send a recall effectiveness form⁴⁵ to the recalling establishment (CPSD, 2010, p. 14). As of May 1, 2012, Standing Operating Procedures for recall monitoring and stop sale monitoring have been in effect (Health Canada, 2012h).
- Standard Operating Procedures (SOPs) provide systematic procedures for conducting various CPA processes, and user guides provide staff with further guidance on implementing CPA and using IT resources related to consumer products.

Information technology systems

Several databases support Health Canada’s compliance and enforcement activities. For example, CPSP’s CCMS database was introduced with the intention of improving Health Canada’s ability to track and monitor industry compliance. Additionally, the Cosmetic Notification System (CNS) database tracks information from each cosmetic notification received. Finally, the Pathfinder⁴⁶ Project was initiated with the goal of creating a common IT platform for compliance and enforcement for all products regulated by Health Canada.

⁴⁵ Completion of the form is voluntary, but is expected to provide Health Canada with an additional tool for oversight on the progress of a recall.

⁴⁶ Health Canada representatives said that the Pathfinder Project has been put on hold indefinitely as a result of costing scope and level of risk.

Some challenges were encountered by the evaluation in using the CCMS data to identify compliance and enforcement-related trends. For example, as one media outlet recently reported, the Minister of Health told the House of Commons that “the department’s new tracking system [CCMS] does not currently allow for counting the exact number of inspections” (Calgary Herald, 2012). In response to this criticism, Health Canada representatives said there is a need to create business rules to ensure consistent data entry, which, in part, involves clearly defining some of the terms used in the Department (e.g., “incident,” “investigation,” “inspection,”⁴⁷ “assessment,” “compliance”) and outlining how to prioritize cases.⁴⁸ Further, Health Canada representatives indicated that work is underway to incorporate data extraction and analysis capabilities in CCMS; however, they said that, prior to doing this, the Department needs to identify what information is required for reporting purposes (e.g., establishing how the Department intends to report on industry compliance). Additionally, Health Canada representatives noted that measures to report against the PMF will be implemented for 2013–14.

Market surveys

Market surveys are one aspect of Health Canada’s compliance monitoring activities. For purposes of this report, these are planned compliance and enforcement activities outside of the Cyclical Enforcement Program. Health Canada undertook market surveys examining phthalates (CPSD, 2009), grey area children’s products⁴⁹, (CPSD, 2010, p. 11), seed-filled toys (CPSD, 2011f), and hair smoothing products (Health Canada, 2011b, p. 65). In 2009–10 and 2011, market surveys of children’s jewellery were also conducted (CPSD, 2012f).

Inspections and product testing

It is difficult to develop comparable summaries of the Department’s inspection and product testing activity due to differences in the way data are captured in PSIS and CCMS.

Historical information from PSIS for the period of 2006 to 2010⁵⁰ provides an indication of the level of inspection and product testing activity undertaken by Health Canada prior to the enactment of the CCPSA. As shown in Table 1, the annual number of inspections/tests has varied over time. Health Canada representatives said caution should be used when comparing yearly sampling data because of the following:

- The number of samples tested each year is dependent on the nature of the CEP projects being conducted, although not all of the samples, tests, and inspections conducted are part of CEP projects.

⁴⁷ For example, Health Canada representatives said several inspections may be conducted to resolve a single case and that any interaction with a retailer or company is considered an “inspection.” They indicated that due to the way resources are added to a case, multiple inspections associated with an individual case cannot be counted. They reported that some of the data entry procedures for CCMS are being revised.

⁴⁸ This has been done for the triage of consumer product incident reports and compliance and enforcement activities. However, for many of the cases in the CCMS data provided to evaluation, the “priority” field was blank.

⁴⁹ Products/categories of products that need further review in order to determine whether or not they are “products intended for use by a child in learning and play” and therefore subject to requirements for toys.

⁵⁰ These data are provided on a calendar year basis. It is unclear if data for 2010 are for a full year.

- The complexity of the tests required is dependent on the type of consumer product being examined. For example, some tests take one day to complete, whereas others may take a week.

Table 1 also shows that the number of cyclical enforcement inspections has declined each year since 2007; Health Canada representatives noted that, during 2010, cyclical enforcement activities were reduced in anticipation of, and preparation for, the passing of the CCPSA.

Table 1: Overview of CPSD inspection and product testing activity, 2006 to 2010 (based on calendar year)

Activities	2006	2007	2008	2009	2010
Number of inspections	8,611	7,918	9,184	12,056	7,070
Number of cyclical enforcement inspections	1,076	1,440	1,330	810	625
Number of products inspected	13,248	11,311	13,385	18,598	10,822
Samples tested by PSL	483	1,014	825	911	260

Source: (CPSD, 2012g)

Given the limitations of CCMS at the time of conducting the evaluation, it is not possible to determine if the number of inspections has continued to decline since 2010. Nonetheless, the above-mentioned media article⁵¹ reported that, based on information tabled by the Minister of Health in the House of Commons, the number of inspections carried out by Health Canada declined significantly, from 12,050 in 2009–10 to “as few as 4,797” in 2011–12 (Calgary Herald, 2012). The article also reported that, over the same period, there was a 57% drop in the number of tests Health Canada carried out in its product safety laboratory, from 627 tests in 2009–10 to 269 tests in 2011–12. Health Canada representatives confirmed that the Department reduced the number of inspections and tests conducted during the first six months following the enactment of the CCPSA because, as reported in the media article, “inspectors have focused on outreach to industry to raise awareness of their obligations under the [new CCPSA]” (Calgary Herald, 2012).⁵² However, Health Canada representatives said the Department has since increased the number of inspections and tests being conducted to pre-CCPSA levels. Although information on the number of inspections conducted in 2011 and 2012 was not available, in each of these years, respectively, the PSL tested 274 samples and 477 samples (CPSD, 2012h).⁵³

The Cyclical Enforcement Program for Consumer Products

The CEP is a system for inspecting high-risk product categories proactively at specified intervals to determine whether industry is meeting requirements (Health Canada, 2011b). Initially, the CEP was used to enforce regulations under the HPA for 23 prioritized product categories. This was increased to 35 product categories as the mandate of CPA expanded to include the *Cosmetic Regulations* and as other legislative and regulatory changes occurred, including the implementation of the CCPSA. Consumer products without specific regulations under the

⁵¹ The data cited in the media article were provided on a fiscal year basis.

⁵² In the same report, it was also noted that “Health Canada could not immediately say...how many [of the mandatory incident reports submitted in 2011–12] resulted in a product recall.”

⁵³ Health Canada representatives noted that not all CE samples are tested in the PSL.

CCPSA are currently not included in the CEP (CPSD, 2012f, p. 12); however, Health Canada representatives indicated that compliance and enforcement activities for these products may occur on an ad-hoc basis. Further, they indicated that the Department is considering how to integrate “unregulated” products into CEP activities.

It appears that, for three product categories, CEP activities have not been completed within the prescribed cycle. Table 2 provides the number of product categories within each cycle length (from one to six years) for the 35 products included in the CEP and indicates how many product categories had their cycle completed in each fiscal year between 2004–05 and 2010–11.

Table 2: Cyclical enforcement product categories and cycle length

Cycle length		Last cycle	
Number of years	Number of product categories	Fiscal year last cycle completed	Number of product categories
One	3	2004–05	3
Two	3	2005–06	1
Three	9	2006–07	2
Four	7	2007–08	5
Five	1	2008–09	5
Six	12	2009–10	6
Total	35	2010–11	12
		Total	34

Note: One product category was identified as prohibited; it is not clear what this means for the cyclical enforcement activity associated with this product category.

Case study example: cyclical enforcement of *Corded Window Covering Products Regulations*

The case study on corded window coverings found that CEP activities for this product have not been completed as planned. The *Corded Window Covering Products Regulations* were brought into force on April 2, 2009 (Department of Justice, 2012). The Performance Measurement and Evaluation Plan (PMEP) for the Regulations noted that, upon coming into force, corded window coverings would be risk assessed (for CEP purposes) and placed into the CEP (CPSD, 2010). However, the risk assessment was not completed, and the planned cyclical enforcement activity for corded window coverings for 2010–11 was replaced by a market survey. The market survey involved inspection and monitoring of products, but not enforcement activity. Health Canada representatives explained that enforcement activity for this product is constrained by the standard upon which the regulations are based, which is unclear about how to perform certain compliance tests on products. As a result, the standard could deem a product compliant or non-compliant depending on interpretation. Furthermore, Health Canada representatives said current testing procedures may identify corded window coverings that clearly expose children to corded loops as compliant. Consequently, Health Canada is working with the Canadian Standards Association (CSA) to clarify testing procedures. Program representatives noted that a cyclical enforcement project for corded window coverings, focusing on both product inspection and record keeping requirements of the regulation, has been initiated. They noted that, as of March 12, 2013, inspections have been conducted at 22 establishments, and approximately 70 products have been reviewed. Further, they said this cyclical enforcement activity has led to three product recalls.

Another element of Health Canada’s monitoring and compliance regime is recall monitoring inspections, which are conducted after a product has been recalled to confirm the effectiveness and completeness of the recall. As Health Canada representatives explained, this involves

conducting inspections, in-person or by phone, to determine if products subject to recall have actually been removed from the point of sale. A single recall may result in multiple recall monitoring inspections being conducted across the country. Table 3 shows that, according to PSIS data, between 2006 and 2010, more than 13,500 recall monitoring inspections were conducted.

Table 3: Number recall monitoring inspections, 2006 to 2010

2006	2007	2008	2009	2010	Total
1,722	1,434	3,070	5,238	2,115	13,579

Source: (CPSD, 2012g)

Similar data for later years could not be located; however, for the period of June 2011 to March 2012, CCMS contained 98 cases whose “case state” is identified as “recall”; there were 33 cases with the case subtype “recall” and five cases with the case subtype “recall/removal monitoring,” all five of which are associated with inspections. Health Canada representatives noted that, in CCMS, recall monitoring inspections are tracked in the “original” recall case.

Strategy 12: Monitor and Enforce Industry Compliance – Consumer Pesticides (PMRA, RAPB)

PMRA has undertaken several initiatives to monitor and enforce industry compliance.

Information and training materials

PMRA has a compliance policy guideline (PMRA, 2006); an Inspector’s Field Operating Manual (PMRA, 2012e); as well as numerous online guidance documents for staff. These documents are part of a “Canadian Pesticide Regulation Course” that provides an overview of the Canadian regulatory process (PMRA, 2010b). The target audience of the course includes new regulatory staff and experienced regulatory staff who wish to refresh their skills. In total, 29 of these documents are available online, covering a variety of topics relating to pesticide regulation at PMRA.

In March 2012, PMRA held a National Pesticide Compliance Workshop, the primary objective of which was “to develop and maintain the specialized skills and abilities required to carry out timely and high quality compliance inspections, compliance verification, enforcement actions and other responsibilities under the *Pest Control Products Act* (PCPA) and its regulations” (PMRA, 2012l, p. 1). There were 64 PMRA participants in the three-day workshop, as well as 12 invited guests.

Information technology systems

PMRA introduced the Investigation Tracking Form (ITF) database, which was intended to “go beyond the current searchable repository of investigations data, to enhance the analysis and identification of trends, and as a risk management tool” (PMRA, 2009b). It was intended to allow PMRA to determine priorities for products of concern for targeted inspections, determine where unregistered consumer pesticides are entering Canada, and analyze consumer product trends (CPSI, 2012).

More recently, according to program representatives, the ITF has been replaced for this purpose by the Compliance Results Tracking (CRT) database. In 2010–11, PMRA implemented a modified version of the CRT, which included new data fields, such as “Consumer Product” to track entries and details related to complaints of non-compliance and detected instances of non-compliance.

In addition to these databases, Health Canada initiated the Pathfinder Project, which was intended to create “a common IT platform for Compliance and Enforcement for all regulated products in Health Canada” (Health Canada, 2012i). The project was to “develop common business processes and common solutions for the Compliance and Enforcement community” (PMRA, 2012g). Moreover, it was expected to enable PMRA to receive pesticide importation data collected by CBSA (Health Canada, 2011b, p. 28). However, Health Canada representatives said that the Pathfinder Project has been put on hold indefinitely as a result of costing scope and level of risk.

Compliance verification program

PMRA implemented a compliance verification program for consumer product vendors in 2009–10 as the “core component” of Strategy 12 (PMRA, 2011f). As part of this program, PMRA conducted inspections of liquidation and discount stores; animal and pet products (flea and tick collars, shampoos); pool and spa products (algaecides, devices, sanitizers); home and garden protection products (moth balls, mildewcides, insect repellents, rodent control products, lawn and plant care products); and personal protection products (insect repellents).⁵⁴

PMRA also introduced a compliance verification program targeting vendors of unregistered international pest control products. The program was intended to address health and safety concerns arising from inadequacies in labelling and packaging and the presence of unknown active ingredients in unregistered products on the Canadian marketplace, many of which are imported from China (PMRA, 2010d). It considered two unregistered products of particular concern — miraculous insecticide chalk and mothballs — and focussed inspections in Chinatown areas in several cities across Canada.

Cyclical compliance monitoring program

In 2011, PMRA implemented a cyclical compliance monitoring program, under which it planned to “systematically monitor a few of the regulated communities per year so that at the end of a five year cycle,⁵⁵ PMRA will have performed some compliance monitoring activities for all of its regulated community” (PMRA, 2011g). In its first year (2011–12), the planned focus of the program in relation to consumer pesticides was users of pesticide in swimming pools and spas, as well as home and garden pest control product vendors. The planned focus on these products was reflected in the compliance verification program described above.

⁵⁴ Refer to Section 5.4.3 for the results of PMRA’s compliance activities.

⁵⁵ Program representatives noted that the five-year plan is contingent on having resources available after addressing known compliance areas of concern.

Investigations

Table 4 provides an overview of PMRA investigations completed between 2007–08 and 2011–12. There were no prosecutions as a result of non-compliances, although a small number of Notices of Violation (NOV) were issued in each year. A large number of “other enforcement responses” were taken, although the source documents do not contain further details about what these entail.

Table 4: Overview of PMRA investigations

Year	Number of investigations		Percent completed within performance target (6 months)	Prosecutions	NOVs issued	Other enforcement responses
	Initiated	Completed				
2007–08	341	324	90%	0	9	363
2008–09	491	532	88%	0	4	812
2009–10	495	449	86%	0	16	887
2010–11	594	569	91%	0	9	1,157
2011–12	598	598	87%	0	20	1,628

Source: (PMRA, 2008a, 2009c, 2010e, 2011h, 2012h)(CPSD, n.d.-a)

Additionally, PMRA conducted inspections of 61 Canadian registrants of consumer products (domestic class products) in 2008 under the Registrant Inspection Program (PMRA, 2009d). Further, Table 5 (page 55) provides an overview of the results of PMRA’s recent compliance monitoring activities, including information on the compliance rate found among inspected parties and actions taken by PMRA.

Other activities

PMRA held consultations with the US Environmental Protection Agency (EPA) on common challenges related to imported unregistered products, false and misleading product claims, and best practices (Health Canada, 2010c, p. 22); sharing compliance and enforcement information with the EPA; and discussing shared issues related to consumer pesticides (Health Canada, 2011b, p. 67).

5.4 Achievement of outcomes

This section presents the findings with respect to the evaluation questions on outcomes. Overall, as described in Section 5.3, while Health Canada has engaged in many activities that should, in theory, produce the expected outcomes, in some instances, data to support a definitive conclusion regarding the extent to which expected outcomes have been achieved are relatively limited.

5.4.1 Increased awareness/understanding of risks related to consumer products

In the short term, Health Canada’s communication and stakeholder engagement activities are expected to produce increased awareness and understanding by external stakeholders of risks related to consumer products, and increased awareness and understanding among industry of the

regulatory framework for consumer products. That said, the performance indicators that Health Canada tracks for this outcome tend to measure the extent to which information has been distributed but do not offer insight into the level of awareness and understanding of risks.

The main sources of information available to assess progress toward this outcome are public opinion research conducted for Health Canada in 2007 and 2010,⁵⁶ and the findings of the survey conducted as part of this evaluation. However, for the most part, the survey only provides baseline information, as comparable information for previous years is generally not available. Further, given that the survey targeted consumers and industry representatives who have had previous contact with Health Canada, either by subscribing to one of Health Canada's electronic information services or participating in a CCPSA information session for industry, the results are not necessarily representative of the public at large or industry as a whole.

Therefore, while it is not possible, on the basis of the available information, to determine definitively if awareness has increased, it is apparent that stakeholders are using some of the available information and are finding it at least somewhat understandable, useful, accessible, of high quality, and timely.

Consumer products: consumers

Consumers' awareness and use of the Health Canada consumer products-related information available online varies by source. While there is high awareness and use of some products, others are not as well-known and/or used. As shown in Table 5, the survey conducted as part of this evaluation found that most consumers were aware of, and had used, information about consumer product advisories, warnings, and recalls (92%),⁵⁷ as well as the Health Canada Consumer Product Safety (CPS) website (76%). More than half (55%) had used the product safety fact sheets (including *Is Your Child Safe?* publications); another 25% were aware of the fact sheets, but had not used them. Although about two thirds (66%) were aware of information on Health Canada's website about the CCPSA, only 31% had used it.

The survey also found that only 10% of the responding consumers had used the information Health Canada makes available through social media,⁵⁸ although another 35% said they were aware of it. Those who were not aware of social media information (55%) were divided on its potential usefulness; about 40% said they would find it useful, while 37% said they would not find it useful. Almost one quarter said they did not know if they would find the information useful.

⁵⁶ Refer to footnotes 58, 60 and 61 for a description of these surveys.

⁵⁷ A 2010 survey of adult Canadians found that about half of the general public (53%, versus 57% of parents) were aware that information about consumer products advisories, warnings, and recall is available online. It also found that about half (54%) of those members of the general public who are aware of this information claim to have used it (Phoenix Strategic Perspectives Inc., 2011). The survey was completed with 1,357 respondents, including 1,006 adults (i.e., general public) and 351 parents/guardians of children ages 12 and younger. As the 2010 survey targeted the general public, the results are not directly comparable with the evaluation survey, which targeted consumers who subscribed to one of Health Canada's electronic information services.

⁵⁸ The survey listed the following examples of social media information: the Healthy Canadians Facebook page, the Health Canada Twitter feed, the Health Canada YouTube channel, and the Health Canada Recall and Safety Alerts mobile app.

Table 5: Consumers' awareness and use of Health Canada's consumer products information

Consumer products-related information	Proportion of evaluation survey respondents	
	Used	Aware, but not used
Advisories, warnings & recalls	92%	5%
Consumer Product Safety website	76%	19%
Fact sheets	55%	25%
<i>Canada Consumer Product Safety Act</i>	31%	35%
Social media	10%	35%

As shown in Table 6, overall, the vast majority of consumers, between 90% and 97%, found Health Canada's information on consumer products to be "very" or "somewhat" useful, understandable, accessible, of high quality, and timely.

