CHEMICALS MANAGEMENT PLAN (CMP)

HORIZONTAL EVALUATION

Final Report

October 2011





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Chemicals Management Plan (CMP) – Horizontal Evaluation Management Response and Action Plan

Recommendations	Response	Planned Management Actions	Deliverables	Expected Completion Date	Accountability/ Responsible Manager
1. CMP Logic Model and Outcomes: Revise the current number and definition of intended outcomes from the CMP, as captured in the logic model, to simplify the alignment and linkages between activities, outputs and outcomes. In doing so, clearly identify measurable results relating to preventing or minimizing health impacts and environmental releases of substances of concern, improving public understanding and management of chemical risks, and reducing threats to Canadians and the environment. 2. Performance Measurement Framework	Agree	phase, as well as evaluation recommendations, have been integrated into a performance measurement strategy for a renewed CMP.	A revised CMP logic model and Performance Measurement Framework as part of CMP renewal.	August 2011 December 2011	Chemical Management Executive Committee (CMEC) –Directors General (CMP DGs) as supported by: Health Canada (HC) – Environment Canada
2.1 Revise the proposed CMP PMF to ensure that the indicators used clearly measure the production of key outputs and provide evidence of progress toward the intended outcomes. The Framework should also be used to track the status of key activities and identify areas where progress is diverging from plans and actions being taken in response to these emerging issues. This revised Framework should then be used to keep senior management responsible for the CMP at HC and EC informed as to the CMP's overall status and results, and as the basis for external reporting on the CMP's performance. 2.2 Define how and when the intended immediate, intermediate and final CMP outcomes will be measured, and implement the development and application of the necessary data collection methodologies at the most appropriate times.	Agree	Sustainable Development (CESD) recommendation. Over the next two years, work will continue to develop a methodology to model the longer term outcomes of CMP activities as well as develop CMP-specific indicators for the evolving emphasis on risk management, compliance promotion and enforcement. There are practical, technical and logistical challenges (such as the number of chemicals involved, whether there is a scientific method to even detect them, the overall cost of such monitoring activities, etc.) which will need to be addressed. Once this work is complete, the performance measurement strategy will be further revised to allow for data collection in advance of the next evaluation. The logic model would also be adjusted as required to better tell the CMP performance story.	validation of methodologies and establishment of baselines for existing indicators. A further revised Performance Measurement Framework,	March 2012 March 2013	Environment Canada (EC) CMP Secretariat – Director, Horizontal International Programs (HIP), Safe Environments Directorate (SED), Healthy Environments and Consumer Safety Branch (HECSB), HC and Director, Regulatory Innovation and Management Systems (RIMS), Legislative and Regulatory Affairs Directorate (LRAD), Environmental Stewardship Branch (ESB), EC

Recommendations	Response	Planned Management Actions	Deliverables	Expected Completion Date	Accountability/ Responsible Manager
		4) support internal and external reporting requirements.			
3. Re-assessment: Develop and implement a formal process and/or criteria for prompting reassessment of substances when new information becomes available.	Agree	and those that have been initiated, taking into account various considerations, including available resources. Given that scientific information and research is not static, it is important for Environment Canada and Health Canada to keep up to date with new information on chemicals, such as hazard and exposure potential. Updating	Criteria and process to trigger reassessment developed. Pilot testing of process to identify priorities for reassessment undertaken in advance of next renewal phase of the CMP.	March 2013 April 2014	Director, Science and Risk Assessment Directorate (SRAD), Science and Technology Branch (STB), EC and Director Existing Substances, Risk Assessment Bureau (ESRAB), SED, HECSB. HC

Note: Health Canada and Environment Canada have taken note of the further suggestions for improvement listed in the report and will address them in an appropriate manner consistent with the management frameworks within each department.



CHEMICALS MANAGEMENT PLAN HORIZONTAL EVALUATION

Final Report

July 2011



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List of Acronyms

CCPSA Canada Consumer Product Safety Act

CEPA 1999 Canadian Environmental Protection Act 1999

CHMS Canadian Health Measures Survey

CMEC Chemicals Management Executive Committee

CMP Chemicals Management Plan

DPR Departmental Performance Report

DSL Domestic Substances List E2 Environmental emergencies

E2 Program Environmental Emergencies Program

EC Environment Canada F&DA Food and Drugs Act

HC Health Canada

HPA Hazardous Products Act

ICL In Commerce List

MIREC Maternal Infant Research on Environmental Chemicals

NPRI National Pollutant Release Inventory

NGO Non-governmental organization
PAA Program Activity Architecture
PCB Polychlorinated Biphenyls
PCPA Pest Control Products Act

HC-PMRA Pest Management Regulatory Agency, Health Canada

POPs Persistent Organic Pollutants

RA Risk Assessment

REACH Registration, Evaluation and Authorization of Chemicals

RM Risk Management

RMAF Results-Based Management and Accountability Framework

RPP Report on Plans and Priorities

S.64 Section 64 of CEPA 1999 relating to the basis for determining if a substance is CEPA-

toxic.

S.71 Section 71 of CEPA 1999 relating to the mandatory collection of information on

substances from any company engaged in any activity involving the substance of interest.

SAC Stakeholder Advisory Council

SNAc Significant New Activity
VE Virtual Elimination List

Executive Summary

A. Background

The Chemicals Management Plan (CMP) is a horizontal initiative of the federal government involving joint actions by Health Canada (HC) and Environment Canada (EC) with a goal of mitigating threats posed by existing chemical substances to human health and the environment. A particular focus of the CMP is the assessment of risks posed by existing high priority chemical substances in commercial use and implementation of appropriate risk management measures as determined to be necessary. The evaluation examined the implementation, delivery and results of the CMP from its inception in December 2006 to December 2010.

The CMP was launched in 2006/07 to accelerate the rate at which HC and EC were assessing the risks to human health and the environment posed by these substances and to implement risk management measures for those that met the conditions in Section 64 (S.64) of the *Canadian Environmental Protection Act 1999* (CEPA 1999) and added to Schedule 1 of the Act, the List of Toxic Substances. A core feature of the CMP is the application of an integrated approach to the selection and implementation of risk management measures using appropriate combinations of CEPA 1999, the *Pest Control Products Act* (PCPA), *Food and Drugs Act* (F&DA), and *Hazardous Products Act* (HPA) taking into account such factors as the uses of and rates of exposure to chemical substances, sub-population groups that may be most at risk, and the relative cost-effectiveness of different potential instruments, both regulatory and non-regulatory.

Funding of \$299.2 million was allocated to HC (\$192.7 million) and EC (\$106.5 million) over the period from 2006/07 to 2010/11 and complemented the existing A-base funding of HC's and EC's risk assessment, risk management and supporting research and monitoring activities for the regulation of chemical substances. Within this total, funding was also provided for complementary actions relating to the regulation of pesticides, labelling of cosmetic ingredients, management of environmental risks of pharmaceuticals and personal care products, and strengthening the regulation of contaminants in the food supply.

Delivery of the CMP is based on seven core activity streams involving the following mix of activities and outputs:

- ➤ Research research into the possible hazards of substances or groups of substances, the toxicological mechanisms of substances and means by which Canadians may be exposed to substances. Findings from research projects are used to better inform risk assessment and risk management decision-making and aid the development and validation of assessment models and tools.
- ➤ Monitoring and Surveillance collection and compilation of data on the environmental and human presence of selected substances, to better inform risk assessment and risk management decision-making and, in the longer-term, track trends in the health and environmental presence of Schedule 1 and other substances of concern. In addition, the Pest Management Regulatory Agency (PMRA) implemented systems to track annual pesticide sales volumes and identify environmental

Chemicals Management Plan — Horizontal Evaluation Health Canada / Environment Canada — July 2011

Part 1 and Schedule 1 of the HPA was replaced by the new Canada Consumer Product Safety Act (CCPSA) on June 20, 2011, which strengthened Canada's product safety and consumer protection system.

- and health incidents believed to be due to pesticides. Updates of the medium priority substances on the Domestic Substances List (DSL) to identify which are still in commerce and their usage characteristics were also initiated.
- ➤ **Risk Assessment** science-based evaluation of substances to determine if and how they may pose threats to human health or the environment. Specific areas of risk assessment (and risk management) activity within the CMP are:
 - Challenge process Assessment of the risks posed by 195 high priority substances and implementation of risk management measures for substances added to Schedule 1 of CEPA 1999.
 - **Petroleum sector stream** Risk assessment and risk management of 164 high priority substances primarily used in the petroleum sector.
 - Rapid screening of substances of lower ecological concern Screening of 1,066 substances of low ecological concern to identify those to be subject to risk assessment as medium priority substances in later phases of the CMP.
 - Accelerated re-evaluation of older pesticides to ensure these substances meet current scientific standards and do not pose unacceptable risks to health or the environment.
 - Evaluation of new reduced risk pesticides to facilitate access to new and safer pesticides.
 - **Revised In Commerce List (ICL)** Identification of ICL substances that are still in commerce from among the approximately 9,000 substances in products regulated under the F&DA and were not added to the DSL.
- ➤ Risk Management development of risk mitigation or elimination strategies and control instruments for substances to be added to Schedule 1 of CEPA 1999 or subject to virtual elimination. Risk management tools available to CMP risk managers include regulations, pollution prevention plans, addition of substances to the environmental emergency regulations and preparation of environmental emergency plans, administrative agreements, codes of practice, environmental quality objectives or guidelines, release guidelines, deposit-refund systems and tradable permits. The CMP risk management stream also involved:
 - Introduction of mandatory labelling of cosmetic ingredients on the labels of cosmetics products.
 - Development of environmental assessment regulations to address environmental risks posed by pharmaceutical and personal care products.
- ➤ Compliance Promotion and Enforcement activities intended to promote awareness and compliance with risk management requirements among regulated entities, and enforcement actions in response to non-compliance.
- ➤ Risk Communication consultations and outreach with stakeholders and Canadians to obtain input to and advice on the delivery of the CMP and proposed risk assessment and risk management decisions, and dissemination of information to stakeholders and the public on the nature and extent of substance risks and their management.
- ➤ Horizontal Management integrated horizontal governance and management of the CMP to ensure consistent and integrated approaches to direction setting, policy development, planning, monitoring of progress and performance measurement and reporting.

B. Evaluation issues

The overall objectives of the evaluation were to assess issues related to the CMP's:

Relevance – Does the CMP continue to be consistent with and contribute to Health Canada, Environment Canada and federal government priorities, roles and responsibilities and does it address actual needs?

Performance (effectiveness, efficiency and economy) – Has the CMP achieved its intended outcomes? Are the most appropriate, efficient and economic means being used to achieve outcomes?

The data collection, analysis and reporting against these issues was structured around 18 evaluation questions, looking at the period from the CMP's inception in December 2006 to December 2010.

In reviewing the evaluation findings it is important to note the longer term context for the CMP. That is, the CMP is expected to take until 2020 to assess the priority substances identified during the Categorization process conducted between 1999 and 2006. During the initial four years of the CMP many new mechanisms and processes were established to better manage and integrate HC and EC risk assessment and risk management activities, focusing on (but not limited to) risk assessment and risk management actions for those substances assigned a high priority under the Categorization process. However, the risk assessment and risk management process for the 195 high priority Challenge substances at the heart of the CMP takes up to five years to complete, which means that the establishment of risk management instruments for the initial Challenge batches was just beginning in December 2010. This means that the evaluation has largely focused on the relevance, implementation and outputs to date, supported by judgements concerning progress toward the achievement of intended immediate and intermediate outcomes.

