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

Evaluation of Phase II of the Chemicals Management Plan 2011-2012 to 2015-2016

Final Report

Prepared by
Office of Evaluation
Health Canada and the Public Health Agency of Canada

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List of Acronyms

ADM	Assistant Deputy Minister
BDE	Brominated diphenyl ethers
BPA	Bisphenol A
BGTD	Biologics and Genetic Therapies Directorate
AFN	Assembly of First Nations
AICS	Australian Inventory of Chemical Substances
CALM	Chemicals Awareness Learning Modules
CAS	Chemical Abstract Services
CCPSA	*Canada Consumer Product Safety Act*
CDW	Committee on Drinking Water
CE	Cyclical enforcement
CELA	Canadian Environmental Law Association
CEP	Cyclical Enforcement Plan
CEPA	*Canadian Environmental Protection Act*
CEPA 1999	*Canadian Environmental Protection Act, 1999*
CHMS	Canadian Health Measures Survey
CICA	*Chemicals in Commerce Act*
CMD	Chemicals Management Division
CMEC	Chemicals Management Executive Committee
CMP	Chemicals Management Plan
CMR	Carcinogenic, mutagenic, or toxic for reproduction
CNHEE	Canadian Network for Human Health and the Environment
COSM	Consultations on Substance Management
CPB	Chemicals Policy Bureau
CPSD	Consumer Product Safety Directorate
CSB	Corporate Services Branch
CSD	Chemicals Sector Directorate
DfE	Design for the Environment
DG	Director General
DRAP	Deficit Reduction Action Plan
dSAR	draft Screening Assessment Report
DSL	Domestic Substances List
EAD	Ecological Assessment Division
EB	Enforcement Branch
ECHA	European Chemicals Agency
ENGO	Environmental non-government organizations
EPA	Environmental Performance Agreements
EPOD	Environmental Protection Operations Directorate
ERHSD	Environmental Radiation and Health Sciences Directorate
ESB	Environmental Stewardship Branch
ESD	Enforcement Services Directorate
ESRAB	Existing Substances Risk Assessment Bureau
EHSRB	Environmental Health Science and Research Bureau
ETD	Energy and Transportation Directorate
EU	European Union
FCSAP	Food and Consumer Safety Action Plan
FD	Food Directorate
FDA	*Food and Drugs Act*

FDWQ	Federal Drinking Water Quality
FNEHIN	First Nations Environmental Health Innovation Network
FPT	Federal/provincial/territorial
fSAR	final Screening Assessment Report
FTE	Full-time equivalent
GLB	Great Lakes Basin
GoC	Government of Canada
HC	Health Canada
HCFC	Hydrochlorofluorocarbons
HECSB	Healthy Environments and Consumer Safety Branch
HPA	*Hazardous Products Act*
HPFB	Health Products and Food Branch
HVC	Hexavalent chromium
ICL	In Commerce List
IMAP	Inventory Multi-tiered Assessment and Prioritisation
ITK	Inuit Tapiriit Kanatami
ISD	Industrial Sectors Directorate
LRAD	Legislative and Regulatory Affairs Directorate
MDI/MDA	Methylenediphenyl diisocyanates and diamines
MIREC	Maternal-Infant Research on Environmental Chemicals
MOU	Memorandum of Understanding
MSF	Monitoring and Surveillance Fund
NAPS	National Air Pollution Surveillance
NBLA	New Brunswick Lung Association
NBP	Northern Biomonitoring Program
NCP	Northern Contaminants Program
NEP	National Enforcement Plan
NGO	Non-governmental organization
NNHPD	Natural and Non-Prescription Health Products Directorate
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NPRI	National Pollutant Release Inventory
NRI	Non-Regulatory Initiative
NSACB	New Substances Assessment and Control Bureau
NSERC	Natural Sciences and Engineering Research Council
NSNR	*New Substances Notification Regulations*
OAG	Office of the Auditor General
OECD	Organisation for Economic Co-operation and Development
OGAED	Oil, Gas and Alternative Energy Division
OHS	Occupational health and safety
OSRM	Office of Science and Risk Management
PAA	Program Alignment Architecture
PAAB	Portfolio Audit and Accountability Bureau
PBDE	Polybrominated diphenyl ethers
PBT	Persistent, bioaccumulative and toxic
PCB	Polychlorinated biphenyl
PCDD	Polychlorinated dibenzo dioxins
PCDF	Polychlorinated dibenzo furans
PCPA	*Pest Control Products Act*
PCRAD	Policy, Communications and Regulatory Affairs Directorate
PERC	Tetrachloroethylene
PFCA	Perfluorinated Carboxylic Acids

PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonate
PHAC	Public Health Agency of Canada
PMF	Performance measurement framework
PMRA	Pest Management Regulatory Agency
POR	Public opinion research
PPA	*Pollution Prevention Act*
PPCP	Pharmaceuticals and Personal Care Products
PPIAD	Policy, Planning and International Affairs Directorate
PPID	Policy, Planning, and Integration Directorate
PRSD	Public and Resources Sectors Directorate
PSL	Priority Substances List
PSSA	Petroleum Sector Stream Approach
RAB	Risk Assessment Bureau
RAPB	Regions and Programs Bureau
RCC	Regulatory Cooperation Council
RCEN	Canadian Environmental Network
RCF	Refractory ceramic fibre
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
RFP	Request for Proposal
RIMS	Regulatory Innovation and Management Systems
RM	Risk Management
RMB	Risk Management Bureau
RMO	Risk management objective
RPP	Report on Plans and Priorities
SAC	Stakeholder Advisory Council
SAICM	Strategic Approach to International Chemicals Management
SED	Safe Environments Directorate
SME	Small and medium enterprises
SNAc	Significant New Activity
STB	Science and Technology Branch
SRAD	Science and Risk Assessment Directorate
SVHC	Substance of Very High Concern
TB	Treasury Board
TDI	Toluene Diisocyanate
TDS	Total Diet Study
TOR	Terms of Reference
TPP	Travelling Public Program
TSCA	*Toxic Substances Control Act*
UNEP	United Nations Environment Programme
US EPA	US Environmental Protection Agency
VOC	Volatile organic compound
VDD	Veterinary Drugs Directorate
WHO	World Health Organization
WPMN	Working Party on Manufactured Nanomaterials

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Executive summary

Evaluation purpose

The purpose of the evaluation was to assess the relevance and performance of Phase II of the Chemicals Management Plan (CMP2). Phase I of CMP (CMP1) covered the period from its launch in December 2006 to 2011, while CMP2 covers the period from 2011-2012 to 2015-2016. The evaluation covered an abbreviated portion (2011 to 2014) of CMP2, and was conducted prior to the end of CMP2, in order to inform the early funding renewal process.

The evaluation fulfills the requirement of the *Financial Administration Act* and the Treasury Board of Canada's *Policy on Evaluation* (2009), as per Health Canada's Five-Year Departmental Evaluation Plan.

Evaluation scope and design

The evaluation assessed the relevance and performance (effectiveness, economy, and efficiency) of CMP2, and covered direct program spending and grants and contributions. Evaluation findings will support decision making for policy and program improvements.

The methodologies used in the evaluation included an extensive document and administrative data review, literature review, key informant interviews with program representatives and external stakeholders (n=88), a web-based survey of industry stakeholders (n=260), and an in-depth case study examining Canada's approach to risk management for bisphenol A (BPA). Limitations of the evaluation were mitigated with various lines of evidence and the triangulation of data collected through various sources.

Program description

The Chemicals Management Plan (CMP) is a jointly-managed initiative between Health Canada and Environment Canada with the broad goal of protecting human health and the environment from harmful toxic substances through an integrated, whole-of-government approach to chemicals management. The CMP brings together various federal chemicals programs under a single strategy aimed at assessing and managing environmental and human health risks posed by chemical substances and ensuring toxic substances are managed according to the risks they present.

Key program activities include risk assessment, risk management, research, monitoring and surveillance, compliance promotion and enforcement, and stakeholder engagement and risk communication. Through the CMP, the federal government aims to assess approximately 4,300 priority existing substances by the year 2020, and undertake risk management actions for substances deemed toxic under s. 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), using appropriate combinations of CEPA 1999, the *Pest Control Products Act* (PCPA), the *Food and Drugs Act* (FDA), the *Canada Consumer Product Safety Act* (CCPSA), and other federal Acts (e.g., the *Fisheries Act*).

Evaluation key findings, conclusions, and recommendations

KEY FINDINGS — RELEVANCE

Continued need for the program

The chemicals used in industrial processes and in a wide range of products contribute significantly to the health and the economic and social well-being of Canadians. However, exposure to certain chemicals may contribute to or cause adverse health effects in humans or harm to the environment. There is a demonstrated ongoing need for the CMP to manage the risks to human health and the environment associated with some chemical substances, and to meet the Government of Canada's commitment to assess the approximately 4,300 priority existing substances by 2020.

Alignment with government priorities and federal roles and responsibilities

The CMP is aligned with the priorities of the federal government, and with the strategic outcomes of Health Canada and Environment Canada. The CMP2 activities of both departments are consistent with federal roles and responsibilities.

KEY FINDINGS — PERFORMANCE

Implementation

The implementation of the whole-of-government approach to chemicals management was further advanced by CMP partners during CMP2 through the implementation of planned activities in all of the CMP functional activity areas. Approaches and methods used to implement the CMP are generally working as intended, and the Program has addressed numerous challenges and complex, emerging issues.

- Program partners completed the major planned information-gathering initiatives, including Phase II of the Domestic Substances Inventory Update and information-gathering for the Substance Groupings Initiative. The information gathered is instrumental in informing risk assessment, risk management, and other program activities. There is a consensus that more flexible approaches to information-gathering and early engagement with industry have resulted in enhanced quality of the information gathered.
- Program partners continued to make progress toward assessing the approximately 4,300 existing substances prioritized through categorization. To date, the CMP has assessed approximately 60% of priority existing substances, although the Petroleum Sector Stream Approach, which includes high-priority substances, has experienced notable delays. In addition, the program was able to consistently manage the assessment of new substances. Approximately 400 to 500 new substance assessments have been completed per year, consistent with targets, and progress has been made toward fulfilling commitments relating to FDA substances and pesticides. The 2011 evaluation of CMP1 identified a need to clarify the program's role with respect to occupational exposure to chemical substances. The evidence

from this evaluation indicates that this is an area of ongoing concern for some stakeholders, suggesting that the issue should be thoroughly examined in a future evaluation of the CMP.

- Risk management measures were actively developed and implemented for substances deemed CEPA-toxic as a result of risk assessment. To date, risk management measures have been approximately equally split between regulatory and non-regulatory measures. Some stakeholders are concerned about the effectiveness of non-regulatory measures at achieving risk management objectives. Although program partners are currently monitoring the performance of some non-regulatory measures on a risk basis, evidence of the effectiveness of such approaches is limited at this time.
- Research activities were strengthened through improved research governance and better alignment of research projects with the needs of regulators, and within Health Canada, increased scientific support and improved laboratory infrastructure. A variety of monitoring and surveillance projects, including human biomonitoring, environmental monitoring, and monitoring of chemical substances in food, were undertaken or are ongoing. Results have been shared internally and externally.
- Steps were taken to improve the coordination and planning of compliance promotion and enforcement activities, as well as the ability to track, analyze, and report on these activities. Current reporting encompasses CEPA risk management measures that predate the CMP, and although CMP funding supports enforcement of risk management measures for all CEPA-toxic substances, greater specificity in compliance reporting is warranted, in the interests of accountability.
- Program partners continued to emphasize stakeholder engagement during CMP2, and while industry stakeholders are generally satisfied with the engagement efforts, non-industry groups expressed some concerns. Program partners also took steps to improve communications to Canadians about the risks and safe use of substances of concern, but as in 2011, communications to Canadians continues to be perceived as a weakness of the program.

Achievement of outcomes

Canada has been internationally recognized as a leader in risk assessment and risk management of chemical substances. As of September 30, 2014, the CMP had assessed approximately 60% of priority substances. In addition, there is evidence of ongoing progress in a number of complex areas. In other areas there are limited data to draw conclusions on the extent to which some CMP outcomes have been achieved.

- **Use of information by program partners.** Information and data are being used by program partners to inform CMP activities and decisions. Priorities for research, monitoring, and surveillance are developed through a consultative approach to ensure alignment with the needs of the regulatory partners, and findings are used to inform risk assessments, risk management, and other program activities. Improvements to information systems are expected to further facilitate program access to and use of information.

- **Canadians' understanding and use of information**. Because the CMP does not actively collect data on Canadians' understanding and use of information on the risks and safe use of substances of concern, it is not possible to draw conclusions on the extent to which this outcome may have been achieved.
- **Industry understanding and compliance**. The available data show a reasonably high overall rate of compliance among inspected entities, although these rates cannot be extrapolated to the regulated industries in general.
- **Risks/threats to human health and the environment**. Trends for environmental and/or human exposure data for some core CMP risk-managed substances are beginning to emerge, and may be more firmly established through monitoring over a longer term.

Unintended consequences arising from the CMP have been mainly positive. Of note are: the international recognition of Canada as a leader in risk assessment and risk management of chemical substances; the development of positive relationships with industry, which has had beneficial impacts beyond the CMP; and the positive impacts on industry awareness, processes, and decisions.

Demonstration of efficiency and economy

The CMP is making progress towards its commitments and has made operational improvements to enhance efficiencies.

The horizontal governance structure and collaborative approach of the CMP has improved mutual understanding among program partners and reduced the siloed approach to chemicals management that was being taken in the past. CMP governance is generally seen as effective; however, it could be further strengthened by clarifying roles and responsibilities of various program partners to ensure relevant partner engagement, and by exploring opportunities for a more streamlined decision-making and approval process for substances deemed toxic to only human health or the environment.

CMP partners have taken steps to address recommendations and suggestions for improvement from the 2011 evaluation relating to performance measurement and financial reporting. There are opportunities to better meet accountability requirements by reviewing the logic model, clarifying and streamlining the expected outcomes, collecting data for all expected outcomes, and where feasible, identifying CMP-specific substances.

Overall, CMP2 funding levels have been adequate and appropriate, and measures have been introduced in all functional areas to increase efficiencies. It is unknown how, or if, anticipated data challenges for CMP3 substances will affect the complexity and cost of assessments. Due to Canada's leadership role and significant differences in regulatory frameworks and the scope of chemicals management programs across jurisdictions, the evaluation did not identify any clear alternative approaches that would result in similar outcomes at a lower cost.

CONCLUSIONS

There is a demonstrated ongoing need for the CMP to manage the risks to human health and the environment associated with some chemical substances, and to meet the Government of Canada's commitment to assess the approximately 4,300 priority existing substances by 2020. The CMP is aligned with federal priorities, the strategic outcomes of Health Canada and Environment Canada, and federal roles and responsibilities.

Progress has been made in all of the CMP functional activity areas. To date, the CMP has assessed approximately 60% of the 4,300 priority existing substances, although there have been notable delays in assessing high priority petroleum substances, which should be addressed in CMP2. The CMP is using a variety of measured risk management approaches. Given the CMP's increasing use of non-regulatory measures to manage the risks associated with toxic substances and stakeholder concerns about the effectiveness of such measures, assessment of the effectiveness of non-regulatory measures could be incorporated into the CMP's risk management review process.

Similarly, given ongoing perceptions that communication to Canadians about the risks and safe use of substances of concern is a weakness of the program, there are opportunities to develop a better understanding of the information that Canadians believe they need, and improve outreach and communications as necessary.

The CMP governance structure is generally seen as effective. The structure could be further strengthened by clarifying roles and responsibilities of various program partners to ensure relevant partner engagement, and by exploring opportunities for a more streamlined decision-making and approval process for substances deemed toxic to only human health or the environment. There are also opportunities to strengthen performance measurement in order to better meet accountability requirements.

RECOMMENDATIONS

Recommendation 1

The horizontal governance structure and collaborative approach of the CMP has improved mutual understanding among program partners and reduced the siloed approach to chemicals management that was being taken in the past. Although the CMP governance structure is generally seen as effective, roles and responsibilities could be clarified, particularly with respect to the oversight of compliance and enforcement activities. In addition, the decision making and approval process could be streamlined in order to help address concerns from program partners, who perceive it as being overly complex and resource-intensive, in particular with respect to the processes related to approvals for substances that are only health-toxic or only environment-toxic.

CMP partners should clarify roles and responsibilities of various program partners to ensure relevant partner engagement, as well as explore opportunities for a more streamlined decision-making and approval process for substances that are toxic to only human health or the environment.

Recommendation 2

To date, the CMP has assessed approximately 60% of priority existing substances, although the Petroleum Sector Stream Approach has experienced notable delays. Assessments for just over half of the Petroleum Sector Stream Approach substances had been completed as of September 30, 2014, leaving the remaining 48% to be completed by the end of 2015–16 in order to meet CMP2 commitments for this substance group.

CMP partners should take necessary steps to address CMP commitments related to the Petroleum Sector Stream Approach substances, and initiate risk management as required.

Recommendation 3

Although CMP partners have taken steps to address recommendations and suggestions for improvement from the 2011 evaluation relating to performance measurement reporting, there are still opportunities for improvements in this area. CMP partners could better meet accountability requirements by reviewing the logic model, and by clarifying and streamlining the expected outcomes, particularly those relating to industry compliance and to the reduction of risks/threats associated with chemical substances. In addition, the program should collect data for all expected outcomes, and identify CMP-specific substances as part of reporting, where possible.

CMP partners should strengthen performance reporting by reviewing the logic model, streamlining the expected outcomes, collecting data for all expected outcomes, and where feasible, identifying CMP-specific substances.

Recommendation 4

While CMP partners are monitoring the performance of some non-regulatory measures (in particular Pollution Prevention Planning Notices and Environmental Performance Agreements), evidence regarding the effectiveness of these and other non-regulatory approaches at achieving risk management objectives is minimal at the present time. Also, some external stakeholders were concerned that non-regulatory measures may not be as effective as regulations. As a result, assessment of the effectiveness of non-regulatory measures could help improve the CMP's risk management review process.

Building on previous work, CMP partners should continue to intensify efforts in relation to reviews of the effectiveness of implemented risk management measures, in particular, non-regulatory measures, as part of the risk management review process, and communicate the results to stakeholders and the public.

Recommendation 5

There are opportunities to improve the program's understanding of the information that Canadians believe they need in order to improve outreach and communications. There are ongoing concerns by stakeholders that communication to Canadians about the risks and safe use of substances is a weakness of the program.

CMP partners should develop a better understanding of the information needs of Canadians with respect to the risks and safe use of substances of concern and enhance outreach and communications as necessary.

Management Response and Action Plan

Phase II of the Chemicals Management Plan

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
1. Chemicals Management Plan (CMP) partners should clarify roles and responsibilities of various program partners to ensure relevant partner engagement, as well as explore opportunities for a more streamlined decision- making and approval process for substances that are toxic to only human health or the environment.	The program accepts this recommendation. Action will be taken to examine the existing governance framework that supports the delivery of the CMP, in two areas: 1) a risk-based review of opportunities for streamlining of processes for substances that are toxic to only human health or the environment, and 2) more generally, CMP program areas will look for opportunities to improve and streamline the decision-making, approvals process and partner involvement in time for the third phase of the CMP.	While respecting the legislative requirements of CEPA, the program will work with the Department of Justice and implicated program partners to undertake a risk-based review of roles and responsibilities and opportunities for administrative options to streamline processes for substances that are toxic to only human health or the environment. The program will launch a review exercise led by an independent third- party to identify areas where priority- setting, decision-making and approvals can be improved. Particular attention will be paid to considering the need for increasing need for involvement of compliance and enforcement as the program evolves. The program collected data on existing formal and informal working groups and committees that support CMP implementation to as background information for a contract to: . validate whether the current framework design is achieving its intended results . analyze the existing structure with regard to the effectiveness and efficiency of decision-making process and consistent application of program policies . determine if decision-making processes and pathways currently supporting CMP are managed well; and . provide recommendations for enhancing operational effectiveness of the Framework	1a Establish HC-EC decision- making framework for substances that are toxic only to human health or the environment in order to allow for effective and efficient delivery of CMP3 commitments. 1b Report on options for streamlining prepared for ADM consideration 1c Implementation of initial changes 2a Data collection on formal and informal committees and seek program partners input on existing TORs for the CMP Committees to update as required 2b Presentation to CEPA DGs on results of pilot use of LEAN approach to develop improved process for approvals of risk assessments originally scheduled for publication in March 2016 2c Presentation to CMP ADMs on draft recommendation on priorities for streamlining (processes and governance structure), including list of processes to be subject to LEAN approach review before the end of FY 2015-16	November 15, 2015 January 15, 2016 March 31, 2016 June 30, 2015 September 15, 2015 By November 30, 2015	1) Accountability: DGs EC LRAD, SRAD, CSD and HC SED Support: All program partners, Department of Justice 2) Overall Accountability: CMEC Responsibility: DG SED as focal point for program management HC CMP: DG SED (ESRAB) Support: All program partners, Department of Justice as required	0.25 FTE each, with review by program partners, from existing resources 0.5FTE HC SED and 0.2FTE EC SRAD and CSD from existing resources to manage RFPs and LEAN events Contribution by all partners from existing resources as required

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
		To support this work, a pilot project to develop capacity in LEAN approaches will be undertaken as an initial step.	2d Implementation of initial changes	March 31, 2016		
2. CMP partners should take necessary steps to address CMP commitments related to the Petroleum Sector Stream Approach	The program accepts this recommendation.	The program will take necessary steps to address CMP commitments related to the Petroleum Sector Stream Approach substances, and initiate risk management as required.	Present work plan and related considerations to CEPA DGs to address substances in the Petroleum Sector Stream Approach and initiate risk management to address risks which have already been identified Completion of 70% of PSSA1 assessments to draft stage Completion of remaining PSSA assessments to final stage.	June 30, 2015 March 31, 2016 March 31, 2020	Accountability: HC DG SED and EC DGs SRAD and ETD 3) Responsibility: HC ESRAB, EC CSD, OGAED and SRAD	No incremental resources as this work was already part of CMP workplan.
3. CMP partners should strengthen performance reporting by reviewing the logic model, streamlining the expected outcomes, collecting data for all expected outcomes, and where feasible, identifying CMP-specific substances.	The program accepts this recommendation. Action is being taken to examine the logic model and performance measurement framework leading up to CMP3 implementation.	Recommendations from this evaluation will be incorporated into a revised performance measurement framework, with a goal of stabilizing the framework to allow for identification of trends over time. Efforts will be made to identify substances assessed and managed since 2006, recognizing that the program extends beyond the work on 4,300 existing substances.	Presentation to CMEC of recommendations from a review of the performance measurement framework to identify areas for improvement Presentation to CMEC of recommendations from validation of logic model longer-term outcomes, baseline and performance indicators taking into account international best practices	October 31, 2015 October 31, 2016	Overall Accountability: CMEC Responsibility: Program Management Steering Committee Overall Support: All program partners	No incremental resources as this work was already part of CMP workplan. However, it could be determined through the review of the performance measurement framework that additional resources would be required to increase monitoring or other data collection activities to support improved indicators.

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
		Several pilot projects for measuring performance of risk management action for substances assessed under the CMP are under development at this time and expected to be completed by 2020. The work on performance measurement will account for the technical and scientific challenges in developing indicators for outcomes and, in particular, in attributing causality.	Revised performance measurement framework approved by CMEC and ADMs Data collection using new PMF to support CMP3 evaluation	December 31, 2016 June 30, 2017		
4. Building on previous work, CMP partners should continue to intensify efforts in relation to reviews of the effectiveness of implemented risk management measures, in particular, non-regulatory measures, as part of	The program accepts this recommendation.	Action will take two forms: 1) improving communications on the use and effectiveness of risk management measures, both regulatory and non-regulatory. Work to understand the information needs of Canadians as per recommendation 5 will be used to address this aspect of the recommendation. 2) the program will continue to refine existing tools to monitor the effectiveness of risk management measures such as substance-based performance measurement and monitoring of environmental performance agreements and Pollution Prevention Plans. This is also a link to recommendation 3, which will consider performance measurement of the program as a whole.	1) Compile an illustrative list of types of risk management measures in use and examples of how they have been used and examine options for communicating this information to stakeholders (e.g. CMP progress report, Chemical Substances website, etc.) As part of the recommendations to strengthen the performance measurement framework under recommendation 3, explore information sources which may be suitable to support indicators on program outcomes, both on compliance with risk management measures and on effectiveness of the measures themselves.	March 31, 2017 December 31, 2016	Responsibility: HC DG SED (RMB) and EC DG CSD Support: EC SRAD, Program Management Steering Committee and Program partners as appropriate	0.1 FTE for each SED and CSD Minimal incremental resources as this is a regular part of program delivery.

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
5. CMP partners should develop a better understanding of the information needs of Canadians with respect to the risks and safe use of substances of concern and enhance outreach and communications as necessary.	The program accepts this recommendation. Communicating to Canadians on complex scientific issues is a challenging, yet key function of the CMP. Program areas will explore opportunities to utilize evidence-based research to determine Canadians' current understanding and information needs with respect to the risks and safe use of substances of concern.	We will engage all CMP partners to leverage their communications efforts and expertise as well as engage our Stakeholder Advisory Council. This approach will enable the program to more effectively target resources to refine existing products and where needed to develop new tools to improve outreach. Communications of health-related risks of complex nature such as chemical risks are well known to be challenging. The program will inform itself via a literature review of best practices, including a review of the upcoming Canadian Council of Academies report on measuring the effectiveness of risk communications. The program is developing, with Communications, a behaviour research survey that will assess the information needs of Canadians with respect to chemicals and associated impacts on health and the environment. A companion pop-up survey on the web version of a few of our outreach products will also be launched in house this spring. Together, these surveys will better define the information needs of Canadians and inform development of future multi-media outreach projects.	Review logic model for clarification of this commitment with the view to identifying key information packages requiring communication to Canadians. 2) Collaborate with program partners to revise and update the Outreach and Communications Plan, if required based on CMP3 risk assessment and risk management plans	March 31, 2016 June 30, 2016	Responsibility: HC DG SED (RMB - except public summaries which is ESRAB lead) Support: SRAD, all program partners, HC and EC Communications and for measuring effectiveness the Performance Management Steering Committee	Minimal incremental resources as this is a regular part of program delivery.

1.0 Evaluation purpose and description

1.1 Evaluation purpose

The Chemicals Management Plan (CMP) is a jointly-managed initiative between Health Canada and Environment Canada with the broad goal of protecting human health and the environment from harmful toxic substances through an integrated, whole-of-government approach to chemicals management. The CMP brings together various federal chemicals programs under a single strategy aimed at assessing and managing environmental and human health risks posed by chemical substances[1] and ensuring toxic substances are managed according to the risks they present.