Table 6: Consumers' assessment of Health Canada's consumer products information

Assessment of consumer products	Proportion of evaluation survey respondents				
	Useful	Understandable	Accessible	High quality	Timely
Somewhat	27%	33%	37%	35%	41%
Very	70%	63%	57%	58%	49%

Some external key informants (representatives of consumer, health, and other associations) expressed concern that posting information on the Internet is not adequate for advising the public of potential safety risks. They explained that all Canadians do not have access to the Internet, and those who do are not reading Health Canada's website every day. However, a survey of the general public and parents conducted for Health Canada in 2010 found that the Internet (72%) ranked as the top effective way among the general public of receiving information to help make an informed purchase decision (Phoenix Strategic Perspectives Inc., 2011).⁵⁹ This compares with family and friends (71%), Health Canada publications (65%), manufacturer product information (64%), newspapers (63%), Health Canada website (62%), consumer watchdog publications (61%), TV shows (60%), and retailers (53%) (Phoenix Strategic Perspectives Inc., 2011). The study also found, that aside from TV shows, parents were more likely than the general public to find the sources of information effective (Phoenix Strategic Perspectives Inc., 2011).

Additionally, some external key informants (representatives of consumer, health, and other associations) suggested that Health Canada's risk communications are not readily understandable for Canadians with lower levels of literacy or those who are not fluent in one of Canada's official languages. Based on the findings of the evaluation survey and a 2007 survey of parents⁶⁰, there may be some opportunity for Health Canada to improve the understandability of the information it provides. Both surveys yielded similar results; the evaluation survey found that 63% of respondents rated Health Canada's information on consumer products as "very" understandable, and the 2007 survey found that 64% of parents believed that Health Canada does a good job of providing easily understandable information on consumer products (MCSD, 2011).

⁵⁹ The survey was completed with 1,357 respondents including 1,006 adults (i.e., general public) and 351 parents/guardians of children ages 12 and younger.

⁶⁰ The survey was conducted with 832 Canadian parents (Ipsos Reid, 2007).

In summary, about two thirds (67%) of the consumers who responded to the evaluation survey agreed that “overall, Health Canada provides enough information to the general public about the human health safety risks associated with consumer products.” This includes 16% who strongly agreed; about 18% disagreed. These results are somewhat similar to the 2007 survey of parents, which found that 53% believed they had the right amount of information about consumer products and 63% agreed that there is enough information available for consumers who want to check products they buy (MCSD, 2011).

Consumer products: industry

Generally, industry tends to have higher awareness of, and is more likely to use, Health Canada documentation about the CCPSA than other media such as webinars and videos. As shown in Table 7, about three quarters of the industry respondents were aware of the following CCPSA documents: electronic newsletter (73%), FAQs (73%), and Quick Reference Guide (72%); about half had used them. Fewer were aware of or had used the CCPSA webinar (56% aware, including 25% who had used it) or the CCPSA video (42% aware, including 13% who had used it).

The CCPSA information sessions held by Health Canada successfully increased participants’ awareness and understanding of their product safety obligations under the CCPSA. About two thirds (n=219) of the industry representatives who responded to the evaluation survey were aware of the information sessions and, of those, about two thirds (n=144) personally attended one of the sessions. As shown in Table 8, of those who personally attended an information session, the proportion of respondents who rated, using a scale of 1 to 5, where 1 is poor and 5 is excellent, their *awareness* of their company/organization’s product safety obligations under the CCPSA as a “4” or “5 – excellent” increased from 44% prior to the session to 90% following the session.⁶¹ Likewise, the proportion of respondents who rated their *understanding* of their company/organization’s product safety obligations under the CCPSA as a “4” or “5 – excellent” increased from 42% prior to the session to 85% following the session.⁶²

Table 7: Industry awareness and use of Health Canada’s information about the CCPSA

Industry awareness of consumer products	Proportion of evaluation survey respondents	
	Used	Aware, but not used
Canada Consumer Product Safety Act electronic newsletter	54%	19%
Canada Consumer Product Safety Act FAQs	48%	25%
Canada Consumer Product Safety Act Quick Reference Guide	49%	23%
Canada Consumer Product Safety Act webinar	25%	31%
Canada Consumer Product Safety Act video	13%	29%

⁶¹ The average rating increased from 3.3 to 4.3

⁶² The average rating increased from 3.3 to 4.2.

Table 8: Industry awareness and understanding of the CCPSA, pre- and post-information sessions

Proportion of evaluation survey respondents; rating of 4 or 5			
Awareness Prior	Awareness Following	Understanding Prior	Understanding Following
44%	90%	42%	85%

Industry representatives who participated in the external interviews indicated that, although Health Canada, in conjunction with industry and trade associations, has made a considerable effort to communicate with industry about the new CCPSA, it is important for the Department to continue its information-sharing and education efforts. While industry representatives believe that the more active, and larger, industry members are well informed of their obligations under the new legislation, they have the perception that many SMEs are not aware of the new CCPSA and/or do not have a strong understanding of their obligations. They suggested that Health Canada should place increased emphasis on reaching SMEs and new entrants, especially those who may not be connected to any industry associations and, therefore, are more difficult to reach. Health Canada representatives reported that outreach to SMEs and new entrants will be a priority in coming years.

On average, based on a scale of 1 to 5, where 1 is poor and 5 is excellent, industry representatives rated the level of knowledge within their company/organization of the new CCPSA as 3.5. Specifically, half of the industry respondents (50%) rated the level of knowledge within their company/organization as a “4” or “5 – excellent.” About one quarter rated it as a “1 –poor” or “2” (15%) or said they “don’t know” (11%).

The majority of industry representatives are aware of other information about consumer products that Health Canada makes available to them. Over 8 in 10 of the industry respondents were aware of information on safety standards (86%) or guidance documents (85%); more than half had used these sources. Just over 7 in 10 (71%) were aware of information on the enforcement actions that Health Canada can take, including 36% who had used it. Almost two thirds (64%) were aware of information on the department’s post-market surveillance activities, including 32% who had used it.

Overall, as shown in Table 9, between 85% and 89% of industry representatives said Health Canada’s information on consumer products was “very” or “somewhat” useful, understandable, accessible, of high quality, and timely. Less than half rated each aspect as “very.”

Table 9: Industry assessment of Health Canada’s consumer products information

Industry assessment of Information on consumer products	Proportion of evaluation survey respondents				
	Useful	Understandable	Accessible	High quality	Timely
Somewhat	41%	48%	42%	46%	43%
Very	48%	40%	45%	40%	42%

Consumer pesticides

For consumer pesticides, some information on industry awareness and understanding of Health Canada’s regulatory requirements can be found in PMRA reporting on completed inspections. The nature and amount of information reported varies greatly among reports, making it difficult

to draw overall conclusions. That being said, it appears that while 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), in other cases, there is low awareness of regulatory requirements (e.g., requirement to sell only registered and properly-labelled pet products).

PMRA external stakeholders reported that PMRA's outreach to industry representatives has been effective and said the information is readily accessible. They appreciate receiving information through PMRA's website, regulatory directives, bulletins, newspaper/magazine articles, and direct communication (verbal and email). They also indicated that PMRA's collaboration with associations and organizations to distribute information has helped identify and reach a broader range of stakeholders. PMRA external stakeholders said they are aware of instances where PMRA has translated pertinent information into languages other than English or French for specific target audiences.

5.4.2 Increased safety of consumer products

In the short term, CPA are expected to contribute to increased safety of consumer products. Since CPA do not involve pre-market review of consumer products,⁶³ the Department influences safety through legislative requirements and its response to the risks associated with products available in the marketplace. Therefore, considering Health Canada's role, key performance measures for this outcome should track information related to the identification of human and health safety risks and the Department's response to these risks. That said, according to the Departmental Performance Measurement Framework for 2013–14, which forms the basis for the DPR, CPSD is responsible for reporting on the triage of the consumer product incident reports it receives from industry and consumers, as well as the risk management actions it takes in relation to non-compliant products identified through the CEP (Health Canada, 2012j).

Health Canada is tracking some information related to the safety of consumer products, such as the number of consumer product incident reports received and the number of advisories, warnings, and recalls issued. However, without additional context, these indicators alone are not sufficient to make conclusions about changes in safety. For example, increased reporting of consumer product incidents could indicate either a growing prevalence of unsafe products on the market or increased awareness by consumers and industry of the need and/or obligation to report. Similarly, increased issuance of advisories, warnings, and recalls could reflect greater recognition by Health Canada of the need to notify the public of safety issues associated with these products as opposed to an increase in the number of safety risks, per se. Further, assessment of changes to the safety of consumer products should be conducted in the context of the number of safety issues identified (e.g., the mere reporting of an incident does not necessarily indicate that a product is unsafe) and the associated response to these risks.

⁶³ However, as previously mentioned, under the *Cosmetic Regulations*, Health Canada must be notified of all cosmetics sold in Canada within 10 days of entering the marketplace. Additionally, pesticides must be registered for sale in Canada and they are subject to re-evaluation every 15 years.

Based on the information provided to the evaluation, it is not possible to determine if the safety of consumer products has changed over time. However, it is believed that the general prohibition against the manufacture, importation, sale, or advertisement of consumer products that pose a danger to human health or safety (introduced through the CCPSA) may deter industry from introducing these products into the marketplace; if not, the legislation provides Health Canada with the authority needed to take action. Additionally, it is expected that, through the mandatory incident reporting requirement for industry, Health Canada will have access to additional information for use in identifying potential health and safety risks. Finally, there is evidence that Health Canada is making information about potential risks available to Canadians through advisories, warnings, and recalls.

Identifying potential human health and safety risks (CPSD)

Health Canada may identify potential human health and safety risks associated with consumer products through its surveillance activities. In part, this involves placing consumer products on Watch Lists,⁶⁴ preparing health event data reports, conducting environmental scans, or completing scientific literature reviews. The evaluation found no information on the number of health event data reports, environmental scans, or scientific literature reviews completed. Potential human health and safety risks may also be identified through the consumer product incident reports that the Department receives.

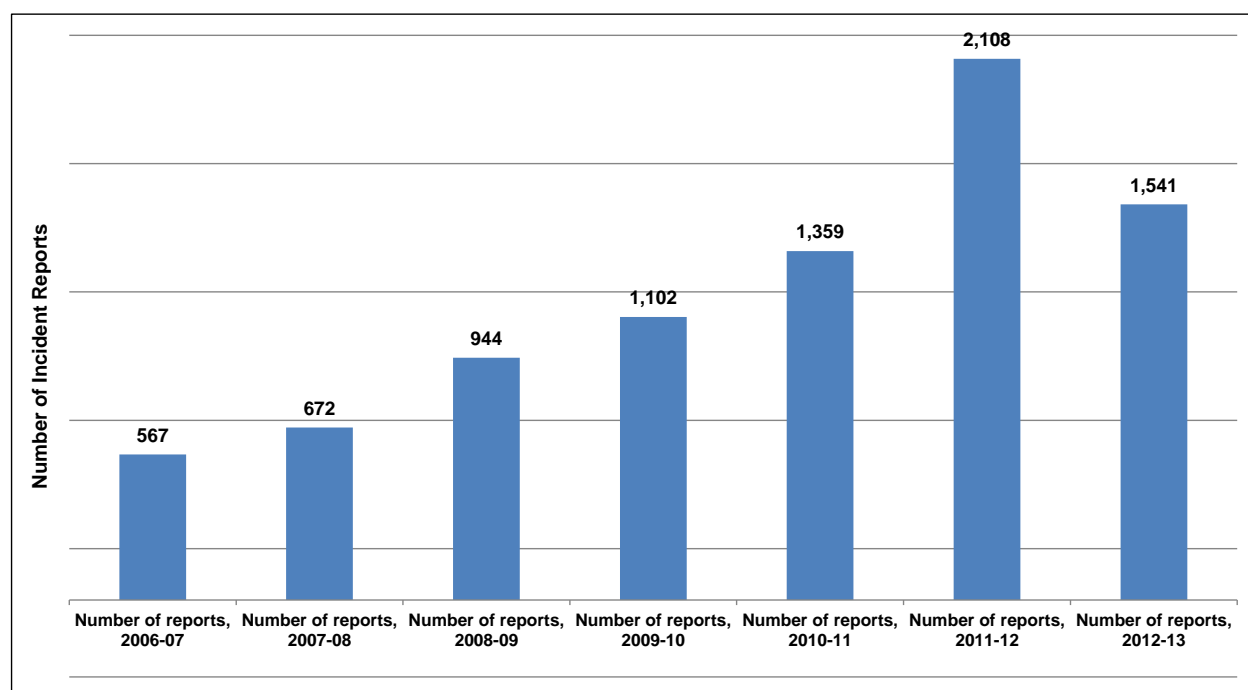
Consumer product incident reports

The annual number of consumer product incident reports received has been increasing over time. As shown in Figure 1, gradual increases were seen in the five-year period (2006–07 and 2010–11) prior to the CCPSA; however, a more distinctive increase was apparent in 2011–12, following the introduction of the mandatory incident reporting requirement for industry. However, although data for 2012–13 are not complete,⁶⁵ it appears that fewer consumer product incident reports were made than in the previous fiscal year.

⁶⁴ The Watch List is “a list of products or product categories that are monitored on a weekly basis” (SCU, n.d.). Items may be added to the list by CPSD staff (e.g., RAB or RMB) and Surveillance SCU staff. Once on the Watch List, items are valid for 12 weeks, after which the SCU contacts the individual who made the request to see if there is reason to keep the item on the Watch List for another 12 weeks (Health Canada, 2012k).

⁶⁵ These data are based on consumer product incident reports received between March 31, 2012 and March 1, 2013.

Figure 1 - Annual number of incident reports received by Health Canada, 2006–07 to 2011–12



In the nine-month period following the introduction of the CCPSA (June 2011 to March 2012), Health Canada received 2,108⁶⁶ incident reports, of which 72% (n=1,520) were from industry and 28% (n=588) were from consumers (CPSD, 2013a). Given that CPSD may receive several reports on a single occurrence or event with a product, the Program treats these multiple reports as a single “case” or unit of work; thus, the incident reports received in 2011–12 represent 1,768 cases. Triage of the incident reports received resulted in the routing of 28% (n=502) of the cases to risk management, 37% (n=652) to risk assessment, and 32% (n=574) to surveillance and monitoring (CPSD, 2013b).⁶⁷

Between March 31, 2012 and March 1, 2013, Health Canada received and triaged 1,541 incident reports, of which 62% (n=960) were industry reports and 38% (n=581) were consumer reports (CPSD, 2013b). Of the reports received, 35% (n=540) were subject to risk management; 29% (n=441) were subject to risk assessment; and 27% (n=420) were subject to surveillance (CPSD, 2013b).⁶⁸ Information on case outcomes for these incident reports was not provided.

⁶⁶ These data conflict with data reported in the FCSAP departmental performance report for 2011–12, which states that a total of 2,202 incident reports were received, including 1,688 mandatory incident reports from industry and 514 voluntary reports from consumers (Health Canada, 2012d). Further, it is worth noting that Health Canada provided the evaluation with several versions of consumer products incident data; the factors influencing the changes/revisions to the data are unknown to the evaluation.

⁶⁷ The remaining 40 cases fell outside of Health Canada’s mandate and therefore were referred or deferred.

⁶⁸ The triage outcome for 93 cases (6%) was not specified, and 47 cases (3%) fell outside of Health Canada’s mandate and therefore were referred or deferred.

General prohibition (CPSD via the CCPSA)

In theory, the new provisions and powers included in the CCPSA (refer to Section 5.3) should improve Health Canada's ability to respond to and address potential human health and safety risks associated with consumer products. The effectiveness of the general prohibition could be assessed by tracking indicators such as the number of potential violations identified; the number of corrective actions (by type, including orders) taken in response to a violation; and the length of time required for the violator to "agree to," or be "ordered to take," corrective action. However, for the most part, this information has not been collected.

Generally speaking, Health Canada representatives indicated that it is too early to tell if the general prohibition has helped reduce the presence of unsafe consumer products in the marketplace; however, they believe its mere presence is a deterrent.

- At the time of the writing of this report, Health Canada issued a news release indicating that some children's products containing small magnets pose a danger to children and are in violation of the general prohibition; the news release stated that Health Canada is "now taking action to identify and have these dangerous products removed from the marketplace" (Health Canada, 2013a).
- Information was not available on the number of times Health Canada identified a potential violation of the general prohibition, though some Health Canada representatives said it was used for recalls of the PeaPod Travel Bed, a child safety latch for cabinet doors, and handheld lasers.
- Since the CCPSA was enacted, Health Canada has not ordered corrective action. Although Health Canada began drafting orders for a recall of children's jewellery containing unsafe levels of cadmium, the order was never formally issued because the company in question eventually complied on a voluntary basis.
- Information was not available on the extent to which the general prohibition changed the duration of negotiations with companies about potential voluntary corrective actions, pre- and post-CCPSA.

Advisories, warnings, and recalls (consumer products, cosmetics, and consumer pesticides)

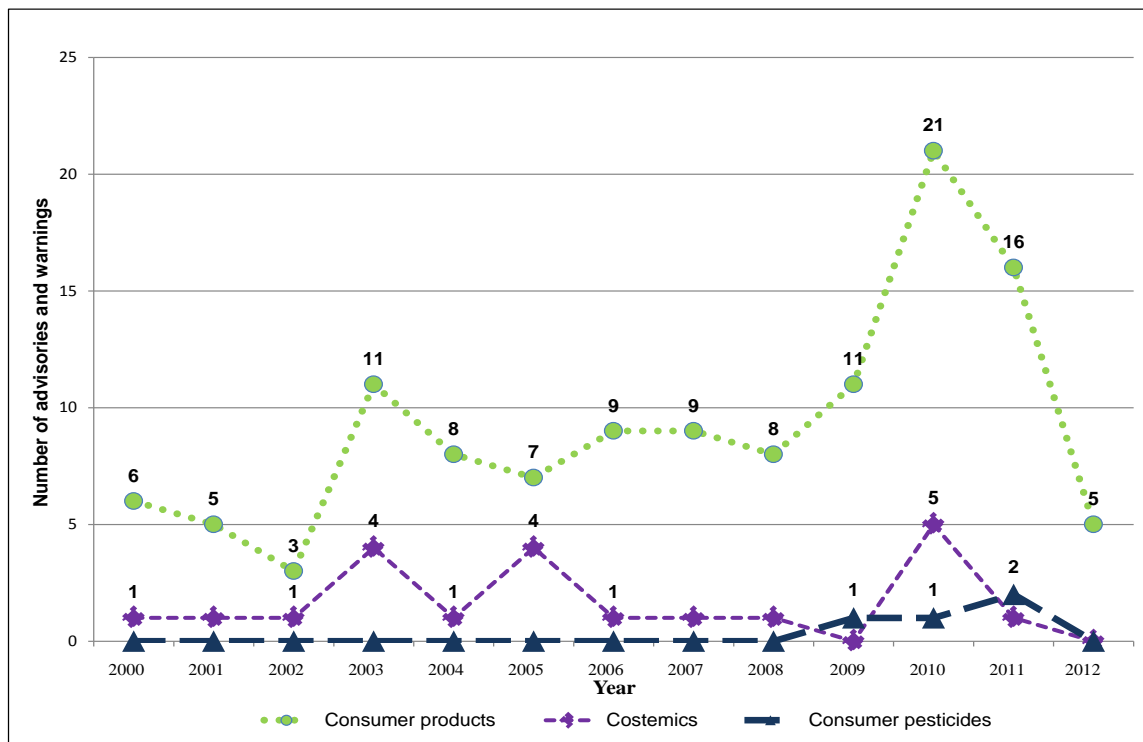
Health Canada communicates potential human health and safety risks associated with consumer products, including cosmetics and consumer pesticides, to Canadians through advisories, warnings,⁶⁹ and recall notices. Advisories "are generally used to help educate consumers about potential health risks associated with the improper use of a consumer product" (Health Canada, n.d.-b), whereas recalls "are used when industry and Health Canada become aware of a danger associated with a specific consumer product, and consumers need to be made aware so that they can stop using the product in its current form" (Health Canada, n.d.-b). Advisories and warnings have been listed on Health Canada's website since at least 2000 (the earliest date for which these data are currently posted online), and Health Canada's online Consumer Products Recall

⁶⁹ Health Canada representatives said the Department no longer issues warnings as a risk communication type.