C. Methodology

The methodology for the CMP evaluation involved:

- A review of CMP documents and performance data provided by program managers and accessed on the CMP website.
- A review of literature investigating aspects of the rationale and relevance of the CMP, considerations in managing horizontal initiatives, approaches to the regulation of existing substances in other jurisdictions, and approaches to measuring the performance of these programs.
- ➤ Key informant interviews with CMP program managers (n=29) and representatives of external stakeholder organizations (n=17) who had participated in one or more elements of the CMP and thus were able to speak knowledgeably about aspects of its design, delivery and results. Interviews were also conducted with representatives of chemicals regulatory agencies in Europe, the US and Australia.
- Three case studies of selected aspects of the CMP relating to the application of the best placed Act approach and the horizontal management of the initiative, and the experience with the application of the CMP risk analysis and risk management and supporting streams (research, monitoring and surveillance) to two selected substances Benzenamine, N-phenyl- (BNST) and bisphenol A (BPA). The methodology for these case studies involved key informant interviews and a review of documentation.

Findings from each line of enquiry were analysed and synthesized leading to the preparation of the evaluation report. The majority of these findings are qualitative in nature (based on key informant and case study interviews) plus supporting factual and quantitative data relating to the major CMP outputs and activities from the CMP documents and performance data. The evaluation was able to comprehensively

assess the relevance and design and delivery of the CMP to date. However, it was not able to completely assess the extent to which outcomes were being achieved nor economy and efficiency, due to the evaluation being conducted at a relatively early point in the life cycle of the CMP (which runs until at least 2020), and limited availability of financial breakdowns and human resource allocations to the various CMP activities undertaken by HC and EC. Data obtained through the various lines of enquiry was used to draw judgements as to the extent to which progress was being made against the expected outcomes.

D. Evaluation findings

1. Overview

Overall, the results of the evaluation of the first phase of the CMP are positive. The findings of the evaluation indicate that a sound foundation for achieving the CMP's long-term objective of mitigating the key threats posed by chemical substances to Canadians' health and the environment has been established. Processes, tools and management structures have been established to assess the risks posed by high priority substances, consult with stakeholders and develop appropriate risk management measures. Implementation of these risk management measures is expected to reduce the exposure of Canadians and the environment to the adverse effects of these substances. In parallel, research and monitoring activities have been initiated to address gaps in the knowledge of chemicals and chemical-related risks, and to measure the presence of key substances in humans and environmental media. Delays in some elements of the CMP will need to be addressed as the CMP moves into the assessment of medium priority substances, most notably the assessment of petroleum sector stream substances, updating the inventory of substances on the DSL, and preparation of the revised ICL. Opportunities to improve the delivery and effectiveness of the CMP were also identified by the evaluation, primarily in terms of strengthening performance measurement systems, updating risk assessments as new knowledge of chemical-related risks becomes available, and refining and streamlining the horizontal management and integration of CMP activities.

2. Relevance of the CMP

Provisions in CEPA 1999 required HC and EC to screen and categorize the approximately 23,000 substances on the DSL to identify those that present or may present a risk to the environment or human health. This Categorization process was completed in 2006 and identified approximately 4,300 high priority substances that warranted further assessment of the risks they posed to human health and/or environment.

The CMP was implemented to accelerate the rate at which these high priority substances would be assessed, reducing the expected end-date from 2050 to 2020. The first phase of the CMP, from 2006/06 to 2010/11, was intended to assess the approximately 500 high priority substances and implement appropriate risk management measures for those determined to be toxic (that is, added to Schedule 1 of CEPA 1999). Future phases of the CMP will implement risk management measures for these high priority substances, assess the risks posed by approximately 3,000 medium priority substances and continue research and monitoring projects initiated during the first phase. Beyond 2020, needs to reassess risks and review risk management measures are expected to arise as new scientific information on hazards and the potential for exposure becomes available. As such, there is a clearly established need for the CMP and this need will extend to at least 2020 in order to satisfy the legislated requirements of CEPA 1999.

The presence of these risks to human health and the environment is a function of a market failure to adequately recognize the social costs of chemicals on human health and the environment that are not reflected in market prices nor decisions by substance producers and users. These social costs include increased costs of health care, social amenity, environmental degradation and remediation, and lost productivity. Risk assessment and risk management decisions under the CMP are intended to correct this

imbalance by taking account of the social and environmental costs and benefits of chemicals in decision-making to approve, restrict or remove substances from commercial use. As such, there is a clear rationale for public intervention to regulate the availability and use of potentially risky chemical substances. Experience with risk management actions for substances identified as hazardous prior to the CMP's implementation is illustrative of the expected CMP outcomes. For example, a variety of actions starting many decades ago have been progressively taken by Canada and other countries to reduce exposure to lead, for example, requiring its elimination from gasoline, house paints, food cans and plumbing components. Surveys of the presence of lead in humans and the environment show a corresponding decline.

The objectives set for the CMP – to take timely action to reduce or eliminate the risks posed by existing chemical substances to the health of Canadians and the environment – are also clearly aligned with the federal government's priorities in that the CMP is central to its environmental agenda and aligned with HC's and EC's Strategic Outcomes related to protecting Canadians from the health and environmental risks of hazardous chemicals. Finally, the assessment and management of toxic substances is a role that falls under various federal heads of power, including primarily the Criminal Law. These powers complement provincial and territorial authority to regulate industries that produce and use chemicals, to regulate the release of effluents and emissions, and to regulate occupational health and safety.

3. Design and delivery

The CMP is a long-term initiative of the federal government that is expected to run until at least 2020. The initial phase of the CMP from 2007/08 to 2010/11 involved the establishment and initial delivery of six of the seven required activity streams. The seventh stream, compliance promotion and enforcement, will become a priority during the second phase as final risk management measures are implemented. This program design and delivery structure is also expected to provide the basis for assessing and managing chemical risks in Canada beyond the 2007 to 2020 timeframe established for the CMP.

During the initial phase of the CMP HC and EC established processes, tools and timelines for assessing the risks posed by high priority substances as well as actions under the PCPA, F&DA and HPA to strengthen the regulatory management of pesticides and products that use chemical substances. The initial outputs from these activities – primarily composed of risk assessments, proposed risk management measures and implementation of some risk management instruments as well as updated conditions of use for older pesticides – suggest that a foundation for managing the health and environmental effects posed by high priority substances has been established. In turn, implementation of the risk management measures now flowing from the Challenge process and the re-evaluation of older pesticides should, by inference, be expected to contribute to the mitigation of chemicals-related threats to human health and the environment.

Supporting research projects have been initiated to investigate gaps in the knowledge of hazards and exposure to substances of concern. Findings from this research will become available during the next phase of the CMP and be used to inform future risk assessments and the development of risk management measures. Some priority research projects on bisphenol A that investigated the exposure of young children to indoor dust and migration from repeat-use polycarbonate baby bottles have been completed and used to help inform the assessment of this substance in 2008. More recent research findings on exposure to bisphenol A from canned and bottled foods and beverages are being used to investigate requirements for risk management measures.

A range of ongoing national environmental studies, and national and targeted biomonitoring and surveillance studies, such as the Canadian Health Measures Survey (CHMS) and the Maternal Infant Research on Environmental Chemicals (MIREC) project, have been initiated or strengthened. These studies are designed to provide data on exposure to hazards and associated health implications, and contribute to the longer-term measurement of the efficacy of risk management measures under the CMP along with other data sources, such as the National Pollutant Release Inventory (NPRI).

Current CMP risk assessment processes do not formally include provisions or criteria to determine if risk assessments or risk management measures need to be re-visited. As new scientific knowledge regarding substance risks or the efficacy of risk management measures becomes available from such sources as CMP research and monitoring initiatives, peer-reviewed research from other jurisdictions and research institutions, and industry research and monitoring, it will be desirable to ensure that the implications of such information are assessed and appropriate revisions made to risk assessments and risk management measures. This need was also highlighted by the Commissioner for Environmental and Sustainable Development in 2009, who recommended that risk management strategies be periodically assessed and criteria established to prompt earlier assessments where warranted.²

The program design and logic for the CMP are basically sound and focus on the identification, assessment and management of risks to human health and the environment in response to societal expectations regarding the protection of health and the environment by government. However, the current specification and ordering of program outputs and outcomes in the CMP logic model could be simplified to clarify and identify the most central results expected of the CMP. These core outcomes are:

- Fill gaps in HC's and EC's knowledge of the hazards posed by priority substances and possible exposure scenarios.
- ➤ Determine if substances should be added to Schedule 1 of CEPA 1999 and implement risk management strategies to prevent or minimize releases of such substances.
- > Increase Canadians' understanding and management of risks posed by chemical substances.
- ➤ Ultimately, to reduce health threats to Canadians and the negative impacts of chemical substances on the environment.

Most CMP areas of activity have been implemented as planned. The Challenge process has been implemented as intended and is largely on schedule; as of December 2010, final risk assessments had been issued for 151 of the 195 high priority substances in the Challenge process and final assessments of the balance are expected to be issued during 2011/12. Other key actions – rapid screening of 1,066 substances of lower ecological concern, introduction of pesticide incident and pesticide sales reporting, ongoing evaluation of new reduced risk pesticides, and mandatory labelling of cosmetic ingredients – have been implemented since the launch of the CMP.

The approach to the DSL Inventory Update was substantially revised in 2010 to focus data collection activities on the commercial status and use characteristics of medium priority substances expected to be assessed after 2015/16 instead of updating the status of all substances on the DSL.

Four other areas of activity have been implemented as intended but are running behind the original schedule. These are the assessment of 164 high priority substances in the petroleum sector stream, reevaluation of older pesticides, development and implementation of regulations to address environmental

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Report of the Commissioner of the Environment and Sustainable Development to the House of Commons: Chapter 2 – Risks of Toxic Substances, Ottawa, Fall 2009, para. 2.66.

risks of new substances in pharmaceutical and personal care products, and preparation of the revised ICL of substances contained in products regulated under the F&DA. Further delays in these areas may potentially mean the continuation of risks to the environment and human health and have an impact on the ability of the CMP to achieve its intended risk assessment and risk management outcomes.

Financial and human resources available to HC and EC for the first phase of the CMP appear to have been adequate for the majority of work undertaken. However, delays in some areas of activity were somewhat affected by resource shortages and other areas indicated that they have very limited "surge capacity" to manage short term increases in workload demands.

Horizontal management and coordination of CMP activities is reasonably effective, particularly relating to the core risk assessment, risk management and supporting research and monitoring activities undertaken by HC and EC. At the operational management level, the majority of internal key informants involved in the delivery of the CMP noted that the management and delivery of the CMP is generally well integrated and coordinated, and has improved steadily since the inception of the CMP.

Most external key informants (external stakeholders familiar with the CMP's delivery) also perceived the horizontal management and integration to be working reasonably effectively and efficiently, aided by clear communications to and transparent engagement with stakeholders. Many of these key informants also highlighted the value and predictability of the timelines applied for the completion of interim and final stages in the Challenge process, and HC's and EC's commitment to meeting these timelines. Some internal key informants suggested the approvals process for documents pertaining to decisions on Challenge substances could be simplified or streamlined by reducing the number of managers who need to review and approve documents, drawing on the experience with approvals for the Challenge process to date.

At the governance level, the Assistant Deputy Minister (ADM) Committee and Director General's (DG) Chemicals Management Executive Committee (CMEC) provide joint HC and EC guidance and direction for the management and delivery of the CMP. Four areas in need of strengthening were identified:

- Performance information collected or available for the various CMP activity streams is almost exclusively focused on activities and outputs. These data, which are often in disaggregated form, have been sufficient to inform management decision-making at the operational level. However, provision and use of performance information to inform more strategic decision-making, planning, direction setting and performance reporting for the CMP is weak. A more integrated and systematic performance reporting system that keeps CMP managers informed as to the status and progress of the key activities in each stream, identifies where issues or delays are being encountered and the responses to these issues, and tracks progress in producing key outputs and outcomes, is needed to address this weakness.
- Strategic planning to translate thinking on the renewal of the CMP into direction setting and coordination of HC and EC activities in the next phase of the CMP.
- ➤ Provision of a common IT system with common software and shared servers for activities that are undertaken jointly by HC and EC personnel to improve the ease and efficiency of information sharing and preparation of key documents.
- Improving systems to track and report on CMP (B-base) and A-base expenditures and human resources involved in CMP activities to support financial reporting, operational management and strategic planning.