Phase I of CMP (CMP1) covered the period from its launch in December 2006 to 2011, while Phase II (CMP2) covers the period from 2011 to 2016. The evaluation of CMP2 covered an abbreviated portion (2011 to 2014) of CMP2. It used and built upon the previous evaluation of CMP1, which was completed in July 2011.

The evaluation of CMP2 was part of the Health Canada/Public Health Agency of Canada Five-Year Evaluation Plan. The evaluation took place between July 2014 and March 2015, in order to inform the early funding renewal process for CMP3.

The evaluation of CMP2 was conducted in accordance with the 2009 Treasury Board Policy on Evaluation and the *Financial Administration Act*, and covered both direct program spending and grants and contributions. The evaluation assessed the relevance and performance (effectiveness, efficiency, and economy) of CMP2, highlighted program achievements, and identified lessons learned and challenges. The results will be used by senior management within Health Canada and Environment Canada to guide decision-making on the CMP.

1.2 Evaluation description

The evaluation was led by the Office of Evaluation of Health Canada and the Public Health Agency of Canada, in cooperation with Environment Canada's Evaluation Division, and with support from an independent evaluation consulting firm. An evaluation matrix for CMP2 was developed to align with the Treasury Board Policy on Evaluation and to address key questions of interest to senior program management. Although the evaluation addressed all of the evaluation questions as required by the Treasury Board, it took a calibrated approach to addressing the questions. In particular, given that the questions related to relevance were thoroughly examined in the evaluation of CMP1, this evaluation updated the findings from that study rather than repeating that analysis. This allowed the evaluation to focus more intensively on the questions related to performance, including the outcomes achievement as well as a demonstration of efficiency and economy.

[1] Chemical substances are defined broadly by the initiative as any element or compound that is deliberately created, produced as a by-product of other processes, or occurs naturally in the environment (GoC, 2013b). CEPA 1999 defines a "substance" as any distinguishable kind of organic or inorganic matter, animate or inanimate, that can be released as a single substance, an effluent, waste, or a mixture into the Canadian environment.

1.2.1 Methods

The evaluation drew on multiple lines of evidence, including a literature review, a review of documents and administrative data, key informant interviews, a survey of industry, and a case study on bisphenol A (BPA).

Literature review. The literature review gathered information from peer-reviewed (scientific) journals and grey literature, such as industry journals, newspapers, magazines, and websites. The literature review addressed evaluation questions relating to relevance, efficiency, and economy, including possible alternatives.

Document and data review. The document/data review provided historical and contextual information for the CMP and responded directly to virtually all of the evaluation questions. Relevant documents and data were provided by the program (in some cases, in response to specific requests made through the evaluation process) and/or were accessed from publically available sources.

Key informant interviews. A total of 88 individuals were interviewed. Interviews were conducted with 53 program representatives from Health Canada and Environment Canada, as well as with 35 external key informants. External key informants represented industry, non-governmental organizations (NGOs), provincial/territorial governments, Aboriginal organizations, research and academia, and international regulatory agencies and organizations. They were selected for their knowledge of and experience with the CMP and/or issues related to chemicals management. The interviews were digitally recorded with the key informants' permission, and the notes were returned to them for review and approval.

Survey of industry. A bilingual web-based survey of industry stakeholders was conducted. Guidance and direction from Public Works and Government Services Canada on public opinion research and surveys limited the evaluation to surveying individuals who were known to have had contact with Health Canada or Environment Canada for reasons related to the CMP. Thus, the survey sample was provided by Environment Canada and consisted of 6,014 email addresses. After cleaning, the final valid sample was 5,595. The survey was launched on November 5, 2014 and closed on December 1, 2014. Three rounds of reminders were issued to increase the response rate. The survey achieved 260 completions, representing a completion rate of 4.6%.

Case study. One case study was completed, focussing on the Government of Canada's approach to BPA. The case study was intended to provide a concrete illustration of the overall CMP process for managing the risks associated with toxic substances, and to identify lessons learned as a result of that experience. Data collection methods included a review of documents and data; a comparison of Canada's approach to risk management of BPA with that of other jurisdictions; and 11 interviews with program representatives (n=8) and external key informants (n=3).

1.2.2 Limitations and mitigation strategies

Like all evaluations, this evaluation faced constraints that may have implications for the validity and reliability of evaluation findings and conclusions. A summary of these limitations, their impacts, and mitigation strategies is provided below. In all cases, the limitations associated with specific data collection methods were mitigated through triangulation, i.e., using the findings in conjunction with those from other lines of evidence.

Table 1: Limitations and mitigation strategies

Limitation	Impact	Mitigation strategy
Due to the program's approach to data tracking and reporting, the evaluation had challenges in obtaining a clear picture of the current status of program activities and establishing basic facts about the program. Examples include the total number of substances that have been assessed as of a given date, the number of risk management measures proposed and/or implemented, and the number of toxic substances covered by the risk management measures proposed and/or implemented, to name a few examples.	Data presented in this report may not be consistent with data reported by the program elsewhere.	None. The CMP has implemented improvements to information technology which are expected to facilitate information management and reporting in the future.
The survey sample consists of a small fraction of implicated industry stakeholders relative to the total population, and does not represent a random or representative draw from the total population. The survey achieved a relatively low response rate.	The survey results cannot be generalized to the larger population of CMP industry stakeholders.	Survey findings are used in conjunction with other lines of evidence. No conclusions are drawn solely on the basis of the survey results.
One case study was conducted of an "atypical" substance. The case study findings are not representative of all substances.	Case study findings cannot be interpreted as being relevant to all substances.	Case study findings are used in the report for illustration purposes only and in conjunction with other lines of evidence. No conclusions are drawn solely on the basis of the case study data.
Limited quantitative information to support analysis of efficiency and economy.	Quantitative analysis of efficiency and economy is limited primarily to comparing planned and actual spending.	Analysis supplemented by qualitative information from interviews and international comparisons.

2.0 Program description

2.1 Program context

During the mid-1980s, growing public concern over environmental contamination caused by toxic substances prompted the federal government to review its existing legislative authorities for dealing with toxic substances. The review found that provisions within the *Environmental Contaminants Act* were inadequate, and a more comprehensive approach was needed to manage the full life cycle of toxic substances (Environment Canada, 2009a). This led to the creation of the original *Canadian Environmental Protection Act* (CEPA), which came into force in 1988, replacing the *Environmental Contaminants Act* and incorporating various other existing environmental laws.

The CEPA 1988 introduced a requirement that all new substances undergo health and environmental risk assessments before being imported or manufactured in Canada. However, substances that were introduced into the Canadian market prior to 1988 were not subject to CEPA's new substances risk assessment requirements and were not specifically addressed prior to CEPA 1988. In 1995, a review of CEPA by the House of Commons Standing Committee on Environment and Sustainable Development recommended shifting CEPA from "pollution management" to "pollution prevention" (Environment Canada, 2009a). Subsequent to the review, the federal government proposed a system for categorizing and screening existing substances.

These proposed changes fed into the revised CEPA 1999 (Environment Canada, 2010), which set out more specific requirements for existing substances. The revised Act provided the government seven years to categorize the 23,000 existing chemical substances on the Domestic Substances List (DSL) based on specific criteria identified in the Act covering properties such as persistence, bioaccumulation, inherent toxicity, and greatest potential for exposure to humans (GoC, 2014a, sec. 73(1)(b)). First compiled in the early 1990s, the DSL is a list of approximately 23,000 substances that were used, imported, or manufactured in Canada for commercial purposes (GoC, 2013a, 2013b).[2]

The categorization process for existing substances was completed in September 2006, resulting in approximately 4,300 substances being identified as requiring further work. These substances were divided into priority levels, with about 500 substances being classified as high priority, about 2,600 being classified as medium priority, and about 1,200 classified as low priority (Health Canada, 2011). Shortly after, in December 2006, the government announced the creation of the CMP (GoC, 2006).

2.2 Program profile

The broad goal of the CMP is to protect human health and the environment from harmful substances through an integrated, whole-of-government approach to chemicals management. As one core component of the CMP, the federal government aims to assess the approximately 4,300 existing substances identified as priorities by the year 2020, and undertake appropriate risk management actions where applicable. The Government of Canada committed to address the 4,300 priority existing substances by 2020 at the 2002 World Summit for Sustainable Development.

A core element of the CMP is the application of an integrated approach to the selection and implementation of risk management measures using appropriate Acts, including CEPA 1999, the *Pest Control Products Act* (PCPA), the *Food and Drugs Act* (FDA), and the *Hazardous Products Act* (HPA), which was replaced by the *Canada Consumer Product Safety Act* (CCPSA) since its coming into force on June 20, 2011.

[2] More specifically, the DSL consists of chemicals introduced between January 1, 1984 and December 31, 1986 known as existing substances; any substances not on the DSL (except those with a certain flag) are considered new substances.

Under Phase I of the CMP (2006 to 2011), the following activities were carried out:

- Approximately 1,100 of the existing substances were assessed, and risk management actions were initiated, as required.
- More than 100 pesticide re-evaluations were completed.
- Approximately 450 new substance assessments were achieved per year.[3]
- Work was initiated to formalize the In Commerce List and criteria to prioritize the original 9,000 substances in FDA-regulated products that were in commerce between 1987 and 2011.
- Monitoring data was collected.
- Research, stakeholder engagement, and risk communications were conducted.
- New governance tools were developed.

In Phase II of the CMP (2011 to 2016), the primary emphasis has been on meeting the 2020 commitment for the assessment of the priority substances and risk management requirements for substances identified as harmful during CMP1. Some of the specific plans for Phase II include the following activities:[4]

- completing an inventory update of the DSL regarding the commercial use/status of in-commerce industrial substances and conducting surveys under CEPA 1999 requiring industry to provide data to support risk assessment and risk management
- assessing and, when required, developing proposed risk management actions for half of the remaining CMP priority existing substances
- implementing a cyclical approach to re-evaluating approximately 88 older active ingredients under the PCPA (including 28 active ingredients from Phase I of the CMP)
- initiating the prioritization and assessment of substances determined to be high priority on the In Commerce List (ICL)
- assessing 2,000 to 2,500 (~450/year) new substances, including chemicals, polymers, products of biotechnology and nanotechnology, and new substances in FDA-regulated products
- developing a regulatory framework for new substances in products regulated under the FDA
- researching and conducting stakeholder consultations on existing Non-Regulatory Initiatives (NRIs) to determine if and where new and/or improved NRIs could help reduce the release to the environment of substances and products regulated under the FDA
- developing national Guidelines for Canadian Drinking Water Quality for approximately 25 chemicals, microbiological substances, and radiological substances
- increasing the information made available to the public and stakeholders through outreach, consultation, engagement, and risk communications

[3] While new substance assessments were not specifically resourced under CMP1, this work was carried out during CMP1 and has been part of the CMP since 2011.

[4] This is not intended to be an exhaustive list of all CMP2 commitments.

- conducting necessary research, monitoring, and surveillance to support risk assessment and risk management actions
- completing the design phase of a one-time capital improvement for retrofitting Health Canada's environmental health laboratory infrastructure

2.2.1 Program activities

Official government and program documents describe the CMP as consisting of the following core functions or activity streams: risk assessment, risk management, compliance promotion and enforcement, research, monitoring and surveillance, stakeholder engagement and risk communications, and policy and program management. Although the monitoring and surveillance function includes information-gathering, information-gathering is described separately below, since it is frequently the first step in the overall regulatory process.

Information-gathering

CMP partners gather information from industry and/or other stakeholders using a variety of mechanisms. Regulations under the Act specify information to be provided before a substance is newly imported or manufactured in Canada. For existing substances, an important mechanism for information-gathering is Section 71 of CEPA 1999, which provides the Minister with the authority to publish notices in the *Canada Gazette* (and in any other manner) requiring anyone involved in activities described in the notice to notify the Minister of these activities and to submit information described in the notice, which could include monitoring data, toxicological data, or other relevant information (GoC, 2014a, sec. 71). Other mechanisms include requests to the industry to generate new data; targeted or directed requests for information; blind and joint submissions; voluntary questionnaires; and use of publicly available sources of information. Information-gathering is the first step in the risk assessment process. Data gathered from industry and other stakeholders is used to inform risk assessment, as well as risk management and other program activities.

Risk assessment

This activity refers to scientific assessments conducted to determine the potential environmental and health risks associated with chemical substances. The assessment provides the evidence needed to determine whether a substance is toxic according to CEPA 1999, and ultimately, whether risk management is required. According to section 64 of CEPA 1999:

> *…a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*
> *(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
> *(b) constitute or may constitute a danger to the environment on which life depends; or*
> *(c) constitute or may constitute a danger in Canada to human life or health.*

Assessments are conducted on existing substances and substances newly introduced into Canada. For existing substances, CEPA 1999 refers to these assessments as "screening assessments" and requires all existing substances prioritized through categorization to undergo such assessment. However, the Act does not define the term "screening assessment." In practice, the CMP uses a fit-for-purpose approach in which some assessments are streamlined while others are as comprehensive as those completed under the previous Priority Substances List (PSL) program. Program representatives noted that as the CMP was implemented, screening assessments were tailored depending on data availability and complexity (in terms of hazard and exposure) of the substance being assessed, as well as the level of evaluation required to produce a scientifically defensible decision.

CMP activities relating to information-gathering and risk assessment are organized into a number of initiatives. Some of the key initiatives include the Challenge to Industry, the Petroleum Sector Stream Approach (PSSA), the Domestic Substances List Inventory Update (DSL-IU), the Substance Groupings Initiative, and the rapid screening approach, among others. Descriptions of these and other CMP initiatives and terms can be found in Appendix 3.

Risk management

If a substance is determined through risk assessment to be harmful to human health or the environment as defined in CEPA 1999, measures can be put in place to prevent or manage the associated risks. Measures may be regulatory or non-regulatory and may include such controls as restrictions on use, how the substance is manufactured, and how much of the substance can be released into the environment. The type of measure is determined through relevant Acts, regulations, agreements, guidelines, and codes of practice.

Examples of regulatory control instruments include regulations that prohibit or set limits on the use, manufacture, import or sale of substances which may be released into the environment or limit exposure to humans; environmental emergency regulations that require industries to plan and be prepared for environmental emergencies, and/or help prevent emergencies from happening; and requirements that industries must notify the government in the event that there is a significant new use for a substance.

Examples of non-regulatory control instruments include pollution prevention notices that necessitate planning and actions by companies to reduce waste or pollution; Environmental Performance Agreements (EPA); codes of practice; national standards and guidelines; developing and updating best management practices; programs to ensure consumers have the option to return products for safe disposal; and promoting the use of safer substitutes instead of harmful chemicals.

Compliance promotion and enforcement

These are activities undertaken to help ensure businesses and other organizations are aware of, understand, and are in compliance with their obligations. This activity may also include enforcement actions taken in response to non-compliance. The CMP compliance promotion activities are delivered through site visits and delivery of workshops, information sessions,

presentations, and information packages, as well as through responses to individual inquiries. Compliance promotion also includes providing information on risk management tools and supporting industry stakeholders' roles in CMP initiatives. Enforcement activities include inspections, investigations, enforcement measures, and prosecutions under various Acts and regulations.

Research

Research is conducted on substances or groups of substances to investigate the toxicological mechanisms of substances, the means by which Canadians may be exposed to substances, and the means by which substances may be released into the environment. Findings from research projects are used to inform risk assessment and risk management decision-making and aid the development and validation of assessment models and tools.

Monitoring and surveillance

This includes a variety of environmental and human monitoring programs for the detection of substances in the air, water, indoor environments, humans, and other organisms, such as fish and birds. Food monitoring and surveillance activities are also conducted to ensure harmful levels of chemicals are not present in foods. Information is also collected through reporting requirements under CEPA 1999, voluntary industry reports, and international cooperation activities.

Stakeholder engagement and risk communications

CMP stakeholder engagement and risk communication activities target a variety of audiences: industry stakeholders; other stakeholders, such as environmental and health NGOs, Aboriginal organizations, academics, researchers, health professionals, early childhood educators, and federal/provincial/territorial (FPT) partners; and the general public, including vulnerable populations and Canadians. The goals of stakeholder engagement are to provide information to support involvement in program implementation and development, to ensure that CMP decision-making is informed by input from a broad range of expertise and viewpoints, to foster transparent and predictable decision-making and program activities, and to avoid duplicating work on chemicals management. The goals of the risk communication activities are to inform the public about the risks and safe use of substances of concern and the CMP, and to encourage the public to take action to protect their health.

Policy and program management

This activity oversees the effective delivery and performance measurement of the CMP. It is internal to government.

2.3 Program Narrative

CMP activities are intended to contribute to specific immediate, intermediate, and long-term outcomes.

Table 2: CMP expected outcomes

Immediate outcomes
• Knowledge, information, and data on substances of concern is used by Health Canada and Environment Canada recipients to inform risk assessment, risk management, risk communication and stakeholder engagement, research, and monitoring and surveillance activities. • Canadians and stakeholder groups understand information on the risks and safe use of substances of concern. • Targeted industry conforms to or complies with the requirements of risk management measures. • Targeted industry understands its obligations to take action to protect Canadians and the environment. • Targeted industry takes voluntary or enforced action to protect Canadians and the environment.
Intermediate outcomes
• Canadians use the information to avoid or minimize risks posed by substances of concern. • Risks associated with harmful substances in humans, the environment, food, and consumer products are prevented, minimized, or eliminated.
Final outcome
• Threats from harmful substances to health and the environment are reduced.

2.4 Program partners

Healthy Environments and Consumer Safety Branch (HECSB)

Within Health Canada, HECSB is the lead branch for the CMP initiative, and within HECSB, the Safe Environments Directorate (SED) is the lead CMP directorate. SED is responsible for collecting information on use patterns, conducting risk assessments, implementing risk management strategies when this is not the responsibility of other directorates, conducting scientific research, conducting monitoring and surveillance related to chemicals, and program management. A variety of bureaus within SED, including the Chemicals Policy Bureau (CPB), the Existing Substances Risk Assessment Bureau (ESRAB), the Risk Management Bureau (RMB), and the New Substances Assessment and Control Bureau (NSACB), carry out these responsibilities. In addition, RMB works with RAPB to deliver compliance promotion and outreach activities.

Also within HECSB, the Environmental Radiation and Health Sciences Directorate (ERHSD) is responsible for conducting scientific research to identify possible hazards or substances or groups of substances, the toxicological mechanisms of substances, and means by which Canadians may be exposed to substances; and for delivering the biomonitoring component of the CMP and providing overall coordination of the CMP monitoring and surveillance program. The Environmental Health Science and Research Bureau (EHSRB) and the Chemicals Surveillance Bureau are responsible for these research, monitoring, and surveillance activities.

Finally, the role of the Consumer Product Safety Directorate (CPSD) is to help protect the Canadian public (consumers) by addressing dangers to human health or safety that are posed by "consumer products," as defined under the CCPSA, as well as risks to human health or safety posed by cosmetics, which are regulated under the FDA. The main focus is on finished products, rather than a specific focus on only the substances used in the making of these products. In the context of the CMP, the CPSD has two key functions: risk assessment and risk management (including laboratory activities). CPSD is also involved in compliance promotion and enforcement, and works with RAPB to implement compliance activities.

Health Products and Food Branch (HPFB)

HPFB is the scientific and regulatory authority for health products and food. Within the Branch, CMP funding was received to conduct risk assessments, implement risk management strategies, conduct scientific research, conduct monitoring and surveillance, conduct stakeholder outreach, and for program management purposes.

Generally, CEPA 1999 requires notification and an assessment of risks to health and to the environment for substances new to Canada prior to their manufacture and importation into the country. Currently, new substances in FDA-regulated products undergo assessment (by the SED) as required by the *New Substances Notification Regulations* (NSNR) under CEPA 1999 for environmental and health risks due to environmental exposure. Within HPFB, the Policy, Planning, and International Affairs Directorate (PPIAD) is responsible for leading the development of a regulatory framework that is more appropriate for these substances, and is supported by SED and Environment Canada's STB in this activity. PPIAD is also mandated under the CMP with researching and conducting stakeholder consultations on existing NRIs and determining if the role that NRIs play in the management of FDA products, in particular their release to the environment, could be improved.

The Food Directorate (FD) received funds to perform risk assessments, risk management, research, monitoring and surveillance, and stakeholder engagement. As part of CMP2, the FD continued to conduct risk assessments and to develop and implement risk management measures to address risks posed by harmful chemicals in foods. The FD also committed to enhancing the Total Diet Study; performing targeted surveys of chemical substances in foods to fill identified CMP data gaps; conducting several research projects with respect to toxicological mechanisms of CMP substances in foods and nanomaterials with food implications; and engaging with stakeholders to keep them informed of CMP implications for the food industry as well as responding to public inquiries and media requests. Finally, the FD committed to continuing work related to the substances and products regulated under the FDA, including the re-evaluation of food additives and food packaging materials and the assessment of food contaminants as indicated by CMP screening assessments and new scientific knowledge.

Other HPFB directorates, including the Biologics and Genetic Therapies Directorate (BGTD), the Natural and Non-Prescription Health Products Directorate (NNHPD), and the Veterinary Drugs Directorate (VDD) received funds for risk management activities.

Regions and Programs Bureau (RAPB)

RAPB is an operational organization that manages the delivery of regulatory, scientific, and laboratory based programs and services across the country. Many of the regional programs are delivered in partnership with Health Canada's regulatory branches. The Bureau manages the food and drugs laboratories across the country, ensuring collaboration across business lines and providing broad-based analytical and scientific support to all regions, and to the department as a whole.

RAPB's work, as it relates to CMP2, involves compliance and enforcement related to consumer products and cosmetics. In addition, the Bureau delivers compliance promotion activities in conjunction with the Information Management Divisions of Health Canada and Environment Canada (the lead department). This includes responding to industry stakeholder inquiries about regulatory requirements mandated under CEPA 1999; ensuring stakeholder compliance by conducting analysis, review, and stakeholder follow-up for mandatory data submissions under the CMP; promoting CMP awareness and compliance through the direct engagement of regional stakeholders to increase awareness of major CMP notices; and conducting regional surveillance and sharing intelligence with other programs in the National Capital Region.

RAPB also delivers public outreach and awareness activities to Canadians on the health risks and safe use of chemicals through dissemination of CMP publications and environmental health guides and delivery of awareness sessions.

Pest Management Regulatory Agency (PMRA)

PMRA's mandate is to help prevent unacceptable risks to human health and the environment through the regulation of pest control products. Under the PCPA, the Agency regulates pest control products for use in Canada, develops policies and guidelines, promotes sustainable pest management, looks to improve the regulatory process to increase efficiencies, and carries out compliance and enforcement. The Agency contributes to risk assessments under the CMP when pest control products are implicated in CMP priorities, and where appropriate, takes action relating to those pesticide active ingredients or formulas consistent with the requirements of the PCPA. The PMRA does not receive any funding with respect to existing substances, but may participate, due to its expertise, in discussions regarding chemicals with pesticide uses.

As part of CMP2, PMRA is continuing to work on the re-evaluation of previously approved pesticides, according to legislated timelines and requirements under the PCPA, as well as on continuing to monitor health and environmental incidents related to pesticides, analyzing trends and sales data and taking regulatory action as needed.

2.4.1 Environment Canada

Environmental Stewardship Branch (ESB)

ESB is Environment Canada's focal point for expertise on the department's legislation, regulations, and other tools to influence the behaviour of Canadians to improve Canada's natural environment. Five of ESB's six directorates are involved in the implementation of the CMP. The Chemicals Sector Directorate (CSD), the Energy and Transportation Directorate (ETD) and the Industrial Sectors Directorate (ISD) share the responsibility of managing the risks from various industrial sectors in Canada through the development, implementation, compliance promotion, and performance monitoring of risk management instruments.[5] In addition, the CSD has the primary risk management coordination role for the CMP.

The Legislative and Regulatory Affairs Directorate (LRAD) supports regulatory development and implementation through the provision of training and advice. In particular, the LRAD provides advice on amendments to Environment Canada's statutes, as well as on relevant amendments to other departments' acts and on private members' bills. It also supports effective environmental risk management by supporting the consistent application of statutory authorities, advising on instrument choice and design, ensuring standardized and efficient decision-making processes, and providing regulatory training to risk managers. The Environmental Protection Operations Directorate (EPOD) conducts selected compliance promotion of CMP risk management instruments and manages the *Environmental Emergency Regulations* that include some CMP substances.

Science and Technology Branch (STB)

Within STB, the Science and Risk Assessment Directorate (SRAD) consists of a number of divisions that play many different roles across the CMP's functional areas. The Program Development and Engagement Division undertakes information-gathering, stakeholder engagement, coordination of all publications and assessment scheduling, New Substance notifications, Significant New Activity (SNAcs) Notices for new and existing substances, and program coordination for CMP delivery. The Emerging Priorities Division undertakes research and monitoring, coordinating science activities with other directorates within STB (Water, Air, Wildlife), and nanotechnology and biotechnology assessments. The Ecological Assessment Division is responsible for conducting all the ecological assessments under the CMP, science, and the development of technical approaches and guidance.

[5] CSD's scope of responsibility includes the industrial, consumer, and commercial chemical sectors, as well as related sectors such as electrical and electronic equipment; ETD's scope of responsibility includes the oil and gas, transportation, and electricity sectors; and ISD's scope of responsibility includes the mining and mineral operations, forest products, and wastewater sectors.

Enforcement Branch (EB)

The EB employs enforcement officers to ensure that individuals, companies, and government agencies comply with pollution prevention and conservation goals of environmental Acts and regulations administered by Environment Canada, such as CEPA 1999. Enforcement officers are responsible for conducting on and off-site inspections to verify compliance and, if necessary, conduct investigations into suspected violations. The overarching goal is to return facilities to compliance quickly. The Enforcement Services Directorate (ESD) also takes part in the regulatory development phase of the CMP, working with other Environment Canada programs to ensure proposed regulations are clear and enforceable. The ESD also develops and delivers training to enforcement officers.

2.5 Program resources

Table 3 shows planned CMP2 expenditures between 2011–12 and 2015–16. CMP2 provided new funding in the amount of $358.6 million for Health Canada, $147.5 million for Environment Canada, and $9.5 million for the Public Health Agency of Canada (PHAC), for a total of $515.7 million over five years. The funds allocated to PHAC were transferred from Health Canada as part of Budget 2012 to support the Travelling Public Program (TPP). The TPP is being evaluated separately and is not discussed in the remainder of this report.