Database lists recalls initiated since 1995.⁷⁰ Health Canada representatives reported that, in 2012, all Consumer Products Recalls were migrated into the Healthy Canadians Recalls and Safety Alerts Database, which provides a central repository of recall data for all participating federal departments.

As shown in Figure 2, there is no clear trend over time in the number of advisories and warnings issued, except for large increases in the number of advisories and warnings in 2010 and 2011 related to consumer products. Data for 2012 are incomplete; therefore, it remains to be seen whether this upward trend will continue. At the time the evaluation was conducted, Health Canada’s Consumer Product Safety section of the website listed a total of 144 advisories and warnings, including 119 documents related to consumer products (83%), 21 related to cosmetics (15%), and 4 related to consumer pesticides (3%).⁷¹ Again, these were all migrated into the Healthy Canadians Recalls and Safety Alerts Database.

Figure 2 - Number of advisories and warnings, 2000 to 2012



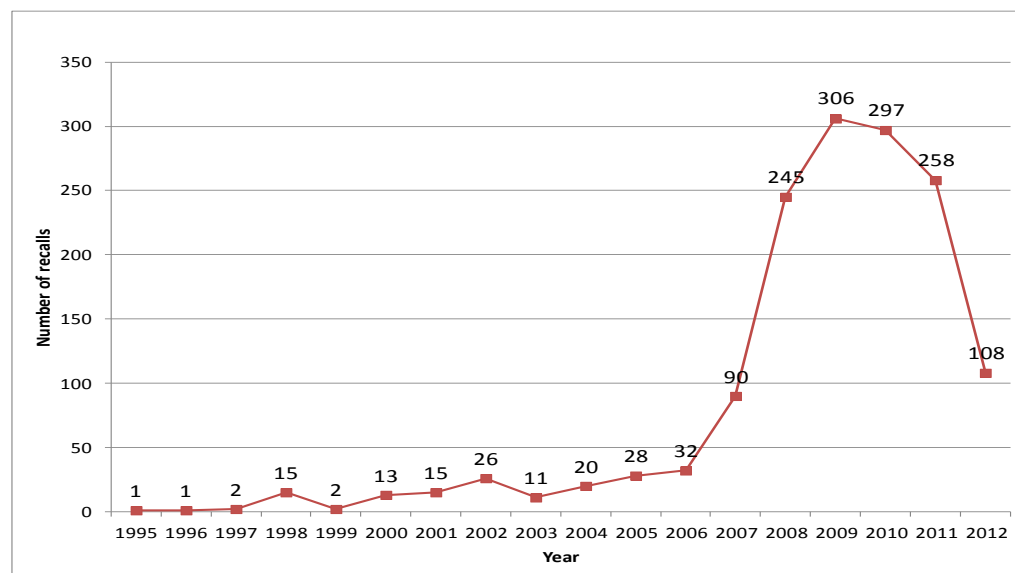
As shown in Figure 3, it appears that, beginning in 2007, there was a substantial increase in the annual number of recalls listed on Health Canada’s website. Health Canada representatives explained that this likely reflects that, prior to 2007–08, typically, only recalls related to children’s products were posted online; since then, all recalls falling under CPSD’s jurisdiction are being posted online.

⁷⁰ The evaluation did not find or receive information on recalls pertaining specifically to consumer pesticides.

⁷¹ PMRA’s website does not appear to include an analogous “advisories and warnings” page for consumer pesticides.

In total, between 1995 and 2012,⁷² a total of 1,470 recalls have been posted on Health Canada's website.⁷³ Given the discussion above, it is not surprising that two of the most heavily represented product categories are children's products (660 recall notices) and toys (303 recall notices).⁷⁴ A large proportion of recalls also related to household items (464 recall notices) and a total of 54 recalls were for cosmetics.

Figure 3 - Number of consumer product recalls, 1995 to 2012



According to Health Canada representatives, as of March 2013, the Healthy Canadian's Recalls and Safety Alerts Database contained 3,264 Consumer Product Recalls and Advisories (English and French).

5.4.3 Increased industry compliance

In the short term, Health Canada's activities are expected to lead to increased industry compliance with regulatory requirements relating to consumer products and consumer pesticides. It is not possible to determine the degree of industry-wide compliance with Health Canada's regulatory requirements since compliance and enforcement activities target instances of suspected non-compliance. Nonetheless, CEP results suggest that while there is high compliance for some product categories, there is persistent non-compliance for others.

Compliance and enforcement activities — consumer products

It is not possible to obtain data on the rate of industry compliance with consumer products legislation. As Health Canada representatives explained, CEP activities target an intentionally biased sample of products and manufacturers with higher risks and therefore may not be representative of overall industry compliance for that particular product category (refer to Section 5.3) for a description of CEP). Nevertheless, consumer product CEP results from fiscal

⁷² Data for 2012 are current to May 7, 2012.

⁷³ It is unclear if the Consumer Products Recall Database includes all recalls related to consumer products.

⁷⁴ It is important to note that a single recall may fall under more than one product category.

year 2008–09 to 2010–11 suggest that compliance was generally high (between 90% and 100%) for most product categories, although some categories had compliance rates under 10%, including utility lighters (7%), and carriages and strollers, cribs and cradles, and tents (all 0%) (CPSD, 2011f); (Health Canada, 2011b); CPSD, 2010; (Health Canada, 2010d)).

The case studies suggest there is ongoing non-compliance with the *Children's Jewellery Regulations* and the *Cribs, Cradles and Bassinets Regulations*. They also found evidence of non-compliance with the *Corded Window Covering Products Regulations*. However, it should be noted that enforcement action was taken on 100% of non-compliant products identified through the CEP (Health Canada (2012r)), for example, information letters, stop sales and voluntary recalls.

Case study examples: compliance with regulations

Children's jewellery

Health Canada's cyclical enforcement plan classifies children's jewellery as "high risk." Since 2000, eight market surveys of children's jewellery have been conducted. The number of products tested as part of the market surveys varies from a low of 52 (in 2011) to a high of 103 (in 2010). The percentage of products tested exceeding the total limits for lead content ranges from a low of 44% (in 2010) to a high of 69% (in 2000). Between 2010 and 2011, the percentage of non-compliant products increased from 44% to 65%. In reviewing these findings, it is important to recall that the market surveys involved targeted activities and therefore do not provide an indication of overall compliance in the Canadian marketplace. Nonetheless, commentary in some of the market survey reports for children's jewellery noted that cheap, low-quality products continue to show compliance issues and, in some cases, previously surveyed companies continue to have issues of non-compliance. Furthermore, Health Canada's 2012–13 cyclical enforcement work plan for children's jewellery noted that many companies did not know about or understand their obligations under the CCPSA, and, in some cases, were non-compliant with not only the *Children's Jewellery Regulations* but also their requirement to maintain documents that indicate the name and address of the person from whom they obtained the product, and to whom they sold the product or the period and location where the product was sold (Health Canada, 2012l).

Cribs, cradles, and bassinets

Since 2001–02, cribs, cradles, and bassinets have been subject to four rounds of cyclical enforcement activities. According to CEP reports, none of the cribs tested in 2005–07 and 2010–11 were fully compliant with the *Cribs, Cradles and Bassinets Regulations*. While all the cribs tested in these two cycles were found to be compliant with the lead limits, none of the cribs met all of the requirements for the mechanical testing.

Corded window coverings

In 2010–11, Health Canada conducted a market survey of corded window coverings at the retail level, examining products sold off the shelf (excluding custom products). The survey focused on product warning labels and the presence of a toll-free Consumer Product Safety (CPS) phone number on products. It also examined whether roman shades and roll-up blinds contained retrofit kits, which were recommended by Health Canada in a letter to industry in June 2010 to reduce the risk of strangulation (Health Canada, 2010f). The survey found that 91% of roman shades and 100% of roll-up blinds did not have retrofit kits as recommended by Health Canada (Health Canada, 2010f).

Additionally, a market survey of hair smoothing products resulted in the removal of 22 products from the market due to high levels of formaldehyde (Health Canada, 2011b).

All non-compliant samples identified through CPSD's CEP (and other activities) are subject to corrective actions such as, but not limited to, "recalls, industry communication, stop-sales, and education and industry commitments" (Health Canada, 2011b). Although CCMS is designed to capture case outcome information for completed cyclical enforcement cases, at this time, business rules have not been developed to accurately capture the information. Nonetheless, as of March 2012, CCMS included case outcomes for 243 *completed cyclical enforcement cases* (CPSD, n.d.-a).⁷⁵ However, the corrective action was not specified in one third of the cases (34%), and for just over one quarter of all cases (27%), the outcome was coded as "no action."⁷⁶

Further, of the 2,926 *completed cases* in CCMS that have an outcome recorded, 1,450 (50%) required some kind of corrective action, while 1,365 (47%) were coded as "no action" (CPSD, n.d.-a).⁷⁷ The most frequent action was education and information (64%), followed by prohibition (13%) and voluntary recall (9%).

Health Canada has developed an SOP for recall monitoring and stop-sale monitoring, which outlines required actions, responsibilities, and timelines (Health Canada, 2012h). According to the SOP, recall monitoring inspections are conducted in-person or by phone for consumer product incidents resulting in death or serious injury, products intended for children under the age of 15, and regulated products with a regulated hazard. For each of the case studies conducted as part of the evaluation, Health Canada representatives reported on the status of recall monitoring for five of the recalls associated with the respective product categories. Based on the information they provided, it appears that the recall monitoring is being conducted unless the recall is being carried out by a large, major retailer or only involves a small number of units.

For publicized recalls, Health Canada asks the recalling establishment to complete a recall effectiveness form, which gathers information about the recall notification measures used; identifies the number of units that account holders returned, destroyed, and corrected; and tracks the number of repair kits, returns/exchanges, and refunds issued to consumers (Health Canada, n.d.-c). The evaluation did not find data on the results of the recall effectiveness assessment processes. However, Health Canada recently developed an SOP for Assessing Recall Effectiveness Form Information (Health Canada, 2013b). Nonetheless, Health Canada representatives said it is difficult to gauge the effectiveness of recalls, as the Department does not have access to information about whether consumers disposed of recalled products.

⁷⁵ Completed cases are those that have a date entered in the closing date field in CCMS. It is unclear why only some of these cases have "complete" entered in the case outcome field. Possible case outcomes are: deleted case, not assessed, under threshold, no action, analysis, education and information, voluntary correction, voluntary removal, voluntary disposal, recall – voluntary, and complete.

⁷⁶ Health Canada representatives said that the "no action" classification means that there were no compliance issues related to the purpose of the CEP.

⁷⁷ The remaining 111 cases (3%) were referred outside of CPSD, since they involved drugs, food, medical devices, veterinary drugs, or other products not related to consumer products. Again, "no action" means no compliance issues related to the purpose of the CEP.

Health Canada representatives indicated that the Department is not tracking information on the proportion of inspected firms that took corrective action by the specified deadline. They said that this information is not considered valuable enough to warrant being collected, particularly given that the information would have to be manually extracted from Inspectors' notes.

Additionally, the Department is not tracking the number of repeat violators of enforcement actions taken between current year and baseline year (beyond Surveillance and Coordination Unit [SCU] data on multiple cases). However, Health Canada representatives mentioned that the Department uses information on repeat violators to plan future CEP activities.

Compliance and enforcement activities — consumer pesticides (PMRA)

Depending on the types of consumer pesticide products involved, compliance ranged 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. Table 10 (next page) provides an overview of the results of PMRA's recent compliance monitoring activities, including information on the compliance rate found among inspected parties and actions taken by PMRA.

Table 10: Overview of PMRA’s compliance monitoring activities

Program	Year	Regulated community	Number of inspections		Compliance	Actions taken by PMRA		Source
			Targeted	Completed				
Registrant inspection program	2008–09	Canadian registrants of domestic class products	65	61	A total of 20 out of 53 registrants had one or more compliance issues, resulting in a non-compliance rate of 38% for this subsection of the registrant community. Non-compliances were mostly minor label errors. No situation posed a significant risk to human health. Compliance rate: 62%	Education letters were issued, due to low level of risk of non-compliances found.	Health Canada representatives stated that any violations requiring immediate corrective action were monitored to ensure they were actioned appropriately.	(PMRA, 2009d)
Marketplace inspection program	2008–09	Discount stores	350	326	Overall rate of compliance was 56%, ranging from 14% in Manitoba to 83% in Saskatchewan (compliance was defined as having no unregistered pest control products available for sale). The majority of non-compliant vendors were found to have only one non-compliant product available for sale. A total of 18% of products inspected were non-compliant; the most common type of violation was the sale of unregistered pest control products. A total of 290 violations were identified. Compliance rate: 56%	227 investigations were undertaken resulting from violations found. Enforcement actions included removal from sale, disposal, re-labelling, letters, voluntary disposal/return, and return to supplier/ manufacturer.	Health Canada representatives stated that all instances of non-compliance are addressed through enforcement actions consistent with the risk involved. They indicated that files are not closed until compliance concerns have been satisfactorily addressed.	(PMRA, 2008b)
Marketplace inspection program	2009–10	Pest control operators selling commercial and domestic class pest control products	93	87	The overall compliance rate was 82%; in total, 16 of the 87 inspected Pest Control Operator (PCO) vendors carried at least one non-compliant product (18%), while 1.6% of the products inspected were non-compliant. The majority of violations were expired products, although some unregistered, mislabelled, and US Environmental Protection Agency (US-EPA)-labelled products were also found. Compliance rate: 82%	17 investigations were undertaken stemming from violations found. In most cases, non-compliant products were either disposed of or returned to the supplier. Non-compliant vendors received warning or education letters.	Additionally, they said follow up occurs with distributors to stop illegal product sales at their source. Finally, they reported that any instances of concern are addressed through follow up surveillance activities.	(PMRA, 2009e)

Program	Year	Regulated community	Number of inspections		Compliance	Actions taken by PMRA		Source
			Targeted	Completed				
Compliance verification of animal and pet product vendors	2009–10	Animal and pet product stores, including veterinary clinics	200	267	122 pet product vendors were non-compliant (46%) where non-compliance was defined as having one or more unregistered, expired, or mislabelled product available for sale. Compliance rate: 54%	109 enforcement actions were undertaken stemming from violations found. In most cases, the product was disposed of or returned to distributors, and non-compliant vendors received warning/educational letters.	Health Canada representatives stated that all instances of non-compliance are addressed through enforcement actions consistent with the risk involved. They indicated that files are not closed until compliance concerns have been satisfactorily addressed.	(PMRA, 2009f)
Compliance verification of unregistered international pest control product vendors	2010–11	Vendors, importers, and distributors	N/A	132	Non-compliant products were found in 63 of the 132 inspections (48%). Compliance rate: 52%	N/A	Additionally, they said follow up occurs with distributors to stop illegal product sales at their source. Finally, they reported that any instances of concern are addressed through follow up surveillance activities.	(PMRA, 2011f)

5.4.4 Adoption of safe behaviours

In the intermediate term, CPA are expected to lead to adoption of safe behaviours by external stakeholders related to consumer products. Many of the performance indicators that Health Canada identified to measure increased adoption of safe behaviours have been discussed in other sections of the report. Examples of the indicators specified for this outcome relate to the nature and extent of communications to consumers, industry compliance with product safety obligations/implementation of corrective actions, and the number of consumer product incident reports received.

The survey of industry and consumers conducted as part of the evaluation provides some additional insight into the extent to which industry and consumers are adopting safe behaviours. As previously mentioned, these results should be viewed with caution. Given that the survey targeted industry and consumers who have ongoing contact with Health Canada, it likely over-represents the extent to which these behaviours are being adopted by industry as a whole and the general public. Nonetheless, the survey results suggest there is a need for more industry education about the requirements of the mandatory incident reporting and document retention requirements included in the CCPSA. Additionally, the survey findings indicate that Health Canada's efforts to inform consumers of the safety risks associated with consumer products is encouraging those who the Department has actively engaged to make some changes to how they purchase and use consumer products.

Consumer products: industry

While the industry survey did not directly measure industry adoption of safe behaviours, it examined the extent to which industry is aware of and understands the mandatory incident reporting requirement and document retention requirement included in the CCPSA. Although the majority of industry respondents are aware of the requirements, it appears that some of them do not understand the requirements clearly; therefore, the extent to which industry is complying with them is uncertain. Further, aside from reviewing incident reports received (and, if needed, asking industry to file a report based on information received from a consumer), Health Canada has not implemented any activities to actively monitor compliance with these requirements. Nevertheless, Health Canada is developing a work plan for 2013–14 to monitor industry compliance with the mandatory incident reporting and document retention requirements; Department representatives said development of the work plan is based on a pilot conducted in 2012–13 (Health Canada, 2013c).

External stakeholders expressed concern that there is a lack of clarity about the requirements for reporting incidents that occur outside of Canada, companies located outside of Canada may be less likely to report incidents, and foreign companies will not face repercussions for failing to report incidents.⁷⁸

⁷⁸ Health Canada representatives said that the Department is not responsible for incidents that occur outside of Canada, that are associated with companies located outside of Canada, and that are associated with foreign companies.

The survey found that most industry respondents agreed (75%, including 39% who strongly agreed) that their company/organization is aware of the mandatory incident reporting requirements. However, they appear to lack clarity about what incidents and information must be reported. Just over half agreed (53%, including 17% who strongly agreed) that Health Canada has clearly defined what consumer product incidents must be reported by companies. Additionally, about 6 in 10 agreed that Health Canada has clearly outlined what information must be included in the report (60%, including 19% who strongly agreed). See Table 11 below.

Table 11: Awareness and understanding of mandatory incident reporting (industry)

Statement	% (n=343)					
	Strongly agree/ agree	Neutral	Strongly disagree/ disagree	N/A	Don't know	Total
My company/organization is aware of the mandatory incident reporting requirements under the CCPSA.	75%	7%	4%	6%	8%	100%
My company/organization knows how to report an incident involving a consumer product to Health Canada.	66%	11%	8%	8%	8%	101%
Health Canada has clearly outlined what information must be included in consumer product incident reports.	60%	16%	6%	5%	13%	100%
Health Canada has clearly defined what consumer product incidents must be reported by companies.	53%	20%	11%	5%	11%	100%

Note Rows may not sum to 100% due to rounding.

Q37-Q42. One area of particular interest to Health Canada is mandatory reporting of incidents involving consumer products. As you may know, the new CCPSA includes provisions for mandatory incident reporting to the Consumer Products Safety Directorate. Please read the statements above and indicate your level of agreement with each one.

Overall, 19% (n=66)⁷⁹ of industry respondents said their company requires additional information about the mandatory incident reporting requirements; the examples they provided include further defining what constitutes a reportable incident (n=11), providing additional information about how to report (n=6), and making general improvements to guidance documents (n=6). Further, when asked how the process for reporting incidents could be improved, some industry respondents again referred to clarifying what incidents are reportable (n=15).