The future success of the CMP will also depend on the effectiveness of compliance promotion and enforcement activities by EC and HC, to ensure that target entities for risk management measures are aware of their obligations and non-compliance is prevented or limited. CMP compliance promotion and enforcement only comes into play once risk management measures are developed and implemented which meant that this activity stream had a very limited role during the first phase of the CMP. Going forward, the need to plan for and implement compliance promotion and enforcement activities linked to the completion of risk management measures for Challenge and petroleum sector stream substances will become progressively more prominent. The experience with the selection of risk management actions for Challenge substances – with combinations of pre- and post-market measures under combinations of Acts – suggests there may be a need for greater coordination between the EC and HC compliance promotion and enforcement functions than was anticipated at the time of the CMP's initial design.

4. Effectiveness

The CMP is four years into what is expected to be at least a fourteen year life cycle (that is, from 2007/08 to 2020/21) and consequently, has made only limited progress toward the achievement of intended immediate outcomes. Each of the activity streams for the CMP has an associated immediate outcome. The status of progress and achievement against each of these outcomes is summarized below:

- ➤ Risk assessment Improved knowledge of chemical-related risks, including identification of substances that may require further action and identification of data gaps to inform researchers and risk managers. The CMP's risk assessment process for high priority substances identified a range of substances that meet the criteria in S.64 of CEPA 1999 and were added to, or are proposed to be added to, Schedule 1 of the Act, and require risk management action. In particular, 38 of the 151 Challenge substances (25%) for which risk assessments were completed by the end of 2010 were determined to meet the criteria in Section 64. This incidence rate is lower than what was anticipated at the outset of the CMP, in part because a higher than expected proportion of the Challenge substances were found to no longer be in commercial use in Canada. Additionally, the PMRA re-evaluated 360 of 401 pesticides first registered prior to 1995 by the end of 2009/10. Data gaps were identified by the risk assessment and research and monitoring functions and used in the planning and design of biomonitoring and environmental monitoring actions, and selection of research projects.
- Risk management—control instruments Effective management regimes are in place and stakeholders understand regulatory and non-regulatory risk management requirements. Judgements as to the extent to which the CMP is on track to achieve this immediate outcome are premature at this stage, given that the majority of risk management instruments under the CMP will only take effect in the next phase due to the timeframes involved in risk assessment and development of risk management instruments. At the end of 2010, risk management instruments for the 38 Schedule 1 substances in Challenge Batches 1 to 9 were in development or, in the case of actions under the PCPA, F&DA or HPA, implemented. The majority of the proposed risk management strategies for these substances involve multiple instruments, with an average of 2.9 different measures per substance under CEPA 1999, the PCPA, F&DA or HPA. With regard to the re-evaluations of the 360 older pesticides, 34% were withdrawn, conditions of use were changed for 64% and left unchanged for the remaining 4%. In terms of stakeholder understanding, stakeholders who have participated in the various engagement and consultation activities would be expected to have at least some understanding of proposed risk management measures by virtue of their involvement in consultation activities and receipt of supporting communications.

➤ Risk communication – Canadians and other stakeholders are consulted and have access to understandable information on the CMP, and on the risks and safe use of chemicals. Stakeholder engagement is generally perceived to be a strength of the CMP by external and internal key informants, with multiple opportunities for interested stakeholders to comment on, and provide input to, proposed decisions. Additionally, information on the CMP and many of its component activities (particularly the Challenge process) is available on the CMP website or EC and HC sites linked to the CMP website. Looking to the next phase of the CMP, many industry stakeholders emphasized that early notification of planned groupings of medium priority substances and the estimated scheduling of data call-ups would facilitate industry planning and data compilation.

Outreach to Canadians, however, has been limited, with only a limited amount of proactive communication activity targeting Canadians undertaken. Public opinion research conducted for the CMP in 2009 found many Canadians to have a fairly superficial understanding of chemical risks and that confidence in the federal government as a source of consumer product and food safety information lagged behind such other sources as health advocacy groups, health professionals and environmental groups. A majority of the participants in this research rated available information on chemicals as "somewhat helpful" with the usefulness limited by such factors as insufficient detail (for some), too much detail (for others) and/or too technical or confusing, suggesting there is scope to improve the content and presentation of such information.

Many of the key informants saw communications to Canadians as an area of weakness in the CMP. Findings from the literature review conducted for the evaluation suggest that building trust and confidence in regulatory systems is not simply a function of the level of public communications by the regulators. Instead, the literature suggests that it is necessary to understand and build on the way members of the public subjectively perceive and manage the perceived risks, which may differ considerably from the "objective" risks identified by regulators.

- Research Improved knowledge of chemicals to support risk assessment, risk management, monitoring and surveillance. Most research projects are on a three-year cycle and the majority of the peer-reviewed results will only start to become available in 2011/12. In a limited number of instances, early findings have been shared with CMP risk assessors and risk managers, and there has been some use of research results in support of risk assessment and risk management, such as the risk assessment of bisphenol A.
- ➤ Monitoring and surveillance Improved monitoring of the effectiveness of control actions and fate of chemicals to support research, risk assessment and risk management. Monitoring and surveillance studies measuring the presence and effects of chemicals substances in the environment and people are in progress. These studies are designed to increase knowledge of the fate of chemicals and understanding of the effectiveness of risk management actions under the CMP. However, the need for multiple cycles of consistent data collection means that it will be quite some time before definitive conclusions can be drawn regarding the effectiveness of control measures.
- ➤ Risk management—compliance promotion and enforcement Regulatees have increased awareness of their legal obligations, and effective compliance promotion and enforcement activities that support identified CMP risk management instruments and are prioritized to address the greatest environmental threats. This activity stream will largely be implemented during the next phase of the CMP due to its dependence on the implementation of final risk management measures for Schedule 1 substances. As such, no conclusion regarding progress towards the achievement of this outcome can be drawn.
- ➤ Integrated horizontal policy and program management Improved program decisionmaking and program performance. Both internal and external key informants perceive that this outcome is being achieved. The CMP's operational management is generally well integrated and

coordinated within and between HC and EC. Governance structures – principally CMEC and the ADM Committee – are also considered to be effective. Opportunities exist to improve support for strategic management in such areas as performance measurement and reporting, strategic planning, financial tracking and provision of supporting IT tools and systems.

At this stage of the CMP's life cycle it is too soon to be able to draw conclusions about progress toward the achievement of the CMP's intermediate and final CMP outcomes. These long-term outcomes involve the prevention or minimization of releases of hazardous substances, improving Canadians' access to and understanding of information on chemical risks and their management, improvements to government decision-making regarding chemical substances, and, ultimately, reduced threats to Canadians and the environment from the harmful effects of chemicals. Progress toward the achievement of the immediate outcomes suggests that the foundations and initial steps for their eventual achievement are in place except in regard to enabling Canadians to better understand the risks posed by chemicals and the actions they can take to avoid them.

5. Efficiency and economy

A detailed quantitative analysis of the efficiency and economy of the CMP was not feasible given the current state of data availability and stage of the CMP's implementation. Conduct of a more detailed analysis in the future will also require information on the cost and resource requirements (both A-base and B-base) of the main activities undertaken within the various streams of the CMP, which is not currently available. Efficiency and economy were examined using available program data and supporting qualitative assessments.

The CMP has adequate capacity to complete most of its key activities. Some re-allocation of funding has been necessary as the CMP has progressed, largely due to differences between actual and anticipated workloads for a number of activities and program areas. Progress in a number of areas has been affected by resource limits, such as the petroleum sector stream and risk assessment and risk management of legacy substances.

In terms of planned versus actual spending, the estimated total CMP expenditures were slightly below planned allocations in each of 2007/08 (4% below), 2008/09 (5% below) and 2009/10 (3% below). Patterns at HC and EC were similar with the exception of 2008/09 where the actual expenditures at HC were 9% below the planned allocation and 1% above at EC. Differences between estimated actual and planned expenditures for the different component activities are due to internal transfers between activities to better respond to actual workload patterns as well as such factors as delays in the initial ramping up of staffing in 2007/08 and lower than anticipated requirements for operating and maintenance expenditures (versus salary costs) in other years.

The CMP incorporates a number of measures to improve its efficiency and timeliness compared to the approach in place previously. Under the CMP the capacity to undertake risk assessment and risk management work was increased to a level that allows for approximately 100 substances to be assessed at any time, compared to a capacity to assess about 10 substances per year prior to the CMP, plus the development of risk management measures for the approximately 25% of substances added to Schedule 1. This increased capacity was achieved with an increase in annual funding for CMP activities of approximately 72% (from about \$118 million prior to the CMP's introduction to about \$204 million in 2010/11). In addition, the application of clear and predictable timelines for the initial data collection and preparation of draft risk assessment documents, in combination with the time limits mandated in CEPA 1999 for final screening assessments and selection of risk management instruments, provided a level of certainty and predictability compared to the open-ended process applied previously. Longer term, the closer alignment of research and monitoring actions to risk assessment and risk management needs and

priorities is expected to improve the availability of risk data and thereby strengthen the capacity of HC and EC to measure the effects of risk management actions. These changes, in combination with heightened horizontal management and coordination between and within HC and EC, suggest that the CMP is on track to achieve its intended outcomes in an economical manner and provide value for the federal dollars spent.

E. Key Recommendations and Suggestions for Improvement

Key Recommendations

1. CMP logic model and outcomes

Revise the current number and definition of intended outcomes from the CMP, as captured in the logic model, to simplify the alignment and linkages between activities, outputs and outcomes. In doing so, clearly identify measurable results relating to preventing or minimizing health impacts and environmental releases of substances of concern, improving public understanding and management of chemical risks, and reducing threats to Canadians and the environment.

2. Performance Measurement Framework

- 2.1 Revise the proposed CMP Performance Measurement Framework to ensure that the indicators used clearly measure the production of key outputs and provide evidence of progress toward the intended outcomes. The Framework should also be used to track the status of key activities and identify areas where progress is diverging from plans and actions being taken in response to these emerging issues. This revised Framework should then be used to keep senior management responsible for the CMP at HC and EC informed as to the CMP's overall status and results, and as the basis for external reporting on the CMP's performance.
- 2.2 Define how and when the intended immediate, intermediate and final CMP outcomes will be measured, and implement the development and application of the necessary data collection methodologies at the most appropriate times.

3. Reassessment

Develop and implement a formal process and/or criteria for prompting reassessment of substances when new information becomes available.

Further Suggestions for Improvement

- 1. Tracking and reporting of financial and human resources engaged in CMP activities

 Develop and implement improvements to the tracking and reporting of actual A-base and CMP financial and human resources engaged in CMP activities to better inform the analysis and reporting of cost and resource requirements for the various CMP activities and outputs.
- 2. Coordinated planning and monitoring of compliance promotion and enforcement activities Establish a mechanism to provide advice to CMEC on the efficacy of CMP compliance promotion and enforcement activities and to support the coordinated delivery of those activities by EC and HC. The purpose of this role should be to provide a bridge between the management of the CMP and the conduct of compliance promotion and enforcement activities by the various compliance promotion and enforcement groups at EC and HC.

Areas of advice and support to CMEC should include:

- Promoting information exchange, application of best practices, and where appropriate, policy coordination recognizing the different legal authorities and broader program mandates involved under CEPA 1999, the PCPA, the FDA and the HPA/CCPSA.
- Providing direction and guidance for the:
 - Establishment of compliance promotion and enforcement indicators and targets.
 - Collection of required performance data.
 - Reporting on CMP compliance promotion and enforcement outputs and outcomes.

This direction and guidance should form part of the development and implementation of the CMP Performance Measurement Framework.

Periodically reporting on CMP compliance promotion and enforcement approaches, outcomes and issues to CMEC and the ADM Committee.

In doing so, CMEC should consider adding EC's Chief Enforcement Officer and the DG of Environmental Protection Operations Directorate to its membership, and making best use of existing structures, including the EC Chemicals Standing Compliance Promotion and Enforcement Steering Committee.