Table 3: Planned CMP2 expenditures for Health Canada and Environment Canada, 2011–2012 to 2015–2016

Funding	2011–12	2012–13	2013–14	2014–15	2015–16	Total
New HC funding under CMP2	$70,700,000	$70,597,650	$67,414,799	$67,414,799	$68,017,149	$344,144,397
Sir Frederick Banting Retrofit (HC)	$3,000,000	$3,000,000	*0	*$6,000,000	$2,500,000	$14,500,000
Total new HC funding under CMP2	$73,700,000	$73,597,650	$67,414,799	$73,414,799	$70,517,149	$358,644,397
New EC funding under CMP2**	$29,500,000	$29,500,000	$29,500,000	$29,500,000	$29,500,000	$147,500,000
New PHAC funding under CMP2***	0	0	$3,182,851	$3,182,851	$3,182,851	$9,548,553
Total new CMP2 funding	**$103,200,000**	**$103,097,650**	**$100,097,650**	**$106,097,650**	**$103,200,000**	**$515,692,950**

Sources: Official government documentation and correspondence with Health Canada representatives.

* Health Canada's Corporate Services Branch (CSB) re-profiled $3.0 million in funding from FY 2013–14 to FY 2014–15 for the purposes of the retrofit project, such that total planned expenditures in the latter year amount to $6.0 million.

** Environment Canada funding includes $200,000 per year in grants and contributions.

*** According to Health Canada representatives, $9.5 million was transferred to PHAC for the TPP as part of Budget 2012; horizontal initiative reports beginning in 2013–14, therefore list this funding as part of PHAC's Health Security Program (Program 1.3 under its Program Alignment Architecture [PAA]).

3.0 Findings

3.1 Relevance — Issue #1: Continued need for the program

The chemicals used in industrial processes and in a wide range of products contribute significantly to the health and the economic and social well-being of Canadians. However, exposure to certain chemicals may contribute to or cause adverse health effects in humans or harm to the environment. There is a demonstrated ongoing need for the CMP to manage the risks to human health and the environment associated with some chemical substances, and to meet the Government of Canada's commitment to assess the approximately 4,300 priority existing substances by 2020.

The evaluation found that CMP2 addresses a demonstrable ongoing need to assess and manage the risks to human health and the environment associated with chemical substances. As noted in the evaluation of CMP1, the chemicals used in industrial processes and in a wide range of products, including pesticides, cosmetics, and pharmaceuticals, as well as consumer products and food, contribute significantly to the health and the economic and social well-being of Canadians (Health Canada, 2011). However, exposure to certain chemicals may contribute to or cause adverse health effects in humans or harm to the environment.

Human health effects can include chronic respiratory diseases, perinatal conditions, congenital anomalies, blood diseases, cancers, neuropsychiatric and developmental disorders, sense organ diseases, cardiovascular diseases, diabetes mellitus, endocrine diseases, digestive diseases, skin diseases, musculoskeletal diseases, and poisonings, among others (Prüss-Ustün, Vickers, Haefliger, & Bertollini, 2011). Although the harm associated with exposure generally increases with the dose (Penningroth, 2010; Williams, James, & Roberts, 2014), there is increasing concern that some chemicals are harmful to human health and/or the environment even at extremely low levels of exposure (UNEP, 2013).[6] The effects of exposure to chemical substances on wildlife can likewise be diverse, and include cancer, immune dysfunction, endocrine disruption, and reproductive disorders (UNEP, 2013), as well as neurotoxicity and nephrotoxicity.

External key informants agreed that having a dedicated, well-funded, coordinated, and systematic approach has greatly improved the Government of Canada's ability to protect Canadians from the risks associated with toxic substances. While progress was made under CMP1 to conduct assessments and begin to manage the risks associated with toxic substances, and further progress has been made under CMP2, there is still work to be done in order to meet the Government of Canada's commitment to assess all of the approximately 4,300 priority existing substances by the year 2020. As of September 30, 2014, final screening assessment

[6] This is one of the issues underpinning current recent debates relating to the safety of BPA (Gies & Soto, 2013; Vandenberg et al., 2012).

reports (fSARs) had been completed for 33% of the priority existing substances, while draft screening assessment reports (dSARs) had been completed for another 6%. In February 2015, dSARs were published for another 20% of the priority existing substances.

Furthermore, in some cases, such as assessments of high priority substances in FDA-regulated products introduced prior to 2001, the CMP life cycle is at an early stage. In other cases, CMP activities will need to be carried out on an ongoing basis. Examples of the latter include conducting an estimated 450 assessments of new substances per year; conducting stakeholder engagement and outreach; ongoing risk management of harmful substances; compliance promotion and enforcement; and conducting research. In addition, monitoring and surveillance will be required on an ongoing basis to measure trends in the presence of toxic substances and determine if risk management actions are effective.

Overall, given the potential implications for human health and the environment from the use of certain chemical substances and the Government of Canada's commitment to assess all priority existing substances by 2020, the evaluation confirmed a demonstrable ongoing need for the CMP.

3.2 Relevance — Issues #2 and #3: Alignment with government priorities and federal roles and responsibilities

The CMP is aligned with the priorities of the federal government as these were articulated in 2011 and in 2015, and with the strategic outcomes of Health Canada and Environment Canada. The CMP2 activities of both departments are consistent with federal roles and responsibilities.

The evaluation found that the CMP is aligned with the priorities of the federal government as they were articulated in 2011 and in 2015, and with the strategic outcomes of Health Canada and Environment Canada. At its launch in 2006, the CMP was part of the federal government's "comprehensive environmental agenda," which also included the Action Plan to Reduce Greenhouse Gases and Air Pollution (Health Canada, 2011). While Speeches from the Throne delivered since the launch of CMP2 (on June 3, 2011 and October 16, 2013) have not specifically mentioned chemicals management (GoC, 2011a, 2013c), the CMP was highlighted in the 2011 federal budget as an initiative aimed at protecting Canada's natural environment and taking action on toxic chemicals (GoC, 2011b) and this was reiterated in the 2015 federal budget.

CMP2 activities and expected outcomes are closely aligned with the strategic outcomes of both Health Canada and Environment Canada, as defined in their respective PAAs. Health Canada's CMP activities align with and support its Strategic Outcome 2, that "Health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians" (Health Canada, 2014a). Environment Canada's CMP activities align with and support its Strategic Outcome 3, that "threats to Canadians and their environment from pollution are minimized" (Environment Canada, 2014a).

Health Canada and Environment Canada activities under the CMP are consistent with federal roles and responsibilities. Under CEPA 1999, Health Canada and Environment Canada are jointly responsible for managing risks to the environment and human health that are posed by chemical substances. In addition, Health Canada has responsibilities under several Acts including the FDA, the PCPA, and the CCPSA for minimizing risks to human health posed by chemical substances. The CMP is intended to provide an integrated approach to the selection and implementation of risk management measures using appropriate combinations of CEPA 1999, the PCPA, the FDA, the CCPSA, and other appropriate federal Acts (e.g., the *Fisheries Act*).

3.3 Implementation

Overall, CMP partners were able to advance the implementation of planned activities for CMP2. Approaches and methods used to implement the CMP are generally working as intended, and the Program has addressed numerous challenges and complex, emerging issues.

3.3.1 Information-gathering activities[7]

During CMP2, program partners completed the major planned information-gathering initiatives, including Phase II of the DSL-IU and information-gathering for the Substance Groupings Initiative. There is a consensus that more flexible approaches to information-gathering and early engagement with industry have resulted in enhanced quality of the information gathered.

Status of information-gathering activities

During CMP2, program partners completed several planned information-gathering initiatives. One major initiative was Phase II of the Domestic Substances List Inventory Update (DSL-IU), which used a s. 71 survey to gather information on many of the approximately 2,700 priority existing substances remaining after CMP1. According to program partners, the online data collection tool was heavily promoted and used more than for previous initiatives and resulted in the highest quality data to date. Stakeholder information workshops and webinars helped to increase participation in the update. Industry key informants indicated that industry appreciated the flexible approach that was taken, which allowed associations to provide data on behalf of their members. They noted that this approach allowed them to correct errors and inconsistencies in reporting, and to send reports to the Government of Canada without concern about the confidentiality of business information. Program representatives indicated that other flexibilities included the ability of foreign suppliers to provide data on behalf of Canadian customers, and supply chain-coordinated reporting through joint submissions.

[7] Information-gathering is funded under CMP2 as a monitoring and surveillance activity, but is described separately since it is frequently the first step in the regulatory process, used to inform risk assessment.

Data were received for approximately 1,340 substances (about 50% of the total number for which information was sought.[8] The data received was used to inform the rapid screening and polymer approaches, while also improving supply chain awareness and informing future program priorities and activities, such as future assessments and DSL updates (GoC, 2014b). A summary of the non-confidential information received from this initiative was posted online in December 2014.

Program representatives indicated that the updates (Phases I and II) were fundamental to providing updated information on the commercial status of chemicals in Canadian commerce. Negotiations with industry are underway for a regularized process for maintaining and updating the DSL. Although the Phase II update was a significant undertaking, due to the large number of substances surveyed (n=2,700), future updates are likely to occur more regularly and benefit from a variety of efficiencies, and are therefore expected to be less onerous.[9] Several non-industry key informants suggested that DSL updates or other specific s. 71 surveys could be used to collect information on the presence and use of nanomaterials, which they believe is currently a significant gap in the Government of Canada's knowledge of substances in the Canadian marketplace.[10]

Progress in information-gathering was also made for the Substance Groupings Initiative and the PSSA. Data collection has been completed for all nine substance groupings through the use of s. 71 surveys, voluntary and sector-based approaches, and agreements with other government departments and industry consortia in other jurisdictions (Environment Canada, 2014d). Program representatives indicated that agreements with industry consortia in other jurisdictions were also used successfully in CMP2, and facilitated the sharing of information where challenges existed with respect to intellectual property, data ownership, and confidentiality.

With respect to the PSSA, program representatives indicated that information-gathering has been completed for high priority PSSA substances using s. 71 surveys, voluntary data collection, and contracts. Preliminary information-gathering has been conducted for remaining priority PSSA substances using internal databases, publically available external sources and the use of industry sector expert contractors. The program is currently reviewing the information gathered through these mechanisms and seeking additional information required from industry.

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8 Program representatives indicated that the remaining 50% of substances were not reported because they are likely no longer in commerce or in activities or applications of concern targeted by the initiative. These substances were included in the Rapid Screening approaches for polymers and non-polymers. Substances that failed rapid screening are now being considered for further data gathering, including 60 polymers proposed to be included in a s. 71 at a lower threshold than used for the DSL-IU2. Other substances are being considered for other action (e.g., SNAc, future inventory updates, etc.).

9 These include greater international harmonization in reporting format (such as the US EPA's Chemical Data Reporting), better explanation of the importance of voluntary information and how it is used by the Government of Canada, and minimizing potential overlap between DSL update reporting and other domestic reporting requirements.

10 Internal key informants indicated that although there was program-level interest in carrying out a s. 71 survey to determine what nanomaterials are currently in the marketplace, this initiative was not supported at the time by all internal CMP partners.

Changes in approach to information-gathering in CMP2

During CMP2, program partners made a number of changes to the approach to information-gathering. Early stakeholder engagement was emphasized to provide greater predictability about upcoming information requests, discuss data needs, and share available information. For example, for the Substance Groupings Initiative, CMP partners focussed engagement efforts on targeted industry sectors that were the most likely users, manufacturers, and importers of the chemicals within specific groupings; and used sector leads within Environment Canada to reach industry when information-gathering notices were published. They indicated that these approaches have been beneficial to obtaining the necessary information to complete screening assessments. Efforts to engage with industry continue throughout the risk assessment and risk management processes.

Industry key informants were highly appreciative of the program's early engagement efforts. They agreed that being made aware of an established plan for information-gathering, with identified priorities and clear timelines for upcoming information requests, allowed industry to focus its efforts and facilitated the information-gathering process. This predictability was particularly beneficial for companies that had to respond to multiple s. 71 surveys or other requests for information. Industry key informants encouraged program partners to continue engaging early with industry during CMP3. They indicated that early engagement could, for example, be helpful in identifying possible approaches to assessing the remaining priority substances, for which data may be lacking and/or which may not lend themselves easily to a groupings approach to information-gathering.

In addition to early engagement with industry, program partners made a number of adjustments to the s. 71 process, based on the recognition that most substances will not ultimately require risk management, in order to reduce the reporting burden for industry. These changes included the following:

- exploring alternative mechanisms and approaches to gather information and capitalizing on existing sources of information to address data needs as much as possible
- refinements and exclusions to the survey based on the information received during the early stakeholder engagement phase and from other sources
- limiting the survey to capturing only critical information (e.g. excluding reporting on imported manufactured items unless this information is critical, and if needed, prescribing the types of reportable items)
- excluding end users, where possible, and focussing on those that manufacture and import substances
- establishing a minimum concentration threshold cut-off for reporting and using a tiered approach when this is not possible

Some program representatives indicated that one impact of the decision to reduce the reporting burden associated with the s. 71 survey is that the information collected may be insufficient in the case of substances that ultimately do require risk management, and may result in an additional s. 71 survey or further follow-up with key sectors involved in activities of concern to fill the gaps for risk management. According to these program representatives, this can make it difficult to meet CEPA timelines for risk management, although they noted that at present it is unclear to them how many substances will be affected by this issue, since risk management for CMP2 substances is still in the early stages.

Just over half (54%) of the 84 industry survey respondents who made a s. 71 submission in both phases of the CMP believe there were improvements in the approach between CMP1 and CMP2. Although respondents who made an s. 71 submission in CMP2 (n=103) reported generally positive experiences, there are opportunities to improve the notice, the guidance documents, and the online reporting tool (see Table 4). Furthermore, just over half (54%) of the respondents who made a s. 71 submission in CMP2 experienced challenges with the process. Most commonly, these related to the time and resources needed to identify implicated products and/or gather data, difficulties obtaining data from foreign suppliers, and difficulties using the online reporting tool.[11] Both program and industry key informants indicated that small and medium enterprises (SMEs) can have greater difficulties in responding to s. 71 surveys, since they do not have the infrastructure and resources that large companies have to devote to regulatory affairs.[12]

Table 4: Industry perspectives on the s. 71 process in CMP2

Survey question	Percent (n=103)			
	Agree	Neutral	Disagree	Don't know
The Government of Canada provided industry with enough advance notification of its intent to issue a s. 71 notice	78%	12%	9%	1%
The Government of Canada provided industry with adequate notification when an s. 71 notice was published	78%	14%	8%	-
The guidance documents were helpful	68%	19%	11%	3%
The notice clearly stated which sections were applicable, based on my organization's activities (manufacture, import, use)	66%	19%	15%	-
It was clear what information my organization was required to provide	66%	19%	15%	-
The time period (excluding the extension period) for responding to the notice was sufficient	65%	18%	18%	-
Based on the notice, it was easy to determine if my organization was required to respond	61%	18%	22%	-
The guidance documents were clear	58%	21%	19%	3%
I am satisfied with the CMP online reporting tool via Environment Canada's Single Window	57%	16%	24%	4%

Source: Industry survey
Note: Row totals may not sum to 100% due to rounding.

CMP partners take a number of steps to promote awareness of and compliance with mandatory surveys among affected industries and sectors, with a particular focus on SMEs. These efforts include conducting early scoping exercises to determine implicated sectors; disseminating information about the surveys as widely as possible; working with industry associations when

[11] Industry key informants echoed these challenges, noting in addition that industries such as the food and petroleum sectors that do not use Chemical Abstract Services (CAS) registry numbers had difficulty identifying the substances for which information was being sought.

[12] The industry survey found no notable or significant differences in responses between SMEs and large companies on questions relating to the s. 71 process. However, the survey used a convenience sample and does not represent the population of small, medium and large companies that have made s. 71 submissions.

specific sectors are implicated and/or to reach SMEs; and promoting compliance through the Chemical Substances website, the Substances Management Information Line, and presentations at workshops and conferences to stakeholders. Mandatory surveys under s. 71 are also promoted through the mailing of advisory letters to a database of approximately 6,000 stakeholders, as well as a list serve with approximately 2,000 contacts. Reminder letters are sent approximately six weeks before upcoming deadlines.

Nonetheless, program representatives acknowledged that the population of industry stakeholders implicated in each s. 71 survey is often unknown to the program, and that these surveys do not provide a comprehensive picture of the way in which substances are used in Canada. As a result, for a more complete picture of the substance marketplace in Canada, the data from these surveys is considered along with information received through other tools and mechanisms, other programs, existing domestic and foreign sources, and stakeholder engagement.

In part to address the shortcomings of the s. 71 process, a "portfolio of approaches" is being used in CMP2 to gather the information necessary to support risk assessment and other program activities.[13] In addition to s. 71 surveys, these approaches include, but are not limited to, the following:

- targeted or directed requests for information to implicated industry sectors (often used for the food sector, since many substances are not used in food at the volumes that trigger mandatory reporting)
- blind submissions
- joint submissions through industry associations or consortia
- voluntary Declarations of Stakeholder Interest for stakeholders that do not meet reporting requirements for a s. 71 submission
- voluntary questionnaires outside of a s. 71 process
- use of publicly available sources of information
- use of consumer product test data generated by CPSD's Product Safety Lab
- requests to industry to generate new data
- working with industry stakeholders and government organizations in Canada and Europe to develop data-sharing agreements, access relevant datasets, and identify opportunities for streamlined, voluntary approaches to information-gathering

In interviews, some industry representatives were concerned about the response rates achieved by s. 71 surveys and other approaches to information-gathering, the nature and comprehensiveness of the data gathered, the relative weight that various sources of data are given in risk assessments, and the possibility that the CMP may be basing risk assessment conclusions on small and/or unrepresentative datasets. There is a desire for greater transparency about the nature and quality of the information upon which risk assessment conclusions are based. This may become particularly important in CMP3, given that the program expects a lack of data to be a challenge for the risk assessment of many CMP3 substances.[14]

[13] This is in contrast to CMP1, which relied primarily on s. 71 surveys.

[14] CMP research activities are expected to be important to addressing this challenge.

3.3.2 Risk assessment activities

Program partners continued to make progress toward assessing the approximately 4,300 existing substances prioritized through categorization. To date, the CMP has assessed approximately 60% of priority existing substances, although the PSSA has experienced notable delays. In addition, the program was able to consistently manage the assessment of new substances. Approximately 400 to 500 new substance assessments have been completed per year, consistent with targets, and progress has been made toward fulfilling commitments relating to FDA substance and pesticides. The 2011 evaluation of CMP1 identified a need to clarify the program's role with respect to occupational exposure to chemical substances. The evidence from this evaluation indicates that this is an area of ongoing concern for some stakeholders, suggesting that the issue should be thoroughly examined in a future evaluation.

Assessment of existing substances

During CMP2, program partners continued to make progress toward completing assessments of the approximately 4,300 existing substances prioritized through categorization (referred to below as "priority existing substances"), as well as substances prioritized through separate processes. A fit-for-purpose approach is being used, in which screening assessments are based on the information necessary to produce a scientifically defensible decision. In response to the recommendations of the 2011 evaluation, program partners also implemented a framework for prompting the assessment or reassessment of substances when new information becomes available.

- **Overall progress**. As of September 30, 2014, the CMP had assessed approximately 60% of priority substances. 33% (n=1,430) of the 4,365 priority existing substances were considered to have reached a final assessment conclusion, and dSARs had been completed for an additional 6% (n=282) of these substances. In February 2015, dSARs were published for an additional 20% (n=887) substances.
- **Progress on CMP1 substances**. Assessments of CMP1 substances, including high priority substances under the Challenge and the PSSA, are nearing completion. As of September 30, 2014, fSARs had been completed for 90% (n=1,064) of CMP1 substances.

  Progress on the PSSA has been slower than in other areas. Just over half (n=88) of PSSA high priority substances had an fSAR as of September 30, 2014, leaving the remaining 48% to be completed by the end of 2015–16 in order to meet CMP2 commitments for this initiative.[15] Program representatives indicated that petroleum substances are more complex and challenging to assess than other substances, necessitating the development of new methodological approaches involving multiple data sources and in some cases, follow-up data collection to fill information gaps.[16] Data collection, analysis, and interpretation were further

[15] Substances covered by the completed fSARS include 68/68 substances in Stream 1; 14/14 in Stream 2, 6/13 in Stream 3, 0/69 in Stream 4; and 0/6 in Stream 0. Planning documents for CMP2 envisioned completing Streams 1–3 during 2011–13 and Stream 4 during 2013–16. Stream 0 is not identified in original planning documents.

[16] Program representatives indicated that this complexity is in part because many petroleum substances are complex mixtures.

complicated by the fact that the petroleum industry typically does not use the CAS naming convention for substances, which made it difficult to identify the specific substances for which information was being sought. This stream has also been affected by changing priorities and the program's focus, early in the CMP, on the Challenge substances.

- **Medium priority substances.** Work is ongoing, as per CMP2 commitments, to assess approximately half of the remaining 3,000 medium priority existing substances identified through categorization. Of 1,643 medium priority substances identified for assessment in CMP2, 22% were considered to have reached a final assessment conclusion as of September 30, 2014, while an additional 14% had a dSAR in place.[17] More recently, progress has been made in assessing substances found in pesticides (n=19), substances from Phase II of the DSL-IU using rapid screening approaches (n=612), and polymers (n=275). DSARs for 887 of these substances were published in February 2015.
- **Substances prioritized through separate processes.** In addition to assessing existing substances prioritized through categorization, CMP partners also assessed substances prioritized through separate processes. As of September 30, 2014, assessments had been completed for 19 of 68 micro-organisms, and 146 of 168 other priority substances.
- **Assessment conclusions.** As of September 30, 2014, 208 substances (12% of all substances with draft or final assessment conclusions, regardless of how they were prioritized for assessment) were concluded to be toxic to human health and/or the environment under s. 64 of CEPA 1999. Of these, 77 were concluded to be toxic to human health, 129 were concluded to be toxic to the environment, and two were concluded to be toxic to both human health and the environment. Of the sub-group of existing substances prioritized through categorization, 150 were concluded to be toxic, including 77 that are toxic to human health, 73 that are toxic to the environment, and two that are toxic to both health and the environment.

Table 5 on the next page provides detailed information on progress in assessing existing substances, based on information provided by the CMP.

[17] Most of the substances that were considered to have reached a final assessment conclusion (n=249) were identified by the Government of Canada as already being assessed or risk managed under CEPA 1999 (GoC, 2014d), and were not assessed under the CMP. The remaining 117 substances with a final assessment conclusion were assessed under the Rapid Screening Approach and had a formal fSAR in place. The medium priority substances with a dSAR in place as of September 30, 2014 were part of the Groupings Initiative.

Table 5: Progress on assessing existing substances (priority existing substances, substances prioritized after categorization, and micro-organisms) as of September 30, 2014

Initiative	Number of substances	CMP1		CMP2		Overall				
		Number of substances with an fSAR completed during CMP1	Number of substances with a dSAR completed during CMP1, but no fSAR	Number of substances with an fSAR completed during CMP2	Number of substances with a dSAR completed during CMP2, but no fSAR	Number of substances with an fSAR as of Sept 30, 2014	Number of substances with a dSAR, but no fSAR, as of Sept 30, 2014	Number of health-toxic substances (fSAR)	Number of environment-toxic substances (fSAR)***	Number of health- and environment-toxic substances (fSAR)
Priority existing substances (substances prioritized during the initial categorization exercise)										
CMP1 substances										
-Challenge to Industry	194	179	9	9	6	188	15	33	30	2
-Petroleum Sector Stream Approach	170	28	0	60	8	88	8	44	0	0
-Legacy substances	58	27	1	25	3	52	4	0	43	0
-SNAc approach	203	151	1	52	0	203	1	0	0	0
-FDA approach	28	0	0	0	28	0	28	0	0	0
-Rapid Screening 1	533	533	0	0	0	533	0	0	0	0
Total CMP1 substances	**1,186**	**918**	**11**	**146**	**45**	**1,064**	**56**	**77**	**73**	**2**
CMP2 substances										
-Groupings Initiative	380			0	226	0	226			
-Rapid screening 2	117			117	0	117	0	0	0	0
-Assessed/managed	249			249*	0	249*	0			
-Polymer rapid screening	271									
-Pesticide rapid screening	54									
-Rapid screening 3	572									
Total CMP2 substances	**1,643**			**366**	**226**	**366**	**226**	**0**	**0**	**0**
CMP3 substances	**1,536**									
Total priority existing substances	**4,365**	**918**	**11**	**512**	**271**	**1,430**	**282**	**77**	**73**	**2**
Existing substances prioritized in separate processes										
CMP1 substances	**148**									
-Challenge to Industry	2									
-Legacy substances	146	108	0	36	1	144	1	0	56	0
CMP2 substances	**20**									
-Groupings Initiative	20	1			1	1	1	0	0	0
Total additional existing substances	**168**	**109**	**0**	**36**	**2**	**145**	**2**	**0**	**56**	**0**
Prioritized micro-organisms**	**68**			**8**	**11**	**8**	**11**	**0**	**0**	**0**
Overall total existing substances	**4,601**	**1,027**	**11**	**556**	**284**	**1,583**	**301**	**77**	**129**	**2**

*A total of 249 of the prioritized existing substances were identified by the Government of Canada as already being assessed or risk-managed under CEPA 1999 and were not assessed under the CMP. Risk assessment of these substances is considered final/complete for the purposes of the CMP.
**Micro-organisms were not subject to the initial categorization exercise but were prioritized for risk assessment under s. 74 of CEPA 1999.
Source: Environment Canada.
*** Due to differences in reporting methodologies between programs, the numbers presented for the environment-toxic substances (fSAR) column may not match the information on the number of toxic substances publicly reported in other documents.

External key informants were generally satisfied with the CMP's rate of progress on assessments, although some, representing both industry and NGOs, wondered about the slower rate of progress on the PSSA. These stakeholders indicated a need for greater transparency when delays occur. International stakeholders who were interviewed praised Canada for being the first international jurisdiction to establish and implement an ambitious plan and schedule for assessing existing substances.

Some external stakeholders raised questions about the methodologies used in risk assessment. In particular, non-industry stakeholders were concerned that Canada's approach to human health risk assessment does not consider low exposures, long-term exposures, multiple exposures, occupational exposures, or gender differences with respect to chemical exposures and effects, and consequently, risk assessments may not give adequate consideration to vulnerable populations such as children, women, low-income individuals, and individuals in occupations with higher exposure to toxic substances.[18]

Program representatives indicated that several measures are taken to ensure that appropriate methodologies are used in risk assessments, including internal and external peer review of risk assessments; consultation with research scientists within Health Canada and with Health Canada's Science Advisory Board; technical consultations with external experts; participation in the Organisation for Economic Co-operation and Development's (OECD) Task Forces on Hazard and Exposure; and publication of methodology development and related work in peer-reviewed journals. Most recently during CMP2, a CMP Science Committee was established, consisting of 10 core members, with a mandate to "contribute expertise…pertaining to scientific considerations" (GoC, 2014e). Committee members have expertise in areas such as environmental/biological science related to ecological or human health effects, exposure/fate, and risk characterization; chemicals management framework expertise, including in other jurisdictions; application of weight of evidence and precaution in science-based decision-making; and knowledge of the chemicals industry.[19]

Addressing stakeholders' specific concerns, program representatives indicated that long-term effects, sex-specific differences, and multiple exposures are currently considered in CMP risk assessments when data and use patterns support these approaches.[20] Incorporating multiple exposures to different chemicals into risk assessments is a challenge facing regulatory agencies

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[18] Such concerns were expressed by some external key informants representing health and environmental NGOs and international regulatory agencies, as well as by some authors (Edge & Eyles, 2013; Lewis & Scott, 2014). Additionally, some non-industry key informants encouraged the CMP to address more robustly certain health end points such as epigenetics, effects on immune function and the endocrine system, and neurodevelopmental effects.