It appears that a slight majority of respondents are aware of and understand the document retention requirements. About 6 respondents in 10 agreed that their company/organization is aware of the document retention requirements (63%, including 24% who strongly agreed). Just over half agreed that Health Canada has clearly defined the document retention requirements (55%, including 16% who strongly agreed). About half (52%) of the respondents agreed that their company/organization has implemented processes to retain the required documents (including 20% who strongly agreed). As shown in Table 12 (next page).

⁷⁹ However, when asked specifically what information they required, 21 of these respondents said no additional information was needed.

Table 12: Preparing and maintaining documents (industry)

Statement	% (n=343)					
	Strongly agree/ agree	Neutral	Strongly disagree/ disagree	N/A	Don't know	Total
My company/organization is aware of the document retention requirements under the CCPSA.	63%	12%	6%	8%	11%	100%
Health Canada has clearly defined the document retention requirements under the CCPSA.	55%	18%	6%	7%	15%	101%
My company/organization has implemented processes to retain the required documents.	52%	15%	7%	15%	12%	101%

Note: Rows may not sum to 100% due to rounding.

Q50-Q52. The CCPSA includes provisions for preparing and maintaining documents so that unsafe products can be traced back to their source. Please read the statements above about the document retention requirements under the CCPSA and indicate your level of agreement with each one.

Consumer products: consumers

Consumers' adoption of safe practices can be assessed through their perceptions of the effectiveness of the information the Department provides, the changes they made to their consumer products-related decision-making processes, and their awareness of the ability to report consumer product incidents to Health Canada.

The majority of consumers agree that the information Health Canada provides has increased their consumer products-related knowledge and influenced their behaviours. As shown in Table 13 (next page):

- Over three quarters of consumers agreed (78%, including 23% who strongly agreed) that the information that Health Canada provides has increased their knowledge of human health safety risks associated with consumer products.
- About three quarters of consumers agreed (74%, including 26% who strongly agreed) that the information that Health Canada provides has influenced their decisions about the consumer products that they purchase.
- About 7 consumers in 10 agreed (69%, including 21% who strongly agreed) that the information that Health Canada provides has influenced how they use consumer products.

Table 13: Effectiveness of Health Canada’s consumer products activities (consumers)

Statement	%				Total
	Strongly agree/ agree	Neutral	Strongly disagree/ disagree	Don’t know	
The information that Health Canada provides has increased my knowledge of human health safety risks associated with consumer products.	78%	13%	7%	2%	100%
The information that Health Canada provides has influenced my decisions about the consumer products that I purchase.	74%	17%	8%	2%	101%
The information that Health Canada provides has influenced how I use consumer products.	69%	21%	8%	2%	100%

Note: Rows may not sum to 100% due to rounding.

Q79-Q81. This section of the survey is designed to gather your views on the effectiveness of Health Canada's activities related to consumer products. Please read each of the statements above and indicate your level of agreement with each one.

When asked to describe how the information that Health Canada provides has changed how they decide which consumer products to purchase, consumers reported using safety information (27%), having increased awareness of product risks or using more caution when purchasing products (23%), and selecting specific products (e.g., choosing certain brand names/retailers, looking at country of manufacture – 14%). However, some 38% of consumers said they have not changed their purchasing behaviour based on the information provided by Health Canada.

According to the survey results, the majority (75%) of consumers knew that the public could report incidents involving consumer products to Health Canada. Of these, 8% (n=45) reported having done so.

However, some Health Canada representatives and external stakeholders expressed concern that some Canadians may have a false sense of security about the safety of consumer products on the marketplace. Both of these groups of key informants suggested that some individuals may not be taking responsibility for their own safety because they believe the Government of Canada undertakes pre-market review of consumer products. Although this evaluation did not assess Canadians’ understanding of Health Canada’s role, a national telephone survey of Canadian adults⁸⁰ completed for Health Canada in 2010 found that approximately two thirds of the general public correctly believed that manufacturers have to ensure that products sold to consumers are safe (65%); that consumer products in Canada are not subject to pre-market testing (64%); and that not all consumer products in Canada are subject to pre-market approval (62%). However, it also found that 52% of the general public incorrectly believed that the government regulates all product labels, and 83% incorrectly believed that the Canadian government has the ability to issue a mandatory recall of a consumer product (this was not true at the time of the survey, as the CCPSA had not yet come into force) (Phoenix Strategic Perspectives Inc., 2011).

⁸⁰ The survey was completed with 1,357 respondents, including 1,006 adults (i.e., general public) and 351 parents/guardians of children ages 12 and younger. Including the “general public” sample, the total number of parents responding to the survey was 545.

5.4.5 Increased use of scientific evidence and risk analysis

In the intermediate term, CPA is intended to lead to an increase in the use of scientific evidence and risk–benefit analysis to inform Health Canada decision-making. Generally speaking, Health Canada appears to use scientific evidence and risk analysis on a regular basis to inform decision-making.

The use of scientific evidence and risk analysis is formally integrated into Health Canada’s decision-making process. The Health Canada Decision-Making Framework for Identifying, Assessing and Managing Health Risks sets out an approach to decision-making in which risk analysis and management activities are central (Health Canada, 2000). Additionally, Health Canada representatives noted that CPSD is in the process of developing a series of decision-making tools specifically for consumer products. For example, CPSD has recently drafted a Consumer Product Safety Program Risk Assessment Framework and is in the process of developing an instrument choice framework, as well as a standards strategy.

While the evaluation did not find any documentation of the establishment of formal scientific advisory panels or expert advisory panels to provide advice on consumer product-related issues, scientists and other experts have provided input into the development of policies and regulations related to consumer products and consumer pesticides. Some examples are listed below.

- Health Canada undertook several studies as part of the Electromagnetic Frequency (EMF) Project, which gathers information on effects of electromagnetic radiation on human health (Health Canada, 2012e, p. 17).
- Health Canada investigated EMF and UV emissions from common brands of compact fluorescent lamps (CFLs), which was done in response to media reports and public concerns over CFLs causing health problems (CCRPB, 2009; Thansandote, 2011, p. 1). An “It’s Your Health” online document on the safety of compact fluorescent lamps refers to the research for further information (Health Canada, 2011h).
- Health Canada conducted studies on radiofrequency (RF) absorption rates in living tissue in an attempt to better understand the effect of RF energy emitted from devices such as cell phones; results were submitted for journal publication (Thansandote, 2011). The extent to which the research has informed policy and regulatory responses is unclear. However, some guidelines and reports relating to the effects of RF energy were published soon after the research. Specifically, Health Canada updated its human exposure guidelines to RF electromagnetic energy (Safety Code 6) (CCRPB et al., 2009). Furthermore, shortly after December 2010, in response to media coverage and enquiries about the safety of wireless technologies, the House Standing Committee on Health issued a report containing recommendations on radio frequency health policy. Recommendations from this report included development of a public risk awareness program and Health Canada developing a process to receive and respond to reports of adverse reactions to wireless devices (HESA, 2010; Thansandote, 2011). Presumably, these activities were informed to some extent by the research on radiofrequency absorption rates, although this is not explicitly stated.

- PMRA chaired the OECD Expert Group on Compliance, which drafted the Pesticide Compliance and Enforcement Best Practice Guidance⁸¹ document, providing guidance on “conducting compliance activities related to the distribution, storage, use, and container recycling/disposal of pesticides” (Health Canada, 2011b).
- Scientific experts have assisted Health Canada in drafting reports to address public concerns. For example, after a group of citizens signed a petition regarding protection from microwave radiation from wireless technologies, the House Standing Committee on Health conducted hearings from public, private, and non-governmental sectors, and issued a report on the resulting recommendations. Scientific experts participated as witnesses in these hearings (HESA, 2010).
- Various cost-benefit analyses, background studies, and evaluations have been performed by external groups to advise Health Canada with respect to regulatory amendments and proposals and to support the development of Regulatory Impact Analysis Statements (RIAS).

The case studies provide examples of risk assessments that Health Canada has conducted. These assessments may be used to justify the need for regulations, inform the establishment of requirements in regulations, or assess the adequacy of existing regulations and/or standards.

Case study example: use of scientific information and risk assessment

Children’s jewellery

Although the recommended and/or allowable total lead limit for children’s jewellery has varied over time, the established limits were based on scientific information and/or risk assessments.

The 1999 call for industry to voluntarily stop selling children’s jewellery containing lead recommended that a warning label be affixed to products containing more than 65 mg/kg total lead. This limit was based on knowledge that 65 mg/kg total lead is the upper boundary of average lead concentrations found in uncontaminated Canadian soils (Health Canada, 1999). It was also the proposed limit included in the first draft of the Strategy for Reducing Lead in Children’s and Other Consumer Products.

- The Children’s Jewellery Regulations, first enacted in 2005 under the HPA and subsequently transferred to the CCPSA, permit the import, advertisement, or sale of jewellery items that appeal primarily to children under 15 years of age only if the items do not contain more than 600 mg/kg of total lead and 90 mg/kg migratable lead (note: migratable lead is the proportion of total lead that might be released from the product under certain conditions such as licking, sucking, or swallowing of the product).
- The 600 mg/kg total lead limit was based on a 1972 risk assessment, which found that 600 mg/kg was the maximum lead content in paint that would produce no adverse effects in children when one square inch of paint was consumed each day (based on repeated exposure). The total lead limit was also consistent with the maximum lead limits proposed for surface coating materials under the HPA (note: the total lead limit for consumer paints and other surface coatings was reduced to 90 mg/kg in 2010). The 90 mg/kg migratable lead standard was the same as the EU migratable lead limit for toys intended for children under six years of age (GoC, 2003).
- In 2004, Health Canada conducted a risk assessment to determine the lead exposure risk associated with repeated handling of a game figurine containing up to 75% lead (Health Canada, 2004). Although this risk assessment did not specifically examine a piece of children’s jewellery, it assessed the risks associated with hand-to-mouth activity for products containing lead. The risk assessment found that “the amount of lead residue likely to be ingested during

⁸¹ This document provides general guidance for pesticide regulators; it is not specific to consumer pesticides.

repeated hand-to-mouth activity while handling the figures would not result in significant exposure to lead” (Health Canada, 2004). However, what this risk assessment does not consider is the health effects associated with ingesting whole products containing high levels of lead.

- The 2003 RIAS prepared for the proposed *Children’s Jewellery Regulations* stated that “the uncontrolled presence of these products in the Canadian marketplace is not acceptable because children’s jewellery containing lead represents a significant risk to the health of young Canadian children” (*Canada Gazette*, 2003). However, it did not define precisely the parameters constituting “significant” risk.

As part of the Lead Risk Reduction Strategy, Health Canada is considering amending the *Children’s Jewellery Regulations* to reduce the allowable limits for lead from 600 mg/kg of total lead and 90 mg/kg of migratable lead to a single limit of 90 mg/kg lead (HDR Inc, 2009).

In 2007, Health Canada learned that “a significant amount of cadmium had been found in a children’s jewellery item tested in the US” (Health Canada, 2010g). In follow-up to this information, Health Canada included testing for cadmium as part of its CEP for children’s jewellery; this testing found high levels of cadmium in some products. Using data collected through cyclical enforcement surveys, Health Canada conducted a risk assessment of cadmium in children’s jewellery to: 1) quantify the acute exposure risk associated with ingestion of a single piece of cadmium-containing jewellery by a small child; and 2) define a limit for cadmium in children’s jewellery that would be protective of small children (Health Canada, 2010g).

It is important to note that while the risk assessments described above examined the risks associated with exposure to lead or cadmium, they did not determine the degree of risk arising from the presence of children’s jewellery containing these substances in the Canadian marketplace (e.g., risk relative to other products; likelihood of serious incidents).

Case study example: use of risk assessment

Corded window coverings

The 2006 and 2008 cost–benefit analyses for the *Corded Window Covering Products Regulations* include assessment of the risks associated with corded window coverings. They suggested that while the risks associated with these products are low, public outrage related to incidents involving them may be sufficient to justify government intervention.

- The 2006 report noted that the likelihood of incidents resulting from corded window coverings is very low. In particular, the chance of death occurring from a corded window covering is approximately 1 in 10 million, which is similar to the likelihood of being struck by lightning (Health Canada, 2006). It is unclear how this cost–benefit analysis estimated this chance of death.
- The 2008 report states “the relatively low number of deaths (27) that have resulted since 1986 [in Canada] suggests that incidents from this hazard are considered rare events. Over the period of 1986 to 2008, the risk of a child dying from an incident related to corded window coverings was just over 6 in 10 million. However, this is small comfort to those who have lost a child” (Blair Consulting Group, 2008). The study calculated the risk of 6 in 10 million by dividing the total number of deaths between 1986 and 2008 by the total population for children ages 0 to 4 over the same period. The study does not specify the comparison when it states that the number of deaths from corded window covering products is “relatively low.”

Additionally, the CBA cites a 2007 report, “Child & Youth Unintentional Injury: 1994-2003 Ten Years in Review,” which notes that Canadian children have a 1 in 132,800 risk of dying because of threats to breathing. It indicates that 94% of hospitalizations due to threats to breathing are from choking on food or other objects, while 6% relate to a “mechanical cause,” including strangulation by blind cords (Safe Kids Canada, n.d.).

Health Canada representatives indicated that it is important to note that there may be underreporting of incidents associated with corded window coverings. In 2012, the Risk Assessment Division (RAD) within the CPSPD conducted a risk assessment for corded window coverings. The risk assessment found that the *Corded Window Covering Products Regulations* do not adequately address the strangulation risk

associated with corded window covering products. In particular, the risk assessment noted that the standard for corded window coverings has not effectively reduced the number of strangulation deaths and near-miss strangulations. Furthermore, there has been little success in reducing risks associated with inner cords, since these risks “are not effectively addressed in the WCMA [Window Covering Manufacturers Association] standard” (Health Canada, 2012m). According to the risk assessment, the major shortcomings of the standard relate to the list of requirements for exposed operating cords, bead chain loops, and inner cords. The issue is that manufacturers must only meet one or more of the listed requirements, and they can thus choose the easiest to comply with, rather than the requirement that is safest for consumers. For example, one requirement related to inner cords is that “the product shall have no inner cords” (Health Canada, 2012m). However, producers rarely select this option, as there are few products on the market lacking inner cords. Manufacturers may choose to meet another requirement, and, as a result, the standard “essentially allows a product to have an accessible inner cord that can be wrapped around a child’s neck” (Health Canada, 2012m). Health Canada has been working with key stakeholders to amend the Standard. In addition, Health Canada can use Section 12 of the *CCPSA* to address compliance and enforcement issues outside of the Standard, for example, using the “danger” threshold to take enforcement action.

Further, Health Canada bases its prioritization of CEP activities on the risk of the product category. Health Canada representatives said that several factors inform the setting of priorities for CEP activities such as, but not limited to, the relative level of risk associated with the product, the Department’s ability to address the risk, historical information about non-compliance, and the level of public concern about the product. Based on the information received for the case studies, it is not immediately clear that the level of effort devoted to cyclical enforcement for specific products reflects the associated risk.

Case study example: risk assessment and prioritization of CEP activities

- Although there has been ongoing non-compliance with the *Children’s Jewellery Regulations*, there have not been any reported deaths in Canada associated with children’s jewellery, and no incidents have been reported since 1998. Health Canada has undertaken eight market surveys of children’s jewellery (2000, 2001, and annually since 2006).
- Between 1990 and 2007, the Canadian Hospitals Injury Reporting and Prevention Program (CHIRRP) collected data on 3,202 injuries associated with cribs used by children in Canada under the age of five (PHAC, 2008). Moreover, since 1986, 42 deaths in Canada associated with non-compliant cribs were reported to Health Canada (Health Canada, 2012n). Health Canada has conducted four cycles of CEP activities for these products since 2001.
- From 1985 to 2011, Health Canada received reports of 30 fatalities and 25 near-misses resulting from corded window coverings (Health Canada, 2012m). Planned CEP activity for this product was replaced with a market survey.

5.4.6 Timely regulatory response to risks

In the intermediate term, a timely regulatory system response to identified risks is expected to result from CPA. However, reliable sources of data regarding the timeliness of some of Health Canada’s activities, such as responding to incident reports after they have been triaged and non-compliances identified through inspections or cyclical enforcement, are not available. Nonetheless, Health Canada representatives indicated that RMB is planning to propose service standards for responding to key risk management actions, which will be tracked in CCMS.

Overall, Health Canada is meeting its performance standards most of the time. However, the process of developing and/or amending regulations is lengthy and can take years to complete. A

minority of the industry representatives and consumers who responded to the evaluation survey agreed that Health Canada has responded in a timely manner to identified risks related to consumer products.

Consumer products (CPSD, ERHSD)

Health Canada is meeting its performance standards most of the time. According to dashboard reports, the performance standard for triage of mandatory incident reports was met 90% of the time in 2010–11 and 87% of the time in 2011–12 (CPSD, 2012e).

Though Health Canada is meeting its performance standards most of the time, the development of regulations is a lengthy process.⁸² As previously reported, Health Canada did not pursue, as initially planned, amendments to the *Cosmetic Regulations* or the development of new legislation for radiation-emitting devices. Additionally, the case studies on children’s jewellery and corded window coverings illustrate that responding to identified risks can be a lengthy process that may involve implementing various strategies to respond to the risk.⁸³

Case study example: response to risks associated with lead and cadmium in children’s jewellery

Lead

Health Canada began to address the specific issue of lead in children’s jewellery in 1998, when two incidents related to potential lead exposure from children’s jewellery were reported to the Department (Health Canada, 2005, 2012i). Although Health Canada was working on a “Strategy for Reducing Lead in Children’s and other Consumer Products” at the same time it became aware of this issue, program representatives indicated that, because of the complexity associated with the Strategy, the Department decided to develop and implement activities specifically targeting children’s jewellery. The Strategy was to be implemented by 2001, as of 2010, Health Canada was continuing to develop and implement it in a phased manner, based on level of risk (note: the Strategy has since been renamed the “Lead Risk Reduction Strategy”).

Health Canada immediately responded to the issue of lead in children’s jewellery by asking industry to voluntarily stop selling children’s jewellery containing lead. The first request was made in April 1999. A second request was made in December 2000 in follow-up to a market survey, which found that almost all of the jewellery tested contained lead amounts in excess of the proposed limits.

However, from the time Health Canada informed industry of its intent to regulate lead content in children’s jewellery products, almost four and a half years passed before the enactment of Regulations.⁸⁴ Health Canada announced its intention to regulate in December 2000. The proposed Regulations were pre-published in the *Canada Gazette* Part I in November 2003, and they came into force in May 2005. Canada was the first country in the world to introduce specific lead limits for children’s jewellery.

Cadmium

In 2007, Health Canada was informed that “a significant amount of cadmium had been found in a children’s jewellery item tested in the US” (Health Canada, 2010g). In a follow-up to this report, Health Canada began to include testing for cadmium in its cyclical enforcement activities for children’s jewellery (Health Canada,

⁸² Health Canada representatives noted that the federal regulatory process is complex and includes requirements for economic analysis and stakeholder consultations, which are inherently time-consuming. Furthermore, they said that regulatory initiatives are subject to delays and cancellations due to factors outside the control of Health Canada (e.g., elections, prorogations, changes in government priorities).