3. Integration of supporting IT systems at HC and EC

Implement an appropriate IT system or tools to support HC and EC activities that require close collaboration and joint development of outputs.

4. Streamlining of approvals processes for batch documents

Review the documents approvals process for Challenge batches to determine if the process can be streamlined without posing risks to the overall integration and consistency of the various outputs, and implement improvement opportunities identified in the review.

5. Strategic planning for the next phase of the CMP

Develop and implement a strategic plan to guide the implementation of activities planned for phase two of the CMP to ensure interdependent areas of activity are appropriately coordinated and target outputs are produced within proposed timeframes, particularly activities that were delayed in the first CMP phase and carried over to the second, post-2010/11 phase.

6. Research into the understanding of chemical risks and their management among Canadians Conduct research into how Canadians perceive, interpret and use information on the risks posed by chemical substances to better inform the design of communications strategies and tracking of Canadians' levels of understanding.

I. Introduction

This report presents the findings from the evaluation of the relevance and performance of Canada's Chemicals Management Plan (CMP). The CMP was formally announced in December 2006 by the Prime Minister with a goal of mitigating threats posed by existing chemical substances to human health and the environment. The CMP is a horizontal initiative of the federal government involving joint actions by Health Canada (HC) and Environment Canada (EC). The evaluation was conducted over the period from December 2009 to March 2011 and examined 18 evaluation questions related to the relevance, design and delivery, effectiveness, economy and efficiency of the CMP.

The genesis of the CMP is found in a requirement in the *Canadian Environmental Protection Act* 1999 (CEPA 1999) to screen and categorize the approximately 23,000 chemical substances on the Domestic Substances List (DSL) to identify those that present or may present a risk to the environment or human health.

This Categorization process was completed in 2006 and identified approximately 4,300 substances that warranted further assessment of the risks they posed to human health and/or the environment. The resources available to HC and EC in 2006 meant that it would have taken until 2050 to assess the risks posed by these substances and establish risk management measures for those that met the conditions in S.64 of CEPA 1999 and were added to Schedule 1 of the Act, the List of Toxic Substances. These substances are often referred to as "CEPA toxic" to differentiate this classification from the more general usage of "toxic" as something that is poisonous and capable of causing injury or death.

The introduction of the CMP and the allocation of \$299.2 million in funding to complement the existing A-base funding of HC and EC's risk assessment, risk management and supporting research and monitoring activities was expected to accelerate the assessment work of the two departments and complete the screening assessments of priority substances required by CEPA 1999 by 2020. In addition, the CMP includes actions relating to the regulation of pesticides, labelling of cosmetic ingredients, regulation of environmental risks of new substances in pharmaceuticals and personal care products, and strengthening the regulation of contaminants in the food supply.

The first four years of the CMP that were the subject for this evaluation need to be viewed in this longer term context. During this period many new mechanisms and processes were established to better manage and integrate HC and EC risk assessment and risk management activities, focusing on (but not limited to) risk assessment and risk management actions for those substances assigned a high priority under the Categorization process. As such, the 2007/08 to 2010/11 timeframe of the CMP was a period in which the foundations were established and initial actions implemented, recognizing that the risk assessment and risk management process for the 195 high priority Challenge substances at the heart of the CMP takes up to five years to complete. As of December 2010, only the first batch of 15 high priority substances had reached the point where the selection of the final risk management instrument(s) had commenced, consistent with the timelines prescribed by CEPA 1999. Final determination and implementation of risk management instruments for all high priority substances added to Schedule 1 is expected to take until early 2015.

This means that the evaluation has largely focused on the CMP's relevance, implementation and outputs to date, supported by judgements concerning progress toward the achievement of intended immediate and intermediate outcomes. Findings are presented against each of the evaluation questions followed by separate sections summarizing the conclusions regarding the CMP's relevance and performance, as well as recommendations and suggestions for improvement. The conduct of the evaluation was overseen by a Joint Evaluation Committee representing the HC and EC evaluation groups and CMP program areas. Data

collection and the assessment of findings also benefited from the assistance and input from the horizontal coordination group at HC and CMP program leads across both departments.

II. Evaluation Approach and Methodology

A. Evaluation objectives

The overall objectives of the CMP evaluation were to assess issues related to the initiative's relevance, design and delivery, effectiveness, efficiency and economy, looking at the period from the CMP's inception in December 2006 to December 2010. The data collection, analysis and reporting were structured around 18 evaluation questions, listed in Exhibit II-1. These questions are also linked to the five Core Issues that the Treasury Board *Policy on Evaluation* requires evaluations to address in order to determine value for money.

Exhibit II-1 CMP evaluation questions

	Evaluation Issues and Questions	Associated Evaluation Policy Core Issues				
Doe	A. Relevance Does the CMP continue to be consistent with and contribute to Health Canada, Environment Canada and federal government priorities and does it address actual needs?					
1.	Is there a continued need for the CMP? 1. Continued Need for Program					
2.	Are the objectives of the CMP aligned with the priorities of HC, EC and the Government of Canada? 2. Alignment with Government Priorities					
3.	Is there a legitimate and necessary role for the federal government in this program area?	3. Alignment with Federal Roles & Responsibilities				
Has	B. Performance - effectiveness, efficiency and economy Has the CMP achieved its intended outcomes? Are the most appropriate, efficient and economic means being used to achieve outcomes?					
 4. a) Is the program design for the CMP appropriate for achieving expected program results? b) Is the program theory for the CMP (i.e., linkage of activities and outputs to intended outcomes, instruments/approaches used) logically sound and does it realistically address the societal needs identified? c) Does the CMP identify clear deliverables and expected results? 						
5. Is the CMP delivered as designed and intended?						
6. Is appropriate performance information collected against CMP outputs and outcomes? If so, is the collected information used to inform senior management/decision makers?						
7. a) b)	a) Are the roles, responsibilities and accountabilities of HC and EC for the CMP clearly defined and implemented as specified?					
8.	8. Are HC and EC roles and responsibilities for the CMP clearly understood by key internal and external stakeholders?					

Evaluation Issues and Questions	Associated Evaluation Policy Core Issues	
 a) How effective is the integrated horizontal management and governance b) To what extent are the various HC and EC groups within the CMP wor c) To what degree are efforts at integrated horizontal management resultir and efficiencies? d) Are any improvements needed to the CMP's integrated horizontal management. 	king together in an integrated manner? ag in improved decision-making processes	
a) Does the CMP have adequate capacity in terms of financial and human b) Are resources allocated appropriately among the major areas of CMP a	resources to achieve its intended outcomes?	
 11. What are the best practices and lessons learned (both strengths and weat 12. a) In addressing the legacy of un-assessed substances under CEPA 1999 be mitigate key threats to Canadians' health and the environment. Is the C the right track to accomplish this objective for 2020? b) In order to facilitate the attainment of this objective, are any refinements 	MP, as currently designed and delivered, on	Delivery
challenges and/or take advantage of key opportunities? 13. To what extent have the intended immediate outcomes been achieved a Improved knowledge of chemicals to support risk assessment, risk man Improved knowledge of chemical-related risks, including identification action and identification of data gaps to inform researchers and risk man Improved monitoring of the effectiveness of control actions and fate of assessment and risk management. d) Canadians and other external stakeholders are consulted and have access CMP, and on the risks and safe use of chemicals. e) Effective management regimes are in place and stakeholders understand management requirements. f) Regulatees have increased awareness of their legal obligations. g) Effective compliance promotion and enforcement activities that support instruments and are prioritized to address the greatest environmental the Improved program decision-making and program performance. 14. To what extent has progress been made toward the intended intermedia outcomes are: a) Government decision-making is improved and Canadians have better are bounded to Canadians better understand the risks posed by chemicals and the action Unlawful releases of listed substances into or from the environment, for pesticides are prevented or minimized. d) Reduced threats to Canadians and impacts on the environment from the	as a result of the CMP? These outcomes are: agement, and monitoring and surveillance. of substances that may require further nagers. chemicals to support research, risk as to understandable information on the dregulatory and non-regulatory risk tidentified CMP risk management reats. The and final outcomes of the CMP? These excess to information on risks. In they can take to avoid them. In the cod, consumer and health products and	
outcome). 15. Have the objectives for CEPA 2005's air, water, new substances notifice achieved?* 16. Are there any external factors outside of the CMP that influence (positive program? 17. Have there been any unintended outcomes, either positive or negative,	ely or negatively) the success of the	
were any actions taken as a result of these outcomes? 18. a) Is the CMP undertaking activities and delivering products in the most e b) Are there alternative, more efficient ways of achieving the objectives o c) How could the efficiency of the CMP be improved? 19. a) Is the CMP achieving its intended outcomes in the most economical may b) Has the CMP provided value for the federal dollars spent?	temonstrat	Economy

^{*} Addressed in Phase I, and excluded from the scope of Phase II of the evaluation.

B. Evaluation methodology

The methodology for the CMP evaluation involved the following steps:

- A review of CMP documents and performance data provided by program managers and accessed on the CMP website.
- A review of literature investigating aspects of the rationale and relevance of the CMP, considerations in managing horizontal initiatives, approaches to the regulation of existing substances in other jurisdictions, and approaches to measuring the performance of these programs.
- ➤ Key informant interviews with CMP program managers (n=28) and representatives of external stakeholder organizations (n=17) who had participated in one or more elements of the CMP and thus were able to speak knowledgeably about aspects of its design, delivery and results. Interviews were also conducted with representatives of chemicals regulatory agencies in Europe, the US and Australia.
- Three case studies of selected aspects of the CMP relating to the application of the best placed Act approach and the horizontal management of the initiative, and the experience with the application of the CMP risk analysis and risk management and supporting streams (research, monitoring and surveillance) to two selected substances Benzenamine, N-phenyl- (BNST) and bisphenol A (BPA). The methodology for these case studies involved key informant interviews and a review of documentation.

Findings from each line of enquiry were analysed and synthesized leading to the preparation of the evaluation report. The majority of these findings are qualitative in nature (based on key informant and case study interviews) plus supporting factual and quantitative data relating to the major CMP outputs and activities from the CMP documents and performance data.

1. Review of CMP documents and performance data

A structured review of documentation and performance data relating to the design, implementation and progress of the CMP was undertaken with the purpose of identifying material relating to the relevance of the CMP, its execution, funding, and outputs and (to a limited extent) outcomes produced to date. These documents pertained to the approval to establish and fund the CMP; descriptions of activities undertaken; presentations to management committees pertaining to implementation progress; issues encountered and lessons learned; regulatory documents published in the *Canada Gazette* and on the CMP, EC and HC websites; and selected presentations to advisory bodies and stakeholder groups.

2. Literature review

The literature review investigated peer-reviewed and other published information on:

- The rationale for public intervention to regulate chemical substances and types of issues addressed by such actions.
- > Governance and success factors for horizontal initiatives in the federal government.
- ➤ Best practices and lessons learned in promoting improvements in managing hazardous chemical substances in other jurisdictions, when these best practices have direct implications for regulatory and non-regulatory approaches for the management of chemicals.
- Approaches to performance measurement of regulatory initiatives designed to improve the management of risks associated with existing chemical substances.

3. Internal and external key informant interviews

Two parallel series of key informant interviews were conducted, involving 28 internal key informants responsible for managing elements of the various CMP streams and program areas at HC and EC, and 17 external key informants from a cross-section of key stakeholder organizations. These stakeholders spanned industry groups subject to regulation by EC and/or HC; public health, Aboriginal and environmental non-government organizations (NGOs); and provincial governments. A number of members of the CMP Stakeholder Advisory Council and Challenge Advisory Panel were included among these external key informants.

A purposive sampling approach was used to select prospective candidates for the key informant interviews, focusing on the selection of respondents who were involved with the CMP's delivery and thus able to provide informed comments on its relevance, performance, likelihood of future success, management and opportunities for improvement. The choice of this method is a function of the start-up status of the CMP, that is, four years into an initiative that is expected to take until 2020, and a need to focus interviewing on program managers and external stakeholders that are most directly involved in the CMP's delivery and thus best able to comment on progress and results.