[19] At the Committee's second meeting in February 2014, the topic of discussion was capturing and communicating uncertainty in screening assessment reports (GoC, 2014c). Prior to the establishment of the CMP Science Committee, industry and other external stakeholder advice was provided by the Challenge Advisory Panel.

[20] For example, sex and gender were incorporated into SED's assessment of triclosan, and recent assessments, such as the Cobalt-Containing Substance Grouping assessment (GoC, 2014f) and the soon-to-be published Draft Approach for the Phthalates Cumulative Risk Assessment, considered combined exposures to multiple chemicals. The Phthalates draft assessment takes into consideration elements of the World Health Organization's (WHO) 2011 framework for assessing combined exposures (World Health Organization, 2015).

around the world,[21] and Canada is actively contributing to international efforts in methodology development. In particular, under the OECD Task Force on Hazard, Canada is leading a two-year project on combined exposures to multiple chemicals that will build on the World Health Organization's (WHO) 2011 framework for assessing combined exposures (World Health Organization, 2015). Long-term effects, as well as sex-specific differences, are being monitored through the Canadian Health Measures Survey (CHMS) and the Maternal-Infant Research on Environmental Chemicals (MIREC) study, although only for certain substances; for more information about these studies, see Section 3.3.5. Some program representatives acknowledged that, as science evolves and assessment methodologies improve, certain risk assessments will likely need to be updated to reflect the combined effects of multiple chemicals.

Various non-industry external stakeholders expressed concern that the CMP does not consider occupational exposure in risk assessments, and in particular, were concerned that this may result in underestimating the health risks associated with some substances. The literature suggests that exposure to one form of chemical or another is probably widespread in occupational settings. According to the United Nations Environment Programme (UNEP), "nearly all workers today are exposed to some sort of chemical hazard because of the ubiquitous use of chemicals in every type of industry, ranging from mining, welding, mechanical and manufacturing work, to office work and other occupations" (UNEP, 2013).

Occupational exposure is considered by other jurisdictions, including Australia, the United States (US), and the European Union (EU), in chemical risk assessments. Program representatives at Health Canada acknowledged that the CMP does not consider occupational exposure in risk assessments.[22] They indicated that because occupational health and safety (OHS) is regulated primarily at the provincial/territorial level and is not addressed in CEPA, addressing it in risk assessments would require a reconceptualization of the CMP, as well as a reassessment of roles and responsibilities for various aspects of OHS in Canada. Furthermore, addressing OHS in risk assessments would be a significant draw on program resources, requiring new policy coverage and associated funding.

[21] The United Nations Environment Programme recently described the lack of methods for incorporating chemical interactions into risk assessments as a significant gap for chemicals regulators worldwide (UNEP, 2013).

[22] More specifically, Health Canada representatives indicated that occupational data is used to understand hazards, but conclusions are based on exposure to the general population.

Program representatives also noted that Health Canada and Environment Canada have indicated to stakeholders that the focus of the CMP is on general population exposure. Health effects information obtained from workplace settings, however, is considered in the assessments as it is of use in predicting potential effects on the general population. In addition, Health Canada has established the Current Issues Committee made up of stakeholders and federal, provincial, and territorial OHS regulators as a forum on matters concerning the interpretation or modification of the Workplace Hazardous Materials Information System (WHMIS), and to facilitate information and knowledge-sharing between government regulators and affected stakeholders in order to improve coordination and collaboration in achieving compliance with WHMIS. Finally, program representatives indicated that a mechanism is in place for notifying provinces and territories of the publication of screening assessment reports, and screening assessments are shared with the provinces and territories, as well as with Aboriginal groups through the CEPA National Advisory Committee.

The 2011 evaluation identified a need to clarify the CMP's role in this area, noting that substances deemed non-toxic for the general population could potentially present issues for OHS (Health Canada, 2011). Given that occupational exposure continues to be an area of concern for some stakeholders, the issue could be more thoroughly examined in a future evaluation of the CMP.[23]

New substance assessments

As of April 1, 2014, the New Substances Program, a joint program of Environment Canada and Health Canada, had completed 1,573 assessments for new substances during CMP2, consistent with the target of approximately 400 to 500 per year. New substances are regulated under the *New Substances Notifications Regulations*, which cover chemicals, polymers (including nanomaterials), and organisms. These regulations help to ensure that no new substances are manufactured in or imported into Canada before an assessment of potential toxicity has been completed, and the required control measures have been implemented (Environment Canada, 2014b).[24] Program representatives indicated that there may be some stakeholders that are not aware that they are required to notify the Government of Canada of new nanomaterials and naturally occurring living organisms, contributing to a gap in knowledge concerning their presence and use in Canada.

Other risk assessment activities

Program partners made progress in implementing CMP2 commitments relating to FDA substances and pesticides.

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[23] This evaluation did not systematically canvass the perspectives of all relevant stakeholders, including federal and provincial/territorial OHS regulators, experts, and other stakeholders with respect to occupational exposure in chemical risk assessments.

[24] Importers and manufacturers must provide Environment Canada with a New Substance Notification package, which is jointly assessed by Environment Canada and Health Canada. Assessment time is typically limited to 60 days, but varies from 5 to 120 days depending on the type of substances and quantities involved (Environment Canada, 2014b).

- Health Canada updated the ICL of FDA substances, a list of substances in FDA-regulated products that were in commerce between January 1987 and September 2001.[25] As of October 2014, Health Canada had prioritized approximately 1,600 substances on the revised ICL into those requiring further consideration and those requiring no further consideration. While Health Canada has completed assessments of some high priority ICL substances, most will be assessed in the next phase of the CMP.
- As of January 2015, the FD had conducted 26 re-evaluations of food additives, food contaminants, and food packaging materials that were flagged through CMP screening assessments or new research findings.[26]
- PMRA initiated 33 out of 60 re-evaluations of active ingredients planned for CMP2, according to legislated timelines and requirements under the PCPA. It is unclear how many of these re-evaluations, if any, have been completed. PMRA also prioritized 28 high and medium priority active ingredients for which re-evaluations were outstanding from CMP1. It is unclear if any of the 28 outstanding re-evaluations have been initiated.
- PMRA initiated 24 special reviews in cases in which there were reasonable grounds that the health or environmental risks were unacceptable. Risk assessments have been completed for two of the special reviews. It is unclear how many of these special reviews, if any, have been completed.

In addition, Environment Canada's Environmental Emergencies Program assesses substances prior to proposing them for addition to the *Environmental Emergencies Regulations*.

3.3.3 Risk management activities

During CMP2, risk management measures were actively developed and implemented for substances deemed CEPA-toxic as a result of risk assessment. To date, risk management measures have been approximately equally split between regulatory and non-regulatory measures. Some stakeholders are concerned about the effectiveness of non-regulatory measures at achieving risk management objectives. Although program partners are currently monitoring the performance of some non-regulatory measures on a risk basis, evidence of the effectiveness of such approaches is limited at this time.

[25] In September 2001, new products under the FDA were required to comply with CEPA 1999. FDA substances include substances in pharmaceuticals, veterinary drugs, biologics, genetic therapies, cosmetics, medical devices, and food additives. If an FDA substance also has non-food uses, then the non-food use is subject to notification under the *New Substances Notification Regulations*. Approximately 9,000 FDA substances were on the market before 2001 and were included on the ICL. However, further analysis of the list by Health Canada lowered these estimates to about 3,400. As of October 27, 2014, the revised ICL listed 3,417 substances (Health Canada, 2014b).

[26] Amaranth, tartrazine, selenium, boron, ethyl carbamate, four cresols, 10 phthalates (DCP, DIBP, DINP, DMP, BBP, DBP, DEHP, DEP, DNHP, DNOP), seven flame retardants (melamine, TBB, TCP, DP, TCPP, ATE, TBPH).

Implementation of risk management measures

During CMP2, risk management measures were developed and implemented for substances deemed CEPA-toxic as a result of risk assessment.[27] Environment Canada's Instrument Choice Framework for Risk Management under the Canadian Environmental Protection Act, 1999 (Environment Canada, 2009b) is used to assist in identifying appropriate risk management instruments through the application of specific assessment criteria.[28] Consistent with the early engagement approach, program partners conducted preliminary discussions, pre-consultations, and formal consultations with affected industry sectors to inform the development of risk management measures, a process that begins as early as the risk assessment phase. For example, risk management scope documents are published concurrently with dSARs for those proposed toxic at the draft assessment stage, which program representatives said allows industry to provide additional information to fill risk management gaps and helps ensure the "right-sized" instrument.

According to data provided by Environment Canada, as of July 2014, 79 risk management instruments for over 200 existing substances had been proposed, were in development, or had been finalized since the launch of the CMP. Of these, 78% (n=62) fall under CEPA 1999.[29] Overall, these risk management measures were approximately equally split between regulatory (52%, n=41) and non-regulatory measures (48%, n=38).[30] See Table 6.

[27] Under s. 77(2) of CEPA there are three possible courses of action for substances concluded to be toxic under s. 64: 1) taking no further action in respect of the substance; 2) adding the substance to the Priority Substances List for further study; or 3) recommending that the substance be added to the List of Toxic Substances in Schedule I and, where applicable under subsection (4), the implementation of virtual elimination under subsection 65(3) (GoC, 2014a, sec. 77(2)).

[28] The five criteria are environmental effectiveness; economic efficiency, including minimizing costs and maximizing benefits; distributional impacts on groups and segments of society; acceptability and compatibility, including stakeholder acceptability and compatibility with other programs in Canadian jurisdictions; and international obligations.

[29] Environmental Performance Agreements are identified in the Environment Canada data as CEPA instruments, and are therefore reflected as such in Table 6 and related calculations. However, according to program representatives from Environment Canada, Environmental Performance Agreements are not necessarily considered to be CEPA instruments. In addition to the risk management measures in Table 6, program partners published two risk management scoping documents in November 2013, covering 76 substances in the Aromatic azo and benzidine-based substance grouping. No risk management instruments have yet been implemented for substances assessed in CMP2. Program partners also implemented risk management actions for eight substances new to Canada for which risk management needs were identified.

[30] In CMP1, 50% of risk management instruments were regulatory. In CMP2, 47% of risk management instruments were regulatory.

Table 6: Types of risk management instruments used in the CMP for existing substances

Type of instrument	Act/RM Instrument	CMP 1		CMP 2		Total
		Proposed/in development	Implemented	Proposed/in development	Implemented	
Regulatory	CEPA 1999 - Significant New Activity	-	-	2	9	11
Regulatory	CEPA 1999 s93 - Prohibition regulation	-	4	1	3	8
Regulatory	CEPA 1999 s93 - Other regulation	1	3	3	4	11
Non-regulatory (enforceable)	CEPA 1999 s56 - Pollution Prevention Plan	-	3	1	5	9
Non-regulatory	CEPA 1999 s54 - Guideline	-	1	5	3	9
Non-regulatory	CEPA 1999 - Environmental Performance Agreement*	-	4	-	2	6
Non-regulatory	CEPA 1999 s55 - Guideline	-	-	-	2	2
Regulatory	CEPA 1999 s65 - Virtual Elimination	-	2	-	-	2
Non-regulatory	CEPA 1999 s54 - EC Code of Practice	-	-	-	1	1
Non-regulatory	CEPA 1999 s55 - HC Code of Practice	-	-	-	1	1
Regulatory	CEPA 1999 s93 - Release regulation	-	1	-	-	1
Regulatory	CEPA 1999 - s200(1) E2 Regulations	-	-	1	-	1
Non-regulatory	FDA - Addition/Amendment to Cosmetic Ingredient Hotlist	-	2	-	1	3
Non-regulatory	FDA - Other actions	-	2	-	2	4
Regulatory	FDA - Lists of Permitted Food Additives	-	-	3	1	4
Regulatory	FDA - Amendment to the Prescription Drug List	-	-	1	-	1
Non-regulatory	FDA - Code of Practice	-	-	-	1	1
Regulatory	CCPSA - Schedule 2 Prohibition	-	-	-	1	1
Regulatory	HPA - Prohibition (prohibition transferred under Schedule 2 to the CCPSA June 2011)	-	1	-	-	1
To be determined		-	-	2	-	2
Total		**1**	**23**	**19**	**36**	**79**

Source: Environment Canada.

Note: The data provided by Environment Canada may not include all risk management measures implemented under the CMP. For example, risk management measures for naphthalene under the PCPA are not included in the data, and the data may not include all substances added to the Lists of Permitted Food Additives under the FDA. In addition, the data may not include all non-regulatory measures taken on substances and uses regulated under the FDA.

* Environmental Performance Agreements are identified in the Environment Canada data as CEPA instruments, and are reflected as such in this table.

In managing substances, partner departments have, at times, availed themselves of a broad federal policy direction known as the “Best Placed Act” approach. The Best Placed Act approach was developed to allow for the management of toxic substances under whichever Act is “best suited” to manage a substance, given its uses and exposures of concern. The approach was developed as it became clear, during CMP1, that Acts other than CEPA 1999 could be better placed to manage risks from certain substances that were found to be harmful to human health and were recommended to be added to Schedule 1. These risks included those from certain substance exposures (in particular, for substances found in products such as food, pharmaceuticals, medical devices, pesticides, cosmetics, other consumer products, and for micro-organisms that are also recognized as pathogens), where these other programs were specifically mandated, under Acts other than CEPA 1999, to address the product or exposure type of concern.

While the Best Placed Act approach has been successfully used to risk-manage some toxic substances (see "Lessons learned on risk management – the BPA experience"), some practical implementation challenges have arisen, which will continue to require resolution on a case-by-case basis. Program partners agree on the desirability of continuing to implement the Best Placed Act approach in the future, as appropriate.

Program key informants reported that the CMP's approach to risk management is evolving as program partners look at using an "expanded toolbox" and applying a "lighter touch," when appropriate. Health Canada representatives indicated that non-regulatory approaches are playing, or are expected to play, a significant role in risk-managing toxic substances in products regulated under the FDA, in particular, pharmaceuticals and food.

- Because substances that are important in medical treatments may be harmful to the environment, risk management must weigh the risks associated with these substances against the need for the Canadian public to have timely access to necessary drugs. Health Canada representatives indicated that non-regulatory approaches may be useful in minimizing the negative impact that these substances may have on the environment, without resorting to a regulatory approach that could impede access. [31] Within HPFB, research is being done by the Environmental Impact Initiative within PPIAD on existing NRIs that mitigate the release of substances from FDA-regulated products, the environmental exposure of these substances, and the potential indirect exposure impacts to human health and the environment.[32]
- Similarly, Health Canada representatives indicated that NRIs, such as codes of practice or consumption advice, may be more appropriate approaches for risk management of naturally-occurring toxic substances in food (e.g., acrylamide, ethyl carbamate, mercury) and for toxic substances that have nutritional benefits in limited quantities (e.g., selenium, boron).

[31] It is possible that pharmaceuticals discharged into the environment may also have human health risks. According to one study cited in a CBC news report, three pharmaceutical drugs (metformin, ranitidine, and hydrochlorothiazide) have recently been found in Canadian drinking water at record levels (CBC News, 2014). The same news story cited Environment Canada officials as having told a Senate committee hearing that more than 165 individual pharmaceuticals and personal care products have been identified in water samples. Scientific experts cited in the report noted that the effects on human health of pharmaceuticals discharged into the environment have not been studied. The WHO, also cited in the report, acknowledges that there is a "knowledge gap" when it comes to "assessing the risks associated with long-term exposure to low concentrations" of drugs and "the combined effects of mixtures of pharmaceuticals."

[32] To date, 17 research papers have been produced on these topics. Stakeholder consultations, focussing on how to improve the performance of existing NRIs and/or to create new ones, are planned for 2014–15.

Lessons learned on risk management — the BPA experience

The Best Placed Act approach can be successfully implemented. BPA was assessed during CMP1 under the second batch of the Challenge initiative. In 2008, it was concluded to be toxic to human health and the environment and was added to Schedule I of CEPA 1999. A range of regulatory and non-regulatory risk management measures were implemented for BPA, consistent with the Best Placed Act approach. The implemented risk management measures include the following:

- under the CCPSA, a ban on polycarbonate baby bottles
- under the FDA, addition of BPA to the Cosmetic Ingredient Hotlist
- under the FDA, continued evaluation of pre-market submissions for infant formula to minimize BPA concentrations in packaging
- under the FDA, prioritized pre-market assessment of BPA replacements for use in food packaging applications
- under CEPA 1999, institution of a Pollution Prevention Planning requirement for four industrial facilities
- implementation of an Environmental Performance Agreement with 13 paper recycling companies
- Environment Canada is currently considering the addition of BPA to the *Environmental Emergency Regulations,* due to the risks the substance is believed to pose to aquatic environments.

Efforts to engage industry facilitates the design of risk management measures and improves compliance with them. The BPA experience indicates that government efforts to engage and demonstrate good faith in working with industry may help in facilitating the design of risk management measures and improving compliance with them. For example, paper recycling industry representatives described how their close interaction with government representatives through an informal working group was pivotal to the design of an instrument that was appropriate for the sector and encouraged high levels of industry participation and compliance.

Program flexibility in response to new information is essential. Program partners demonstrated willingness and capacity to revise their approach to managing the risks posed by BPA, as they received new information from various sources, ultimately modifying or cancelling a subset of originally-planned risk management activities. For example, the rationale for establishing migration targets for canned foods (including infant formula cans) dissipated as it became clear that manufacturers were already replacing their packaging with BPA-free alternatives. Similarly, the acknowledgement that there had already been a significant reduction in the amount of BPA imported into Canada contributed to the decision to attempt to reduce BPA emissions from industrial facilities by introducing a Pollution Prevention Planning requirement, rather than by pursuing a regulatory approach.

The media and public perception can influence regulatory processes and industry action. The BPA experience highlights the complex inter-relationships that may exist in some cases between media and public perception, regulatory processes and actions, and market outcomes. Media, NGO, and

> public scrutiny and pressure motivated industry to withdraw BPA-containing products from the market and seek acceptable alternatives. In turn, this altered the set of risk management measures that the Government of Canada deemed necessary to achieve risk management objectives, while simultaneously increasing industry willingness to comply with the measures that were ultimately implemented.

Emphasizing non-regulatory measures is consistent with the federal government's Red Tape Reduction Action Plan and the Cabinet Directive on Regulatory Management, both of which emphasize alternative or "flexible" compliance approaches that impose less administrative burden on industry. Nevertheless, industry key informants noted that some NRIs, such as Pollution Prevention Plans and Environmental Performance Agreements, entail a considerable burden in the form of reporting requirements. According to program representatives, risk management instruments are selected and designed based on a number of considerations that aim to achieve the desired risk management outcome in the most efficient manner possible. As such, both regulatory and non-regulatory instruments may require various elements, such as reporting requirements, which are needed to effectively manage risk.

The appropriateness of emphasizing non-regulatory approaches to the risk management of toxic substances was also questioned by some external key informants outside of industry, who were concerned that NRIs may be less effective and that their use may have a negative impact on the environment and the health of Canadians. There is evidence that regulatory approaches are effective; for example, a recent US study estimated that 75% or more of the reduction in pollution emissions from manufacturing observed in the US between 1990 and 2008 was due to environmental regulation (Shapiro & Walker, 2015). However, evidence of the effectiveness of non-regulatory measures is scarce in the literature.

Program representatives indicated that performance measurement of regulatory and non-regulatory risk management measures is an evolving field in Canada and internationally. Currently, Environment Canada is monitoring the extent to which two types of non-regulatory measures (Pollution Prevention Planning Notices and Environmental Performance Agreements) are achieving their risk management objectives, and several pilot projects are under development for measuring the performance of risk management actions for toxic substances.[33] In particular, during CMP2, the program developed a guidance document on Substance-Based Performance Measurement and selected four substances (polybrominated diphenyl ethers (PBDEs), BPA, mercury, and lead) to act as pilot substances to test the criteria for developing performance measurement plans.[34] Program representatives indicated that the results of periodic effectiveness reviews undertaken by Environment Canada (under CEPA) have led to the identification and incorporation of various improvements in a series of guidance documents on NRI. Finally, Environment Canada has developed a working group on instrument effectiveness that has developed a work plan to ensure that the design and implementation or risk management instruments more systematically accounts for the need to measure effectiveness.

[33] A summary of the results of these performance monitoring activities is in Section 3.3.3.

[34] PBDEs, lead, and mercury were assessed before the launch of the CMP.

Finally, some non-industry stakeholders expressed concerns that insufficient emphasis is being placed on pollution prevention and virtual elimination of persistent and bioaccumulative chemicals (two of the guiding principles of CEPA 1999), identification of alternatives, and achieving an overall reduction in exposure to toxic chemicals. Program representatives indicated that CEPA1999 guiding principles are the basis for all work under the CMP, noting further that pollution prevention is one of the key considerations of the Instrument Choice Framework.

Other risk management activities

In addition to implementing risk management measures for CEPA-toxic substances, program partners undertook a number of other initiatives related to risk management under CMP2, including the following:

- developing proposed regulatory frameworks for new substances in products regulated under the FDA, as part of the proposed Environmental Assessment Regulations; in particular, frameworks were developed for Class 1 substances, which are medicinal ingredients in drugs that have a Drug Identification Number;[35] and for Class 2 substances, which are all other substances contained within products regulated under the FDA
- updating the *Environmental Emergency Regulations* to add 41 existing substances under CEPA 1999 to the regulations, and another 49 substances are being considered for addition; the Regulations are intended to minimize the occurrences and impacts of environmental emergencies, such as the accidental or uncontrolled release of a substance into the environment by requiring companies to take preventative measures and be prepared to respond to, and recover from, emergencies
- establishing the *Wastewater Systems Effluent Regulations* in 2012, with effluent quality standards achievable through secondary wastewater treatment; secondary treatment is a combination of mechanical, chemical, and biological processes that aims to reduce conventional pollutants, such as biochemical oxygen demanding matter and suspended solids — certain emerging pollutants may also be reduced or removed during treatment prior to effluent discharge to the Canadian waters
- initiating a partnership with the PHAC to eliminate regulatory duplication in the risk management of existing micro-organisms that are recognized as pathogens subject to requirements under the *Human Pathogens and Toxins Act*
- introducing several updates to the Guidelines for Canadian Drinking Water Quality, in partnership with the provinces and territories through the FPT Committee on Drinking Water (approximately five per year)

[35] The most recent proposed definition of a Class I substance is “a medicinal ingredient in a human drug, veterinary drug or biologic, but does not include natural health products, medical devices or drugs listed on Schedule C to the FDA (i.e., radiopharmaceuticals).

- initiating or implementing 13 cyclical enforcement plans (CEP) for consumer products (such as, for example, baby bottles, children's jewelry, surface coatings, face paint, pencils, and art brushes) and cosmetics, covering substances risk-managed under the CMP as well as legacy substances under Schedule 1 of CEPA 1999 (e.g., lead)[36]
- reviewing Cosmetic Notifications to determine whether restricted or prohibited substances (including CMP substances) on the Cosmetic Ingredient Hotlist are present
- analyzing and considering pesticide incident and sales data in 49 reviews during 2013–14, the majority of which were pesticide re-evaluations; incorporating incident and sales data into regulatory actions and decisions; and using sales and incident reporting data to monitor whether previous regulatory actions have had the desired impact

Amendments to the NSNR for nanotechnology and products of biotechnology were planned as part of risk management activities under CMP2. CMP progress reporting from the Fall of 2013 indicates that work to date "has allowed Canada to understand that there is no need to develop a specific regulatory regime to deal with nanomaterials; the current regulatory framework, with some adjustment, is suitable" (Environment Canada, 2013a). Other program documents state that a decision was made to not pursue NSNR nanotechnology amendments "as it was felt that there was not yet sufficient science knowledge base"; "regulatory efforts were instead focused on alignment between Canada and the United States, under the umbrella of the Regulatory Cooperation Council".[37]

3.3.4 Research activities

Research activities were strengthened through improved research governance and better alignment of research projects with the needs of regulators, and within Health Canada, increased scientific support and improved laboratory infrastructure.

During CMP2, CMP partners took a variety of steps to strengthen research activities through improved research governance, better alignment of research projects with the needs of regulators, increased scientific support, and improved laboratory infrastructure.

- Research projects undertaken during CMP1 were analyzed and key results and lessons learned were identified, along with implications for future projects.

[36] Cyclical enforcement (CE) was funded as a risk management activity, although it is usually considered a compliance and enforcement activity.

[37] It is unclear if this decision also pertains to products of biotechnology.

- Research priorities for CMP2 were identified through internal Health Canada and Environment Canada workshops and consultations, based on key risk assessment, risk management, and policy needs. Research priorities were classified under three themes: effects; exposure; and development and validation of predictive tools, models, and approaches for use by risk assessors and risk managers.[38] Priority groups of chemicals for CMP2 included endocrine disrupting compounds, metals, mixtures, and azo benzidine compounds. For the second half of CMP2 (2014–2016), priority areas are substituted diphenyl amines, resins and rosin acids, musks, hindered phenols, remaining CMP3 flame retardants (phosphate-based), benzothiazole and benzotriazoles, brominated chemicals and polymers, and inorganics/metals. Characterization and pathogenicity/toxicity testing of existing micro-organisms has also been an area of research under CMP2.
- To improve alignment of research projects with the needs of regulators, steps were taken for early engagement between research and regulatory partners, risk assessment and risk management input on proposal review committees, and risk assessment and risk management sign-off on letters of intent and proposals. Research templates were developed within Health Canada and Environment Canada that require scientists to describe the consultations with regulators that occurred when they created their research proposals. According to program representatives, early engagement, joint planning processes and regular meetings between research and regulatory partners have helped to mitigate the challenges that can be encountered in aligning research activities and timelines with regulatory activities.[39]
- A mid-cycle review of all CMP2 projects was undertaken, and annual assessment of all research projects is done jointly by HECSB and SRAD on an ongoing basis.
- A CMP Research Network was developed as a forum to discuss priorities, improve collaboration, and exchange information on the CMP or chemical research underway within Health Canada. A representative of Environment Canada participates in the network.
- Needs analysis and design of the retrofit of the environmental health laboratory at the Sir Frederick Banting Building was completed, and a construction company was hired to complete the retrofit.