⁸³ Health Canada is required to go through the Canadian drafting convention.

⁸⁴ The passage of the CCPSA introduced a “general prohibition” which reduces the need to rely on Governor in Council regulations to address health or safety issues.

2010g). Based on the timeline below, it appears that more than two years passed before Health Canada began to communicate more formally with industry and consumers about the issue:

- In January 2010, Health Canada advised consumers of lead and cadmium hazards in children's jewellery (Health Canada, 2010h).
- In October 2010, Health Canada requested industry to voluntarily stop using cadmium in children's jewellery (Health Canada, 2010i).
- In July 2011, Health Canada developed a draft proposal for cadmium guidelines in children's jewellery (Health Canada, 2011i).
- In fall 2011, Health Canada began informing industry that the general prohibition included in the CCPSA could be used to enforce compliance with cadmium guidelines.
- In February 2012, Health Canada prepared a draft proposal for a regulatory limit for cadmium in children's jewellery (Health Canada, 2012o).

Despite these efforts, product testing has shown continued use of cadmium in children's jewellery. Health Canada is currently considering two risk management options for cadmium in children's jewellery: i) continued use of the general prohibition included in the CCPSA; or ii) amending the *Children's Jewellery Regulations* to include a total cadmium limit.

Case study example: developing and implementing regulations for corded window coverings

It took almost four years from the time Health Canada announced its intention to regulate corded window coverings to enact the Regulations. In June 2005, Health Canada announced its intention to regulate corded window coverings. Two of the factors contributing to the decision to pursue regulations were: i) without regulations, Health Canada's Product Safety Inspectors could not enforce compliance with the Canadian standard, which had been in place since 1999; and ii) despite Health Canada's efforts to implement awareness campaigns, in addition to issuing advisories and information bulletins, since 1993, the rate of deaths and near-misses associated with corded window coverings remained unchanged (one or two per year, except in 1999, when there were three incidents) (GoC, 2010c). Just over two years later, in September 2007, the Regulations were pre-published in the *Canada Gazette Part I* (GoC, 2010c). The *Corded Window Covering Products Regulations* were officially brought into force in April 2009.

As described below, the findings of the case study on cribs, cradles, and bassinets suggest that Canada can be slower than the US to respond to some identified potential safety risks.

Case study example: Health Canada's response to safety issues associated with drop-side cribs

In November 2009, Stork Craft voluntarily recalled drop-side cribs in collaboration with Health Canada and the US CPSC; this was one of the largest crib recalls in history (The Globe and Mail, 2009). The following highlights how the US and Canada responded to the safety issue.

- In the summer of 2010, following the recall, and in alignment with a previous ASTM International voluntary industry guideline requiring cribs to have four fixed sides (ASTM International, n.d.), the CPSC voted to ban drop-side cribs due to safety concerns. The ban came into effect in July 2011 and prevents drop-side cribs from being resold or used in hotels or daycare centres in the US (CPSC, 2011).
- In the fall of 2010, following two other large joint recalls of drop-side cribs with the US CPSC, Health Canada held a public consultation regarding regulatory options concerning drop-side cribs. Health Canada indicated in the consultation that its preferred option was to align the regulations with those of the US and require the bottom portion of all crib sides to be rigidly fastened to the crib frame; however, this option would still allow the uppermost portion of a crib side to fold, pivot, or move (Health Canada, 2010j). Since the consultation, Health Canada has completed a cost-benefit analysis of the proposed regulatory changes outlined in the consultation document, including the proposed prohibition of

traditional drop-side cribs. The cost–benefit analysis concluded that the regulatory amendment will provide net benefits of more than \$16 million to Canadians and that, therefore, Health Canada has a strong basis for implementing the regulatory amendment (Cheminfo Services Inc, 2011). However, to date, drop-side cribs have not been prohibited in Canada.

It is worth noting that Australia and Europe do not prohibit the sale and manufacture of drop-side cribs. However, generally speaking, it appears that Australia and Europe have less stringent regulations for cribs than Canada.

Health Canada is currently drafting an amendment to the *Cribs, Cradles and Bassinets Regulations*. According to Health Canada representatives, the proposed changes will also improve the general safety of cribs, cradles and bassinets and further align Canadian and U.S. requirements. The amendment seeks to further align standards with the US, prohibit traditional drop-side cribs, and increase other safety parameters of cribs, cradles, and bassinets.

The survey of industry and consumers offers some additional insight into stakeholders' perceptions of the timeliness of Health Canada's response to identified risks associated with consumer products. The survey found that overall, just over 4 respondents in 10 agreed (44%, including 6% who strongly agreed) that over the past two years, Health Canada has responded in a timely manner to identified risks related to consumer products. Although industry (45%) and consumers (44%) were equally likely to agree with this statement, industry (9%) was less likely than consumers (18%) to disagree. Industry (23%) was more likely than consumers (16%) to say they "don't know."

Consumer pesticides (PMRA)

For consumer pesticides, PMRA met the established performance standard six months for investigations 88% of the time, on average, over the five-year period between 2007–08 and 2011–12.

5.4.7 Increased international collaboration

In the intermediate term, CPA are expected to lead to increased international harmonization of regulatory requirements for consumer products. Ultimately, increased harmonization is expected to contribute to improved health and safety of Canadians. The evaluation found evidence that Health Canada has been working toward greater international harmonization and has made progress in some areas.

Health Canada participates in the development of international standards relating to consumer products through participation in a variety of international standards committees such as, but not limited to, the American Society for Testing and Materials (ASTM), the American National Standards Institute (ANSI), ISO Technical Committees and Working Groups, and the International Electrochemical Commission (IEC). Health Canada also collaborates with other international institutions/organizations, such as the Organisation for Economic Co-operation and Development (OECD), the International Consumer Product Health and Safety Organisation (ICPHSO), the Organization of American States (OAS), and the Commission for Environmental Cooperation, on various consumer product-related activities. Further, Health Canada has a number of confidentiality and regulatory cooperation arrangements with other jurisdictions, including the US CPSC; the General AQSIQ of the People's Republic of China; the Irish

Medicines Board; and the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency of Japan (Health Canada, 2012p).

Health Canada representatives and external stakeholders reported that enactment of the CCPSA helped better align Canada's legislation with other countries. For example, the CCPSA introduced the general prohibition on unsafe consumer products, which is similar to the EU's General Product Safety Directive (2001/95/EC), which requires Member States to "ensure that products placed on the market are safe" (Commission of the European Communities, 2009). Additionally, through the CCPSA, Health Canada was granted the power to order recalls; in the US, the CPSC holds this same power.

The case studies offer some specific examples of international collaboration.

Case study examples – international collaboration

Joint recalls with the US CPSC

Based on information on Health Canada's website, Canada and the US have issued 148 joint recalls since 2009 (Health Canada, 2012p).

Cribs, cradles, and bassinets

Health Canada representatives said the Department actively collaborates with the US CPSC through participation in ASTM standard subcommittees; monthly teleconferences to discuss emerging compliance, enforcement, and regulatory issues; and informal communication with US CPSC subject matter experts. Further, Health Canada representatives noted that both the US CPSC and Health Canada have publicly expressed their intention to further align Canadian and US requirements for cribs, cradles, and bassinets.

Corded window coverings

Health Canada, the US, and the EU have been working together to strengthen standards for window coverings. In June 2010, they put forward a joint call for stronger window covering standards, "urging standards development organizations and manufacturers to create comprehensive worldwide safety standards" (Health Canada, 2010k). Issued in response to the number of strangulation deaths and significant injuries in children due to corded window coverings, this call for increased standards represents the first time these three agencies have made joint safety standard demands on a specific product (Health Canada, 2010k).

Additionally, Canada and the US both participate in meetings of the Window Covering Manufacturers Association (WCMA), which is the industry group responsible for the ANSI standard for window covering safety. Through these meetings, both countries have asked for improvements to the standard, and Canada is involved in technical task groups that assist the standard writing process (CPSD, n.d.-b). However, Health Canada representatives noted that the most recent WCMA standard, which was implemented by the US in January 2013, may contain inconsistencies, gaps, interpretation problems, and poor explanations, and that Health Canada has been working to have these shortcomings addressed. Since Health Canada's *Corded Window Coverings Regulations* are based on this standard, these shortcomings also apply to the Regulations. According to Health Canada representatives, the Department will mitigate this risk by clarifying with industry how it interprets any ambiguous text in the Regulations.

Another area of international collaboration activities related to corded window coverings is the Pilot Alignment Initiative (PAI) between Canada, the US, the EU, and Australia, which began in January 2011. Product safety regulators in these countries established the PAI to "examine the obstacles and opportunities for alignment of safety requirements for three widely used consumer product categories, including corded window coverings" (CPSC, 2012). It resulted in the drafting of a consensus paper that describes the main hazards and identifies possible solutions to mitigate corded window strangulation risk (CPSC, 2012).

5.4.8 Long-term outcomes

In the long term, CPA are expected to contribute to reduced adverse events associated with consumer products, increased public confidence in consumer products and the related regulatory system, and the existence of a sustainable, cost-efficient, responsive and science-based regulatory system for consumer products. It seems reasonable to assume that CPA have had an impact in these areas, although it is important to realize that many other factors may also influence these outcomes.

Reduced adverse events associated with use of consumer products

In theory, CPA, including the development of standards and regulations; consumer education and outreach activities; and compliance and enforcement activities, should contribute to reducing adverse events associated with the use of consumer products. While Health Canada established reasonable performance indicators to demonstrate achievement of this outcome, limited data were available.

The data availability for the identified performance indicators is listed below.

- **Percentage change in consumer product incident reports.** The available data on consumer incident reports is provided in Section 5.3.2. However, it is important to recognize that increases in the number of incidents reports may, in part, reflect increased awareness of the mandatory incident reporting requirement for industry and the ability for consumers to submit voluntary reports.
- **Removal of unsafe consumer products from the marketplace.** Health Canada may use various mechanisms to remove unsafe products from the marketplace, such as voluntary removals, voluntary disposals, seizures, and recalls. While this information is tracked in CCMS, as previously mentioned, the reliability of the data at this point in time is questionable. Section 5.3.2 provided the available data on recalls; however, Health Canada does not have information on the effectiveness of the recalls.
- **Trends in consumer product related injuries and events.**
 - *CHIRPP Database.* PHAC representatives noted that, as planned, the CHIRPP Database added a new data element tracking consumer product injuries as a proportion of all injuries reported in CHIRPP. The data show that consumer product incidents represent 48% of CHIRPP cases, which is an increase from 45% in the previous cycle (Health Canada, 2011b). The time period covered by these data is not clear from the documentation.
 - *CCMS.* The CCMS database also tracks consumer product cases that involve reported injury (not necessarily confirmed). Between June 2011 and March 2012, of the 2,202 reported victims of consumer product incidents, the majority (70%, n=1,535) did not incur any injury (CPSD, n.d.-a). However, there are 30 cases involving death, 45 involving serious injury, and 390 involving injury. Data for injuries in previous years was not provided (CPSD, n.d.-a).

The case studies provide some information on injuries and deaths associated with specific consumer products.

Case study examples – trends in consumer product injuries and deaths

Children's jewellery

There have been two incidents associated with lead in children's jewellery in Canada. In April 1998, Health Canada received a consumer report that a five-year-old child from Calgary developed elevated blood lead levels as a result of chewing off the decorative coating and sucking on a pendant, which was almost pure lead. In October 1998, another Canadian child was found to have chewed the decorative coating off two necklace pendants and was sucking on the exposed cores, which were almost 75% lead (Health Canada, 2012l). There have been no reported incidents associated with lead in children's jewellery in Canada since the *Children's Jewellery Regulations* were first enacted in 2005. However, Health Canada continues to find lead (and cadmium) in these products through its cyclical enforcement activities.

Cribs, cradles, and bassinets

Between 1972 and 1986, 74 crib-related deaths were reported to Health Canada. Since the implementation of the amended regulations in 1986, no crib-related deaths have been reported for compliant cribs (GoC, 2010a).

Between 1986 and 2012, there were 42 infant deaths reported to Health Canada related to cribs. In the majority of the cases (95%), the cribs were simply not compliant with the regulations. Some of the non-compliances included cribs that pre-dated 1986, cribs that had been modified by the caregivers, and mattresses that were not the proper size for the crib (Health Canada, 2012n).

Corded window coverings

Between 1985 and 2011, Health Canada received reports of 30 fatalities and 25 near-misses resulting from corded window coverings (Health Canada, 2012m). Over this same period, corded window covering fatalities represented 16% (n=29) of all deaths to children under 3-years-old involving consumer products reported to Health Canada (n= 177) (CSA, 2012). However, there does not appear to be a clear trend in the child fatality rate from corded window coverings. In Canada, the number of fatalities per million children younger than 3-years-old per year varies from 0 to 3.9, while in the US it varies from 0.3 to 1.4 (CSA, 2012).

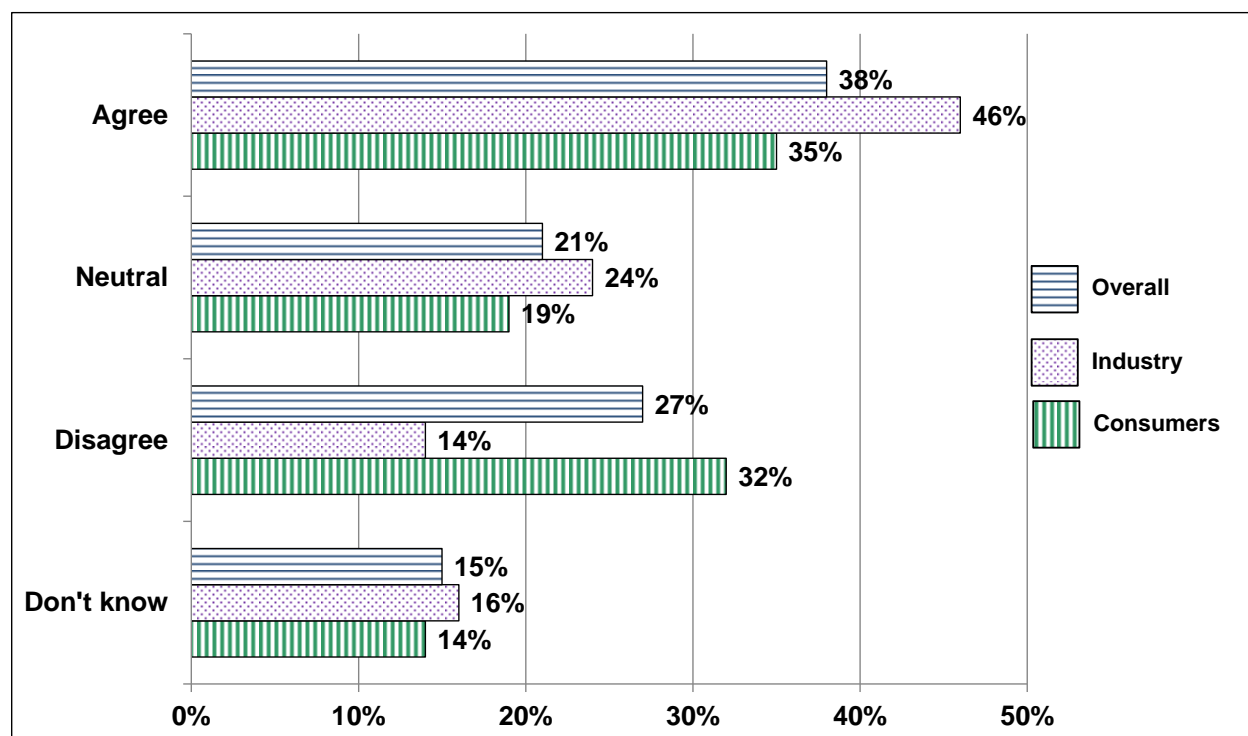
Further, Health Canada representatives reported that the Department's consumer education activities are integral to reducing the number of injuries and deaths associated with consumer products. Thus, the survey of consumers asked respondents to rate their level of agreement with the following statement: "the information that Health Canada provides has increased my knowledge of human health safety risks associated with consumer products." Over three quarters of consumers agreed (78%, including 23% who strongly agreed) with this statement. Less than 1 in 10 (7%) disagreed. Section 5.4.4 provides information on consumers' adoption of safe behaviours as a result of receiving information from Health Canada. The following section provides information on reduced adverse events (e.g., injuries and death) associated with the use of consumer products.

Increased public confidence

Generally speaking, Health Canada representatives and external stakeholders indicated that Health Canada is beginning to be viewed as a world leader in consumer products. The survey of industry and consumers offers some insight into perceptions of Health Canada's CPA.

- Overall, fewer than 4 in 10 respondents agreed (38%, including 5% who strongly agreed) that Health Canada does enough to monitor the safety of consumer products on the market. Just over one quarter disagreed (27%, including 7% who strongly disagreed).
- Industry (46%, including 8% who strongly agreed) was more likely than consumers (35%, including 4% who strongly agreed) to agree with the statement. Consumers (32%, including 9% who strongly disagreed) were more likely than industry (14%, including 4% who strongly disagreed) to disagree.

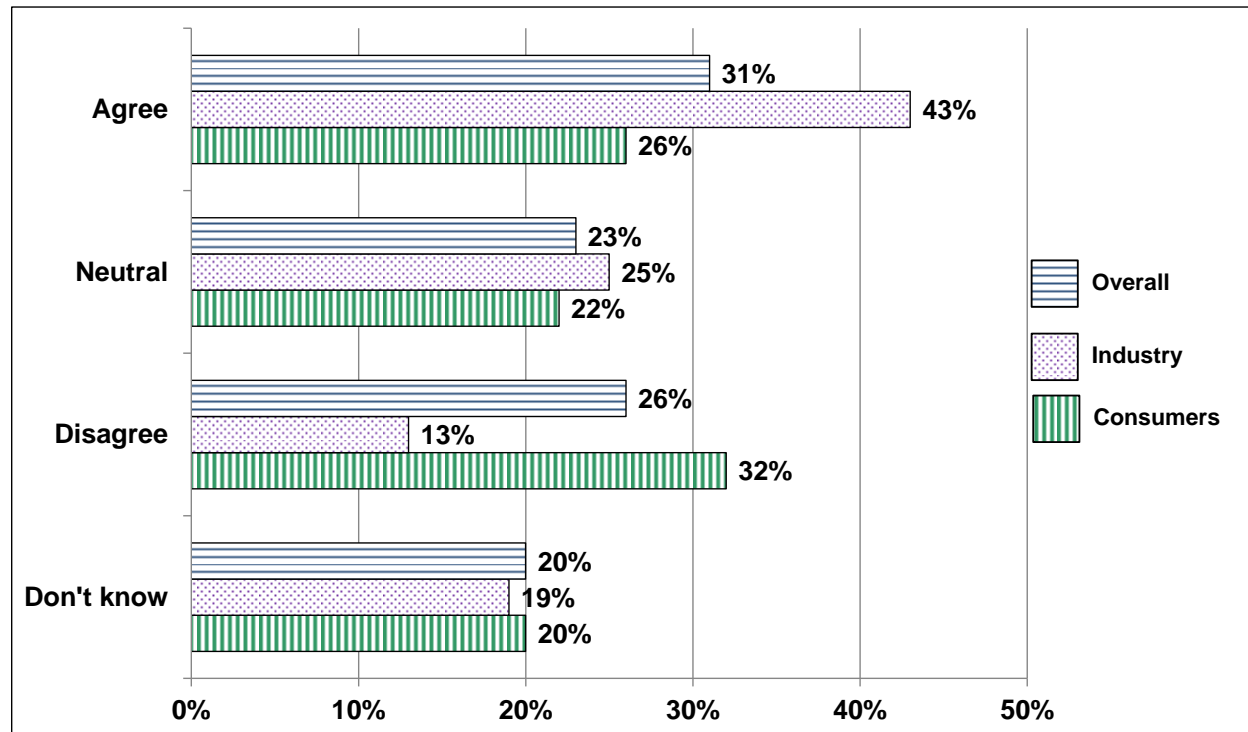
**Figure 4. Level of agreement:
“Health Canada does enough to monitor the safety of consumer products on the market”**



Overall, about 3 in 10 respondents agreed (31%, including 5% who strongly agreed) that Health Canada does enough to enforce its consumer products regulations. Just over one quarter disagreed (26%, including 6% who strongly disagreed).