4. Case studies

Data collection for the case studies involved:

- A review of relevant background documentation, files and data.
- Internal case study interviews with selected HC and EC representatives who were most directly involved in decision-making related to the risk assessment and risk management of BNST and bisphenol A, and the horizontal management and integration of the CMP.
- External interviews with a small number of stakeholder representatives for each case study. These key informants were actively involved in applicable aspects of the CMP and considered to be aware of the applicable case study subject areas.

The case study interviews were conducted largely in parallel with the internal and external key informant interviews on the overall design and delivery of the CMP. Some internal respondents were identified as candidates for both the case study and overall key informant interviews. The content of these interviews covered both the general performance of the CMP and the specific focus of one or more of the case studies.

5. International analysis

The international analysis investigated the experiences of three other jurisdictions – the United States, European Union and Australia – in managing hazardous chemical substances using interviews with representatives of the principal regulatory agency in each jurisdiction. The interviews also investigated perspectives on the effectiveness of the CMP, the degree of alignment of approaches in the various jurisdictions, and the extent of current and potential future international cooperation and sharing of results. These interviews were supplemented by a review of material on the participating agencies' websites and pertinent findings from the literature review.

C. Limitations of the evaluation methodology

The CMP has a complex structure compared to most federal government programs with multiple streams of activity encompassing multiple directorates within HC and EC. This complexity is a function of there being seven activity and outcome streams in the CMP combined with multiple fields of application (for example, the Challenge process, petroleum sector stream, DSL Inventory Update, revised ICL, consumer products regulated under the F&DA, and pesticides regulated under the PCPA).

This complexity, combined with the relatively small number of interviewees meant that it was a challenge to obtain comparable depth of coverage of the various streams and areas of application of the CMP, and only subsets of the respondents were able to speak to each of these aspects. This result is a function of the purposive sampling approach used for the selection of key informants (that is, targeting candidates with a high degree of familiarity or involvement with the initiative) and the breadth of CMP activities in progress. It is also a function of the current stage of implementation of the CMP in that the majority of streams have yet to reach the point where they are fully implemented, and one – compliance promotion and enforcement – will only be fully implemented in the next phase of the CMP.

Following on from the previous point, the CMP is four years into a life cycle expected to last at least fourteen years, which means that only limited progress has been made toward the achievement of intended outcomes. As a result, the participants in key informant interviews were essentially asked to speculate regarding the extent of outcome achievement with only limited (at best) recourse to data on progress. The analysis assessed the comments of key informants regarding these more speculative aspects of performance in the light of evidence of outputs produced to date and implementation of key activities to draw conclusions regarding both the delivery of the CMP and the achievement of intended outcomes.

The reliance on key informants who were intimately familiar with various activity streams of the CMP also carried with it the risk of bias in the findings due to the involvement of the internal key informants in the management and delivery of the program. Similar risks of bias applied to the external key informants given that they were responsible for providing information on substances use and/or commenting on proposed risk assessment conclusions and risk management measures. These potential biases were managed by carefully comparing the comments made by the internal and external key informants, and triangulated with the findings from the document and literature review to identify areas of consistency and to qualify areas of differing or conflicting views.

Finally, the design of the data collection activities did not permit investigation of the awareness and understanding of the chemicals regulatory system and actions proposed for various substances among members of the public. To the extent possible the analysis relied on findings from public opinion research conducted for the CMP and key informants' own observations and judgements regarding public perceptions. Future evaluations of the impacts and success of the CMP should also include (or draw upon) research into public perceptions, awareness and understanding of the regulatory system and regulatory actions in order to assess the degree of achievement of outcomes relating to public understanding and actions to manage exposure to chemical risks.

D. Reporting note – ratings against evaluation questions

In Chapters IV to VII, the findings of the evaluation are presented by evaluation issue (relevance, design and delivery, effectiveness, efficiency and economy) and by the related evaluation questions.

A rating is also provided for each evaluation question. The ratings are based on a judgment of whether the findings indicate that:

- ➤ The intended outcome or goal has been fully achieved or met labelled as **Achieved**.
- Considerable progress has been made to meet the intended outcome or goal, but attention is still needed labelled as **Progress Made**; **Attention Needed**.
- Little progress has been made to meet the intended outcome or goal and attention is needed on a priority basis labelled as **Little Progress**; **Priority for Attention**.
- ➤ It is too early at this stage of the CMP to assess whether the intended outcome or goal has been achieved labelled as **Too Early to Observe Achievement**.

If a rating does not apply to an evaluation question, this is labelled as **Not Applicable.** Typically, Not Applicable ratings are applied when the subject matter of the evaluation question is outside of a program or initiative's direct control or influence, for example, whether there are any external factors that influence the success a program.

An abbreviated version of the key indicators for each evaluation question is presented at the beginning of the section on the findings for that question. A full listing of all evaluation questions and indicators can be found in Appendix B. A summary of the ratings for each of the evaluation questions is presented in Appendix D.

III. Profile of the Chemicals Management Plan

A. Background to the CMP's establishment

The CMP was launched on December 8, 2006 by the Prime Minister and Ministers of Environment and Health with a goal of mitigating key threats posed by existing chemical substances to human health and the environment in Canada. The core element in the Plan is to further assess the environmental and health risks posed by substances identified as having potential concerns during the DSL Categorization process completed in September 2006 and take appropriate risk management actions under CEPA 1999, where necessary.

The Categorization process screened the approximately 23,000 existing substances on the DSL to identify those that:

- (a) may present, to individuals in Canada, the greatest potential for exposure; or
- (b) are persistent or bioaccumulative in accordance with the regulations, and inherently toxic to human beings or to non-human organisms, as determined by laboratory or other studies. (CEPA 1999, Section 73 (1))

Categorization identified approximately 4,300 substances for further assessment, which were further classified as high (~500 substances), medium (~2,600) or low (~1,200) priority. The initial four-year period of the CMP from 2007/08 to 2010/11, inclusive, focused on the assessment of the high and low priority substances, and performance of foundational work for the subsequent assessment of medium priority substances. In addition, the CMP includes actions relating to the regulation of pesticides, labelling

of cosmetic ingredients, environmental risks of new substances in pharmaceuticals and personal care products, and strengthening the regulation of contaminants in the food supply. CMP funding of \$299.2 million was allocated to HC and EC for the period from 2007/08 to 2010/11.

B. Goals and objectives of the CMP

The goals of the CMP, as defined in the RMAF for the CMP prepared in March 2007, are:

- > Timely action on the key threats to Canadians' health and the environment from chemical substances.
- Ensuring that industrial and commercial producers and users of chemical substances assume a high level of responsibility for identifying, preventing and managing risks from those substances.
- Enhanced competitiveness in an international market that is increasingly focussed on chemical and product safety.
- Confidence among Canadians that the Government is taking action to protect their health and the environment.
- From an operational perspective, HC and EC define the objectives of the CMP as being to:
- > Significantly strengthen the existing substances regime based on the application of clear science-based priorities for assessing and managing chemical substances used in Canada.
- Integrate government activities by strengthening CEPA 1999's coordination with other federal statutes, most notably the *Hazardous Products Act* (HPA), *Food & Drugs Act* (F&DA), *and Pest Control Products Act* (PCPA).
- > Cooperate with international programs related to chemicals management.
- Establish government accountability through enhanced monitoring and surveillance activities to identify priorities and measure effectiveness of regulatory actions, increase research activities to ensure that action is informed by best available science, enhance risk communications to Canadians, and conduct cyclical updates of the DSL.
- Strengthen industry's stewardship role in proactively identifying and safely managing risks associated with chemicals they produce and use.⁴

The underlying logic of the CMP is based on the application of an integrated, government-wide approach to assessing and managing the risks posed by existing chemical substances. Seven core activities that are expected to achieve a series of immediate, intermediate and final outcomes are undertaken by HC and EC. Ultimately, achievement of these outcomes is expected to contribute to reduced threats to Canadians and impacts on the environment from the harmful effects of chemicals. These actions and associated outcomes are shown in Exhibit III-1.

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HC and EC, Results-based Management and Accountability Framework (RMAF): Chemicals Management Plan, March 19, 2007, p.10.

Based on material presented in the following presentations: Canada's Chemicals Management Plan (September 17, 2009), An Overview of the Chemicals Management Plan and the Challenge (NICNAS briefing, September 21, 2009), and Prioritization of Existing Substances under the Canadian Environmental Protection Act and Canada's Chemicals Management Plan (Briefing for NICNAS visit, no date).

Exhibit III-1
Core activities and associated immediate and intermediate outcomes of the CMP

Core Activities	Immediate Outcomes	Intermediate Outcomes	
Research – generation and dissemination of science-based information necessary to identify risks and support risk assessment and risk management processes.	Improved knowledge of chemicals to support risk assessment, risk management, monitoring and surveillance.		
Monitoring and Surveillance – collection and generation of human health and environmental data to better inform decision-making and ensure the effectiveness of control actions.	Improved monitoring of the effectiveness of control actions and fate of chemicals to support research, risk assessment and risk management	Government decision-making is improved and Canadians have better access to information on risks.	
Risk Assessment – science-based evaluation of substances to determine if and how they may pose threats to human health or the environment.	Improved knowledge of chemical-related risks, including identification of substances that may require further action and identification of data gaps to inform researchers and risk managers.		
Risk Management – development of risk mitigation or elimination strategies and control instruments.	Effective management regimes are in place and stakeholders understand regulatory and non-regulatory risk management requirements.	Unlawful releases of listed substances into or from the environment, food, consumer and health products and pesticides are prevented or minimized.	
Compliance Promotion and Enforcement – to promote awareness and compliance with risk management requirements among regulated entities, and enforcement actions in response to non-compliance.*	Regulatees have increased awareness of their legal requirements. Effective compliance promotion and enforcement activities that support identified CMP risk management instruments and are prioritized to address the greatest environmental threats.		
Risk Communication - consultation and outreach with stakeholders and, provision of relevant information to the public on which informed decisions can be made.	Canadians and other external stakeholders are consulted and have access to understandable information on the CMP, and on the risks and safe use of chemicals.	Canadians better understand the risks posed by chemicals and the actions they can take to avoid them.	
<i>Horizontal Management</i> – integrated horizontal governance and management.	Improved program decision-making and program performance.		

^{*} Implementation of compliance promotion and enforcement activities by EC will not commence until risk management measures under CEPA 1999 (for Challenge and petroleum sector substances) have been developed and formally implemented, after the second phase of the CMP commences in 2011/12.

Source: CMP Logic Model, June 2010.

C. Planned activities – 2007/08 to 2010/11

The core focus of the CMP is to assess and implement risk management measures for approximately 500 substances identified as high priority substances by HC and EC through the DSL Categorization process. Risk assessments are conducted to determine if these substances met the criteria in S.64 of CEPA 1999 and should be added to Schedule 1, that is:

"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.⁵"

Section 64, Canadian Environmental Protection Act, 1999, accessed at: laws-lois.justice.gc.ca

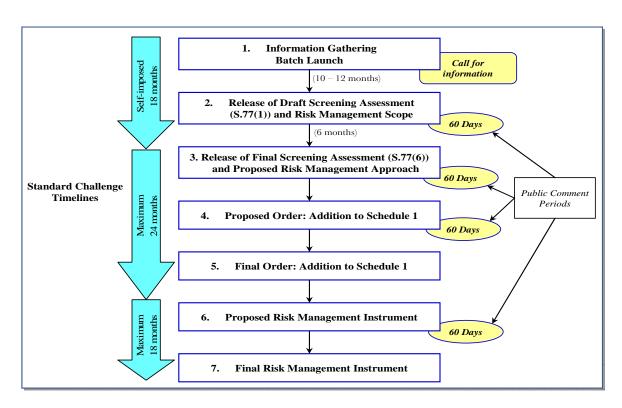
In addition, the CMP includes a range of other complementary activities intended to lead to, or support, better management of hazardous substances under CEPA 1999, the HPA, the F&DA or the PCPA. The purpose and nature of these various activities is summarized below.