CMP research projects are supported through several funding streams, including the Health Canada-Environment Canada CMP Research Fund; the EHSRB CMP Research Program; Annual Chemicals Research within Environment Canada; and Environment Canada's grants and contributions to fund university-based researchers to undertake four research projects during CMP2. Research funds are also provided to SED's NSACB, HPFB's FD, and PMRA.

[38] A separate process is used by the Food Directorate to identify research priorities. Within the Directorate, an integrated planning cycle is carried out with participation of the risk assessors, risk managers, and research and surveillance employees. The planning project considers all initiatives and funding sources for the management of chemicals and allergens in food. Only projects identified as priorities for the CMP and for the Directorate as a whole are approved for funding under the CMP envelope.

[39] These challenges include responding to shifting priorities and identifying research needs early enough for results to inform risk assessment and risk management.

Between 2011–2012 and 2013–2014, Health Canada and Environment Canada completed a total of 243 research projects; only one planned project was not completed. Of these, 181 projects were conducted by Health Canada, while 62 were conducted by Environment Canada. Research projects addressed a variety of topics consistent with the identified themes and priority areas for research.

To disseminate research findings, Health Canada and Environment Canada undertook numerous knowledge transfer activities, including publishing the results in peer-reviewed scientific journals, as well as publishing and disseminating the results through reports, posters, workshops, and via other mechanisms. Both departments aimed to conduct at least one knowledge transfer activity for each research project completed. Several hundred knowledge transfer activities were undertaken during CMP2, and a joint Environment Canada-Health Canada workshop is held annually to disseminate the findings from research, monitoring, and surveillance activities. While external key informants had relatively little to say about the research component of the CMP, several industry key informants mentioned that more outreach could be done to communicate the goals and results of the research program to industry, other external stakeholders, and the general public.

Moving forward, as previously noted, the program expects a lack of data to present challenges for risk assessment of many CMP3 substances. According to the program, this will make models and informed assumptions increasingly important, and underscores the current need to identify priorities for research and generate data to inform risk assessment and risk management in the future.

3.3.5 Monitoring and surveillance activities

A variety of projects, including human biomonitoring, environmental monitoring, and monitoring of chemical substances in food, were undertaken and/or ongoing during CMP2. Results have been shared internally and externally.

As part of the CMP, data from monitoring and surveillance activities are intended to provide up-to-date evidence and performance measurement to support CMP key functional areas. As with research, structures and processes have been put in place to ensure a coordinated approach to priority setting for monitoring and surveillance that is linked to risk assessment and risk management.[40] Results from monitoring and surveillance activities are shared internally among CMP partners through annual results workshops, and disseminated externally through publication in peer-reviewed journals and national and international reports.

A variety of projects, including human biomonitoring, environmental monitoring, and monitoring of chemical substances in food, were undertaken and/or ongoing during CMP2. Health Canada's monitoring and surveillance activities during CMP2 include the following:

[40] This coordinated approach is particularly important, given the significant amount of planning and lead time (between three and five years) that is required in order to be included in some monitoring and surveillance activities, particularly large national surveys such as the CHMS.

- 23 projects funded under the CMP's Monitoring and Surveillance Fund (MSF) between 2011 and 2016 — the MSF funds smaller targeted studies to fill knowledge gaps under the themes of targeted population biomonitoring; biomonitoring supportive research; targeted environmental monitoring; and data analysis
- 30 projects funded under the Northern Biomonitoring Program (NBP), which monitors northern populations for exposure to substances such as polychlorinated biphenyl (PCBs), various pesticides, mercury, lead, and PBDEs, which accumulate globally in the Arctic
- the MIREC study, a longitudinal study of a cohort of pregnant women, with follow-up research on infant and child development that is examining exposure to 15 substances or substance groupings, including lead, mercury, cadmium, phthalates, BPA, PBDE, PCBs and others; during CMP2, Health Canada began an analysis of samples collected during CMP1 and undertook four additional MIREC projects
- the biomonitoring component of the CHMS, a joint undertaking of Statistics Canada, Health Canada, and PHAC (the biomonitoring component measures exposure to 106 environmental substances); during CMP2, Health Canada undertook cycles 2, 3, and 4 of the biomonitoring component of the CHMS
- the Total Diet Study (TDS), which examines levels of toxic substances in 210 individual food items, providing an estimate of exposure to certain chemicals in different cities across Canada
- targeted surveys of several substances of concern, including BPA and several phthalates, in specific foods, in order to fill identified data gaps for risk assessment and risk management

Environment Canada's monitoring and surveillance activities during CMP2 include the following:

- environmental monitoring and surveillance of priority chemicals in air, surface water, sediments, aquatic biota (fish) and birds (eggs) at sites across Canada; during CMP2, sampling sites were identified across Canada, and were used to collect and analyze samples for approximately 45 substances, including BPA, siloxanes, chlorinated paraffins, PFCs, and PBDEs, and Environment Canada also developed analytical methods and data quality assurance methods for various CMP2 substances, including siloxanes and PFOS
- monitoring for chemicals from consumer products and industry found in wastewater

In addition to these monitoring and surveillance activities, Environment Canada maintains the National Pollutant Release Inventory (NPRI), which provides air, water, and land pollutant release and transfer data on over 300 substances compiled from over 7,000 facilities that have s. 46–50 reporting requirements under CEPA 1999. The CMP uses NPRI data to inform risk assessments, develop risk management instruments, evaluate performance and effectiveness of risk management actions, and assess program outcomes. In addition, the NPRI program has leveraged CMP results to help inform its program. Recent changes include aligning thresholds with risk management actions to ensure that releases from facilities are better captured and to provide consistency in reporting across similar substances. At least 30 of the over 200 substances that have been risk-managed through the CMP were included in the 2012 and 2013 NPRI (Environment Canada, 2013c, 2014c).

Industry key informants generally agreed that CMP monitoring and surveillance activities are important in supporting risk assessment and risk management, and in the longer term, will help to demonstrate the extent to which risk management measures are effective. As with research, several suggested that more should be done to communicate the objectives and results of monitoring and surveillance activities to industry, other stakeholders, and the general public. The environmental monitoring program at Environment Canada was identified as requiring greater transparency and reporting.

3.3.6 Compliance promotion and enforcement activities

Steps were taken to improve the coordination and planning of compliance promotion and enforcement activities, as well as the ability to track, analyze, and report on these activities. Current reporting encompasses CEPA risk management measures that predate the CMP, and, although CMP funding supports enforcement of risk management instruments for all CEPA-toxic substances, greater specificity in compliance reporting is warranted, in the interests of accountability.

During CMP2, program partners implemented measures to improve coordination and planning of compliance promotion and enforcement activities and the ability to track, analyze, and report on these activities, consistent with the recommendations of the 2011 evaluation. Environment Canada:

- launched the National Enforcement Plan (NEP), which is updated annually and targets regulated communities at the highest risk of environmental damage as a result of non-compliance;
- carried out the following compliance and enforcement activities:
  - contacted 30,442 regulatees through compliance promotion activities on risk management instruments
  - completed 9,979 on- and off-site (i.e., paper-based) inspections
  - conducted 211 of 339 investigations ordered (62%)[41]
  - took a total of 13,137 enforcement actions, most commonly written warnings (60%), compliance orders (24%), no action being required (11%), investigation recommended (3%), or ticketed/prosecution (1%);[42]
- improved the ability to track, analyze and report on compliance promotion, and enforcement activities through improved information management systems;[43] and

[41] It is unclear why the remaining 128 investigations that were ordered were not conducted.

[42] It is unclear why "no action required" is considered an enforcement action.

[43] The EB is in the final stages of completing its Intelligence Renewal Project. This project includes updates which are expected to make the EB's database more efficient and easier to use, and enable more accurate reporting, than the existing enforcement database. Representatives of Environment Canada indicated that the Compliance Promotion Client Relation Management database, which currently contains over 125,000 stakeholders and 165,000 facilities, is a valuable tool for identifying regulates, recording activities, and determining what risk management instruments apply to them

- developed indicators and a methodology for reporting on compliance promotion and enforcement that will allow the EB to quantitatively measure the results of its actions under partially-controlled circumstances.[44]

Additional Health Canada representatives were added to Environment Canada's Chemicals Standing Compliance Promotion and Enforcement Steering Committee, and a reporting policy was established for the Committee. However, according to feedback from program representatives, this Committee is no longer active. Program representatives further indicated that given that risk management is developed under a number of Federal Acts, including CEPA, there is no one central entity responsible for the compliance and enforcement activities of the CMP. Rather, each program responsible for administering its respective compliance and enforcement activities under these various Federal Acts.

Except for the data on compliance promotion, the data reported above encompass CEPA 1999 regulations that predate the CMP (i.e., pre-2006). Information on compliance and enforcement activities relating specifically to the risk management measures stemming from CMP risk assessments was not available to the evaluation. Program representatives explained that CMP funding supports enforcement of risk management instruments for all substances on the CEPA List of Toxic Substances, not only those developed under the CMP.[45] Nonetheless, in the interest of accountability, greater specificity in reporting on compliance and enforcement activities for CEPA risk management instruments seems warranted. This could include, where feasible, separating out substances assessed during the CMP and/or risk management measures developed under the CMP.

In addition to Environment Canada's activities, as reported in Section 3.3.3, CPSD and RAPB Product Safety Program initiated or implemented cyclical enforcement (CE) for a variety of consumer products and cosmetics. CPSD considers all CE projects that involve chemicals to be part of the CMP, although the regulations enforced through these projects were not necessarily implemented as a result of CMP risk assessments. In 2010–11 and 2013–14, CPSD and RAPB Product Safety Program carried out CE of baby bottles to verify compliance with the BPA prohibition in the CCPSA, which was introduced during CMP1, as well as relevant requirements under the CCPSA and the *Phthalates Regulations*. Other CE projects monitored consumer products such as (but not limited to) children's jewellery, pacifiers, liquid-filled teethers, toys, glazed ceramics and glassware, pencils and artists' brushes, artists' paints, and furniture and other articles for children, as well as cosmetics including hair smoothing products and face paint.

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[44] The Targeted Outcomes Project currently focusses on the *Storage Tank Systems for Petroleum Products and Allied Petroleum Products Regulations*, while the environmental compliance rate project approach currently focusses on the *Tetrachloroethylene (Use in Dry Cleaning and Reporting Requirements) Regulations.*

[45] Program representatives also explained that there is only a limited number of enforceable regulations in place for substances assessed under the CMP. Based on feedback from various partners within Environment Canada, there is a lack of consensus within the program on an approach to reporting on compliance and enforcement activities under the CMP. Some support the current approach, while others support a more focussed approach that singles out compliance and enforcement activities relating specifically to risk management measures implemented as a result of CMP risk assessments.

To date, there have been no enforcement activities relating to the risk management measures for substances in food, since the majority of the measures are NRIs. Overall, it is unknown to the evaluation how many of the 59 risk management measures implemented under the CMP as of July 2014 (23 in CMP1 and 36 in CMP2) have been subject to compliance and enforcement activities.

3.3.7 Stakeholder engagement and risk communication activities

Program partners continued to emphasize stakeholder engagement during CMP2, and while industry stakeholders are generally satisfied with the engagement efforts, non-industry groups expressed some concerns. Program partners also took steps to improve communications to Canadians about the risks and safe use of substances of concern, but as in 2011, communications to Canadians continues to be perceived as a weakness of the program.

Stakeholder engagement

The 2011 evaluation of CMP1 singled out industry and other stakeholder engagement as a notable strength of the program. During CMP2, program partners continued to emphasize engagement with industry stakeholders through the following:

- implementing efficiencies to the stakeholder notification process for key risk assessment and risk management milestones, such as posting combined notifications of planned groupings of medium priority substances and transitioning to a notification subscription service through the Chemical Substances website; subscriptions have trended upward over the past three fiscal years, reaching 1,077 in 2013–2014
- building on its ability to communicate with stakeholders by implementing a Substances Management Information Line, which received and responded to 3,805 inquiries between 2011–12 and 2012–13; another 325 inquiries were received through the Chemical Substances website and received responses, approximately 500 inquiries are received annually at Environment Canada via the Management of Toxic Substances website
- providing a variety of opportunities and mechanisms for early engagement and consultation. Examples include consultations on the design/scope of information-gathering initiatives; preliminary discussions, pre-consultations, and formal consultations with affected sectors to inform the development of risk management measures; establishment of sector working groups (e.g., auto manufacturing, paints, and coatings) to facilitate exchange of information of particular relevance to the sector; and holding sector-specific briefings as required — program staff conducted about 20 stakeholder consultations per year, involving a total of 11 different industry sectors, to support decision-making on which risk management options should be implemented for the identified priority substances; the FD hosted 21 stakeholder calls when the results of group assessments indicated potential adverse impacts for stakeholders

- establishing a biotechnology industry-government working group to better engage with a sector previously underrepresented in stakeholder engagement initiatives, establishing an international multi-stakeholder network on microbial-based cleaning products, and broadcasting webinars to inform stakeholders of assessment conclusions and proposed actions for existing micro-organisms requiring risk management

Program partners also engaged with non-industry stakeholders though the following:

- renewing the CMP Stakeholder Advisory Council (SAC), which brings together representatives from key stakeholder groups (within and outside of industry) to inform and advise the government's implementation of the CMP, foster dialogue on CMP issues between various stakeholders and the government, and provide stakeholders with information on CMP activities; during CMP2, the SAC gained additional representation from environmental and health NGOs, as well as representatives from the import/export, electronics, and retail sectors[46]
- establishing capacity contracts with the Assembly of First Nations (AFN), the New Brunswick Lung Association (NBLA), and Inuit Tapiriit Kanatami (ITK), to facilitate their participation in the SAC and ongoing consultation on proposed risk assessment and risk management decisions and conclusions

Most industry key informants were satisfied or extremely satisfied with the extent to which the CMP has engaged and consulted with industry stakeholders during CMP2. Many remarked on improvements in this area compared to CMP1, characterizing the Government of Canada as open and approachable, and the communication and consultation processes as "world class." Industry key informants said that engagement and consultation has been particularly strong with respect to risk assessment and risk management. Industry also noted comparatively little consultation or exchange with industry relating to compliance and enforcement activities, although it was pointed out that close consultations between industry and government in this area could undermine public confidence in regulatory oversight.

Compared to industry key informants, industry survey respondents hold more diverse views concerning industry engagement and consultation, although it should be noted that the survey results cannot be generalized to the larger population of CMP industry stakeholders Forty-one percent (41%) agreed that the Government of Canada consults adequately with industry and takes the concerns and interests of industry into account in decision-making, and a similar proportion agreed that the existing consultation mechanisms are an effective way for industry to express to the Government of Canada its concerns and interests related to the CMP (see Table 7). In all cases, about one-third were neutral, while the remainder disagreed or did not know.

These results may reflect the relative lack of familiarity among survey respondents with many of the consultation mechanisms. Results from the industry survey showed that while the majority of respondents have received and/or accessed CMP-related information through letters, guidance documents, and the Chemical Substances website, fewer have actively participated in stakeholder engagement opportunities such as teleconferences, workshops, working groups, and

[46] These groups were added to broaden the scope of the SAC, as well as fill a vacancy left by labour group representatives, who are no longer members of the SAC.

meetings; and fewer still have provided comments on proposed or final screening assessment or risk management documents, although it should be noted that the survey results cannot be generalized to the larger population of CMP industry stakeholders.

When asked if the CMP, as it is being implemented, provides regulatory certainty for industry, a majority of industry survey respondents either agreed (29%) or were neutral (41%). The remainder disagreed (13%) or did not know (17%).

Table 7: Industry perspectives on consultation processes

Survey question	Percent (n=260)			
	Agree	Neutral	Disagree	Don't know
The existing consultation mechanisms are an effective way for industry to express to the Government of Canada its concerns and interests related to the CMP.	41%	32%	12%	15%
The Government of Canada consults adequately with industry as part of the CMP.	41%	33%	13%	13%
The Government of Canada takes the concerns and interests of industry into account in decision-making.	38%	35%	14%	14%
The CMP, as it is being implemented, provides regulatory certainty for industry.	29%	41%	13%	17%

Source: Industry survey
Note: Row totals may not sum to 100% due to rounding.

Compared to industry key informants, other external key informants were less enthusiastic about the CMP's efforts at engagement and consultation. While many appreciated the opportunities afforded through the SAC, it was noted that it can be challenging to become knowledgeable in all of the areas addressed by the SAC in order to provide fulsome, relevant commentary and represent their constituencies at SAC meetings. Because membership is limited, the opportunity to participate in the SAC is seen as a big responsibility.

Related to this, non-industry key informants indicated that Environment Canada's decision in October 2011 to end its annual funding to the Canadian Environmental Network (RCEN), which represented 640 small environmental groups across the country, has limited the ability of NGOs to participate in consultations on the CMP and other environmental issues.[47] The termination of

[47] In October 2011, the RCEN was informed by Environment Canada that its annual contribution agreement would not be renewed. The RCEN "acted as a link between 640 small environmental groups across the country and the federal government;" it engaged these groups in formal consultations on environmental policies and new laws (including CEPA) and provided this input to the federal government (McDiarmid, 2011). In addition to this core funding, program representatives indicated that in CMP1, the RCEN was awarded a three-year contract through a competitive bid process to "strengthen the capacity of the NGO sector and other Civil Society Organizations to provide input on the CMP." When the contract ended, Health Canada posted another RFP in 2012 for an NGO to conduct capacity building under CMP2. This contract was awarded to the NBLA. The RCEN did not submit a proposal at the time of the second RFP process in 2012. By that time, it had been informed that its funding would not be renewed. A media report from October 2011 indicates that following the termination of its funding, the national RCEN office closed and five people lost their jobs; a few provincial offices were to remain open because they received provincial funding (McDiarmid, 2011).

this funding has particularly affected the ability of NGOs to participate in face-to-face meetings with government and industry stakeholders, which they said is important to their understanding of the issues and the perspectives of other stakeholders, and their capacity to provide informed feedback. Similar feedback was provided by external key informants who participated in the BPA case study.

Finally, during CMP2, program partners continued as required by law to publish notices of intent that invite the public and stakeholders to comment on dSARs, as well as proposed and final risk management instruments published in *Canada Gazette*. Some industry and non-industry stakeholders indicated that it can be difficult to determine how responsive the CMP is to the feedback it receives during these public comment periods. They indicated that although the CMP provides summary reports of the comments it receives and its response to them, the comments are "rolled up" in such a way that nuances are lost. As a result, those who provided comments are unable to recognize their contributions or discern how, or if at all, they influenced decision making.

Risk communication

In contrast to stakeholder engagement, the 2011 evaluation identified proactive risk communication to Canadians as a weakness of CMP1 and recommended that the program undertake research to better understand Canadians' understanding of chemical risks. The program does not appear to have pursued other fact-based research on awareness or behaviour change.

However, program partners have responded to the 2011 recommendation by routinely tracking outreach activities, undertaking contract projects aimed at better communicating risks and outcomes from the CMP,[48] and seeking feedback on risk communications through the capacity-building arrangements with AFN, ITK, and the NBLA. ITK has provided advice on how to communicate risk and CMP outcomes to Inuit and northern communities, and the Canadian Network for Human Health and the Environment (CNHHE) has provided expert feedback on the content and presentation of draft communications projects.

More broadly, the capacity contracts require these organizations to use their networks to disseminate CMP information to their stakeholders. AFN aimed to disseminate information among First Nations to raise awareness of the CMP and its outcomes, which was primarily done through the First Nations Environmental Health Innovation Network (FNEHIN), a website that includes a monthly e-newsletter and CMP-related postings. The NBLA targeted the public and non-industry stakeholders through the CNHHE website. The ITK's capacity contract has a similar requirement to target Inuit, which was still in the planning stages as of March 2014.

[48] One example given was the Review of Tools used by National Regulatory Authorities and International Chemicals Management Authorities to Communicate Chemical Risk Information to the General Public.

During CMP2, program partners also sought to improve communication to Canadians through the following:

- improving the Chemicals Substance website to ensure that it meets accessibility requirements and includes up-to-date, non-duplicative content — the site is intended as a single window source for the publication of notices of intent, draft and final screening assessment and risk management documents, and summaries of stakeholder and public comments; the "Chemicals at a Glance" webpage, which provides a summary of key information on the chemicals being assessed under the various CMP initiatives, is a central feature of the website, and users can subscribe to receive emails regarding all publications to the website
- expanding communications about risks and safe use of chemicals in the home into social media through the Healthy Canadians website, Facebook and Twitter accounts, and through external partners such as the CNHHE
- disseminating products such as *Hazardcheck* and the *Our Health, Our Environment* guide to inform the public and non-industry stakeholders about substances of concern[49]
- developing and launching the Chemicals Awareness Learning Modules (CALM) Sessions to inform intermediaries, such as nurses and daycare providers, about the CMP as well as risks and safe use of hazardous substances
- establishing a Public Outreach Working Group to promote a coordinated national approach to outreach, and conducting a variety of outreach activities including briefings, workshops, conferences, webinars, and regional and international events
- completing over 200 risk communication activities targeting non-industry stakeholders and the public.

While some CMP-related information and communications, such as the Chemicals Substances website, are accessible to all stakeholders and the general public, some program representatives indicated that, overall, the CMP is taking a more focussed approach to communications. Rather than trying to reach all Canadians with information about substances of concern, they indicated that the program has begun to tailor its communications, to ensure that those who need specific information about the safe use of substances will receive it. For example, program representatives suggested that not all members of the general public require information about industrial chemicals, and therefore the program is targeting its communications to the specific groups that do. Nonetheless, some program key informants said that the CMP could improve its communications to Canadians by first developing a better understanding of the information that Canadians feel they need.

Almost all non-industry key informants indicated that the CMP is not communicating effectively with the Canadian public, and in particular, it is not responding effectively to Canadians' need for information about the risks and safe use of substances of concern. These key informants believe that most Canadians are unaware of the CMP and that the CMP has not made much effort to communicate with Canadians, even though they believe environmental and health concerns are of high interest to the general public. While these key informants recognized that

[49] *Hazardcheck* targets the Canadian public with information related to health risks common in the home environment, such as household chemicals, air quality, lead exposure, and consumer products, while the *Our Health, Our Environment* guide targets "informed Canadians," such as researchers, and includes background, status, trends on biomonitoring, and information on indoor air and drinking water quality.

the Chemicals Substances website contains a large amount of information, they characterized that information as highly technical, inaccessible, focussed mainly on managerial objectives (i.e., the number of substances assessed), and irrelevant to what Canadians care about, which in their view is straightforward messaging about the risks associated with toxic substances and practical advice on what individuals can do to limit their exposure to those chemicals.[50]

Several non-industry key informants acknowledged that communicating effectively with Canadians about the risks associated with toxic substances is challenging, particularly in a context where media reports can influence public opinion. They also noted the unique challenges (such as limited access to computers and language barriers), as well as the costs associated with disseminating information among First Nations and Inuit. Non-industry key informants agreed that the CMP has a role to play in improving Canadians' understanding of the risks associated with toxic substances, and what they can do to mitigate those risks. It was suggested that NGOs have been valuable intermediaries between the Government of Canada and the general public, and that they can continue to play an important role in translating complex scientific information into a format that is accessible to Canadians.

3.3.8 International activities

While international activities are not defined as one of the CMP's core activity areas, the Government of Canada participates in a number of bilateral and multilateral fora related to chemicals management that are important to note. For example, Canada is a party to several legally binding international conventions relating to chemicals management, including the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, and the Stockholm Convention on Persistent Organic Pollutants. Canada is also a signatory to the new Minamata Convention on Mercury.

Other international activities include the following:

- bilateral collaboration with the United States through the Canada-US Regulatory Cooperation Council (RCC), the Canada-US Great Lakes Water Quality Agreement, and the Consultations on Substance Management (COSM)
    - Through the first phase of the RCC, Canada and the US adopted common Policy Principles for the regulation of nanomaterials and worked with stakeholders to develop classification schemes and industrial use profiles. The second phase will seek to enhance regulatory alignment and compliance promotion on information requirements for significant new uses of chemicals, and to communicate common approaches for emerging areas in risk assessment, such as combined exposures to multiple chemicals.

[50] The Chemicals Substances website does contain some Fact Sheets, Frequently Asked Questions, and similar documents aimed at the general public. These documents provide an overview of CEPA 1999 and the CMP, and some provide general information about risks and on how people can reduce exposure to chemicals. In addition, there is some substance-specific information relating to BPA and triclosan.

  - Through the renewed 2012 Great Lakes Water Quality Agreement (which entered into force in February 2013), Canada and the US agreed on a new process to identify chemicals of mutual concern, and to develop plans and actions to reduce or eliminate these chemicals in the Great Lakes.
  - Through COSM, Canada and the US undertake informal discussions aimed at sharing resources and knowledge to strengthen the risk assessment and risk management activities of both countries.
- bilateral collaboration with the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the European Chemicals Agency (ECHA), and the Chinese Ministry of Environmental Protection; under these arrangements, the under both arrangements, the partners aim to share information and experiences concerning risk assessment and risk management strategies, and to collaborate to address common challenges
- trilateral collaboration with the US and Mexico through the Sound Management of Chemicals Working Group, which delivers regional projects to advance chemicals management outcomes across North America; current work is focussed on chemicals in products, with a focus on flame retardants
- multilateral collaboration through the WHO International Programme on Chemical Safety, the OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides, and Biotechnology (OECD JM); the SAICM; and several Codex Alimentarius committees
  - Through participating in the WHO International Programme on Chemical Safety, Canada collaborates on the development or revision of risk assessment methodologies and participates in the WHO Risk Assessment Network to foster collaboration and address identified issues related to chemical risk assessment.
  - Through the OECD JM, Canada participates with other OECD countries on technical issues related to chemicals management, including test method development, risk assessment, emerging scientific issues, and information exchange. Technical work is completed by a series of task forces working in the areas of exposure assessment, hazard assessment, manufactured nanomaterials, harmonization of regulatory oversight in biotechnology, and new chemicals.
  - Canada participates in the SAICM, a multi-stakeholder voluntary policy forum supporting the 2020 World Summit on Sustainable Development goal to minimize the impact of significant effects on human health and the environment.
  - Canada participates in several Codex Alimentarius committees, including the Joint Food and Agriculture Organization/WHO Expert Committee on Food Additives, the Codex Committee on Food Additives and the Codex Committee on Food Contaminants. Through Codex Alimentarius work, Health Canada ensures that the risk assessment and risk management of substances with food implications remains in line with that of the international food community.

3.4 Performance — Issue #4: Achievement of expected outcomes

Overall, while there is evidence of progress in some areas, in other areas there are limited data to draw conclusions on the extent to which some CMP outcomes have been achieved.