- Industry (43%, including 9% who strongly agreed) was more likely than consumers (26%, including 3% who strongly agreed) to agree with this statement. Consumers (32%, including 8% who strongly disagreed) were more likely than industry (13%, including 4% who strongly disagreed) to disagree.

**Figure 5. Level of agreement:
“Health Canada does enough to enforce its consumer products regulations”**



Sustainable, cost-efficient, responsive, and science-based regulatory system

Ultimately, Health Canada hopes to achieve a sustainable, cost-efficient, responsive, and science-based regulatory system for consumer products in Canada. However, limitations of the Departmental financial system, including the lack of a time reporting component for accurate FTE utilization data, make it difficult to draw conclusions regarding the sustainability and cost-efficiency of CPA (see Section 5.5 for a more detailed discussion). As for the responsiveness and scientific basis of the regulatory system, Health Canada has made progress in addressing risks associated with consumer products, and appears to base many of its policy and regulatory decisions in scientific evidence and risk-based analysis. On the other hand, its failure to act on some of its planned activities suggests that other considerations have, at times, influenced its decision-making.

5.4.9 Unintended consequences

The evaluation did not identify any concrete unintended consequences of Health Canada's regulatory activities in relation to consumer products. However, external stakeholders speculated that some companies may have to hire additional staff to ensure they meet the requirements of the CCPSA, manufacturers may relocate to other jurisdictions with fewer legislative requirements, importing goods may become more onerous, and provincial authorities may stop addressing certain issues because they believe they now fall under Health Canada's jurisdiction.

5.5 Efficiency and economy

The demonstration of efficiency and economy is defined by the Treasury Board *Policy on Evaluation* (2009) as an assessment of program resource utilization in relation to the production of outputs and progress toward expected outcomes. This assessment is based on the assumption that departments have standardized performance measurement systems and that financial systems link information about program costs to specific inputs, activities, outputs and expected results.

The data structure of the detailed financial information provided for the FCSAP did not facilitate the assessment of whether program outputs were produced efficiently, or whether expected outcomes were produced economically. Departmental financial data for the FCSAP is not linked to the quantity and type of outputs and, as Health Canada representatives indicated, several CPA apply to more than one FCSAP strategy and/or pillar, and, therefore, the reported allocation of resources does not reflect the true level of resources devoted to individual components. For example, Health Canada representatives said that individuals working primarily on one particular FCSAP strategy may also spend a small proportion of their time on another strategy; however, given the lack of a corporate time reporting system in Health Canada, accurate and sustainable reporting of FTE utilization by FCSAP strategy was not possible. Considering these issues, the evaluation provides observations on economy and efficiency based on findings from the key informant interviews and available relevant financial data.

According to internal key informants, CPA have been implemented efficiently and similar results could not have been achieved at a lower cost. Examples of operational approaches that created efficiencies included new approaches to information dissemination (e.g. webinars rather than information sessions in every city), working with other jurisdictions to learn from their experiences, and developing consistent templates and standards to facilitate processes.

Resource utilization has largely reflected the initial allocations for CPA. According to official government documents, planned spending for the consumer products component of the FCSAP, over the period of 2008–09 to 2011–12, was \$68.54 million. Based on information provided by Health Canada and PHAC, Table 14 and Table 15 (below) compare Health Canada's and PHAC's planned spending against actual spending under the FCSAP, respectively, for fiscal years 2008–09 to 2011–12, by major program area (consumer products and pesticides) and FCSAP pillar (active prevention, targeted oversight, and rapid response). As shown, actual spending ranged from 37% of planned spending to 142% of planned spending, depending on the program area and FCSAP pillar. Health Canada's actual spending was 98% of what was planned, while PHAC spent 73% of what was planned. Overall, actual spending for the consumer products component of the FCSAP over this period was 98% of planned.

FCSAP annual reports contain comments on variances that provide explanations for major divergences between planned and actual spending. The reports make the following comments regarding consumer product spending from fiscal year 2008–09 to fiscal year 2010–11:

- Most resources in fiscal year 2008–09 were allocated to tabling the CCPSA and increasing the capacity of regional officers to support compliance and enforcement. Delays in tabling of CCPSA resulted in delayed progress on strategies dependent on the legislation (TBS, 2011a).

- The prorogation of Parliament in fiscal year 2009–10 resulted in a delay in Royal Assent of the CCPSA and the deferral of several planned activities. This resulted in a variance of approximately \$1 million. Delays in passing the CCPSA also resulted in amendment to the planning schedule for the development of information technology systems for mandatory reporting. This led to the deferral of \$1 million in operations and maintenance spending to fiscal year 2010–11 (TBS, 2011b).

Health Canada representatives provided the following explanation for the variances related to consumer products spending in 2011–12:

- A rapid coming-into-force date of June 20, 2011, was established for the CCPSA, which received Royal Assent in December 2010. Consequently, actual spending on Active Prevention was lower than anticipated, given the need to focus efforts on industry outreach to raise awareness of their obligations under the CCPSA. This led to delays in consumer outreach and standards development activities.
- Overspending in Targeted Oversight and Rapid Response related to the need to develop and implement the CCMS; create risk assessment capacity for the triage and assessment of risks identified in consumer product incident reports; enhance risk management capacity; and develop policy, business process, and regulatory support for the CCPSA.
- There were staffing delays across all areas of the Program.

Table 14: FCSAP planned versus actual spending for consumer products and consumer pesticides – Health Canada component

Year	Program area	FCSAP pillar	Planned spending (\$ millions)	Actual spending (\$ millions)	Ratio (Actual/Planned)
2008–09	Consumer products	Active prevention	\$1.5	\$1.17	78%
		Targeted oversight	\$0.6	\$0.22	37%
		Rapid response	\$0.9	\$1.1	120%
	Pesticide regulation	Active prevention	\$0.6	\$0.5	83%
		Rapid response	\$0.7	\$0.3	43%
2009–10	Consumer products	Active prevention	\$4.16	\$3.15	76%
		Targeted oversight	\$2.1	\$1.15	55%
		Rapid response	\$3.40	\$3.95	116%
	Pesticide regulation	Active prevention	\$1.34	\$1.34	100%
		Rapid response	\$1.00	\$1.00	100%
2010–11	Consumer products	Active prevention	\$9.3	\$7.76	83%
		Targeted oversight	\$3.8	\$5.43	142%
		Rapid response	\$4.6	\$6.20	135%
	Pesticide regulation	Active prevention	\$1.64	\$1.64	100%
		Rapid response	\$2.10	\$2.10	100%

Year	Program area	FCSAP pillar	Planned spending (\$ millions)	Actual spending (\$ millions)	Ratio (Actual/Planned)
2011–12	Consumer products	Active prevention	\$12.5	\$8.64	69%
		Targeted oversight	\$4.3	\$5.7	132%
		Rapid response	\$4.6	\$6.4	139%
	Pesticide regulation	Active prevention	\$1.60	\$1.60	100%
		Rapid response	\$2.10	\$2.10	100%
TOTAL			\$62.84	\$61.45	98%

Sources: (Health Canada, 2012d; TBS, 2011a, 2011b, 2011c) and information provided by Health Canada representatives.

Table 15: FCSAP planned vs. actual spending for consumer products– PHAC component

Year	Program area	FCSAP pillar	Planned spending (\$ millions)	Actual spending (\$ millions)	Ratio (Actual/Planned)
2008–09	Consumer products	Targeted oversight	\$0.4	\$0.38	95%
2009–10	Consumer products	Targeted oversight	\$1.0	\$0.47	47%
2010–11	Consumer products	Targeted oversight	\$2.0	\$1.1	55%
2011–12	Consumer products	Targeted oversight	\$2.3	\$2.2	96%
TOTAL			\$5.70	\$4.15	73%

Sources: (Health Canada, 2012d; TBS, 2011a, 2011b, 2011c)

6.0 Conclusions and recommendations

This section of the report summarizes the main findings from the evaluation, draws conclusions, and makes recommendations.

Relevance

The potential for some of the substances used in the manufacture of consumer products, cosmetics, and consumer pesticides to pose risks to human health, as well as the potential safety risks associated with the design and use of these products suggest an ongoing need for Health Canada's CPA. Moreover, consumer product safety emerged as a major federal priority with the launch of FCSAP in December 2007 and was reaffirmed in the 2010 Speech from the Throne.

Performance – program implementation

Health Canada and PHAC have made significant progress in establishing and implementing the *Canada Consumer Product Safety Act* (CCPSA) and have conducted a myriad of activities to support the CCPSA and other existing legislation, including providing information to industry and Canadians, developing standards, expanding product-related injury surveillance and risk assessment, collaborating with international partners, and enhancing compliance and enforcement activities. Work remains to be done to further develop information technology systems to support the CCPSA, and modernize the *Cosmetics Regulations* and the *Radiation-Emitting Devices Act* (REDA). The following highlights the status of some of the CPAs included in the consumer products component of the FCSAP.

Canada Consumer Product Safety Act (CCPSA)

One of Health Canada's major accomplishments was the coming into force of the CCPSA, which includes new provisions and powers that improve Health Canada's ability to respond to and address potential human health and safety risks associated with consumer products. In support of the CCPSA, Health Canada developed and implemented the Consumer Product Safety Program (CPSP) Case Management System (CCMS). It also centralized its risk assessment and risk management activities, and established dedicated divisions to handle the monitoring and triage of incident reports.

Some of the ongoing, but yet to be completed, CCPSA-related activities include developing clear guidance on interpreting and applying the general prohibition against the manufacture, importation, sale, or advertisement of consumer products that pose a danger to human health or safety; and for CCMS, establishing business rules for data entry and further developing data extraction/reporting capabilities.

Modernization of the Cosmetic Regulations and the Radiation-Emitting Devices Act

Although Health Canada intended to amend the *Cosmetic Regulations* and propose amendments to existing legislation, or even a new Act, for radiation-emitting devices, the Department has since decided not to pursue legislative/regulatory changes. Instead, for the *Cosmetic Regulations*, the Department is examining opportunities for improvement using non-regulatory approaches. And, for REDA, 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.

Information to Canadians and Industry Understanding its Obligations

Health Canada has conducted a wide range of outreach activities:

- In an effort to develop a consistent Departmental approach to communications, Health Canada created the Consumer Information Bureau (CIB). However, it was later disbanded and activities were integrated into the ongoing work of the Public Affairs Directorate whose mandate aligns with this objective.
- To provide consumer products-related information to Canadians, Health Canada launched the Consumer Safety Portal; conducted Healthy Canadians web writing; revamped the Consumer Products Recall Database; and introduced a Twitter feed, a mobile app, and a widget.
- To inform industry of its new obligations under the CCPSA, Health Canada conducted extensive industry outreach activities, including updating its website and holding cross-Canada information sessions.
- To inform Canadians about the safe use of consumer pesticides, PMRA launched consumer awareness and outreach campaigns, added more information to its compliance and enforcement website, and expanded the consumer pesticides-related content on the Healthy Canadians website.

Product-Related Injury Surveillance and Risk Assessment

PHAC implemented several projects to improve product-related injury surveillance and risk assessment. Examples include modernizing the Canadian Hospitals Injury Reporting and Prevention Program (CHIRPP) and expanding the number of participating hospitals; 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 in the Canadian Population Longitudinal Health Survey.

Monitoring and Enforcing Industry Compliance

Health Canada increased the level of resources, including the number of inspectors, it devoted to compliance and enforcement activities. Specifically, for consumer products, Health Canada expanded the coverage of its Cyclical Enforcement Program (CEP) from 23 product categories 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.

PMRA also undertook several initiatives to monitor and enforce industry compliance with the *Pest Control Products Act*. Specifically, it implemented a compliance verification program for consumer product vendors, introduced a compliance verification program targeting vendors of unregistered international pest control products, and it implemented a cyclical compliance monitoring program.

Performance – performance measurement and achievement of outcomes

While Health Canada has engaged in many activities that should, in theory, contribute to the expected outcomes, data to support a definitive conclusion regarding the extent to which expected outcomes have been achieved are relatively limited. In part, this reflects the following weaknesses associated with the performance measurement framework (PMF) for the consumer products component of FCSAP: many of the performance indicators are activity-based; in some cases, the same indicators are used to demonstrate progress toward different outcomes; and some critical performance indicators are not being tracked. It also reflects the current limitations of the CCMS, which has constrained the ability to report on some performance indicators.

Immediate outcomes

The intended immediate outcomes of CPA are increased awareness and understanding among external stakeholders of risks related to consumer products, increased awareness and understanding among industry of Health Canada's regulatory framework for consumer products, increased safety of consumer products, and increased industry compliance with Health Canada's regulatory requirements related to consumer products.

Ultimately, the evaluation was not able to determine the extent to which consumers' awareness of the risks related to consumer products had changed. Nonetheless, the survey, conducted as part of this evaluation, of consumers who subscribe to one or more of Health Canada's electronic information services found that the vast majority of respondents were aware of at least some of

the consumer products-related information Health Canada has produced. Further, those who had used the information tended to rate it as “very” or “somewhat” useful, understandable, accessible, of high quality, and timely. In summary, about two thirds of consumers agreed that “overall, Health Canada provides enough information to the general public about the human health safety risks associated with consumer products.”

The evaluation found that Health Canada’s outreach activities have raised industry’s awareness of its consumer product safety obligations under the CCPSA. However, it is apparent that there is a need for ongoing and continued outreach efforts as industry lacks clarity about the mandatory incident reporting and document retention requirements, 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, the survey of industry, conducted as part of the evaluation, found that, using a scale of 1 to 5, where 1 is poor and 5 is excellent, only half of the industry respondents rated the level of knowledge within their company/organization of the CCPSA as a “4” or “5 — excellent.”

For consumer pesticides, based on PMRA reports on completed inspections, it appears there is reasonably high understanding of regulatory requirements in some sectors (e.g., requirement for pest control operators to sell only registered and properly-labelled commercial and domestic class pest control products), but, in other cases, there is low awareness of regulatory requirements (e.g., requirement to sell only registered and properly-labelled pet products).

It is not possible to determine the degree of industry compliance with Health Canada’s regulatory requirements for consumer products since compliance and enforcement activities target instances of suspected non-compliance. Nonetheless, the evaluation found that 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 being developed. That being said, the case studies suggest there is ongoing non-compliance with the *Children’s Jewellery Regulations* and the *Cribs, Cradles and Bassinets Regulations*. They also found evidence of non-compliance with the *Corded Window Covering Products Regulations*. Further, survey findings indicated that fewer than 4 in 10 respondents agreed that Health Canada does enough to monitor the safety of consumer products on the market and about 3 in 10 respondents agreed that Health Canada does enough to enforce its consumer products regulations.

For consumer pesticides, the evaluation found that PMRA has developed a compliance and enforcement policy guideline, held a National Pesticide Compliance Workshop, and developed a database to track compliance activities. According to PMRA’s compliance monitoring activities, depending on the types of products involved, compliance ranged 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.

Intermediate outcomes

The intended intermediate outcomes of CPA are external stakeholders' adoption of safe behaviours associated with consumer products, increased use of scientific evidence and risk-benefit analysis by Health Canada to inform decision-making, timely regulatory response to identified risks, harmonization of Canada's regulatory framework for consumer products with international approaches, and reduced exposure to identified risks associated with the use of consumer products.

It is reasonable to assume that Health Canada's efforts to increase consumer and industry awareness and understanding of the health and safety risks associated with consumer products and the regulatory framework for these products risks will lead to some degree of adoption of safe behaviours. It appears that although industry may require additional information about specific aspects of the mandatory incident reporting and document retention requirements under the CCPSA, the majority seem to know the requirements exist. Additionally, the results of the survey of consumers (who have had previous contact with Health Canada), which was conducted as part of this evaluation, suggest that the information that Health Canada provides has increased consumers' knowledge of human health safety risks associated with consumer products, influenced their decisions about the consumer products that they purchase, and has influenced how they use consumer products.

The evaluation relied on qualitative evidence to assess the extent to which Health Canada uses scientific evidence and risk analysis to inform decision-making. Although the evaluation confirmed that Health Canada uses this type of information in decision-making, it was not possible to determine if use of this information has increased.

The program aims to provide timely regulatory responses to identified risks. Regulatory responses in the form of new regulations can be lengthy, frequently due to factors beyond the Department's control. Based on the case studies, it has taken about four years to enact regulations for children's jewellery and corded window covering products, from the time that the department had announced its intent to regulate. In November 2009, Stork Craft voluntarily recalled drop-side cribs in collaboration with Health Canada and the US CPSC. The US prohibited drop side cribs effective June 28, 2011. The process of drafting an amendment to the Canadian *Cribs, Cradles and Bassinets Regulations* to address the safety risk posed by drop-side cribs is underway. According to Health Canada representatives, the proposed changes will also improve the general safety of cribs, cradles and bassinets and further align Canadian and U.S. requirements. This has required additional time in amending the regulations.

The coming into force of the CCPSA will provide the department with a broadened suite of instrument choice to address human health and safety risks associated with consumer products. The CCPSA introduces a "general prohibition" which reduces the need to rely on Governor in Council regulations to address health or safety issues, resulting in an enhanced capacity for Health Canada to respond.

The evaluation relied on qualitative evidence to assess the extent to which Canada's regulatory framework for consumer products has been harmonized with international approaches. The evaluation found that enactment of the CCPSA has helped better align Canada's legislation with other countries. It also noted that Health Canada is participating in a variety of standards committees, collaborating with a range of international institutions/organizations, and issuing joint recalls with the US CPSC.

Long-term outcomes

The intended long-term outcomes of CPA are reduced adverse events and/or incidents associated with the use of consumer products and increased public confidence in consumer products and the related regulatory system. Concrete data to support conclusions on these outcomes has not been collected.

In theory, Health Canada's CPA should contribute to reducing adverse events associated with the use of consumer products. It seems that, given the mandatory incident reporting requirement for industry and Health Canada's efforts to raise public awareness of the ability for consumers to voluntarily report incidents, the Department is beginning to receive an increased number of reported incidents. Given the information provided to the evaluation, it was not possible to determine trends in consumer product-related injuries and deaths. Nonetheless, based on the case studies, there has been little change over time in the annual number of crib-related injuries, although the annual number of deaths has decreased since 1986. Further, there does not appear to be a clear trend in the child fatality rate associated with corded window coverings.