1. Actions on high priority substances

a) Challenge to industry

Under the Challenge process, 195 high priority substances (including two previously thought to be no longer in commerce) were divided into a series of batches of between 12 and 19 substances each, and a sequence of steps implemented to assess the risks and implement risk management actions for each substance added to Schedule 1 of CEPA 1999, as shown in Exhibit III-2, below. The allocation of substances to batches was made by a HC and EC working group based on their knowledge of the various substances as well as grouping suggestions provided by stakeholders.

Exhibit III-2
Summary overview of the CMP Challenge process



Source: Adapted from Challenge process documentation.

The key steps in this process are:

- Issuing, at the launch of each batch:
 - Profiles summarizing the scientific information on hazards, exposures and any relevant
 uncertainties for substances in the batch. Information for these profiles is obtained from such
 sources as published scientific journals and databases, equivalent regulatory agencies in other
 jurisdictions, modelling work and direct contacts with industry representatives.

- A mandatory S.71 notice to industry requiring manufacturers, importers, distributors and users to report available information on substance production, usage characteristics, releases and their management/minimization, and degree of exposure to individuals and the environment.
- A voluntary completion questionnaire inviting external stakeholders to provide information
 they may have relating to "the sectors using the substances, the use patterns, existing
 management practices, release and exposure pathways, potential substitution options, substance
 analysis methods and financial implication of elimination of the substances". CMP
 stakeholders include chemical manufacturers and importers, manufacturers of products
 incorporating chemical substances, environmental and public advocacy groups, other levels of
 government, Aboriginal organizations, public health organizations, and unions.
- Information collected through this information gathering process is used by HC and EC to prepare draft risk assessments (also referred to as "screening assessments" in CEPA 1999) and risk management scope documents that are issued for public review and comment. The draft risk assessments include proposed conclusions regarding whether one or more of the criteria of S.64 are met. Risk management scope documents contain preliminary outlines of the risk management options being examined, based on the proposed conclusions of the draft screening assessments.
- Following the receipt and review of public comments on the draft risk assessment and risk management scope documents, HC and EC issue the final risk assessment and proposed risk management approach documents. The proposed risk management approach documents are issued for public comment and build on the previously released risk management scope documents and present more detailed risk management proposals for substances to be added to Schedule 1.
- Issuing proposed and final orders to add substances meeting one or more of the S.64 criteria to Schedule 1 of CEPA 1999. Public comments on the proposed additions are invited.
- ➤ Issuing proposed and final risk management instruments for substances added to Schedule 1 with provision for public comments on the proposed actions by HC and/or EC.

The maximum time period for the completion of risk assessment and risk management activities for each batch of Challenge substances is five years. This is composed of:

- ▶ Up to 18 months for the work of HC and EC's risk assessment and risk management functions in collecting information on substances in each batch, and preparation and issuance of the draft and final risk assessments plus the accompanying risk management scope and proposed approach documents. This timeline was established by HC and EC to enable the CMP to complete the risk assessments of the 195 high priority substances by the end of 2010/11, as committed to by the Ministers of Health and the Environment in the Government's Interim Response to the 1999 CEPA Review. ⁷
- ➤ Up to 24 months to issue proposed and final orders adding substances to Schedule 1, and the proposed risk management instruments for those substances, as defined in Section 91 of CEPA 1999.
- ➤ Up to 18 months to finalize and issue the risk management instruments for substances added to Schedule 1, as defined in Section 92 of CEPA 1999.

[&]quot;Guidance document for responding to the Questionnaire that forms part of the Challenge", issued for each Challenge batch. Accessed through the CMP website, www.ec.gc.ca/ese-ees/default.asp?lang=En&n=EF9F998D-1

Health Canada and Environment Canada, *Canadian Environmental Protection Act*, 1999 Review: The Interim Government Response, October 2007, p.5.

The first of twelve batches in the Challenge process was launched in February 2007. Subsequent batches were released about every three months with Batch 12 launched in December 2009. As of December 2010, final risk management instruments for Batch 1 substances added to Schedule 1 were in development; additions to Schedule 1 and development of proposed risk management instruments were in progress for substances in Batches 2 to 9; final risk assessments and proposed risk management approaches were in development for Batches 10 and 11; and the issuance of draft screening assessments and the scope of possible risk management measures was imminent for Batch 12.

b) Petroleum sector stream

High priority substances that are primarily related to the petroleum sector and are typically complex mixtures of chemicals are being addressed separately from the Challenge process. These 164 substances span raw materials, such as crude oil and natural gas, intermediate process streams produced during refining processes, and final refined products. The approach to risk assessment and risk management for these substances follows the same sequence as the RA and RM process for the Challenge substances, shown in Exhibit II-2, above.

However, unlike the Challenge process, HC and EC did not set a maximum time period for the initial information collection and preparation of the draft risk assessments for these substances, due to the uncertainty regarding data availability and time required to assess the mixtures of substances involved. Draft risk assessments and risk management scope documents were released for 30 site-restricted petroleum substances during 2010 (10 in May plus 20 in August) and for a further 40 in early January 2011.

c) Restrictions on re-introduction and new uses

New uses of 148 high priority substances believed to be no longer in commerce were to be made subject to the Significant New Activity (SNAc) requirements of Sections 80 and 81 of CEPA 1999. Two of these substances were subsequently found to be still in commercial use and transferred to the Challenge process and a third was found to no longer satisfy the categorization criteria for bioaccumulation and inherent toxicity and held over for later assessment.

d) Continuing RA and RM actions for substances that were already in process

A number of risk assessment and risk management actions for various Schedule 1 and Priority Substance List (PSL)⁹ substances were already in progress at the outset of the CMP and work on these substances by HC and EC is continuing. Key amongst these actions was the:

- Prohibition of five categories of substances due to the risks they posed to the environment or human health. These substances, and the times of publication of regulations prohibiting their production and use (except for permitted activities and exceptions) in *Canada Gazette II*, were as follows:
 - Pentachlorobenzene, tetrachlorobenzenes (impurities or resulting from waste incineration) and 2-methoxyethanol (anti-icing agent in jet fuels and chemical/industrial processes) – November 2006.

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CMP website, Stream 1, retrieved February 1, 2011, www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/stream-circuit-1-eng.php. Site-restricted petroleum substances are not expected to be transported off petroleum refinery, upgrader and natural gas processing facility sites, and often serve as a fuel used in petroleum facilities or are further refined or blended into other products.

Substances that require investigation on a priority and in-depth basis to determine if they are toxic under *CEPA1999*. Addition to the PSL generally means that data gaps preclude the determination of toxicity under S.64.

- Fifty PFOS (perfluorooctane sulfonate) substances used in some non-stick coatings and stain repellents prohibition regulations were published in June 2008, and regulations adding PFOS to the Virtual Elimination List in February 2009.
- Six PBDE (polybrominated diphenyl ether) flame retardant substances July 2008.
- ➤ Creation of the Virtual Elimination (VE) List to identify substances on Schedule 1 for which the government intends to reduce releases to the environment to a quantity or concentration below that which can be accurately measured (known as the "level of quantification"). The VE List currently contains the PFOS substances and hexachlorobutadiene; seven Challenge substances have been identified as potential additions to the VE List to date.

2. Rapid screening of lower risk chemical substances

The Categorization process conducted prior to the CMP identified a subset of substances on the DSL that were expected to have a low likelihood of causing harmful ecological effects. These substances were categorized as being persistent and inherently toxic to non-human organisms (PiT(eco)) or bioaccumulative and inherently toxic to non-human organisms (BiT(eco)) but believed to be used in quantities of less than 1,000 kilograms per year. Environment Canada developed and applied a rapid screening process to assess the potential risks posed by 1,066 of these substances and determined that 312 (29%) should be subject to further assessment as part of the assessment of medium priority substances.

3. Research, and monitoring and surveillance

Under the CMP a variety of monitoring and research programs are being undertaken. Scientific research by HC and EC under the CMP is being used to identify and investigate substance risks, and support risk assessment and risk management processes. A common HC-EC research fund was established and three research themes established: effects, exposure and validation and development of models and predictive tools for application by risk assessors and managers. Priority areas for research under these themes were:

- > Endocrine disrupting compounds
- Metals
- Exposures and effects of mixtures of substances
- Perfluorinated alkyl compounds (PFCAs)
- > Medium priority substances.

Appendix C contains a list of the research projects funded under the CMP.

Monitoring and surveillance activities are being used to identify and track exposure to substances in the environment and the associated human exposures and health implications, and in the longer term, enable the impact of selected risk management controls to be tracked. Monitoring activities span:

- National biomonitoring initiatives:
 - Canadian Health Measures Survey (CHMS) Collection of blood and urine samples to provide information on exposure to 91 environmental chemicals in 12 groups (for example, metals and trace elements, organochlorines, PCBs, phthalates).

- Maternal-Infant Research on Environmental Chemicals (MIREC) Study of exposure of 2,000 pregnant women and their babies to 13 groups of substances involving a range of environmental chemicals.
- Northern Contaminants Program Biomonitoring and health outcomes studies to characterize human exposures to and the health impacts of environmental chemicals in the northern population.
- Total Diet Study (TDS) monitoring to estimate the levels of chemicals to which Canadians in different age-gender groups are exposed through the food supply.
- > Targeted population biomonitoring initiatives Biomonitoring or exposure studies targeting subpopulations of interest.
- ➤ Biomonitoring supportive research Research to advance biomonitoring scientific methods and techniques and to develop tools to better understand, interpret, and communicate biomonitoring results.
- National environmental monitoring Monitoring of chemicals in multiple environmental media (air, water, sediment, non-human biota (fish and wildlife)) as well as source monitoring (wastewater treatment plant effluents and sludge; landfill leachate and biogas). The following substances are currently monitored by EC in at least one environmental media: bisphenol A, siloxanes, chlorinated paraffins, metals (including platinum group elements) perfluorinated compounds (PFCs), polybrominated diphenyl ethers (PBDEs) and other flame retardants.

4. Updating of information on medium priority substances on the DSL

A large amount of data on companies producing or importing DSL substances, quantities involved, and uses dates from the early 1990s and, based on the experience with the Challenge substances, is often out of date. Under the CMP, cyclical updates of the DSL are to be initiated to provide EC and HC with information on substances in use and their volumes, focusing initially on medium priority substances. Cyclical updates of the DSL inventory are also intended, on a five-year cycle following the initial data collection period which was expected to take two years.

5. Development of a revised ICL of F&DA substances

A group of approximately 9,000 substances in products regulated under the F&DA that entered commerce between January 1987 and September 2001 were not added to the DSL. The environmental and health risks of these substances have not been determined. As part of the CMP, HC is undertaking work to identify the substances on the ICL, determine their current use patterns and annual volumes, and use this information to identify and categorize those that should be subject to further, more detailed risk assessment.

6. Regulatory activities under other Acts

Pest Control Products Act: Under the CMP, action is being taken by the Pest Management Regulatory Agency (HC-PMRA) in four areas:

Accelerated re-evaluation of older pesticides to ensure these active ingredients meet current scientific standards and do not pose unacceptable risks to health or the environment.

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Domestic Substances List Inventory Update (DSL IU), presentation to the ADM Committee, June 2009.

- Pre-market evaluation of new active ingredients and pest control products leading to more timely introduction of new and safer pesticide products to replace products and/or uses no longer considered acceptable.
- > Reporting of health and environmental incidents believed to be due to pest control products.
- Annual reporting of pesticide sales volumes to support risk assessment and risk management decision-making.