3.4.1 Use of information by CMP partners

Information and data are being used by program partners to inform CMP activities and decisions. Priorities for research and monitoring and surveillance are developed through a consultative approach to ensure alignment with the needs of the regulatory partners, and findings are used to inform risk assessments, risk management and other program activities. Improvements to information systems are expected to further facilitate program access to and use of information.

The evaluation found evidence that information and data about substances of concern are being used by Health Canada and Environment Canada to inform CMP activities and decision-making. Research priorities and plans are developed through a consultative approach involving the research and regulatory groups within the CMP to ensure that research efforts align with the needs of the latter. In general, a more directed approach to research is being taken in CMP2. Research projects may be undertaken to fill data gaps, complement existing data, refine assumptions, or improve methodologies and models. Research findings are then used to inform risk assessment and risk management. Similarly, priorities for monitoring and surveillance are developed through consultations between the monitoring and surveillance and regulatory partners. The data generated through monitoring and surveillance activities are used to inform risk assessment and risk management, and will be used in the future to evaluate the effectiveness of risk management measures and determine if updates are required.

Research findings and/or data from monitoring and surveillance studies have been used to inform CMP decision-making with respect to BPA, certain flame retardants, PFOA, phthalates, and triclosan, among other substances. According to one tracking tool, in one six-month period between April and September 2014, 17 different datasets/results generated by EHSRB had been used in various ways by CMP partners, including SED, CPSD, PMRA, and ERHSD. In addition, specific datasets/results had been used by external parties, including the National Research Council and the US Environmental Protection Agency (US EPA).

The BPA case study highlights the important role of research, as well as monitoring and surveillance activities, to inform CMP decision-making.

Lesson learned on research and monitoring and surveillance — the BPA experience

The role of research and surveillance. While emphasizing that uncertainty about BPA's human health and environmental effects could not be used to justify inaction on that substance, the Government of Canada also recognized the importance of eliminating some of this uncertainty in order to inform future action. Accordingly, the CMP invested in significant research and surveillance to eliminate data gaps and improve the information available to researchers and regulators with respect to BPA exposure and effects. BPA was incorporated into the TDS, the MIREC, the CHMS, and Environment Canada's environmental monitoring and surveillance program, among other studies, and a number of research projects were undertaken. Findings from research and monitoring and surveillance activities have played a role in guiding Canada's approach to BPA risk management and/or have provided evidence of the effectiveness of these activities. For instance, data obtained through the TDS was critical in updating Health Canada's assessment of Canadian BPA exposure in food sources.

For chemicals used in consumer products, early involvement by the CPSD has helped to ensure that risk assessment conclusions are appropriate, that "right-sized" risk management actions are being taken, and/or that unnecessary risk management is avoided. For example, CPSD conducted testing to inform the assumptions used for the risk assessment for azo dyes and, in particular, assumptions about the concentrations of these substances used in consumer products. In the absence of this testing, CPSD key informants noted that the risk assessment may have reached a conclusion regarding toxicity in consumer products that was not warranted.

There are numerous regular venues for information-sharing among CMP partners. For example, for the Substance Groupings Initiative, the creation of the Groupings Working Group has helped to facilitate knowledge sharing across the risk assessment and risk management functions within Health Canada and Environment Canada. Within Environment Canada, Regulatory Working Groups serve as a forum for facilitating the implementation of risk management measures, by promoting information-sharing, problem solving, and coordination among the internal partners involved. Other examples include Environment Canada's Monitoring and Surveillance Working Group and Health Canada's CMP Research Network.

Finally, improvements to information systems are currently being implemented, which is expected to facilitate the ease with which program partners can access and use data from across CMP partners to inform their activities. For more information about information-sharing mechanisms and improvements to information technology, see Sections 3.5.1 and 3.5.2.

3.4.2 Understanding and use of information by Canadians

Because the CMP does not actively collect data on Canadians' understanding and use of information on the risks and safe use of substances of concern, it is not possible to draw conclusions on the extent to which this outcome may have been achieved.

Canadians and stakeholder groups are expected to understand information on risks and safe use of substances of concern, and then use that information to avoid and minimize risks posed by substances of concern. Results from POR carried out during CMP1 (in 2009) showed that Canadians had limited knowledge about chemical risks, limited confidence in the government as a source of information on consumer products and food safety, and generally considered available information on chemicals to be "somewhat helpful" (Health Canada, 2011).

With limited exceptions, the CMP does not collect data to support conclusions on the extent to which Canadians understand and use information on risks and safe use of substances.[51] As a result, no conclusions can be drawn about the extent to which the CMP may have influenced Canadians' understanding and use of information on risks and safe use of substances of concern. As described elsewhere in this report, external key informants believe the CMP is not responding effectively to Canadians' need for information about the risks and safe use of substances of concern.

3.4.3 Industry understanding and compliance

The available data show a reasonably high overall rate of compliance among inspected entities, although these rates cannot be extrapolated to the regulated industries in general.

Industry awareness and understanding

Self-report data from the industry survey suggest opportunities to improve awareness and understanding among industry stakeholders affected by CMP risk management measures. Among respondents, one-quarter (26%, n=67) indicated that risk management measures have been implemented under the CMP that apply to their company or member companies. Notably, a similar proportion (27%) did not know if any such measures have been implemented, while 47% indicated that no risk management measures have been implemented that were applicable to them.

Most of the 67 respondents, who said that CMP risk management measures have been implemented that apply to them, reported that they received information from (n=47) or participated in activities organized by (n=39) the Government of Canada to inform them of risk management measures implemented under the CMP that apply to them. A large majority of those who received information or participated in activities found them to be useful. Nevertheless, only

[51] During CMP2**,** RAPB conducted workshops and sessions aimed at educating intermediaries (such as nurses and daycare workers) in an effort to build awareness and understanding of the risks and safe use of substances of concern. Exit surveys were collected from event attendees, and respondents reported that these sessions had increased their awareness and understanding of chemical substances and associated health issues. Results from these evaluations cannot be extrapolated to Canadians or stakeholder groups in general.

62% of these respondents understand what action they need to take to come into compliance with the risk management measures that apply to them, and slightly fewer (58%) believe they have a strong understanding of these measures (see Table 8). Although based on a limited and unrepresentative sample, overall these results suggest a need for additional compliance promotion and outreach to industry to ensure awareness and understanding of the risk management measures that have been put in place under the CMP.

Table 8: Industry perspectives on risk management measures

Survey question	Respondents in agreement (n=67)	
	Percent	Frequency
My organization understands what action it/its member companies needs to take to come into compliance with the CMP risk management measures that apply to it/them.	62%	42
My organization has a strong understanding of the CMP risk management measures that apply to it/its member companies.	58%	39

Source: Industry survey

Industry compliance with risk management measures

The available compliance data show that, overall, compliance with risk management measures is reasonably high among inspected industries. According to data provided by Environment Canada, for regulations implemented under CEPA 1999, over 80% of inspected industries were in compliance with regulatory requirements over the period 2011–12 to 2013–14.[52] However, compliance rates ranged from 44% to 100%, depending on the regulation and year involved. Table 9 below shows the specific regulations included in these figures and their corresponding compliance rates.

It should be noted that the data reported in Table 9 are not limited to regulations introduced as a result of CMP risk management, but also include some regulations that pre-dated the CMP (although some may have been amended since the CMP was launched). In addition, since industries were targeted for inspection based on risk criteria, the reported rates are not statistically valid and cannot be extrapolated to the regulated industries in general. One exception is the compliance rate reported for the PERC regulations in 2012–13 (51%), for which Environment Canada has developed a statistically valid methodology. Environment Canada intends to achieve a 10% increase in PERC regulation compliance by 2015–16 (Environment Canada, 2013b).

Environment Canada data also show that 82% of non-compliant entities returned to compliance in 2013–14, compared with 91% in 2012–13 and 31% in 2011–12.

[52] Inspections include on- and off-site inspections, and depending on the regulation, the number of parties inspected in each year ranged from one to a few hundred and in one case — the *Tetrachloroethylene (Use in Dry Cleaning and Reporting Requirements) Regulations* — over 1,000.

Table 9: Percentage of inspected industry in compliance/conformity with regulatory requirements under CEPA 1999

Regulation	2011–2012	2012–2013	2013–2014
Tetracloroethylene (Use in Dry Cleaning and Reporting Requirements) Regulations	55%	51%	61%
Solvent Degreasing Regulations	88%	100%	56%
CEPA Section 56 Notices — P2 Plans	100%	94%	100%
Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations	100%	100%	50%
PCB Regulations	81%	87%	88%
Chromium Electroplating, Chromium Anodizing, and Reverse Etching Regulations	79%	84%	44%
Environmental Emergency Regulations	-	-	65%
Export and Import of Hazardous Waste Recyclable Material Regulations	-	-	91%
Interprovincial Movement of Hazardous Waste Regulations	-	-	100%
New Substances Notification Regulations (Chemicals and Polymers)	-	-	100%
New Substances Notification Regulations (Organisms)	-	-	100%
Pulp and Paper Mill Defoamer and Wood Chip Regulations	-	-	100%
Pulp and Paper Mill Effluent Chlorinated Dioxins and Furans Regulations	-	-	100%
Secondary Lead Smelter Release Regulations	-	-	100%
Storage Tank Systems for Petroleum Products and Allied Petroleum Products Regulations	-	-	61%
Percentage of inspected industries in compliance (average)	**84%**	**86%**	**81%**

Source: Environment Canada.

Some additional information on industry compliance, pertaining specifically to Pollution Prevention Planning Notices and Environmental Performance Agreements (EPA), is available in progress reports posted on Environment Canada's website. Overall, the results show that most companies subject to Pollution Prevention Planning Notices and participating in EPA comply with the reporting requirements, and in some cases, performance objectives have been achieved and/or progress is being made toward them.

With respect to CMP risk management measures implemented under Acts other than CEPA 1999, the 2010–11 CE project for polycarbonate baby bottles found 96% compliance with the prohibition on BPA (25/26 samples tested), while the 2013–14 CE project found 100% compliance among three polycarbonate baby bottles tested (in that year, the vast majority of bottles were composed of materials other than polycarbonate, thus only three were tested). Based on the 2013–14 results, Health Canada concluded that "good marketplace compliance" has been observed and recommended that assessment of polycarbonate baby bottles be removed from the CE program.

In addition, activity reports for other CE projects involving chemicals show generally high rates of compliance with regulatory requirements among the monitored entities for lead, cadmium, mercury, phthalates and other chemicals between 2011–12 and 2014–15. As already noted, CPSD considers all CE projects that involve chemicals to be part of the CMP.

Lessons learned on industry compliance — the BPA experience

Industry compliance with BPA risk management is high. The available evidence suggests industry compliance with risk management measures for BPA has been high. A recent report indicates full compliance among importers with the ban against polycarbonate baby bottles, within the sample of firms selected. Furthermore, all four facilities subject to the P2 Planning requirement have begun to prepare Pollution Prevention Plans and are anticipated to meet the risk management objectives identified in the Notice, and one has already achieved this goal. Finally, compliance among the 13 paper recycling companies participating in the Environmental Performance Agreement has been high, although the extent to which performance objectives have been met will not be evaluated until 2017. In addition, although there was no formal requirement to do so, manufacturers of infant formula have phased out the use of packaging materials containing BPA in favour of BPA-free alternatives.

Voluntary industry action

It is challenging to assess the extent to which industry takes "voluntary action" to protect Canadians and the environment. About 40% of the 67 survey respondents who said that CMP risk management measures have been implemented that apply to them reported having implemented voluntary risk management measures for toxic substances since the inception of the CMP in 2006 (n=26), although it should be noted that the survey results cannot be generalized to the larger population of CMP industry stakeholders. Examples included introducing internal policies, controls, processes, best management practices, audits, or monitoring; eliminating or phasing out certain toxic chemicals; discouraging the use of certain chemicals; and identifying formulation alternatives.

According to a 2013 study completed by an external consultant, drivers of "early industry action"[53] included CMP processes as well as industry programming; consumer perceptions; international or provincial risk management action; market positioning; and corporate culture, The study noted that three conditions tended to be in place when industry decided to take early action: industry agreed with scientific conclusions of an assessment; the proposed risk management approach was seen as proportionate and targeted; and alternative substances or technologies were available, cost effective, and delivered appropriate performance.

3.4.4 Risk/threats to health and environment

Trends for environmental and/or human exposure data for some core CMP risk-managed substances are beginning to emerge, and may be more firmly established through monitoring over a longer term.

[53] Program representatives defined "early action" as action taken by industry to address a risk before a risk management measure is in place (whether voluntary or regulatory).

In the intermediate term, the CMP expects that risks associated with harmful substances in humans, the environment, food, and consumer products are prevented, minimized, or eliminated, and in the long-term, hopes to achieve a reduction in threats from harmful substances to health and the environment. These two outcomes are highly similar and are treated as one in the discussion that follows.

CMP partners have proposed to measure risks to health and the environment by monitoring exposure concentration or release levels for a pilot group of 10 chemicals or groups of chemicals.[54] Some of these chemicals/groups of chemicals, namely mercury, PBDEs, PFOS and PFOA, hexavalent chromium, and BPA, are currently being risk-managed under the CMP (although risk assessments may have been completed prior to the launch of the CMP). A summary of the risk management actions put in place for these substances, as well as trend data on exposure concentration and release levels as described in a 2014 study prepared for Health Canada by an external consultant, is provided below.

- **Mercury.** Risk management actions for mercury implemented under the CMP target mercury-containing products, dental amalgam waste, steel mills that process end-of-life vehicles containing mercury switches, and base metal smelters, refineries, and zinc plants that release mercury. The available data show that environmental releases of mercury have trended downward since 2006, which program representatives indicated is due to significant reductions in the base metals smelting sector. There has been no change in human exposure levels.
- **PBDEs. PBDE** regulations were finalized in July 2008 and Federal Environmental Quality Guidelines for concentrations in water, sediment, and biological tissue were finalized in February 2013. While there is a decreasing trend in environmental levels of PBDEs in a number of media, air quality data show an increase in PBDE concentrations in the Arctic and the Great Lakes Basin since 2008. However, data sets for individual BDE compounds exhibited significant seasonal variations and an actual trend in total BDEs could not be confirmed. Program representatives indicated that global use of PBDEs and long-range transport may be influencing levels of PBDEs in northern Canada.
- **PFOS/PFOA.** Regulations for PFOS were finalized in June 2008 and an EPA covering PFOA was signed in March 2010. Plasma concentrations for PFOS have decreased for all age groups, in alignment with the 2008 regulations prohibiting/eliminating the manufacture, use, sale, or importation of PFOS in Canada. Plasma concentrations for PFOA also declined, but to a lesser degree. There has been no clear trend in airborne concentrations for this group of chemicals.

[54] The pilot chemicals are lead, mercury, cadmium, hexavalent chromium, BPA, polybrominated ethers (PBDEs), perflurooctane sulfonate (PFOS) and perfluorooctanoic acide (PFOA), polychlorinated dibenzo dioxins (PCDD) and dibenzo furans (PCDF), phthalates, and volatile organic chemicals (VOC).

- **Hexavalent chromium (HVC).** The Chromium Electroplating, Chromium Anodizing and Reverse Etching Regulations were put in place in 2009 with the objective of minimizing HVC releases from metal finishing facilities.[55] Overall, there has been no clear trend in airborne concentrations of HVC since that time, and environmental releases have varied yearly between 2000 and 2012 with no discernable trend. However, NPRI data for 2005–06 show an 80% decline in atmospheric releases of HVC from the metal finishing sector, which is attributed to actions taken by the metal finishing industry to reduce emissions in anticipation of the (then) forthcoming regulations. According to a 2013 performance analysis report on the regulations, HVC air emissions were reduced to below the target level by 2010 and were on-track to meet the longer-term target of over 25 years, although the report noted that these conclusions were based on incomplete release data.
- **BPA.** There have been no apparent trends in BPA disposal or release to the environment since 1994. BPA levels in human tissue increased between the first (2007–09) and second (2009–11) cycles of the CHMS, but data for the third cycle, which might begin to capture the impact of the risk management measures that have been put into place for BPA, are not yet available. In 2012, dietary exposure to BPA was assessed as lower than in 2008, corresponding to industry's move away from the use of BPA in can linings, and in December 2014, Health Canada confirmed that BPA is no longer being used in infant formula packaging. Key exposure data (surface water, breast milk) are not available.

While the preliminary results for some substances are showing decreases that correlate to the timelines during which domestic action was taken, trends may be more firmly established through monitoring over a longer term. Moreover, program representatives indicated that exposure in Canada to some substances may be influenced by foreign use. For example, at present, an estimated 96% of mercury pollution deposited in Canada comes from foreign sources, and as noted above, long-range transport by foreign sources may be influencing PBDE levels in northern Canada. This suggests an ongoing need for international risk management efforts such as the Stockholm Convention on Persistent Organic Pollutants and the Minamata Convention on Mercury, in addition to domestic risk management.

During CMP2, program partners assessed the feasibility of developing an Index of Risk based on the 10 pilot chemicals. Overall, the study concluded that it was feasible to develop a risk indicator, but pointed out that the current conceptual model for human exposure does not account for exposure through consumer and other products which may represent significant sources of exposure. These products are not included in the conceptual model because they are typically not captured by existing monitoring programs, and this gap in coverage could affect the accuracy of the proposed risk indicator.

[55] Metal finishing facilities are not the only source of HVC releases.

3.4.5 Unintended consequences

Unintended consequences arising from the CMP have been mainly positive, including recognition of Canada as an international leader in risk assessment and risk management of chemical substances, development of positive relationships with industry; and positive impacts on industry awareness, processes, and decisions.

The evaluation identified a number of unintended consequences arising from the CMP. Some positive results have been the following:

- Canada has been recognized as an international leader in risk assessment and risk management of chemical substances. Elements of the CMP approach, particularly the initial prioritization process and the establishment of an ambitious timeline for addressing the 4,300 prioritized substances, are highly regarded by Canada's international regulatory counterparts and other international organizations. Australia has modelled its risk assessment program on the Canadian approach.
- Relationships with industry developed through the CMP have had beneficial impacts beyond the CMP. Program key informants indicated that the positive relationships with industry, developed through early engagement and close consultation, have helped to facilitate other activities with the same stakeholders. For example, these relationships have facilitated work on federal greenhouse gas policy, which may not have been possible had those relationships not been developed. Overall, there is a greater awareness of the need for industry and government to work collaboratively on regulatory and sustainability issues.
- The CMP has had positive impacts on industry awareness, processes, and decisions. Key informants and survey respondents identified a variety of positive impacts for industry, including increased awareness of the chemicals used in production processes; increased awareness of the need to take proactive action to manage the risks associated with chemicals; improved approaches to data management and development of research methodologies to allow industry to respond more easily to requests for information; and greater respect for those within industry who work in regulatory affairs (they have come to be seen as adding value). While only a minority of survey respondents indicated that the CMP has affected their business decisions, all gave positive examples of its impact, such as eliminating toxic substances and introducing reformulations; ongoing monitoring of CEPA compliance status and risks; increased awareness and focus on the human and environmental impacts of chemicals; and selecting vendors or suppliers based on their compliance.[56]

[56] A total of 67 industry survey respondents reported that CMP risk management measures have been implemented that apply to their organization. Of these respondents, 39% reported that the CMP has influenced their business decisions.

Some negative unintended consequences for industry and/or the Canadian economy were also identified. A few industry key informants reported a "blacklisting mentality" is leading some customers to avoid products containing categorized/prioritized substances prior to a risk assessment conclusion. On the other hand, these key informants indicated that going through the risk assessment process and having a substance determined *not* to be toxic is a very positive outcome for industry.

Program key informants indicated that Canada's leading role in chemicals management can create difficulties for industry and, ultimately, the Canadian economy in the context of a global marketplace, if risk management measures are implemented in Canada that do not exist elsewhere. Based on results from the industry survey, this appears to be a concern for a minority of respondents. Most industry survey respondents either believe the CMP allows industry to comply with the federal government's requirements while remaining internationally competitive (32%) or were neutral on the issue (39%). Only 13% disagreed, while the remaining 17% did not know. In interviews with industry, one or two examples of negative impacts for the Canadian economy, such as a decision to locate a production facility in another country, were described.

Finally, the CMP's schedule for assessing substances and the prescribed timelines under CEPA 1999 for implementing risk management measures for toxic substances were perceived by key informants as having both positive and negative consequences. On a positive note, program key informants indicated that the prescribed timelines for implementing risk management means that deliverables are less subject to changes in priorities and direction or protracted lobbying. On the other hand, it was also noted that meeting CEPA timelines can require program partners to reallocate non-CMP human resources to CMP activities. This re-allocation is not necessarily appropriate if the risks being addressed through the CMP are lower than those being addressed by other activities. Similarly, a few external key informants indicated that adhering to the CMP schedule can mean reduced flexibility to respond to emerging and/or regional issues.

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

3.5.1 Governance

Though CMP governance is generally seen as effective, roles and responsibilities could be clarified with respect to oversight of compliance and enforcement activities and the decision-making and approval process for substances that are toxic to only human health or the environment.

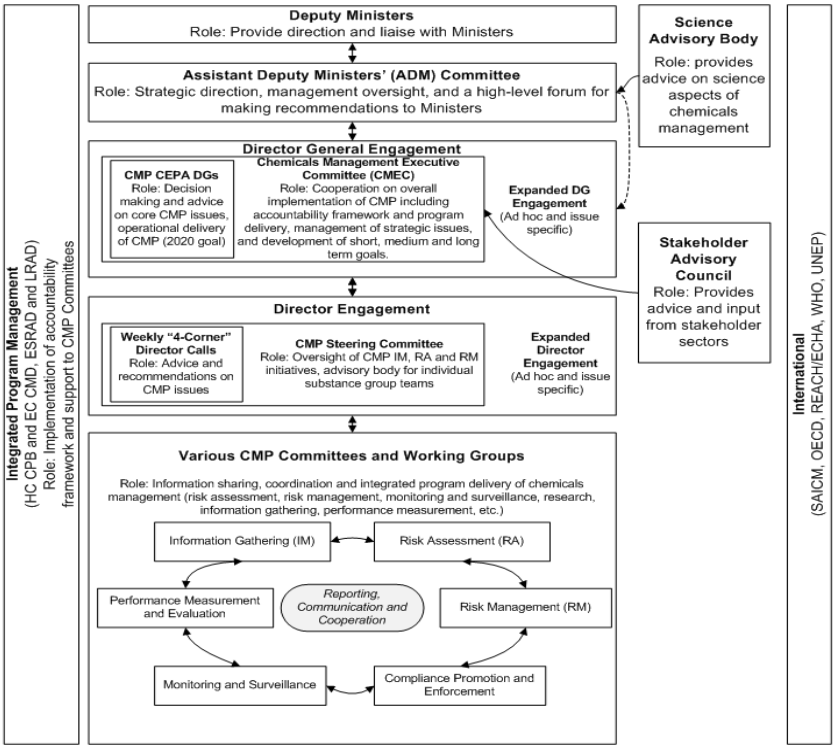
The governance structure for the CMP is intended to promote collective accountability and is based on the principles of practicality, transparency, inclusiveness, and impartiality. While Health Canada and Environment Canada must meet their respective departmental commitments (as indicated through their PAAs), they share a collective responsibility for achieving the CMP's objectives and results.

Program governance is managed through the CMP's Integrated Horizontal Governance Framework, which involves three executive committees and three program delivery committees. Executive management committees include the Assistant Deputy Ministers' Committee (ADM CMP), the Chemicals Management Executive Committee (CMEC), and the CEPA Directors General (DG) Committee, while program delivery and integration committees include the CMP Steering Committee, the 4 Corners Directors' Committee, and the Program Management Steering Committee.[57] The CPB with SED acts as the secretariat to the CMP governance structure.

RAPB, which is responsible for some compliance promotion and enforcement activities, is not included in the membership of any of the six formal governance committees and structures mentioned above. RAPB key informants suggested that integrating RAPB into CMP governance would better enable the CMP to maximize the utility of regional staff in determining priorities and meeting commitments. As already noted, it is unknown what structure is currently place for overseeing CMP compliance promotion and enforcement activities.

The six governance committees are supported by various ad hoc working groups that are established as new issues arise, as well as by external advisory bodies such as the CMP SAC and the CMP Science Committee. Figure 1 below maps the CMP governance process.

Figure 1: CMP governance



[57] Program representatives indicated that the 4 Corners Directors' Committee is actually a regular teleconference of the Directors, rather than a formal Committee.

Program key informants indicated that the horizontal governance structure and collaborative approach of the CMP has caused CMP partners to better understand each of their respective mandates, as well as their strengths and weaknesses, and has reduced the siloed approach to chemicals management that was being used in the past. It has also enabled the partners to produce timely, coherent responses to questions from external stakeholders, and to deal more effectively with unexpected issues that arise.

While program key informants agreed that there is good information-sharing, integration, and engagement among the CMP partners and across the two departments, many observed that there is "a lot of governance at all levels," that the program is "heavy on governance," or that "sometimes there is more than we need." Their main concern was what they perceived as an overly complex and resource-intensive approval process, and in particular the need, under CEPA 1999, for both Environment Canada and Health Canada approval even if the substance(s) involved is only health-toxic or only environment-toxic. Information provided by the program illustrates the delays that have been encountered with respect to approval packages for several substances/groups of substances. There is a perceived need for a more streamlined decision-making and approval process in such instances.

Among industry survey respondents, 38% agreed that the federal government partners in the CMP work together effectively, while 37% were neutral and only 3% disagreed; 22% did not know, although it should be noted that the survey results cannot be generalized to the larger population of CMP industry stakeholders.

Lesson learned on governance — the BPA experience

Productive and harmonious relationship. The relationship between Health Canada and Environment Canada was generally described by program key informants as productive and harmonious, and characterized by openness and willingness to collaborate and coordinate activities as circumstances warranted. Because BPA was addressed relatively early in the Challenge, each department's work pertaining to that substance may have played a role in building and strengthening inter- and intra-departmental capacity to interact and collaborate on activities involving other substances.

3.5.2 Accountability, performance measurement, and financial reporting

CMP partners have taken steps to address recommendations and suggestions for improvement from the 2011 evaluation relating to performance measurement and financial reporting. There are opportunities to better meet accountability requirements by reviewing the logic model, clarifying and streamlining the expected outcomes, collecting data for all expected outcomes, and where feasible, identifying CMP-specific substances.

The 2011 evaluation made two recommendations related to performance and outcome reporting: first, that program partners revise and simplify the CMP logic model and outcomes; and second, that they revise the PMF, define how and when expected outcomes will be measured, and implement necessary data collection methodologies.