Aside from key informant opinion and the results of a survey of industry and consumers who have had contact with Health Canada, there is no data upon which to assess whether public confidence in consumer products and the related regulatory system has increased. Generally speaking, Health Canada representatives and external stakeholders indicated that Health Canada is beginning to be viewed as a leading regulator of consumer products. However, only 38% of survey respondents agree that "Health Canada does enough to monitor the safety of consumer products on the market." Further, only 31% agree that "Health Canada does enough to enforce its consumer products regulations."

Performance – 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 systems link information about program costs to specific inputs, activities, outputs and expected results. There was a lack of departmental financial data linked to the quantity and type of outputs, and since several CPA apply to more than one FCSAP strategy and/or pillar, the amount of financial and human resources reported as being used for each component does not accurately reflect the actual level of resources required to implement them.

According to internal key informants, CPA have been implemented efficiently and similar results could not have been achieved at a lower cost. Examples of operational approaches that created efficiencies included new approaches to information dissemination (webinars rather than information sessions in every city), working with other jurisdictions to learn from their experiences, and developing consistent templates and standards to facilitate processes

According to information provided by Health Canada and PHAC, overall, over the period of 2008–09 to 2011–12, actual spending (\$65.6 million) for the consumer products component of FCSAP was 96% of planned spending (\$68.54 million). Although Health Canada tracks planned and actual spending by FCSAP pillar and strategy, it was not possible to determine if program outputs were produced efficiently, or whether expected outcomes were produced economically.

Recommendations

The following are the recommendations stemming from the evaluation.

The CCPSA includes several new authorities intended to expand Health Canada’s ability to respond to health and safety concerns associated with consumer products. These include, but are not limited to, the introduction of a general prohibition against consumer products that pose a danger to human health or safety, as well as the authority to: order recalls; order a supplier to take other corrective actions; require tests and studies to verify compliance or prevent non-compliance with regulations; and provisions for (increased) fines and/or AMPs for violations.

Of particular importance, Health Canada should introduce guidance pertaining to the AMPs regulations, which were published in Canada Gazette Part II on June 5, 2013. Additional departmental policies, guidelines, and procedures outlining the decision-making processes associated with, and the application of, the general prohibition and the other new powers under the CCPSA, should be developed. This includes further clarifying some of the definitions and/or conditions that have to be met to take action on violations of the general prohibition (e.g., explaining what constitutes “reasonable grounds”).

Recommendation 1.

Health Canada (CPSD, RAPB) should take further steps to enable the use of new powers granted through the CCPSA.

The evaluation found that CPSD is tracking performance standards for the triage of consumer product incident reports, and PMRA is tracking performance standards for inspections. Additionally, Health Canada representatives said the Department is in the process of developing, or has recently developed, performance standards for follow-up on incident reports, recall monitoring, lab testing, border response times, and risk assessment activities. Health Canada representatives indicated that dashboard reports based on the triage performance standard are used to monitor progress, set priorities, define resource needs, and inform the need for adjustments to processes. Therefore, given likely increases in the number of consumer product incident reports that will be received in the future, as well as the increases to level of compliance and enforcement activities conducted, performance standards have the potential to serve as a value monitoring tool.

Recommendation 2.

Health Canada (CPSD, RAPB, PMRA) should implement service standards for risk assessment and risk management.

The Performance Measurement Framework (PMF) for the consumer products component of FCSAP identifies numerous indicators against which progress toward intended outcomes is to be measured. The PMF comprises a multitude of indicators, including some of which are associated with several outcomes. Although FCSAP participants proposed revisions to the PMF, some of the identified indicators provide limited evidence of achievement of outcomes, and some key indicators are not tracked.

Further, in some instances, the evaluation's ability to report on progress toward intended outcomes was constrained by the quality of data captured in CCMS, as well as challenges associated with extracting information from the system. Although the evaluation received some CCMS output, through the process of discussing the data with Health Canada representatives, it became apparent that the information was unreliable and did not reflect the true extent of Health Canada's consumer products activities. To improve the capacity of CCMS to support performance measurement and monitoring, business rules are needed to facilitate consistency in data entry and "templated" reports are needed to extract data from the system. Further, now that Health Canada has gained experience using CCMS, it should reassess the systems capacity to provide information on the performance indicators specified for consumer products activities.

Recommendation 3.

Health Canada (all participants) and PHAC should take steps to improve the Performance Measurement Strategy (PMS) for the consumer products component of FCSAP.

Recommendation 4.

Health Canada (CPSD, RAPB) should implement measures to improve the quality of CCMS data.

The evaluation found that Health Canada's outreach activities have raised industry's awareness that it has to meet certain consumer product safety obligations under the CCPSA. However, it appears that some industry representatives do not have a thorough understanding about the details of the requirements or how to meet them. Specifically, industry lacks clarity about what consumer product incidents must be reported and what information must be included in the reports. Additionally, they do not have a strong understanding of the document retention requirements. Further, external stakeholders have the perception that some small and medium enterprises (SMEs) may not be aware of the CCPSA and how it affects them.

Recommendation 5.

Health Canada (CPSD, RAPB, CPAB) should continue to inform and educate industry about their obligations under the CCPSA.

The evaluation found that Health Canada is implementing cycle enforcement activities for 35 categories of consumer products, which are explicitly regulated under the CCPSA; however, it has not developed a formal strategy for examining “unregulated” consumer products. Further, although Health Canada has begun preparing to undertake compliance and enforcement activities for radiation-emitting consumer products, it has yet to implement them. Therefore, to strengthen Health Canada’s ability to protect the health and safety of Canadians using these products, and ensure these products are examined at regular intervals, the Department should formally integrate them into its cyclical enforcement activities.

Recommendation 6.

Health Canada (CPSD, ERHSD, RAPB) should ensure that the risk-based Cyclical Enforcement Program aligns with the broader scope of relevant products regulated under the CCPSA, REDA and FDA.

Appendix A – List of references

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Appendix B – Logic model

FCSAP Logic Model for Consumer Products

	Active Prevention				Targeted Oversight				Rapid Response			
Strategies	1: Industry Understanding its Obligations (HECSB)	2: Consumer Pesticides Industry Understanding its Obligations (PMRA)	3: Standards Development and Adoptions (HECSB)	4: Information to Canadians (HECSB, PMRA, CPAB)	5: Mandatory Reporting of Consumer Product Incidents and Risk Assessment/ Risk Mitigation (HECSB)	6: Modernized Cosmetic Regulations & Enhanced Risk Assessment/ Management Activities (HECSB)	7: International Collaboration (HECSB)	8: Increased Product-Related Injury Surveillance & Risk Assessment (PHAC)	9: New Canada Consumer Product Safety Act (HECSB)	10: Modernizing and Enforcing Radiation Emitting Devices Act (HECSB)	11: Promote and Enforce Industry Compliance (HECSB)	12: Monitor and Enforce Industry Compliance - Consumer Pesticides (PMRA)
Program Activity Architecture (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 <i>Cosmetic Regulations of the Food and Drugs Act</i>	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			
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	-Epidemiological data (Coroners/ Medical Examiners Database) -Risk assessments completed and prevention interventions assessed and disseminated	-New <i>Canada Consumer Product Safety Act/</i> modernized REDA -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, analyze, 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

Appendix C – Evaluation matrix

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX		
Evaluation issues and questions	Indicators	Data sources ⁸⁵
SECTION 1: RELEVANCE		
Issue #1: Continued need for the program		
1. Is there a continued need for the CP activities?	▶ Need for program identified/documented	Document review: - Treasury Board submissions, Memoranda to Cabinet - Capacity Assessment
	▶ Evidence of current/emerging human health and safety issues related to CPs	Literature review
	▶ Expert/stakeholder assessment of ongoing need	Key informant interviews (internal and external)
	▶ Responsiveness of program to needs of Canadians	Document review Literature review Key informant interviews (external) Survey of industry/consumers (potential)
Issue #2: Alignment with government priorities		
2. Are the CP activities aligned with the priorities of the Government of Canada?	▶ Extent to which program objectives are linked to Federal Government priorities	Document review: - recent Speeches from the Throne/Budgets - Food and Consumer Safety Action Plan (FCSAP) RMAF
	▶ Extent to which program objectives are linked to the strategic outcomes/priorities of Health Canada/PHAC	Document review: - recent Health Canada Reports on Plans and Priorities - HECS/CPSP/ERHSD/PHAC/CPAB/RAPB/PMRA strategic plans (draft/final, as available)
Issue #3: Alignment with federal roles and responsibilities		
3. Are the CP activities consistent with federal roles and responsibilities?	▶ Extent to which the program objectives are consistent with the legislative framework of the Federal Government	Document review: - federal Acts and Regulations (<i>Department of Health Act, Food and Drugs Act, the Canada Consumer Product Safety Act, the Cosmetic Regulations under the Food and Drugs Act, the Radiation Emitting Devices Act, the Pest Control Products Act, etc.</i>)

⁸⁵ The specific data sources (particularly documents and administrative data) identified in this matrix are examples only and/or reflect information that is expected or known to be available. Some of the data sources identified in this matrix may ultimately prove to be unavailable, while additional data sources may be identified over the course of the evaluation.

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<ul style="list-style-type: none"> ▶ Extent to which the program objectives are consistent with the legislative framework of Health Canada/PHAC 	Document review: <ul style="list-style-type: none"> - federal Acts and Regulations (<i>Department of Health Act, Food and Drugs Act, the Canada Consumer Product Safety Act, the Cosmetic Regulations under the Food and Drugs Act, the Radiation Emitting Devices Act, the Pest Control Products Act, etc.</i>) - recent Health Canada Reports on Plans and Priorities
SECTION 2: PERFORMANCE (EFFECTIVENESS, EFFICIENCY, ECONOMY)		
Issue #4: Achievement of expected outcomes		
4. Is the governance structure for CP activities likely to support the achievement of expected outcomes?		
a) Is there an established governance structure to coordinate delivery of CP activities?	<ul style="list-style-type: none"> ▶ Extent to which internal and interdepartmental partners' roles, responsibilities, accountabilities, and decision-making authorities are documented and understood ▶ Extent of collaboration among internal and interdepartmental partners, as evidenced by: <ul style="list-style-type: none"> - existence of committees, working groups, and teams - frequency of meetings of committees, working groups, and teams ▶ Nature of industry involvement in governance of CP activities 	Document review: <ul style="list-style-type: none"> - descriptions of the organizational structures, mandates, and activities of program partners, as available from: <ul style="list-style-type: none"> o Health Canada and PHAC websites o FCSAP RMAF o FCSAP annual reports (governance structure) o organizational charts/reorganization documents o Letters of Agreement (e.g., CCRPB, Industry Canada, Electrical Safety Authority) o CBSA single window proposal o other internal documents as available Key informant interviews (internal and external, i.e., other federal departments)

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
5.a) Has a performance measurement framework been designed and implemented?	<ul style="list-style-type: none"> ▶ Existence of performance measurement framework(s) ▶ Extent to which performance data are collected 	<p>Document review</p> <ul style="list-style-type: none"> - FCSAP RMAFs <p>Document review:</p> <ul style="list-style-type: none"> - Health Canada DPRs - FCSAP annual reports - FCSAP crosswalk of indicators - CPSD/ERHSD/PHAC/CPAB/RAPB/PMRA performance reports (as available) - milestone reports - Integrated Planning and Performance Reporting System (IPPRS) planning reports, quarterly reports <p>Key informant interviews (internal)</p>
b) Is the performance measurement framework used to support decision-making?	<ul style="list-style-type: none"> ▶ Extent to which performance data are used to support decision-making 	<p>Document review:</p> <ul style="list-style-type: none"> - HECS/CPSD/ERHSD/PHAC/CPAB/RAPB/PMRA strategic plans (draft/final, as available) - Deputy Minister dashboards - year-end reports - environmental scans - IPPRS reports - other management planning documents (if available) <p>Key informant interviews (internal)</p>
6. To what extent have CP activities been implemented as planned?		
a) Have CP activity partners effectively addressed challenges, emerging issues, and changing priorities?	<ul style="list-style-type: none"> ▶ Extent to which challenges, emerging issues, and changing priorities have been effectively addressed, e.g.: <ul style="list-style-type: none"> - Transition from the <i>Hazardous Products Act</i> to the <i>Canada Consumer Product Safety Act</i> - Joint regulation of CPs (e.g., consumer lasers) 	<p>Document review</p> <ul style="list-style-type: none"> - HECS/CPSD/ERHSD/PHAC/CPAB/RAPB/PMRA strategic plans (draft/final, as available) - letters of agreement (e.g., Industry Canada) - REDA Issue Analysis documents - communications/consultations with stakeholders including reports of such consultations - policies, regulations, and guidelines implemented to address challenges, emerging issues, and changing priorities <p>Key informant interviews (internal and external)</p> <p>Case studies</p> <p>Survey of industry/consumers (potential)</p>

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
b) Have activities been implemented as planned?	▶ Extent to which CP activities have been implemented as planned	Document review: For planned implementation: <ul style="list-style-type: none"> - Treasury Board submissions - Memoranda to Cabinet - CPSD/ERHSD/PHAC/CPAB/RAPB/PMRA operational and implementation plans (as available) - FCSAP RMAF For actual implementation: <ul style="list-style-type: none"> - FCSAP implementation templates - CPSD/ERHSD/PHAC/CPAB/RAPB/PMRA performance reports (as available) - milestone reports - Health Canada DPRs - actual spending data Key informant interviews (internal) Case studies
c) Have the activities produced the expected outputs?	▶ Enumeration of outputs (policies, guidelines, regulations, research, MOUs, etc.) produced for each activity	Document review: For expected outputs: <ul style="list-style-type: none"> - Treasury Board submissions - Memoranda to Cabinet - HECS/PHAC/PMRA strategic plans (if available) - FCSAP RMAF For actual outputs: <ul style="list-style-type: none"> - CPSD/ERHSD/PHAC/CPAB/RAPB/PMRA performance reports (as available) - milestone reports - Health Canada DPRs - actual spending data - policies, guidelines, regulations, research, MOUs, etc. Case studies
d) Have requirements/ commitments to Central Agencies (i.e., Office of the Auditor General, Cabinet Directive on Streamlining Regulations, Policy on Public Consultation, Policy on Gender- Based Analysis) been addressed?	▶ Extent to which requirements and commitments to Central Agencies have been addressed	Document review (to extent relevant documents may be available) Key informant interviews (internal and external)

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
7. To what extent has progress towards expected outcomes been achieved?		
<i>Immediate outcomes</i>		
a) To what extent is there increased awareness and understanding among external stakeholders of risks and benefits related to CPs?	<ul style="list-style-type: none"> ▶ Extent and nature of Health Canada communications to/consultations with external stakeholders (e.g., consumers, industry, OGDs, NGOs) regarding risks and benefits of CPs 	Document review: <ul style="list-style-type: none"> - Health Canada communications, meetings, and consultations with external stakeholders regarding risks and benefits of CPs - consumer/product information brochures/pamphlets/videos - HC consultation documents Case studies
	<ul style="list-style-type: none"> ▶ External stakeholder (e.g., consumers, industry, OGDs, NGOs) perceptions of their understanding of the information made available by Health Canada 	Document review: <ul style="list-style-type: none"> - public opinion research reports Key informant interviews (external) Case studies Survey of industry/consumers (potential)
	<ul style="list-style-type: none"> ▶ External stakeholder (e.g., consumers, industry, OGDs, NGOs) perceptions of their level of awareness and understanding of risks and benefits related to CPs 	Document review: <ul style="list-style-type: none"> - public opinion research reports Key informant interviews (external) Case studies Survey of industry/consumers (potential)
	Indicators related to FCSAP Strategy #2: Consumer Pesticides Industry Understanding its Obligations (PMRA) <ul style="list-style-type: none"> ▶ Proportion of the target population aware/engaged/confident regarding risks ▶ Number of stakeholder partnerships formed 	Document review: <ul style="list-style-type: none"> - Health Canada meetings, and consultations with external stakeholders Key informant interviews (internal and external) Survey of industry/consumers (potential)
	Indicators related to FCSAP Strategy #4: Information to Canadians (HECS, PMRA) <ul style="list-style-type: none"> ▶ Number, type, and reach of information and education activities, including: <ul style="list-style-type: none"> - Activities directed at consumers, including regional activities - Number of unique visitors/visits on the CP Safety website - Number of unique visitors/visits on the consumer recall website - Number and type of multiplier groups, such as public health organizations subscribed to CPSD listservs ▶ Proportion of programs/information meeting the needs of consumers ▶ Proportion of consumers aware/knowledgeable of health and safety issues of consumer products, including: <ul style="list-style-type: none"> - Number and subtype of consumer incident reports received in CCMS in co-relation to recalls and media coverage of CP-related incidents (to show public interest awareness) 	Document/administrative data review (if available) <ul style="list-style-type: none"> - consumer/product information brochures/pamphlets/videos - public opinion research reports, participant awareness statistics (as available) Key informant interviews (external) Survey of consumers (potential)

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<ul style="list-style-type: none"> ▶ Extent and nature of Health Canada communications to/consultations with industry regarding the regulatory framework for CPs ▶ Industry perceptions of its level of awareness and understanding of Health Canada’s regulatory framework for CPs 	<p>Document review:</p> <ul style="list-style-type: none"> - Health Canada communications, meetings, and consultations with industry stakeholders regarding the regulatory framework for CPs (e.g., national outreach activity reports) - HC consultation documents <p>Document review:</p> <ul style="list-style-type: none"> - public opinion research reports, participant awareness statistics (as available) <p>Key informant interviews (external) Case studies Survey of industry (potential)</p>
<p>b) To what extent is there increased awareness and understanding among industry of Health Canada’s regulatory framework for CPs? (continued)</p>	<p>Indicator related to FCSAP Strategy #1: Industry Understanding its Obligations (HECS)</p> <ul style="list-style-type: none"> ▶ Proportion of planned industry outreach activities completed as designed, including: <ul style="list-style-type: none"> - Number of publications disseminated - Number of listserv industry members on the CPS email each fiscal year ▶ Proportion of companies aware/knowledgeable about safety obligations including: <ul style="list-style-type: none"> - Number of unique visitors/visits to the CPS web pages for industry - Number of views/downloads of the online educational video for industry - Number of attendees for the educational webinars - Click-through rate for the video and webinars promoted via an email distribution list - Number of insertions and impressions for the Public Notice - Proportion of companies/industry aware of product safety obligations <i>pre</i>-information sessions - Proportion of companies/industry aware of product safety obligations <i>post</i>-information sessions <p>Indicators related to FCSAP Strategy #2: Consumer Pesticides Industry Understanding its Obligations (PMRA)</p> <ul style="list-style-type: none"> ▶ Proportion of the target population aware/engaged/confident regarding regulatory activities, including: <ul style="list-style-type: none"> - Number of insertions and impressions for the Public Notice - Number of views/downloads of the online educational video for industry - Number of attendees for the educational webinars - Click-through rate for the video and webinars promoted via an email distribution list - Number of stakeholder partnerships formed ▶ Number of violations where absence of knowledge of requirements is the cause 	<p>Document/administrative data review:</p> <ul style="list-style-type: none"> - implementation plans - milestone reports - Health Canada communications, meetings, and consultations with external stakeholders - public opinion research reports, participant awareness statistics (as available) - CCMS/PSIS data <p>Key informant interviews (external) Case studies Survey of industry (potential)</p>