For re-evaluation of pesticide active ingredients the HC-PMRA typically prepares a proposed re-evaluation decision designed to bring the active ingredient and its uses into line with current requirements, which is issued for public comment and consultation. The risk assessment and proposed risk management approach presented in the proposed decision is based on information and data available to and provided by registrants, other government departments (for example, environmental monitoring studies by EC), other levels of government as well as information obtained from internal sources, equivalent regulatory agencies in other jurisdictions (primarily the US Environmental Protection Agency) and published scientific journals and databases. The HC-PMRA may also require registrants to perform new studies to address any significant data gaps or questions. A final decision is prepared that takes feedback from registrants and other stakeholders as well as any new data requested or made available into account. Evaluations of new active ingredients and pest control products require applicants to submit a full range of studies and data relating to the efficacy and human health and environmental risks posed by the substance. Proposed registration decisions are also issued for public comment.

Some of the pesticides subject to re-evaluation, and formulants used in the preparation of pesticide products, are also on the list of CMP Challenge substances.

Food and Drugs Act: Under the CMP, actions are being taken to strengthen several aspects of the regulation of products subject to the F&DA:

- ➤ Development of appropriate environmental assessment regulations for new substances contained in products regulated under the F&DA, to replace the assessment of potential risks to the Canadian environment and human health through environmental exposure to these products under the New Substances Notification Regulations under CEPA 1999.
- Mandatory ingredient labelling on all cosmetics products.
- Re-evaluation and regulatory updates for food additives, food contaminants and food packaging materials based on CMP priorities.

D. Resource allocations

The allocation of CMP funding and planned staffing for HC and EC (including employee benefits plan (EBP) and accommodation costs) is shown in Exhibit III-3, below. (More detailed breakdowns of the planned and actual resource allocations to components of the CMP are provided in section F of Chapter V.)

Exhibit III-3 CMP funding and planned staffing allocations

Funding	2007/08	2008/09	2009/10	2010/11	Total	
Allocations	(\$ mill.)	(%)				
Health Canada	23.50	42.00	60.30	66.90	192.70	64%
Environment Canada	16.20	23.60	29.70	37.00	106.50	36%
Total	\$39.70	\$65.60	\$90.00	\$103.90	\$299.20	100%

Planned Staffing Levels	2007	/08	2008	/09	2009	0/10	2010	/11
(FTEs)	(#)	%	(#)	%	(#)	%	(#)	%
Health Canada	80.9	51%	132.0	50%	167.5	50%	187.7	47%
Environment Canada	77.3	49%	131.3	50%	166.8	50%	208.4	53%
Total	158.2	100%	263.3	100%	334.3	100%	396.1	100%

Source: Chemicals Management Plan RMAF, March 2007.

Work on the CMP by HC and EC during the 2007/08 to 2010/11 period was also funded through A-base budgets – approximately \$29 million and \$45.6 million, respectively, in 2010/11 – for the management of new and existing chemicals. HC also received other B-base funding of \$114.9 million over the 2005/06 to 2010/11 period to strengthen its capacity to undertake CEPA-related work.

IV. Relevance

Relevance relates to the extent to which a program addresses a demonstrable need, is appropriate to the federal government, and is responsive to the needs of Canadians. In the context of regulatory programs designed to protect health and the environment, such as the CMP, the assessment of need takes into account both the rationale for public intervention to regulate the commercial availability of chemical substances and the products that use these substances as well as the nature of the associated legislative requirements.

A. Is there a continued need for the CMP (EQ1)

Evaluation Issue: Relevance	Indicator(s)	Rating
Is there a continued need for the CMP?	Demonstration of societal/environmental need to ensure that legacy chemicals are managed and used in a safe and effective manner by industry and Canadians. Presence/absence of other programs that complement or duplicate the objectives of the program. Gaps would exist in addressing societal/ environmental need in absence of the program. Reach and activities are connected to societal/ environmental needs. Views on connection of program objectives with societal/environmental needs.	Achieved

A continuing need exists for the CMP to enable the health and environmental risks posed by all priority substances identified through the Categorization process to be assessed by 2020. Supporting research and monitoring activities are needed to increase knowledge of substance risks and to measure the long-term efficacy of risk management actions under the CMP.

Chemicals are used extensively and make a vital and necessary contribution to the health, economic and social well-being of Canadians. However, exposure to chemicals may contribute to or cause social costs in the form of adverse health effects in humans or harm the environment and give rise to increased costs of health care, social amenity, lost productivity and environmental remediation.

Public intervention – in the form of regulatory actions to assess and approve the use of chemical substances, and post-market monitoring and enforcement – is a response to these external outcomes ("externalities") that would not otherwise be recognized in the supply, demand and pricing of chemical substances in commercial use and functioning of the private market.

In the absence of regulatory intervention to manage the risks of activities using potentially hazardous chemical substances, society will be faced with an "excessive" amount of risk because these risk costs are not generally borne by producers and users. The full nature and extent of these risks for existing chemicals that were not subject to a pre-market review of potential hazards and effects can not be known without conducting retroactive risk assessments such as those required by the CMP. A lack of information on the nature of these human health and/or the environmental hazards and associated exposure patterns means that understanding of the extent to which existing chemicals may impose social costs and the potential scale of these potentially avoidable costs is limited. A variety of risk management activities within the CMP are intended to correct this imbalance, that is, to take account of the social and environmental costs of chemical substances as well as their benefits in decision-making regarding approvals (or otherwise) for their commercial use.

Experience with substances such as lead, mercury, PCBs and DDT is illustrative of the hazards and effects that may accrue when human health and environmental risks are not assessed prior to the marketing of chemicals as well as the types of actions required to reduce or minimize their effects. For example, high lead levels in humans can increase the risk of brain and kidney damage. Surveys of the presence of lead in humans and the environment show a steady rate of decline that can be attributed to a variety of actions starting several decades ago, such as the elimination of lead from gasoline, house paints, food cans and plumbing components (Bushnik, *et al.*, 2010). Similarly, mercury has been shown to bioaccumulate and biomagnify as it moves up the food chain, which can lead to slower growth, reproductive failure and the development of abnormal behaviours in fish and wildlife and damage the nervous systems of humans, particularly young children and infants. Exposure to elemental mercury through inhalation of mercury vapours can cause neurological and behavioural disorders. Emissions of mercury caused or produced by humans have declined significantly in Canada since the 1970s as a function of regulatory actions to restrict releases and changes in industrial production and commercial use of mercury (Risk Management Strategy for Mercury, 2010).

When CEPA was first introduced in 1988 it established requirements to assess the potential environmental and human health risks posed by new chemical substances and significant new uses of existing substances prior to their commercial introduction. Substances that were already in commerce in Canada between January 1, 1984 and December 31, 1986 were grandfathered (that is, continued use was allowed without requiring the same risk assessments applied to new substances) and added to the DSL.

CEPA 1999 recognized that the approximately 23,000 substances on the DSL had not been subject to thorough assessments of their environmental and health risks and obligated the Ministers of Environment and Health to categorize, by September 2006, the substances on the DSL. Substances suspected of meeting the criteria set in S.64 of the Act were to be subject to a "screening assessment" (S.74) to determine whether they are toxic or capable of becoming toxic.

The core focus in phase one of the CMP, described in the previous chapter, is to complete the required screening assessments of approximately 500 high priority existing substances identified through the Categorization process by the end of 2010/11 and implement appropriate risk management measures for those substances added to Schedule 1 (that is, determined to be "CEPA toxic"). While this is an ambitious goal, requiring an order of magnitude increase in the capabilities of HC and EC to perform the necessary risk assessment and risk management tasks, it is only the first phase of a multi-phase initiative of the federal government to complete screening assessments by 2020 of approximately 3,000 other substances identified as medium priority by the earlier Categorization process or during the rapid screening of low priority substances completed in 2007/08 as part of phase one of the CMP.

This long-term nature of the CMP was explicitly recognized in both the commitment to implement the CMP made in the federal government's interim response to the CEPA review report of the Standing Committee on Environment and Sustainable Development in 2007 and the design of the initial phase of the CMP in 2006/07. The government response noted:

The Plan has set an ambitious goal of completing all assessments by 2020—a ten-fold increase in the previous rate of assessments. Specific timelines include assessing 1,200 low-concern chemicals by spring 2007 (complete), assessing 500 high-priority chemicals still in commerce by 2010, and assessing the final 2,600 medium-priority substances by 2020. ¹¹

This statement clearly identifies and supports the need to continue the CMP in order to assess and then implement appropriate risk management measures. Beyond 2020, needs to reassess the risks posed by existing substances and review risk management measures are expected to arise as new scientific information on hazards and the potential for exposure becomes available.

In addition, there is a continuing need for research and monitoring to assess the environmental and human health effects of existing substances, and measure trends in the presence of these substances to determine if risk management actions are effective. The timeframes required to determine if sustained declines in the presence of existing substances are achieved, and the risks to environmental and human health reduced, are extensive. This timing is a function of such factors as the time required to establish appropriate monitoring methods and collect time series data, and the rate at which changes in the presence of persistent and/or bioaccumulative substances may occur. For example, data collection for cycle 1 of the major biomonitoring tool for the CMP, the CHMS, commenced in 2007 and the data on human levels of environmental chemicals was released in August 2010. Subsequent cycles will provide data for comparison against this initial baseline, with cycle 2 expected to be completed in 2012 and additional cycles (if funded) at intervals beyond 2012.

The CMP is also intended to integrate actions to manage the use of chemical substances under other statutes – principally the PCPA, F&DA and HPA – to provide a comprehensive approach to managing risks associated with both the production of chemicals and their uses in processing and final products. With regard to pesticides, the PCPA requires ongoing evaluation of new active ingredients and end-use products as well as cyclical re-evaluations of older pesticides to identify and assess risks they may pose to health and the environment. Ongoing needs for action under the F&DA also exist, flowing from the conclusions of substance risk assessments under the CMP that have a bearing on substances used in cosmetics, food packaging and potentially present in food products as well as the ongoing application of the F&DA and supporting regulations.

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Health Canada and Environment Canada, *Canadian Environmental Protection Act*, 1999 Review: *The Interim Government Response*, October 2007, p.15.

Both internal and external key informants consistently supported the view that there is a continued need for the CMP. The view advanced by these key informants was essentially that the CMP is a further step in a process that began with Categorization, as required by CEPA 1999, leading to better risk management and reduced hazards from chemical substances. The CMP is also seen to contribute to a need for a more coordinated approach to the management of substances through increased coordination and integration between the HC and EC research, monitoring and surveillance, risk assessment and risk management functions to address gaps in the knowledge of health and environmental effects, and monitor and assess the effectiveness of risk management actions.

B. Are the objectives of the CMP aligned with the priorities of HC, EC and the Government of Canada? (EQ2)

	Evaluation Issue: Relevance	Indicator(s)	Rating
2.	Are the objectives of the CMP aligned with the priorities of HC, EC and the Government of Canada?	Program's objectives correspond to recent/current federal government priorities. Program's objectives are aligned to current HC and EC strategic outcomes. Views on the alignment of program objectives to recent/current federal government and departmental priorities.	Achieved

The CMP was described by the Prime Minister as "part of the government's comprehensive environmental agenda" at the time of its launch in 2006. This importance of the CMP was further underlined in the government's interim response to the Parliamentary Review of CEPA 1999 in 2007. CMP activities and expected outcomes are also closely aligned with the Strategic Outcomes of both HC and EC.

The CMP was launched by the Prime Minister and Ministers of Environment and Health on December 8, 2006 with the purpose of improving the environment and protecting the health and safety of Canadians and is aligned with federal government priorities in this area. In announcing the CMP, the Prime Minister positioned it as "part of the government's comprehensive environmental agenda". The interim response to the Standing Committee on Environment and Sustainable Development by the Ministers of Health and the Environment provided a more extensive overview of the actions committed to under the CMP and referred to the CMP as one of the government's two main environmental priorities (the other being the Action Plan to Reduce Greenhouse Gases and Air Pollution).

The response established the priorities and key expectations of the CMP in the following terms:

The Chemicals Management Plan protects Canadians and the environment from these sorts of effects while supporting and promoting a strong Canadian economy, by ensuring that the Government:

- gives Canadians the information they need to make decisions about what risks are acceptable to them;
- moves quickly to reduce risks from chemicals when they are identified, using measures ranging from distributing information to requiring labelling of products, and regulating or prohibiting the use of certain substances;
- encourages industrial users and producers of chemicals to take proactive measures ranging from sharing information to changing product formulations in order to protect Canadians and the environment; and
- uses all of its legal powers to manage risks from chemicals in ways that are clear and predictable to producers, users, and consumers of chemicals and products.