While the CMP logic model and outcomes were revised prior to Phase II of the CMP, additional revisions could further clarify, differentiate, and streamline the expected outcomes, particularly the three immediate outcomes relating to industry compliance and the two outcomes (one intermediate and one long-term) relating to reduction of risks/threats associated with chemical substances.

With respect to the second recommendation, a PMF has been developed and is being used for reporting. Although the PMF focusses primarily on tracking program outputs and activities in detail, it is challenging to obtain a clear picture of the current status of program activities and establish basic facts about the program. As a result, the evaluation spent considerable time and effort obtaining and attempting to verify information about the program, including the total number of substances that have been assessed as of a given date, the number of risk management measures proposed and/or implemented, and the number of toxic substances covered by the risk management measures proposed and/or implemented, to name a few examples.

Furthermore, for various reasons, relatively little or no data is currently being collected by CMP partners for some of the expected outcomes, most notably, those relating to public understanding and use of information about risks and safe use of substances of concern. For others, namely those relating to industry compliance and reduction of risks/threats associated with chemical substances, methodologies are currently in development. However, CMP performance reporting relating to industry compliance and risk/threat reduction currently encompasses substances assessed and risk management measures implemented, prior to the CMP. Reporting could be strengthened by focussing, where feasible, specifically on substances assessed under the CMP and their corresponding risk management measures.

In response to suggestions for improvement made by the 2011 evaluation, improvements to human resource and financial reporting, as well as new information technology (IT) tools, have been developed and are in the process of being implemented. Health Canada and Environment Canada have developed and implemented a financial coding structure that allows alignment of financial information with program partners and activities, in order to support improved analysis of cost and resource requirements.[58] A new IT tool (Phoenix) is in the process of being implemented.

3.5.3 Resource allocation and use

Overall, CMP2 funding levels have been adequate and appropriate, and measures have been introduced to increase efficiencies in all functional areas. It is unknown how or if anticipated data challenges for CMP3 substances will affect the complexity and cost of assessments.

[58] All CMP partners have implemented the new financial coding structure, with the exception of the PMRA, which expects to fully implement the new structure in 2015–16.

Comparing planned and actual CMP spending suggests that, overall, funding levels have been both adequate and appropriate. As shown in Table 10, program partners spent 94% of planned CMP funding and used 95% of planned full-time equivalents (FTEs) between 2011–12 and 2013–14. Environment Canada spent 91% and Health Canada spent 95%, respectively, of planned funding.

Table 10: Planned versus actual CMP2 expenditures, 2011–12 to 2013–14, by department

Expenditures by Department	2011–2012		2012–2013		2013–2014		Total	
	Spending (M)	FTEs	Spending (M)	FTEs	Spending (M)	FTEs	Spending (M)	FTEs
Planned expenditures								
TOTAL	$103.20	540.00	$103.10	543.30	$96.91	545.36	$303.21	1628.65
EC	$29.50	162.35	$29.50	166.49	$29.50	168.55	$88.50	497.39
HC	$73.70	377.65	$73.60	376.81	$67.41	376.81	$214.71	1131.26
Actual expenditures								
TOTAL	$95.18	507.19	$99.15	527.16	$90.84	517.45	$285.17	1551.81
EC	$25.29	134.64	$26.44	155.65	$28.59	170.29	$80.32	460.58
HC	$69.89	372.55	$72.71	371.52	$62.25	347.16	$204.86	1091.22
Actual/planned								
TOTAL	0.92	0.94	0.96	0.97	0.94	0.95	**0.94**	**0.95**
EC	0.86	0.83	0.90	0.93	0.97	1.01	**0.91**	**0.93**
HC	0.95	0.99	0.99	0.99	0.92	0.92	**0.95**	**0.96**

Sources: Official government documentation and correspondence with Health Canada representatives.
Notes:
- Excludes funds transferred to PHAC for the TPP.
- Environment Canada funding includes $200,000 per year in grants and contributions.

Although actual spending was within 10% of planned for most program activities, there were some notable exceptions.

- Research spending was 111% of what was originally planned, with Health Canada (111%) and Environment Canada (113%) both spending more on this activity.
- Conversely, spending on monitoring and surveillance was 87% of what was planned, with Environment Canada primarily responsible for the variance. In fact, Environment Canada spent only 66% of its planned monitoring and surveillance funding and used only 46% of planned FTEs. According to Environment Canada, international reallocation and coding error may have contributed to variances.
- Spending on stakeholder engagement and risk communication was 83% of what was planned. Health Canada was solely responsible for this variance, as Environment Canada did not receive funding for this activity. It is notable in light of stakeholder perceptions that the CMP has not done enough to communicate with Canadians.

While most branches/agencies within Health Canada and Environment Canada were within 10% of planned expenditures, there were a few exceptions. Within Environment Canada, STB and Strategic Policy Branch spent 85% and 75%, respectively, of their planned expenditures, and

within Health Canada, RAPB spent 125% of what was planned. Program documents indicate that funds were transferred to RAPB from other CMP partners at various points in time to support specific testing and analysis activities, which may account for its higher than anticipated expenditures.

A summary of CMP expenditures by program activity is in Table 11.

Table 11: Planned versus actual CMP2 expenditures, 2011–12 to 2013–14, by program activity

Expenditures by Activity Program	2011–2012		2012–2013		2013–2014		Total	
	Spending (M)	FTEs	Spending (M)	FTEs	Spending (M)	FTEs	Spending (M)	FTEs
Risk assessment								
Planned	$25.43	141.19	$25.63	142.67	$25.63	142.73	$76.69	426.58
Actual	$22.79	146.75	$24.20	147.49	$23.82	149.39	$70.81	443.64
Actual/planned	0.90	1.04	0.94	1.03	0.93	1.05	0.92	1.04
Risk management, compliance promotion, and enforcement								
Planned	$42.08	251.50	$41.89	254.07	$38.69	256.07	$122.66	761.65
Actual	$39.88	239.47	$37.78	248.60	$35.17	231.55	$112.83	719.62
Actual/planned	0.95	0.95	0.90	0.98	0.91	0.90	0.92	0.94
Research								
Planned	$14.74	64.18	$14.64	63.43	$11.64	63.43	$41.03	191.04
Actual	$14.77	51.49	$17.10	58.40	$13.88	61.64	$45.75	171.53
Actual/planned	1.00	0.80	1.17	0.92	1.19	0.97	1.11	0.90
Monitoring and surveillance								
Planned	$15.78	45.45	$15.78	45.45	$15.78	45.45	$47.33	136.35
Actual	$12.82	32.11	$15.24	35.30	$13.21	37.49	$41.27	104.89
Actual/planned	0.81	0.71	0.97	0.78	0.84	0.82	0.87	0.77
Policy and program management (Health Canada only)								
Planned	$2.62	20.79	$2.62	20.79	$2.62	20.79	$7.86	62.37
Actual	$2.85	20.49	$2.79	20.49	$2.54	20.49	$8.17	61.47
Actual/planned	1.09	0.99	1.06	0.99	0.97	0.99	1.04	0.99
Stakeholder engagement and risk communication (Health Canada only)								
Planned	$2.55	16.89	$2.55	16.89	$2.55	16.89	$7.64	50.66
Actual	$2.07	16.89	$2.05	16.89	$2.22	16.89	$6.34	50.66
Actual/planned	0.81	1.00	0.81	1.00	0.87	1.00	0.83	1.00
TOTALS								
Planned	$103.20	540.00	$103.10	543.30	$96.91	545.36	$303.21	1628.65
Actual	$95.18	507.19	$99.15	527.16	$90.84	517.45	$285.17	1551.81
Actual/planned	0.92	0.94	0.96	0.97	0.94	0.95	0.94	0.95

Sources: Official government documentation and correspondence with Health Canada representatives
Notes: Excludes funds transferred to PHAC for the TPP. Monitoring and surveillance information-gathering

Operational Efficiencies

Program representatives reported that a variety of measures have been taken to increase efficiencies in all program activity areas.

Information-gathering and risk assessment

Measures to increase efficiencies in gathering information and assessing existing substances include the following:

- using innovative approaches to prioritize substances
- using rapid screening approaches for lower-risk substances
- using substance groupings to streamline assessments[59]
- employing use-driven approaches
- developing high throughput tools to more efficiently screen substances for potential risks
- undertaking early engagement with stakeholders to develop data-sharing agreements and identify opportunities for streamlined voluntary approaches
- documenting guidance and standard procedures for assessors to reduce time spent on assessments

Program representatives report that, due to these measures, the program has been successful at increasing the rate at which risk assessments are completed. They indicated that whereas CMP1 addressed an average of 275 existing substances per year, CMP2 is addressing an average of 300 substances per year — a 9% increase. By the end of CMP2, program partners anticipate a 35% increase in risk assessment output relative to CMP1. Since the definitions and calculations used to arrive at these estimates were not provided to the evaluation, it was not possible to validate these figures.[60]

It is known that, as of September 30, 2014, draft or final risk assessments had been completed for 39% of the priority existing substances, leaving 61% to be assessed in the last year of CMP2 and in the final cycle of the CMP. This analysis would suggest additional efficiencies will need to be found in the final cycle of the CMP in order to meet the 2020 target. However, dSARs for an additional 887 priority existing substances were published in February 2015. If these substances are taken into account, approximately 60% of the priority existing substances have already been assessed, while the remaining 40% are outstanding.

Moving forward, it is unknown if the anticipated data limitations associated with many CMP3 substances will significantly increase the complexity, time, and cost of assessments.

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[59] Program representatives from Environment Canada indicated that, for petroleum substances, as a means of introducing additional efficiencies, they are shifting their approach to group assessment, allowing the assessment to be applied to additional similar substances, even if the specific numbered substances were not included in the initial assessment.

[60] For example, it is unclear what the program considered a “completed” risk assessment for the purpose of these calculations, and what is meant by “addressing” a substance.

Finally, it is important to note that regardless of any increases in the rate at which risk assessments for existing substances have been completed over time, the unit costs of completing existing substance risk assessments for high, medium, and low priority substances are unknown. Although this information would speak more directly to efficiencies, it is methodologically complex and, for this reason, was not undertaken as part of this evaluation.

Risk management

Program representatives indicated that efficiencies have been gained from having a reasonably stable workforce over time, leading to well-established lines of communication, and from the ability to leverage previous work as a result of repeat or similar circumstances. In addition, efficiencies are thought to have been gained by considering what kinds of risk management measures have been taken in other jurisdictions, although it is unclear how exactly this has contributed efficiencies. Moving forward, program representatives recommended more extensive use of the sector-based approach and grouping substances based on function. Program representatives indicated that the latter would encourage industry to compare substances and consider the least hazardous alternative. Program representatives indicated that the risk management function is expected to grow and to require more resources over time.

Research, monitoring, and surveillance

Program representatives reported that efficiencies in research, monitoring, and surveillance have been gained through an improved approach to research governance, which ensures that research activities respond to regulatory needs; improved knowledge exchange; leveraging of external infrastructure and new and existing partnerships to conduct monitoring and surveillance activities; and using internal laboratories instead of commercial ones. The research program expects to realize further efficiencies once the Banting Research Centre is completed.

Lesson learned on efficiencies — the BPA experience

> ***Efficiencies gained through leveraging.*** The CMP gained considerable efficiencies by taking advantage of data collection and analysis frameworks that either pre-dated BPA risk management activities and/or were partially developed, administered, or funded by other federal government departments or other orders of government. For example, the TDS is an on-going Health Canada activity, while Health Canada administers the CHMS in partnership with Statistics Canada.

ERHSD representatives indicated that the research function relies heavily on post-doctoral fellows from the Natural Sciences and Engineering Research Council (NSERC); approximately 30 post-doctoral fellows are currently involved in CMP research activities. According to ERHSD representatives, the NSERC Visiting Post-doctoral Fellowship program will be ending, which they anticipate will have a significant impact on ERHSD's CMP research program. Currently, the program has been extended for one year while opportunities are explored for a new program that meets the needs of all Federal Science Based Departments and Agencies. A Working Group representing all implicated Departments and Corporate Human Resources is developing options.

Stakeholder engagement and risk communication

Program representatives reported that efficiencies have been gained through targeted approaches to risk communication; greater use of technologies, such as social media and webinars; operational efficiencies gained through changes to program operations, such as the development of CALM; and working with partner programs to reduce duplication and leverage opportunities to share CMP information. As an example of the latter, RAPB representatives indicated that regional staff capitalize on opportunities to convey information about the risks and safe use of substances of concern by incorporating CMP information into regional information sessions offered by other environmental health programs or by other Health Canada programs, such as Aboriginal Head Start, Brighter Futures, or the Canada Prenatal Nutrition Program.

Program management

Program representatives reported that tracking systems have been improved to more accurately track financial expenditures and human resources against CMP activities. Program representatives also reported that efficiencies gained during CMP2 resulted in a reduction of 35.3 program FTEs at Health Canada and an additional 9.9 program FTEs at Environment Canada. Within Health Canada, 30 of the 35.3 FTEs involved the support function.

Compliance and enforcement

Program representatives indicated that challenges can arise with priority setting and resource allocation for both compliance promotion and enforcement activities. To respond to this challenge, the compliance promotion program in Environment Canada has focussed CMP activities on hard-to-reach, geographically dispersed, resource-limited SMEs. The Federal House, including First Nations as large enterprises, are expected to be sufficiently resourced and knowledgeable. The program has also adjusted its priority setting process and responsibilities in response to the resources allocated. While using in-person workshops and meetings for compliance promotion, Environment Canada expects to also realize efficiencies by relying on electronic means of information dissemination. With respect to enforcement, program representatives indicated that these activities are targeted at high-risk products and sectors. Compliance and enforcement activities are expected to grow and require more resources as new regulations are added.

3.5.4 Alternatives

Due to Canada's leadership role and significant differences in regulatory frameworks and the scope of chemicals management programs across jurisdictions, the evaluation did not identify any clear alternative approaches that would result in similar outcomes at lower cost.

Canada is widely regarded by international stakeholders as a leader and model for other countries for its approach to assessing existing substances. The 2011 CMP evaluation noted that chemicals regulators in other jurisdictions viewed the CMP approach as "pragmatic and effective" and described Canada as a "trailblazer" in managing the inventory of existing substances; they particularly approved of the initial priority-setting exercise with respect to the DSL (Health

Canada, 2011). Australia explicitly credits Canada with providing information and expertise used in the establishment of its Inventory Multi-tiered Assessment and Prioritisation (IMAP), which is effectively that country's equivalent to the risk assessment component of the CMP (Commonwealth of Australia, 2006; Milieu Ltd., 2013; NICNAS, 2013). In addition, CEPA 1999 is unique in the world in requiring the assessment of naturally occurring micro-organisms used in biotechnology applications.

In interviews, international stakeholders praised numerous aspects of Canada's approach, singling out the legislated mandate and established timeline for assessing existing chemicals, the initial prioritization process, the comprehensiveness and flexibility of the approach, and the efforts to engage with industry. International stakeholders also commented favourably on the relative speed with which Canada has managed to assess a large number of existing substances, comparing Canada's progress against their own jurisdictions, where the absence of a legislated mandate for assessing existing substances (in the US) and a more complex program (in the EU) have been constraining factors. Finally, international stakeholders remarked upon the quality of Canada's risk assessments, although some questioned why Canada does not consider occupational exposure, as is done in Australia and the EU, and suggested that doing so would contribute to greater international harmonization of the risk assessment effort. Overall, there is a general consensus that, through the CMP, Canada has made a significant contribution to international efforts in chemicals management and the safety of chemicals.

Reviewing international approaches to chemicals management did not identify any clear alternative approaches that might produce similar outcomes at lower cost. This is due in part to Canada's leadership role (other jurisdictions are emulating elements of its approach or benefiting from work that it has completed), and in part to significant differences in regulatory frameworks and the scope of chemicals management programs across jurisdictions. See Table 12 for a brief description of selected international approaches.

Table 12: Overview of selected international approaches to chemicals management

United States (US)
The US has no legislated mandate or schedule for assessing existing substances, and no equivalent to CEPA-toxic. The US EPA's Existing Chemicals Management Program currently focusses on assessing 83 existing substances, and the Agency completes between 20 and 40 assessments of existing substances each year (excluding rapid screening). The US EPA is also responsible for assessing new substances, and completes approximately 1,000 new substance assessments each year. Unlike Canada, which can access information directly from industry, the US must use data in the public domain to inform its risk assessments. Also unlike Canada, the US EPA has limited authorities for risk management; risk management can only be implemented for substances that pose an "unreasonable risk" to human health and the environment, which means that the burden of scientific proof needed to support risk management is much higher than it is in Canada (i.e., Canada can move to risk management based on greater uncertainty than US legislation allows). The US EPA assesses genetically modified, but not naturally occurring living organisms.
European Union (EU)
The European Chemicals Agency (ECHA) is responsible for administering the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation. Under REACH, substances that are manufactured or imported in the EU must be registered with the ECHA; the registration process, which applies equally to all substances, requires industry to submit detailed information about the substance, including a risk assessment. The ECHA is responsible for evaluating the quality of the dossiers. The ECHA or member states can request that a substance be identified as a Substance of Very High Concern (SVHC) if it is carcinogenic, mutagenic, or toxic for reproduction (CMR), or if it is known to be persistent, bioaccumulative, and toxic (PBT), or there is scientific

evidence of probable serious side effects. Such substances cannot be placed on the market or used after a specified date unless authorization is granted for a specific use (ECHA, n.d). Under the authorization process, it is up to industry to demonstrate that the chemicals can be used safely and that there is no alternative. REACH is seen as a more complex program than the CMP, but international stakeholders indicated that progress under REACH in assessing substances has been slower than in Canada. REACH operates with a significant cost recovery component. Unlike CEPA 1999, REACH does not apply to living organisms, and regulatory oversight in Europe of naturally occurring micro-organisms is limited to specific applications (e.g. micro-organisms used in pest control).

Australia

The NICNAS explicitly modelled its approach to risk assessment, the IMAP framework, on the CMP. Key features of the IMAP framework that were based on the Canadian model include "the screening of chemicals against risk based criteria, using a tiered risk based model to align the assessment effort with the human health and environmental impacts of chemicals, and the use of separate approaches for human health and environmental assessments" (NICNAS, 2014a). Under the program, Australia aims to assess ~39,000 existing chemicals, with 3,000 selected for assessment over first four years, beginning in 2012; it also undertakes new substance assessments. By early March 2014, the NICNAS had published 1,524 human health and/or environment assessments for existing substances, for a total of 1,155 unique chemicals (NICNAS, 2014b). This implies that the Agency is approximately 38.5% of the way toward the original goal of assessing 3,000 existing chemicals over four years. While NICNAS can recommend risk management actions to state governments, unlike Canada it has no authority to implement risk management. NICNAS operates with an annual budget of $15 million and 80 FTEs and operates a significant cost recovery program.[61] Unlike CEPA 1999, NICNAS does not apply to living organisms, and regulatory oversight in Australia of naturally occurring micro-organisms is limited to specific applications (e.g., micro-organisms used in pest control). Like Canada, Australia has a New Substances Program. Australian legislation recognizes Canada as a competent authority and thus can use Canadian risk assessments within its New Substances Program.

Canada is currently exploring options for increased collaboration, including more extensive use of international data sources, increased information sharing, collaborative work on exploring and developing new technologies and computational approaches, and use of joint reviews among international jurisdictions. These approaches could potentially further increase efficiencies in the risk assessment process. However, progress is likely to be constrained by a number of factors, including differences in chemicals management legislation and its application;[62] the need for regulators to protect confidential business information; and the presence of a legislative framework and timelines for assessing existing substances in Canada, which leaves less leeway for international collaboration. Furthermore, international collaboration requires a significant investment in time and effort, and may not always result in efficiencies, particularly in the short term.

[61] Both the ECHA and Australia operate significant cost recovery programs. Program key informants were generally unsupportive of cost recovery for the CMP; some were opposed in principle, while others raised practical challenges and/or questioned whether a cost recovery program would lead to reduced costs, particularly in the short term. In any event, any cost recovery regime would have to be implemented under the *User Fee Act*, which is unlikely to be achieved during the current lifetime of the CMP.

[62] For example, Canadian and US legislation differ in terms of the burden of proof needed to support risk management.

4.0 Conclusions and recommendations

The implementation of the whole-of-government approach to chemicals management was further advanced by CMP partners during CMP2 through the implementation of planned activities in all of the CMP functional activity areas. Canada has been internationally recognized as a leader in risk assessment and risk management of chemical substances.

Relevance

There is a demonstrated ongoing need for government intervention to manage the risks to human health and/or the environment associated with some chemical substances. There is a continued need for an approach and resources that will allow the Government of Canada to meet its commitment relating to the approximately 4,300 priority existing substances by 2020.

The CMP is aligned with the priorities of the federal government, and with the strategic outcomes of Health Canada and Environment Canada. Health Canada and Environment Canada activities under the CMP2 are consistent with federal roles and responsibilities.

Performance — implementation

Information-gathering

During CMP2, program partners completed the major planned information-gathering initiatives, including Phase II of the DSL-IU and information-gathering for the Substance Groupings Initiative. To reduce the reporting burden and improve information quality and comprehensiveness, changes to the s. 71 process were introduced, and alternative approaches and early engagement with industry were emphasized. There is a consensus that more flexible approaches to information gathering and early engagement with industry have resulted in enhanced quality of the information gathered. However, some industry stakeholders continue to experience challenges with mandatory information gathering. Given the diversity of information sources that may be used to inform risk assessments, there is a desire among some industry stakeholders for greater transparency about the nature and quality of the information used to support risk assessment conclusions.

Risk assessment

During CMP2, program partners continued to make progress toward assessing the approximately 4,300 existing substances prioritized through categorization. As of September 30, 2014, final or draft screening assessment reports had been published for 39% of priority existing substances, with dSARs published for another approximately 20% of these substances in February 2015. CMP partners also made progress in fulfilling commitments to update and prioritize the ICL of FDA substances, re-evaluate older pesticides, and assess new substances.

Stakeholders within and outside of Canada were generally pleased with the progress made in risk assessment, although delays in assessing petroleum substances were noted. Canada is highly regarded by its international counterparts for being the first jurisdiction to establish and implement an ambitious plan and schedule for assessing existing substances.

The methodologies used in risk assessment were questioned by some external stakeholders, who worried that vulnerable populations may not be given adequate consideration. A variety of measures are taken to ensure that appropriate methodologies are used, including expert input by the CMP Science Committee, which was established during CMP2. Exposures of concern to stakeholders, such as combined exposures to multiple chemicals, long-term exposures and sex-specific effects, are considered when data and use patterns support these approaches, and Canada is actively contributing to international efforts in methodology development.

Unlike Australia, the US, and the EU, Canada does not currently consider occupational exposure in CMP risk assessments. According to program representatives, doing so would require new policy coverage and associated funding. The evaluation of CMP1 identified a need to clarify the CMP's role with respect to occupational exposure, and the evidence from this evaluation indicates that this remains an area of concern for stakeholders. Evidence from the literature indicates that occupational exposure to chemicals is widespread and linked to a variety of health issues. The issue of occupational exposure could be examined more thoroughly in a future evaluation of the CMP.

Risk management

During CMP2, 79 risk management measures were implemented or in development for over 200 substances deemed CEPA-toxic as a result of risk assessment, of which 59 had been implemented and 20 were in development as of July 2014. Some challenges have been encountered in implementing the Best Placed Act approach, and to date, most risk management measures have been implemented under CEPA 1999. While some issues and differences of perspective are yet to be resolved, program partners agree on the desirability of pursuing the Best Placed Act approach as appropriate in the future.

To date, risk management measures have been approximately equally split between regulatory (52%) and non-regulatory (48%) measures. The latter are expected to play an especially significant role in risk-managing toxic substances found in pharmaceuticals and food in CMP3. While there is evidence that regulatory approaches are effective, and CMP partners are monitoring the performance of some non-regulatory measures (in particular Pollution Prevention Planning Notices and Environmental Performance Agreements), evidence regarding the effectiveness of non-regulatory approaches at achieving risk management objectives is minimal at the present time. Some external stakeholders were concerned that non-regulatory measures may not be as effective as regulation.

In addition to implementing risk management measures, progress was also made in regulatory and policy development, notably with respect to the proposed Environmental Assessment Regulations for new substances in FDA-regulated products, and in developing a substance-based approach to performance measurement of risk management measures. CE of consumer products and analysis and use of pesticides sales and incident data were conducted, and the Guidelines for Canadian Drinking Water Quality were updated.

Research

Research activities were strengthened through improved research governance, better alignment of research projects with the needs of regulators, increased scientific support, and improved laboratory infrastructure. A total of 243 research projects were undertaken by Health Canada and Environment Canada. Research findings are used to inform decision-making with respect to risk assessment and risk management, and are expected to be particularly important in assessing data-poor CMP3 substances. Industry stakeholders suggested that more could be done to communicate the goals and the results of the research program to stakeholders and the general public.

Monitoring and surveillance

During CMP2, program partners undertook a variety of monitoring and surveillance activities. Health Canada is tracking exposure to approximately 450 substances through several large-scale national and other biomonitoring surveys, as well as exposure to 210 substances in food through the TDS. Environment Canada is conducting environmental monitoring and surveillance of approximately 45 priority chemicals in air, surface water, sediments, aquatic biota (fish), and birds (eggs) at sites across Canada. Data from monitoring and surveillance projects are used to inform risk assessment and risk management activities, and will be used in the future to assess the effectiveness of risk management actions. As with research, external stakeholders believe more should be done to communicate the objectives and results of monitoring and surveillance activities to stakeholders and the public.

Compliance promotion and enforcement

In response to suggestions for improvement made by the 2011 evaluation, program partners took steps to improve the coordination and planning of compliance promotion and enforcement activities, as well as the ability to track, analyze, and report on these activities. Given that compliance promotion and enforcement is becoming an increasingly important function within the CMP as the number of risk management instruments grows, there are opportunities to further improve coordination, planning and reporting on these activities.

A committee established to oversee CMP compliance promotion and enforcement activities is no longer in existence. For risk management measures under CEPA 1999, current reporting is not limited to activities related to risk management measures stemming from CMP risk assessments, but encompasses all CEPA regulations implicated in enforcement activities. For risk management measures implemented under other legislation, cyclical enforcement for consumer products and cosmetics was carried out, covering substances risk-managed under the CMP as

well as legacy substances under Schedule 1 of CEPA 1999. Although CMP funding supports enforcement of risk management instruments for all CEPA-toxic substances, greater specificity in compliance reporting is warranted in the interest of accountability.

Overall, it is unknown to the evaluation how many of the 59 risk management measures that have been implemented to date under the CMP (23 in CMP1 and 36 in CMP2) have been subject to compliance and enforcement activities.