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<p>Indicators related to FCSAP Strategy #3: Standards Development and Adoption (HECS)</p> <ul style="list-style-type: none"> ▶ Number of external standards committees and boards with active participation from CPSD and ERHSD ▶ Proportion complete against plans to have guides and information produced and distributed to industry ▶ Proportion of the target population aware of standards 	<p>Document/administrative data review:</p> <ul style="list-style-type: none"> - implementation plans - milestone reports - Health Canada communications, meetings, and consultations with external stakeholders - public opinion research reports, participant awareness statistics (as available) - CCMS/PSIS data <p>Key informant interviews (external) Case studies Survey of industry (potential)</p>
<p>c) To what extent is there increased safety of CPs?</p>	<p>Indicator related to FCSAP Strategy #2: Consumer Pesticides Industry Understanding its Obligations (PMRA)</p> <ul style="list-style-type: none"> ▶ Number of complaints and/or incidents 	<p>Document/administrative data review:</p> <ul style="list-style-type: none"> - PMRA databases (as available)
	<p>Indicator related to FCSAP Strategies #5 and #6 (HECS)</p> <ul style="list-style-type: none"> ▶ 14(3) reports received in compliance by Canadian importers and manufacturers ▶ Proportion of CP inspections that are compliant/non-compliant with product safety obligations ▶ Number of products subject to mitigation strategy (CPs and cosmetics), including: <ul style="list-style-type: none"> - Proportion of inspected firms that took corrective action by the specified deadline (follow-up) 	<p>Document/administrative data review:</p> <ul style="list-style-type: none"> - CCMS/PSIS data - other internal documents as available
	<ul style="list-style-type: none"> ▶ External and internal stakeholder perceptions of safety and effectiveness of CPs, including perceptions of adequacy of processes in place to improve safety and effectiveness 	<p>Literature review Document review, e.g.: <ul style="list-style-type: none"> - public opinion research reports Key informant interviews (internal and external) Case studies Survey of industry/consumers (potential)</p>

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
d) To what extent is there increased industry compliance with Health Canada’s regulatory requirements related to CPs?	Indicators related to FCSAP Strategy #11: Promote and Enforce Industry Compliance (HECS) ▶ Number of activity requests completed, including: - Watch list items tracked - Environmental scans completed ▶ Emerging issues identified by surveillance, including: - Number and nature of CP incidents sent to surveillance for risk assessment ▶ Number of products in compliance and enforcement (cyclical enforcement) cycle, including: - Number of cyclical enforcement inspections and samples per cycle ▶ Recall effectiveness (voluntary industry information), including: - Number of inspections of recall monitoring per year ▶ Compliance rates, including: - Proportion compliant to inspectors’ orders - Proportion of fines paid on time	Document/administrative data review: - implementation plans - milestone reports - CCMS/PSIS data - CPSD/RAPB performance reports - other internal documents as available
	Indicators related to FCSAP Strategies #1, #2, #11, and #12 (HECS/PMRA) ▶ 14(3) reports received in compliance by Canadian importers and manufacturers ▶ Proportion of inspected/verified registrants/firms/users that are compliant/non-compliant with product safety obligations ▶ Proportion of voluntary compliance versus inspectors’ orders ▶ Proportion of inspected registrants/firms/users that took corrective action by the specified deadline ▶ Number of repeat violators of enforcement actions taken between current year and baseline year	Document/administrative data review: - CCMS/PSIS data - PMRA databases (as available) - CPSD/RAPB/PMRA performance reports - other internal documents as available
	Indicator related to FCSAP Strategy #2: Consumer Pesticides Industry Understanding its Obligations (PMRA) ▶ Number of industry situations noted and self-corrected	Document/administrative data review: - PMRA databases (if available)
	▶ Industry self-report data related to compliance and enforcement	Document review Key informant interviews (external – industry representatives) Case studies Survey of industry (potential)
e) To what extent is there increased industry	▶ Adequacy of information technology tools to support compliance tracking	Document review Key informant interviews (internal)

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
compliance with Health Canada’s regulatory requirements related to CPs? (continued)	▶ Adequacy of training related to CPs delivered to RAPB staff	Document review <ul style="list-style-type: none"> - Compliance and enforcement policy, guidance documents, risk evaluation guides, technical guides, standard operating procedures - Compliance/enforcement training sessions Key informant interviews (internal)
Intermediate outcomes		
f) To what extent do external stakeholders adopt safe behaviours associated with CPs?	▶ Extent and nature of Health Canada risk communications to consumers and industry regarding CPs	Document review, e.g.: <ul style="list-style-type: none"> - Consumer/product information brochures/pamphlets/videos - Watch lists/recall notices - Guidance documents
	▶ Number of educational materials published to bring about awareness of health safety issues	Document review, e.g.: <ul style="list-style-type: none"> - Consumer/product information brochures/pamphlets/videos - Watch list/recall notices
	▶ Extent to which external stakeholders report using Health Canada publications, advisories, guidance, policies, regulations, and risk communications for decision-making	Key informant interviews (external) Case studies Survey of industry/consumers (potential)
	Indicator related to FCSAP Strategies #3: Standards Development and Adoptions (HECS) <ul style="list-style-type: none"> ▶ Proportion of inspected/verified registrants/firms/users that are using standards (where available) ▶ Proportion of CP inspections that are compliant/non-compliant with product safety obligations ▶ Proportion of inspected firms that took corrective action by the specified deadline (follow-up) ▶ 14(3) reports received in compliance by Canadian importer and manufacturer 	Document/administrative data review: <ul style="list-style-type: none"> - CCMS/PSIS data Key informant interviews (external) Survey of industry (potential)
	Indicator related to FCSAP Strategy #4: Information to Canadians (HECS/PMRA) <ul style="list-style-type: none"> ▶ Number of times the “What to do when there is a recall” information is accessed on the Health Canada/Healthy Canadians website ▶ Number of visits and views on the website ▶ Number of posts, comments, and likes on the CPS-related content on the Healthy Canadians Facebook page ▶ Number of downloads of the Recalls and Safety Alerts mobile application ▶ Number of incidents reported of improper/unsafe use of products ▶ Proportion of unforeseeable use incidents related to CPs 	Document/administrative data review: <ul style="list-style-type: none"> - CCMS/PSIS data - other internal documents as available

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<p>Indicators related to FCSAP Strategy #5: Mandatory Reporting of CP Incidents and Risk Assessment/Risk Mitigation (HECS)</p> <ul style="list-style-type: none"> ▶ IT system and capacities developed to better support increased information/input and analysis (CCMS) ▶ Number and type of consumer and industry reports received ▶ Timelines/usability of information received from partner organizations ▶ Proportion of companies compliant against mandatory reporting requirements (reporting product-related incidents) ▶ Proportion of companies with assessment and mitigation strategy in place ▶ Proportion of CP inspections that are compliant/non-compliant with product safety obligations ▶ Proportion of inspected firms that took corrective action by the specified deadline (follow-up) ▶ 14(3) reports received in compliance by Canadian importers and manufacturers 	<p>Document/administrative data review: - CCMS/PSIS data Key informant interviews (external) Case studies Survey of industry (potential)</p>
	<p>Indicator related to FCSAP Strategy #6: Modernized Cosmetic Regulations & Enhanced Risk Assessment/Management Activities (HECS)</p> <ul style="list-style-type: none"> ▶ Proportion of companies with assessment and mitigation strategy in place ▶ Proportion of CP inspections that are compliant/non-compliant with product safety obligations ▶ Proportion of inspected firms that took corrective action by the specified deadline (follow-up) ▶ 14(3) reports received in compliance by Canadian importer and manufacturer 	<p>Document/administrative data review: - CCMS/PSIS data Key informant interviews (external) Case studies Survey of industry (potential)</p>
	<ul style="list-style-type: none"> ▶ Extent of mandatory problem reports related to CPs by industry 	<p>Document/administrative data review: - CCMS/PSIS data Key informant interviews (internal and external) Case studies Survey of industry (potential)</p>
<p>g) To what extent is there increased use of scientific evidence and risk-benefit analysis by Health Canada to inform decision-making?</p>	<ul style="list-style-type: none"> ▶ Description of Health Canada’s approach to decision-making, including extent to which approach is risk-based ▶ Extent to which recommendations of expert/scientific advisory groups are used to inform and develop policy/regulatory responses ▶ Extent to which regulatory changes include Regulatory Impact Analysis Statements (RIAS) 	<p>Document review Key informant interviews (internal)</p> <p>Document review: - Terms of Reference, meeting minutes, and reports/recommendations of expert/scientific advisory groups - policies, guidelines, regulations Key informant interviews (internal) Case studies</p> <p>Document review: - RIAS in <i>Canada Gazette</i> - Cost-benefit analysis reports</p>

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<ul style="list-style-type: none"> ▶ Evidence that information gathered through post-market monitoring/surveillance is used to inform decision-making 	Document review (if available) Key informant interviews (internal) Case studies
	<ul style="list-style-type: none"> ▶ Stakeholders' perceptions of extent to which use of scientific evidence and risk-based analysis to inform decision-making has increased 	Key informant interviews (external and internal) Case studies Survey of industry (potential)
h) To what extent is there a timely regulatory system response to identified risks?	<ul style="list-style-type: none"> ▶ Description of regulatory process 	Document review Key informant interviews (internal)
	<p>Indicator related to FCSAP Strategy #6: Modernized Cosmetic Regulation & Enhanced Risk Assessment/Management Activities (HECS)</p> <ul style="list-style-type: none"> ▶ Proportion of Regulatory amendments completed against plan (<i>Cosmetics</i>) 	Document review
	<p>Indicators related to FCSAP Strategy #7: International Collaboration (HECS)</p> <ul style="list-style-type: none"> ▶ Number of requests for advice by CBSA regarding CPs safety and procedures ▶ Number and nature of “customs look-outs” for CPs ▶ Proportion of issues/incidents assessed that result in a risk response within standards/targets (imported products) ▶ Proportion of issues identified at the point of import versus the proportion of issues identified post-import 	Document/administrative data review
	<p>Indicator related to FCSAP Strategy #8: Increased Product-Related Injury Surveillance & Risk Assessment (PHAC)</p> <ul style="list-style-type: none"> ▶ Proportion of issues/incidents assessed ▶ Proportion of issues/incidents assessed that result in a risk response within service standards/targets 	Document/administrative data review
	<p>Indicators related to FCSAP Strategy #9: New Canada Consumer Products Safety Act (HECS)</p> <ul style="list-style-type: none"> ▶ Proportion complete against plans to have CCPSA brought into force ▶ Proportion complete against plans to have new regulations brought into force ▶ Proportion complete against plans to have existing regulations revised and updated ▶ Proportion of issues relating to unsafe CPs addressed by legislation/regulations 	Document/administrative data review: <ul style="list-style-type: none"> - Legislative/regulatory affairs work plan - Legislative/regulatory agenda (listed by priority and completeness) - CCPSA working documents

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<p>Indicators related to FCSAP Strategy #10: Monitoring and Enforcing Radiation Emitting Devices Act (HECS)</p> <ul style="list-style-type: none"> ▶ Percentage of policy work completed to support REDA modernization ▶ Proportion complete against plans to have revised REDA brought into force ▶ Number of regulatory tools developed to facilitate the administration of the REDA and REDA regulations ▶ Proportion of compliance and enforcement activities completed as defined by cyclical enforcement plan ▶ Proportion of issues relating to unsafe CPs addressed by legislation/regulations 	<p>Document/administrative data review:</p> <ul style="list-style-type: none"> - REDA modernization documents, options papers - policies, guidelines, regulations
	<p>Indicators related to FCSAP Strategy #12: Monitor and Enforce Industry Compliance – Consumer Pesticides (PMRA)</p> <ul style="list-style-type: none"> ▶ Number of monitoring reports ▶ Number and proportion of targeted inspections on products/industries/sector of high-risk to health ▶ Number of follow-up inspections ▶ Number and/or proportion of pest management products monitored 	<p>Document/administrative data review</p>
	<ul style="list-style-type: none"> ▶ Elapsed time between initial identification of risk and policy/regulatory response 	<p>Document review (if information available) Key informant interviews (internal)</p>
	<ul style="list-style-type: none"> ▶ Percentage change in number of adverse incidents responded to in a timely fashion ▶ Timeliness of adverse event analysis 	<p>Document/administrative data review</p> <ul style="list-style-type: none"> - CCMS/PSIS data - PMRA databases (as available) <p>Key informant interviews (internal)</p>
	<ul style="list-style-type: none"> ▶ Trends in number and closure rate of CP incidents 	<p>Document/administrative data review</p> <ul style="list-style-type: none"> - CCMS/PSIS data - PMRA databases (as available)
	<ul style="list-style-type: none"> ▶ Internal and external stakeholder perceptions of timeliness of Health Canada’s response to identified risks associated with CPs 	<p>Key informant interviews (external and internal) Case studies Survey of industry/consumers (potential)</p>
<p>i) To what extent is Canada’s regulatory framework for CPs harmonized with international approaches?</p>	<ul style="list-style-type: none"> ▶ Extent to which main features of Canada’s regulatory framework for CPs is harmonized with that of other jurisdictions 	<p>Literature review:</p> <ul style="list-style-type: none"> - comparison of main features of Canada’s regulatory framework with that of selected other jurisdictions (EU, US, Australia, UK) <p>Key informant interviews (internal and external) Case studies</p>
	<ul style="list-style-type: none"> ▶ Description of program’s decision-making process regarding harmonization (especially factors considered in decision whether to harmonize) 	<p>Key informant interviews (internal)</p>

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<ul style="list-style-type: none"> ▶ Extent to which Health Canada is recognized as a responsible CP regulator and scientific expert (nationally and internationally) 	Document review Literature review Key informant interviews (external)
	<ul style="list-style-type: none"> ▶ Percentage change in the number of requests for implementation of a similar safety system internationally 	Document review Key informant interviews (internal)
	<p>Indicator related to FCSAP Strategy #3: Standards Development and Adoption (HECS)</p> <ul style="list-style-type: none"> ▶ Number of external standards committees and boards with active participation from CPSD and ERHSD ▶ Proportion complete standards against plans that align with international standards 	Document/administrative data review
	<p>Indicators related to FCSAP Strategy #7: International Collaboration (HECS)</p> <ul style="list-style-type: none"> ▶ Number of MOUs and agreements with producers/receivers completed against plan ▶ Proportion MOUs with the EU, China, Mexico, and India completed against plan ▶ Number and nature of activities with other international regulators (e.g., working groups, conference presentations, workshops) ▶ Proportion of imported products covered by international agreements in quality ▶ Number and nature of joint recalls in partnership with other international jurisdictions 	Document/administrative data review - MOUs, other agreements Key informant interviews (internal)
j) To what extent is there reduced exposure to identified risks associated with the use of CPs?	<ul style="list-style-type: none"> ▶ Number and nature of risk communications issued by Health Canada due to identified risks 	Document review: - Health Canada risk communications (e.g., Cosmetic Ingredient Hotlist)
	<ul style="list-style-type: none"> ▶ Trends in post-market enforcement actions due to identified risks for CPs 	Document/administrative data review: - CCMS/PSIS data
	<ul style="list-style-type: none"> ▶ Trends in ratio of number of serious problem reports to total number of problem reports 	Document/administrative data review - CCMS/PSIS data
	<ul style="list-style-type: none"> ▶ Expert assessment of changes in exposure to health risks related to CPs 	Literature review Key informant interviews (internal and external)

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
	<p>Indicators related to FCSAP Strategy #8: Increased Product-Related Injury Surveillance & Risk Assessment (PHAC)</p> <ul style="list-style-type: none"> ▶ Number and type of databases created/improved against plan <ul style="list-style-type: none"> - Number of enhancements to CP-related information contained in the narratives of CHIRPP ▶ Number of cases of product-related injuries <ul style="list-style-type: none"> - Proportion of CP-related cases captured in the CHIRPP database by target age groups - Percentage of CP-related deaths reported to CCMED ▶ Risk assessment of consumer related-injuries <ul style="list-style-type: none"> - Number/assessment of enhanced studies on CP-related injuries ▶ Number of collaborations with key stakeholders on CP-related injuries <ul style="list-style-type: none"> - Number and type of data/reports produced collaboratively with key stakeholders on CP-related injuries - Number and type of data/reports from key stakeholders 	<p>Document/administrative data review</p> <ul style="list-style-type: none"> - CHIRPP databases - Research reports/publications <p>Key informant interviews (internal and external)</p>
Long-term outcomes		
<p>k) To what extent have adverse events associated with the use of CPs been reduced?</p>	<ul style="list-style-type: none"> ▶ Percentage change in the number of adverse event reports related to safety and effectiveness of CPs ▶ Removal of unsafe CPs from the market place 	<p>Document/administrative data review</p> <ul style="list-style-type: none"> - CCMS/PSIS data - PMRA databases (if available) <p>Key informant interviews (internal)</p>
	<ul style="list-style-type: none"> ▶ Trends in CP-related illnesses and adverse events 	<p>Document/administrative data review (if available)</p> <p>Literature review</p>
	<p>Indicators related to all FCSAP Strategies (HECS/PMRA/PHAC):</p> <ul style="list-style-type: none"> ▶ Number and characteristics (type, severity, age, gender, etc.) of incidents related to product safety issues ▶ Number of incidents reported due to product issues 	<p>Document/administrative data review (if available)</p> <ul style="list-style-type: none"> - CCMS/PSIS data - PMRA databases (if available) - CHIRPP databases - Research reports/publications
<p>l) To what extent is there increased public confidence in CPs and the related regulatory system?</p>	<ul style="list-style-type: none"> ▶ Level of public confidence in safety of CPs and the related regulatory system 	<p>Document review:</p> <ul style="list-style-type: none"> - Public opinion research reports (if available) - Health Canada DPRs <p>Key informant interviews (external)</p>
	<ul style="list-style-type: none"> ▶ Percentage change in the number of reviews (positive/negative) by media outlets ▶ Percentage change in the number of positive feedback from public surveys/interviews 	<p>Document review</p>

EVALUATION OF CONSUMER PRODUCTS (CP) ACTIVITIES – EVALUATION MATRIX

Evaluation issues and questions	Indicators	Data sources ⁸⁵
m) To what extent is there a sustainable, cost-efficient, responsive, and science-based regulatory system for CPs in Canada?	▶ Cumulative evidence from all outcome indicators	All data sources
8. Were there any unintended consequences, either positive or negative, of CP activities?	▶ Unintended consequences identified by internal and external stakeholders	Key informant interviews/consultations(internal and external) Case studies Survey of industry/consumers (potential)
Issue #5: Efficiency and Economy		
9. Were resources for CP activities used as planned? What accounted for overruns or lower-than-planned expenditures?	▶ Comparison of planned versus actual spending for components of CP activities and explanations for variances	Administrative data review, e.g.: - planned versus actual spending, SAP data, financial derivation reports, management variance reports (if available) Key informant interviews (internal)
10. Are there lower-cost approaches to producing CP activity-related outputs?	▶ Extent to which existing resources could be used to produce outputs at lower cost ▶ Availability/accessibility of other, lower cost resources to produce outputs	Document review Key informant interviews (internal)
11. Are there alternate ways to achieve similar results at lower cost?	▶ Approaches used in other jurisdictions and their costs ▶ Internal and external stakeholder assessment of other options	Literature review Key informant interviews (internal and external) Case studies