Stakeholder engagement and risk communication

The 2011 evaluation identified stakeholder engagement as a notable strength of the CMP. During CMP2, program partners continued to emphasize engagement and consultation with industry and other stakeholders. Industry key informants were intimately involved in, and quite satisfied with, these engagement efforts, while the broader group of industry survey respondents tended to have less active involvement and more varied opinions.

Non-industry key informants, though appreciative of the opportunities afforded by the SAC, indicated that it can be challenging to become knowledgeable in the issues and make relevant commentary on behalf of their constituencies. The federal government's decision to end funding to the Canadian Environmental Network in 2011 has reportedly limited the ability of NGOs to participate in consultations, particularly face-to-face meetings with government and industry stakeholders, on the CMP and other environmental issues.

Risk communication to Canadians was identified in the 2011 evaluation as a weakness of CMP1, and the evidence available to this evaluation suggests that this is still the case. Although a variety of efforts have been made to improve risk communications, many external key informants believe the CMP is not responding effectively to Canadians' need for information about the risks and safe use of substances of concern. The views of Canadians are unknown, since, despite the recommendations of the 2011 evaluation, the program has not undertaken POR in this area since 2009.

Performance — achievement of expected outcomes

Use of information by CMP partners

In the immediate term, Health Canada and Environment Canada are expected to use knowledge, information, and data on substances of concern to inform CMP activities. The evaluation evidence indicates that information and data are being used by program partners to inform CMP activities and decisions. Priorities for research and monitoring and surveillance are developed through a consultative approach to ensure alignment with the needs of the regulatory partners, and findings are used to inform risk assessments, risk management and other program activities. There are numerous venues for information-sharing among program partners, and improvements to information systems are expected to further facilitate their access to and use of information.

Understanding and use of information by Canadians

In the immediate term, Canadians and stakeholder groups are expected to understand information on risks and safe use of substances of concern, and in the intermediate term, to use that information to avoid and minimize associated risks. Since the CMP does not (with limited exceptions) collect data on Canadians' understanding and use of this information, it is not possible to draw conclusions on the extent to which these outcomes may have been achieved.

Industry understanding and compliance

In the immediate term, the CMP expects that industry will understand its obligation to take action to protect Canadians and the environment, to comply with the requirements of risk management measures, and to take voluntary or enforced action to protect Canadians and the environment. Results from the industry survey suggest a possible need for additional compliance promotion and outreach activities to ensure industry stakeholders are aware of, and understand, the CMP risk management measures that apply to them, although it should be noted that the survey results cannot be generalized to the larger population of CMP industry stakeholders.

For risk management measures implemented under CEPA 1999, the available compliance data show a reasonably high overall rate of compliance with regulatory requirements (over 80%) among inspected industries, although rates ranged from 44% to 100%, depending on the specific regulations and year involved. These data are not statistically significant and cannot be extrapolated to the regulated industries in general. Performance monitoring of Pollution Prevention Planning Notices and Environmental Protection Agreements indicates that most companies comply with the reporting requirements, and in some cases, performance objectives have been achieved or progress is being made toward them.

For risk management measures implemented under other Acts, CE of baby bottles found 100% compliance with the prohibition on BPA in 2013–14. Other CE projects involving chemicals in consumer products and cosmetics likewise show high rates of compliance among the monitored entities.

Risks/threats to health and the environment

In the intermediate and long-term, the CMP hopes to achieve a reduction in risks to health and the environment from harmful substances. Trends for environmental and/or human exposure data for some core CMP risk-managed substances are beginning to emerge, and in some cases are showing decreases that correlate to the timelines during which domestic action was taken. These trends may be more firmly established through monitoring over a longer term. For some substances, exposure in Canada can come from foreign sources, highlighting an ongoing need for international risk management efforts in addition to domestic action. Although progress is being made to develop an overall risk index for measuring changes in risks to human health and the environment, the model does not account for exposure through consumer and other products, which may affect the accuracy of the risk index.

Unintended consequences

Positive unintended consequences arising from the CMP include international recognition of Canada as a leader in chemicals management; development of positive relationships with industry which have had beneficial impacts beyond the CMP; and positive impacts on industry awareness, processes, and business decisions. Based on the evidence available to this evaluation, there do not appear to be significant negative unintended consequences arising from the CMP.

Performance — demonstration of efficiency and economy

Governance

The horizontal governance structure and collaborative approach of the CMP has improved mutual understanding among program partners and reduced the siloed approach to chemicals management that was being taken in the past. CMP governance is generally seen as effective; however, it could be further strengthened by clarifying roles and responsibilities of various program partners to ensure relevant partner engagement, and by exploring opportunities for a more streamlined decision-making and approval process for substances deemed toxic to only human health or the environment.

Accountability, performance measurement, and financial reporting

CMP partners have taken steps to address recommendations and suggestions for improvement from the 2011 evaluation relating to performance measurement and financial reporting. There are opportunities to better meet accountability requirements by reviewing the logic model, clarifying and streamlining the expected outcomes, and collecting data for all expected outcomes. CMP reporting on industry compliance and risk/threat reduction could be strengthened by identifying CMP-specific substances, where feasible.

Resource use and allocation

Overall, CMP2 funding levels have been adequate and appropriate. In the first three fiscal years of CMP2, program partners spent 94% of planned funding. Spending has been higher than anticipated for research (111%), and lower than anticipated for monitoring and surveillance (87%) and stakeholder engagement and risk communication (83%). Environment Canada was responsible for the lower spending on monitoring and surveillance; it used only 66% of its planned funding in this area. The lower than expected spending on stakeholder engagement and risk communication is also notable, given stakeholder dissatisfaction with the CMP's efforts at outreach to Canadians.

Several measures have been introduced to increase the efficiency of the risk assessment process, and to gain efficiencies in other functional areas. It is unknown how or if anticipated data challenges for CMP3 substances will affect the complexity and cost of assessments.

Alternatives

Canada is widely regarded by international stakeholders as a leader and model for other countries for its approach to assessing existing substances. Elements of the Canadian approach that are viewed positively include the legislated mandate and established timeline for assessing existing chemicals, the initial prioritization process, the comprehensiveness and flexibility of the approach, and the efforts to engage with industry. International stakeholders commented favourably on the relative speed with which Canada has managed to assess a large number of existing substances. There is a general consensus that Canada has made a significant contribution to international efforts in chemicals management and safety.

Due to Canada's leadership role and significant differences in regulatory frameworks and the scope of chemicals management programs across jurisdictions, the evaluation did not identify any clear alternative approaches that would result in similar outcomes at lower cost. While Canada is exploring options for increased international collaboration in order to increase efficiencies in the risk assessment process, progress may be constrained by a variety of factors.

Recommendations

Recommendation 1

The horizontal governance structure and collaborative approach of the CMP has improved mutual understanding among program partners and reduced the siloed approach to chemicals management that was being taken in the past. Although the CMP governance structure is generally seen as effective, roles and responsibilities could be clarified, particularly with respect to the oversight of compliance and enforcement activities. In addition, the decision making and approval process could be streamlined in order to help address concerns from program partners, who perceive it as being overly complex and resource-intensive, in particular with respect to the processes related to approvals for substances that are only health-toxic or only environment-toxic.

CMP partners should clarify roles and responsibilities of various program partners to ensure relevant partner engagement, as well as explore opportunities for a more streamlined decision-making and approval process for substances that are toxic to only human health or the environment.

Recommendation 2

To date, the CMP has assessed approximately 60% of priority existing substances, although the Petroleum Sector Stream Approach has experienced notable delays. Assessments for just over half of the Petroleum Sector Stream Approach substances had been completed as of September 30, 2014, leaving the remaining 48% to be completed by the end of 2015–16 in order to meet CMP2 commitments for this substance group.

CMP partners should take necessary steps to address CMP commitments related to the Petroleum Sector Stream Approach substances, and initiate risk management as required.

Recommendation 3

Although CMP partners have taken steps to address recommendations and suggestions for improvement from the 2011 evaluation relating to performance measurement reporting, there are still opportunities for improvements in this area. CMP partners could better meet accountability requirements by reviewing the logic model, and by clarifying and streamlining the expected outcomes, particularly those relating to industry compliance and to the reduction of risks/threats associated with chemical substances. In addition, the program should collect data for all expected outcomes, and identify CMP-specific substances as part of reporting, where possible.

CMP partners should strengthen performance reporting by reviewing the logic model, streamlining the expected outcomes, collecting data for all expected outcomes, and where feasible, identifying CMP-specific substances.

Recommendation 4

While CMP partners are monitoring the performance of some non-regulatory measures (in particular Pollution Prevention Planning Notices and Environmental Performance Agreements), evidence regarding the effectiveness of these and other non-regulatory approaches at achieving risk management objectives is minimal at the present time. Also, some external stakeholders were concerned that non-regulatory measures may not be as effective as regulations. As a result, assessment of the effectiveness of non-regulatory measures could help improve the CMP's risk management review process.

Building on previous work, CMP partners should continue to intensify efforts in relation to reviews of the effectiveness of implemented risk management measures, in particular, non-regulatory measures, as part of the risk management review process, and communicate the results to stakeholders and the public.

Recommendation 5

There are opportunities to improve the program's understanding of the information that Canadians believe they need in order to improve outreach and communications. There are ongoing concerns by stakeholders that communication to Canadians about the risks and safe use of substances is a weakness of the program.

CMP partners should develop a better understanding of the information needs of Canadians with respect to the risks and safe use of substances of concern and enhance outreach and communications as necessary.

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Appendix 2 – Summary of Findings

Rating of Findings

Ratings have been provided to indicate the degree to which each evaluation issue has been addressed.

Relevance Rating Symbols and Significance:

A summary of Relevance ratings is presented in Table 1 below. A description of the Relevance Ratings Symbols and Significance can be found in the Legend.

Table 1: Relevance Rating Symbols and Significance

Issues	Indicators	Overall Rating	Summary
1. Continued Need for the Program			
Does the CMP continue to address a demonstrable need? Is the CMP responsive to the needs of Canadians?	• Consequences of hazardous substances to health and environment • Responsiveness of CMP to needs of Canadians • Expert/stakeholder assessment of responsiveness of CMP • Expert/stakeholder assessment of ongoing need and responsiveness	**High**	The chemicals used in industrial processes and in a wide range of products, including pesticides, cosmetics, and pharmaceuticals, as well as consumer products and food, contribute significantly to the health and the economic and social well-being of Canadians. However, exposure to certain chemicals may contribute to or cause adverse health effects in humans or harm to the environment. There is a demonstrated ongoing need for government intervention to manage the risks to human health and/or the environment associated with some chemical substances. There is a continued need for an approach and resources that will allow the Government of Canada to meet its commitment to assess the approximately 4,300 priority existing substances by 2020.
2. Alignment with Government Priorities			
Do the objectives of the CMP align with federal government priorities? Do the objectives of the CMP align with relevant strategic outcomes identified by Health Canada and Environment Canada?	• Correspondence of CMP objectives with federal government priorities • Correspondence of CMP objectives with strategic outcomes of Health Canada and Environment Canada	**High**	The CMP is aligned with the priorities of the federal government as these were articulated in 2011 and in 2015, and with the strategic outcomes of Health Canada and Environment Canada.
3. Alignment with Federal Roles and Responsibilities			
Do Health Canada and Environment Canada activities in delivering the CMP align with federal government roles and responsibilities?	• Correspondence of CMP activities with Health Canada and Environment Canada roles and responsibilities	**High**	Health Canada and Environment Canada activities under the CMP2 are consistent with federal roles and responsibilities.

Legend – Relevance Rating Symbols and Significance:

High	There is a demonstrable need for program activities; there is a demonstrated link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are clear.
Partial	There is a partial need for program activities; there is some direct or indirect link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are partially clear.
Low	There is no demonstrable need for program activities; there is no clear link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program have not clearly been articulated.

Performance Rating Symbols and Significance:

A summary of Performance Ratings is presented in Table 2 below. A description of the Performance Ratings Symbols and Significance can be found in the Legend.

Table 2: Performance Rating Symbols and Significance

Issues	Indicators	Overall Rating	Summary
4. Achievement of Expected Outcomes (Effectiveness)			
Implementation Have CMP activities been implemented as planned? Have the activities produced the expected outputs and/or are processes in place to produce the expected outputs prior to the end of CMP2? Are the approaches and methods used to implement the CMP working as intended, and are they effective? What lessons have been learned from their implementation? Has the Program effectively addressed challenges, emerging issues, and changing priorities? To what extent has the Program addressed recommendations and suggestions for improvement from the previous evaluation of the CMP? How have requirements/commitments to Central Agencies (i.e., Office of the Auditor General, Commissioner of the Environment and Sustainable Development) and to policy (e.g., Cabinet Directive on Regulatory Management, Policy on Public Consultation) been addressed?	• Correspondence of actual activities and outputs with original plans • Number/nature of CMP outputs • Evidence that approaches and methods used to implement the CMP are working as intended • Key informant perspectives on effectiveness of CMP approaches/methods • Key informant perspectives on lessons learned • Extent to which challenges, emerging issues, and changing priorities have been effectively addressed • Extent to which progress has been made in implementing recommendations and suggestions for improvement • Extent to which requirements and commitments to Central Agencies and policy have been addressed • Feedback provided to Health Canada and Environment Canada by Central Agencies	**Progress made; further work warranted**	Overall, program partners were able to advance the implementation of planned CMP2 activities. Approaches and methods used to implement the CMP are generally working as intended, and the Program has addressed numerous challenges and complex, emerging issues. • Program partners completed the major planned information-gathering initiatives, including Phase II of the Domestic Substances Inventory Update and information-gathering for the Substance Groupings Initiative. The information gathered is instrumental in informing risk assessment, risk management and other program activities. There is a consensus that more flexible approaches to information-gathering and early engagement with industry have resulted in enhanced quality of the information gathered. • Program partners continued to make progress toward assessing the approximately 4,300 existing substances prioritized through categorization. To date, the CMP has assessed approximately 60% of priority existing substances, although the Petroleum Sector Stream Approach has experienced notable delays. In addition, the program was able to consistently manage the assessment of new substances. Approximately 400 to 500 new substance assessments have been completed per year, consistent with targets, and progress has been made toward fulfilling commitments relating to FDA substance and pesticides. The 2011 evaluation of CMP1 identified a need to clarify the program's role with respect to occupational exposure, and the evidence from this evaluation indicates that this is an area of ongoing concern for some stakeholders, suggesting that the issue should be thoroughly examined in a future evaluation. • Risk management measures were actively developed and implemented for substances deemed CEPA-toxic as a result of risk assessment. To date, risk management measures have been approximately equally split between regulatory and non-regulatory measures. Some stakeholders are concerned about the effectiveness of non-regulatory measures at achieving risk management objectives. Although program partners are currently monitoring the performance of some non-regulatory measures on a risk basis, evidence of the effectiveness of such approaches is limited at this time. • Research activities were strengthened through improved research governance, better alignment of research projects with the needs of regulators, and within Health Canada, increased scientific support and improved laboratory infrastructure. A variety of

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
Little Progress; Priority for Attention	Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Issues	Indicators	Overall Rating	Summary
			monitoring and surveillance projects, including human biomonitoring, environmental monitoring, and monitoring of chemical substances in food, were undertaken or are ongoing. Results have been shared internally and externally. • Steps were taken to improve the coordination and planning of compliance promotion and enforcement activities, as well as the ability to track, analyze and report on these activities. However, it is unclear what entity, if any, is currently responsible for overseeing CMP compliance promotion and enforcement activities. In addition, current reporting encompasses CEPA risk management measures that predate the CMP. Although CMP funding supports enforcement of risk management measures for all CEPA-toxic substances, greater specificity in compliance reporting is warranted, in the interests of accountability. • Program partners continued to emphasize stakeholder engagement during CMP2, and while industry stakeholders are generally satisfied with the engagement efforts, non-industry groups expressed some concerns. Program partners also took steps to improve communications to Canadians about the risks and safe use of substances of concern, but as in 2011, communications to Canadians continues to be perceived as a weakness of the program.
Achievement of outcomes To what extent has progress been made toward the immediate, intermediate, and long-term outcomes of the CMP? To what extent do Health Canada and Environment Canada use knowledge, information, and data on substances of concern to inform CMP activities? To what extent do Canadians and stakeholder groups understand information on the risks and safe use of substances of concern? To what extent does targeted industry understand its obligations to take action to protect Canadians and the environment? To what extent does targeted industry conform to or comply with the requirements of risk management measures?	• Evidence that knowledge, information, and data is used by CMP partners to inform activities • Level of satisfaction of CMP partners with knowledge, information, and data • Level of understanding of Canadians and stakeholder groups of the risks posed by substances and their safe use • Number and percentage of regulated firms by sector that understand their obligations to protect Canadians and the environment; in conformity to or in compliance with requirements of risk management measures; and that take voluntary or enforced action to protect Canadians and the environment • Targeted industry self-reports • Health Canada/Environment Canada perspectives on industry understanding and compliance • Stakeholder perspectives on extent to	**Progress made; further work warranted**	While there is evidence of progress in some areas, in other areas there are limited data to draw conclusions on the extent to which some CMP outcomes have been achieved. • **Use of information by program partners**. Information and data are being used by program partners to inform CMP activities and decisions. Priorities for research and monitoring and surveillance are developed through a consultative approach to ensure alignment with the needs of the regulatory partners, and findings are used to inform risk assessments, risk management and other program activities. Improvements to information systems are expected to further facilitate program access to and use of information. • **Canadians' understanding and use of information.** Because the CMP does not actively collect data on Canadians' understanding and use of information on the risks and safe use of substances of concern, it is not possible to draw conclusions on the extent to which this outcome may have been achieved. Risk communications to Canadians continues to be perceived as a weakness of the CMP. • **Industry understanding and compliance**. The available data show a reasonably high overall rate of compliance among inspected entities, although these rates cannot be extrapolated to the regulated industries in general. • **Risks/threats to human health and the environment**. Trends for environmental and/or human exposure data for some core CMP risk-managed substances are beginning to emerge, and may be more firmly established through monitoring over a longer term.

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
Little Progress; Priority for Attention	Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Issues	Indicators	Overall Rating	Summary
To what extent does targeted industry take voluntary or enforced action to protect Canadians and the environment? To what extent are risks associated with harmful substances in humans, the environment, food, and consumer products prevented, minimized, or eliminated? To what extent have threats from harmful substances to health and the environment been reduced?	which Canadians use information generated by Health Canada/Environment Canada to avoid or minimize risks posed by substances of concern • Trend levels for a selected group of representative or significant harmful substances • Level and frequency of releases of selected controlled substances • Key informant perspectives on degree to which risks/threats have been prevented, minimized, or eliminated		
5. Demonstration of Economy and Efficiency			
Governance How effective is the CMP governance structure? How effective is the working relationship between Health Canada and Environment Canada? How well-aligned are the two departments? Does the CMP governance structure effectively provide overall direction for the CMP?	• Evidence of a functioning governance structure • Evidence of effective working relationships among partners • Perceived effectiveness of CMP governance structure • Perceived alignment between partners • Satisfaction of key partners with governance structure	**Progress made; further work needed**	The horizontal governance structure and collaborative approach of the CMP has improved mutual understanding among program partners and reduced the siloed approach to chemicals management that was being taken in the past. Although the CMP governance structure is generally seen as effective, it could be strengthened by clarifying roles and responsibilities of various program partners to ensure relevant partner engagement, and by exploring opportunities for a more streamlined decision-making and approval process for substances deemed toxic to only human health or the environment.
Accountability, performance measurement, and financial reporting Is an effective performance measurement system in place for the CMP? Does the performance measurement system permit measurement of the expected immediate, intermediate, and long-term outcomes? Is performance measurement information used in CMP decision making? Do financial systems link information about CMP costs to specific inputs, activities, outputs, and outcomes?	• Evidence of implementation of a performance measurement system with baseline data and targets • Availability of appropriate performance data for measuring outcomes • Evidence that performance data is used in decision making • Perceived utility of performance data for decision making • Degree to which financial reporting systems link CMP cost information with specific CMP inputs, activities, outputs, and outcomes • Perceived ability of financial reporting	**Progress made; further work needed**	CMP partners have taken steps to address recommendations and suggestions for improvement from the 2011 evaluation relating to performance measurement and financial reporting. There are opportunities to better meet accountability requirements by reviewing the logic model, clarifying and streamlining the expected outcomes, collecting data for all expected outcomes, and where feasible, identifying CMP-specific substances.

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
Little Progress; Priority for Attention	Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Issues	Indicators	Overall Rating	Summary
	systems to make these linkages		
Resource allocation and use and alternatives Were CMP resources used as planned? What accounted for overruns or lower-than-planned expenditures? How appropriate were the resource allocations to the various CMP activities and commitments? Have opportunities to improve the efficiency of key processes and activities been explored and implemented? Are there further opportunities to improve the efficiency of key processes and activities? Are there lower-cost approaches to producing CMP outputs? Are there alternate ways to achieve similar results at lower cost?	• Comparison of planned and actual spending • Explanations for variances • Analysis of resource allocations and actual outputs relative to targets/commitments (e.g., analysis of extent to which failure to meet targets or commitments was due to inadequate resources) • Key informant perspectives on appropriateness of resource allocations • Evidence of actions taken to explore and implement efficiencies • Potential efficiencies identified by CMP partners • Approaches taken by other jurisdictions to carrying out similar activities and processes • Unit costs of CMP outputs (if available) • Unit costs of outputs produced by other similar programs, including internationally (if available) • Potential lower-cost approaches to producing outputs identified by CMP partners • Potential alternatives identified by CMP partners • Approaches taken by other jurisdictions to achieve similar results	**Progress made; further work needed**	Overall, CMP2 funding levels have been adequate and appropriate. In the first three fiscal years of CMP2, program partners spent 94% of planned funding. Spending has been higher than anticipated for research, and lower than anticipated for monitoring and surveillance and stakeholder engagement and risk communication. Several measures have been introduced to increase the efficiency of the risk assessment process, and to gain efficiencies in other functional areas. It is unknown how or if anticipated data challenges for CMP3 substances will affect the complexity and cost of assessments. Canada is widely regarded by international stakeholders as a leader and model for other countries for its approach to assessing existing substances and there is a general consensus that Canada has made a significant contribution to international efforts in chemicals management and safety. Due to Canada's leadership role and significant differences in regulatory frameworks and the scope of chemicals management programs across jurisdictions, the evaluation did not identify any clear alternative approaches that would result in similar outcomes at lower cost.

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
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Appendix 3 – Definitions of Key CMP Terms

Definitions of key CMP terms

Challenge to Industry. One of the CMP's earliest initiatives, the Challenge includes 194 high priority chemical substances, which were divided into 12 smaller batches that have been addressed sequentially over CMP1 and CMP2. The Challenge Initiative receives advice from the Challenge Advisory Panel, which consists of independent experts in the fields of chemical policy, production, economics, as well as health and safety risks, environmental and biological sciences, and other fields,

Petroleum Sector Stream Approach. This initiative, launched in CMP1 and continuing in CMP2, covers approximately 160 high-priority petroleum substances that are primarily related to the petroleum sector. The initiative consists of five streams of petroleum substances, which range from site-restricted and industry-restricted substances (Streams 1 and 2), which do not have contact with the public, to substances used by industry and consumers as fuels (Stream 3) and substances that may be found in consumer products (Stream 4). Stream 0 covers substances that are not produced by the petroleum sector.

Domestic Substances List Inventory Update. During CMP1 and CMP2, the DSL was subject to a comprehensive update (the first in 30 years), based on information gathered from industry, in order to ensure that the information contained within it was current and accurate.

Substance Groupings Initiative. Launched in CMP2, this initiative covers nine substance groupings, which include approximately 500 chemicals that have been selected for further action based on the DSL categorization project and feedback from the first phase of the CMP. These groupings were identified based on the structural or functional similarity of the chemicals in an effort to improve the efficiency of the risk assessment and management process. The nine groupings are: Aromatic azo- and benzidine-based substances (360 substances); Cobalt-containing substances (50 substances); Selenium-containing substances (29 substances); Boron-containing substances (15 substances); Phthalates (14 substances); Substituted diphenylamines (13 substances); Certain organic flame retardants (10 substances); Internationally classified substances (6 substances); and Methylenediphenyl diisocyanates and diamines (MDI/MDA) (7 substances).

Rapid Screening Approach. The Rapid Screening Approach aims to streamline decision making on a large number of substances by using information collected under the DSL inventory update. To be identified for rapid screening, the substance must have been in commerce across Canada at less than or equal to 1,000 kilograms per year. The approach uses qualitative and quantitative methods to evaluate the likelihood that low concern chemical substances may cause harm. Substances that appear to present a potential for harm require further assessment, while substances that pose no harm are concluded to be non-toxic under Section 64 of CEPA 1999. Three rapid screening approaches have been used in CMP1 and CMP2 covering 1,222 substances.

Polymer Approach. This covers approximately 570 polymer-based substances that were listed on the DSL and categorized as a priority, but have not been handled by other CMP initiatives. Polymers account for a considerable portion of the 4,300 priorities identified during categorization (~14%). Information from the DSL inventory update will feed into the Polymer Approach, and polymers will be triaged and specific information-gathering initiatives will occur in 2015 for a subset of polymers.

DSL micro-organisms. This involves the screening assessment of 68 microorganisms on the DSL, which are divided into three priority levels based on known hazard characteristics. This initiative includes microorganisms used in industrial manufacturing processes and those used in products regulated under the FDA. The CMP defines a micro-organism as a "bacteria, fungi, yeast, protozoa, algae, virus, eukaryotic cell culture, and any culture other than a pure culture (i.e., consortium)".

New Substances. This is an ongoing information-gathering initiative aiming to assess 400 to 500 new substances per year under the NSNR, which ensures no new substances (including chemicals, polymers, organisms, and nanomaterials) are introduced to the Canadian marketplace (through import or manufacture) before an assessment has been completed and, if required, appropriate risk management measures are put in place. Under the NSNR any company or individual who intends to import or manufacture a new or flagged[63] substance in Canada is required to notify Environment Canada using a New Substance Notification package. Import or manufacture cannot begin until the assessment period has expired. If a new substance is suspected of meeting one or more of the CEPA 1999 s. 64 criteria, risk management measures are imposed.

Significant New Activity (SNAc) Notice. Under CEPA 1999, a SNAc Notice may be used by Environment Canada and Health Canada if the departments suspect that a significant new activity (for a new or existing substance) may pose new or increased risks to the environment or human health, as indicated in s. 64. The notices require that specific information be provided by proponents who want to manufacture, import, or use the substance for new activities. The new activity cannot begin until the assessment period has expired.[64]

[63] Flagged on the DSL with a SNAc Notice or Reduced Regulatory Requirement.

[64] On a case-by-case basis, the government may choose to waive the information requirements for significant new activity. This may happen if information is not needed, the applicant demonstrates satisfactory ability to contain the substance, or it is not practicable or feasible to obtain test data.