The Plan's objective is to address all priority chemical substances in Canada by 2020. The Government will accomplish this by accelerating existing activities, reinvesting in science, and developing new and innovative partnerships with industry and other countries to work collectively towards common goals.

As noted in other government documents, without the CMP appropriate risk management of potentially toxic substances on the DSL would require an additional 30 years to implement and continuation of associated health and environmental effects for up to 30 years longer than anticipated for the CMP.

CMP activities and expected outcomes are also closely aligned with the Strategic Outcomes of both HC and EC, as defined in their respective annual Reports on Plans and Priorities (RPPs) and Departmental Performance Reports (DPRs). For example, EC's 2009-2010 DPR identifies the CMP as one of three Program Activities that contribute to the achievement of one of four Strategic Outcomes in the department's Program Activity Architecture (PAA), Canadians and their environment are protected from the effects of pollution and waste. 13 Similarly, the CMP activities take place primarily under two Program Activities in the HC PAA – Sustainable Environmental Health and Pesticide Regulation – that contribute to one of four HC Strategic Outcomes, Reduced health and environmental risks from products and substances, and healthy, sustainable living and working environments. CMP-related work undertaken under the Consumer Products Program Activity also contributes to this Strategic Outcome, and CMPrelated work under the Food and Nutrition Program Activity contributes to another HC Strategic Outcome, Access to safe and effective health products and food, and information for healthy choices. ¹⁴ As such, the PAAs of both departments position the CMP as a major contributor to protecting Canadians from the health and environmental risks of hazardous chemicals. In turn, these departmental outcomes are aligned to two whole-of-government Outcome Areas: Healthy Canadians and a Clean and Healthy Environment. 15

C. Is there a legitimate and necessary role for the federal government in this program area? (EQ3)

	Evaluation Issue: Relevance	Indicator(s)	Rating
3.	Is there a legitimate and necessary role for the federal government in this program area?	Program mandate aligned with federal government jurisdiction. Extent to which there is duplication or overlap with other jurisdictions, or opportunities to increase their roles in fulfilling this mandate. Views on the appropriateness of federal involvement.	Achieved

Public intervention to regulate the pre-market approval and post-market use of chemical substances is justified on the grounds that the social costs of chemical hazards would not otherwise be recognized and incorporated into the supply, pricing and use of these substances. Action by the federal government to limit these risks to human health and the environment is authorised under the Constitution by virtue of federal powers to pass laws relating to interprovincial and international trade and commerce, and complements the regulation of industries that produce and use chemicals, and release effluents and emissions, by the provinces and territories.

Environment Canada, 2009-2010 Estimates: Part III – Departmental Performance Report, 2010, p.55.

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Ibid, pp.3-4.

Health Canada, 2009-2010 Estimates: Part III – Departmental Performance Report, 2010, p.36 (Food and Nutrition), p.40 (Sustainable Environmental Health), p.42 (Consumer Products), and p.47 (Pesticide Regulation).

Annual HC and EC RPPs and DPRs for the period from 2007/08 to 2010/11.

A further aspect of relevance is whether regulatory intervention under the CMP is a legitimate role of the federal government versus regulatory action by other levels of government in Canada. Responsibility for environmental regulation and management is shared among all three levels of government in Canada. Under the Constitution, the federal government has powers to pass laws relating to interprovincial and international trade and commerce (among others), which provide the authority to regulate the import, manufacture, availability and national distribution of chemical substances.

HC and EC are jointly responsible for minimizing risks posed by chemical substances to the environment and human health, principally under CEPA 1999 but also including Acts under the authority of the Minister of Health, such as the F&DA, PCPA and HPA. The CMP is intended to provide a single integrated approach to protection against the risks posed by substances and products manufactured or imported for sale in Canada using the regulatory tools and instruments available under all four of these Acts.

Provincial and territorial government roles complement the federal role, in that they regulate industries that produce and use chemicals, the associated release of effluents and emissions, and occupational health and safety including workplace hazards and exposures. CEPA 1999 includes provisions for the Minister to consult with the provinces and territories regarding proposed actions as well as Aboriginal, municipal and other interested stakeholders, and to establish a National Advisory Committee to enable cooperative and coordinated approaches between federal, provincial, territorial and aboriginal governments.

Internal key informants and the majority of the external key informants supported the participation of the federal government in the regulation of chemical substances. Key reasons for this support were the power of the federal government under the Constitution to regulate the import, manufacture and trans-provincial border distribution of chemical substances, the scientific resources and capacity of the CMP (compared to capacity at the provincial level) to undertake risk assessment work as well as supporting research and monitoring activities, and the cost-effectiveness (particularly for industry stakeholders) of a single national regulatory system. Many key informants also noted that environmental regulation is a shared and complementary responsibility between the federal and provincial levels of government, with the provinces and territories focusing their efforts on the regulation of point-source emissions and occupational safety. Some also commented that these complementary roles would become more important as risk management actions under the CMP are finalized and implemented, and benefit from cooperative approaches. A few industry stakeholders were also concerned that the introduction of the Ontario Toxics Reduction Strategy (announced in 2008) would result in duplication of regulatory requirements and reporting.

In summary, public intervention to regulate the pre-market approval and post-market use of chemical substances is justified on the grounds that the social costs of chemical hazards would not otherwise be recognized and incorporated into the supply, pricing and use of these substances. Action by the federal government to limit these risks to human health and the environment is authorised under the Constitution by virtue of federal powers to pass laws relating to interprovincial and international trade and commerce. CEPA 1999 provides the foundation for ensuring that the health and environmental risks of substances are assessed and regulated by EC and HC, supported by regulatory actions that may be taken under a number of other Acts, depending on the nature of, and risks posed by, the use of a particular substance or group of substances. This federal role complements the regulation of industries that produce and use chemicals, and release effluents and emissions, by the provinces and territories.

V. Design and Delivery

A. Appropriateness of the CMP's program theory and design (EQ4)

	Evaluation Issue: Design and Delivery	Indicator(s)		Rating
4(a)	Is the program design for the CMP appropriate for achieving expected program results?	Plausible link between program activities, outputs, and intended outcomes.	(a)	Achieved
(b)	Is the program theory for the CMP (that is, linkage of activities and outputs to intended outcomes, instruments/approaches used) logically sound and does it realistically	Demonstration that the CMP has clear deliverables and expected results that are agreed to among CMP management.	(b)	Progress made; attention needed
(c)	address the societal needs identified? Does the CMP identify clear deliverables and expected results?	Views on the appropriateness of	(c)	Progress made; attention needed

The program design for the CMP is basically sound and responds appropriately to a legislated need to address the social and environmental costs associated with harmful exposure to chemicals, which is linked to societal expectations regarding the protection of health and the environment.

The current CMP logic model (that is, program theory for the CMP) specifying the linkages between activities, outputs and intended outcomes could be simplified to identify and better summarize the relationships between the various activity streams and the intended immediate and intermediate outcomes of the CMP.

Output deliverables are clearly identified for the most part. However, the specification of a number of the expected results needs to be reviewed and revised to clearly identify the distinct intended outcomes (that is, changes in the behaviour or knowledge of the targeted beneficiaries or audiences).

1. Foundations of the CMP's design

Traditional science-based approaches to risk assessment and risk management are being challenged to become more open and to respond to a variety of pressures to manage risks more effectively. In the literature on the design of risk management policies and approaches this traditional science-based approach is described as "scientific consensual" while more recent approaches are moving in the direction of "participatory-transparent". In the scientific consensual approach, regulators review scientific evidence and attempt to determine and manage objective risk. In the extreme form of this top-down model, regulators inform the public of risks and risk management measures only following the completion of risk management reviews. For a variety of reasons, generally referred to as the decline of public trust, this system is changing to one in which there is more transparency, including widespread public and related interest group involvement prior to making regulatory decisions.

The aspect of public trust in regulatory systems is particularly important and plays a role in determining the perceptions of the public about the risks attached to various activities. In this context, if the public has become less trustful of risk regulators it will become more risk averse. In an environment in which risk regulators are not trusted, public fears of the risks they manage are amplified relative to statistical or "objective" measures of the same risks.

The findings from the literature presented in this section draw heavily upon work by Rainer Lofstedt, found in: How Can Better Risk Management Lead to Greater Public Trust in Canadian Institutions: Some Sobering Lessons from Europe, paper prepared for the Privy Council Office as part of the Smart Regulation Initiative, Ottawa (2003). Risk Communication and Risk Management in the 21st Century, Washington, AEI-Brookings Joint Center for Regulatory Studies (2004). Risk Management in Post-Trust Society, London, England, Palgrave Macmillan Limited (2005).

The participatory-transparent approach attempts to counter the decline in public trust by providing greater opportunities for stakeholder participation and input to regulatory decision-making and holding regulators more accountable for explaining and justifying their decisions. Research on this approach suggests that it has the following defining characteristics:

- ➤ Greater inclusiveness, particularly at the interface between scientific data on risk and the development of regulatory approaches to manage risk.
- More open and transparent regulatory measures with more accountability for regulators.
- More specific discussion and application of the precautionary principle and other approaches to greater risk aversion.
- More separation of "objective-scientific" risk measurement and assessment from risk management policies.
- Rebalancing the pre-eminence of "science" in decision-making to give equal importance to external stakeholder consultation and input. 17

The design of the CMP incorporates many of the features of the participatory-transparent approach to risk management, particularly with regard to the provision of multiple opportunities for stakeholder engagement and input. Opportunities include: draft risk assessments and proposed risk management measures during the operation of the Challenge process; the petroleum sector stream; and the evaluation of proposed new pesticides and re-evaluation of older pesticides.

This transparency includes two advisory structures for stakeholder input to the overall CMP and technical aspects of the risk assessment process as well as opportunities to comment on risk assessments and proposed risk management actions. The Stakeholder Advisory Council has two goals: to provide advice and input to government on the implementation of the CMP and to foster dialogue on issues pertaining to the CMP between stakeholders and government, and among different stakeholder groups. Stakeholders represented on the Council come from industry associations whose members produce, import and/or use chemical substances; consumer, public health, and environmental non-government organizations; trade unions; and Aboriginal organizations. A second advisory body, the Challenge Advisory Panel, advises on the application of the precautionary and/or weight of evidence approach to assessments of the high priority substances in the Challenge program. Members of the Panel are independent individuals with relevant experience in such areas as the precautionary principle, chemical policy, chemical production and economics, environmental and health risks, environmental and biological sciences, environmental health social movements, Aboriginal communities, chemicals and health and safety, and health care planning and delivery.

The introduction of the CMP is a response to a legislated requirement in CEPA 1999 and, in doing so, responds to broader societal expectations regarding the control and reduction of threats to human health and the environment that underlie public trust in, and support for, the regulatory system. In this regard, the CMP RMAF noted several conclusions from public opinion research conducted for the government in 2001 and 2002:

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Lofstedt R., op cit.

CMP website, Stakeholder Advisory Council, accessed at www.chemicalsubstanceschimiques.gc.ca/plan/council-conseil/index-eng.php

CMP website, *Challenge Advisory Panel*, accessed at: www.chemicalsubstanceschimiques.gc.ca/challenge-defi/panel-groupe/index-eng.php

- Environmental factors such as water/air quality are clearly seen as having an impact on health. Ninety-seven percent believe they are either very important (74%) or somewhat important (23%) in determining whether people are generally healthy on a day-to-day basis. (Environics Research Group, National Pulse on Health Strategy, 2002)
- Canadians feel these effects in a personal way. Six in ten feel that their health is affected either a great deal (29%) or a fair amount (32%) by environmental problems. (Environics Research Group International, International Environmental Monitor, 2001 and 2002)²⁰

2. Logical soundness of the CMP's design

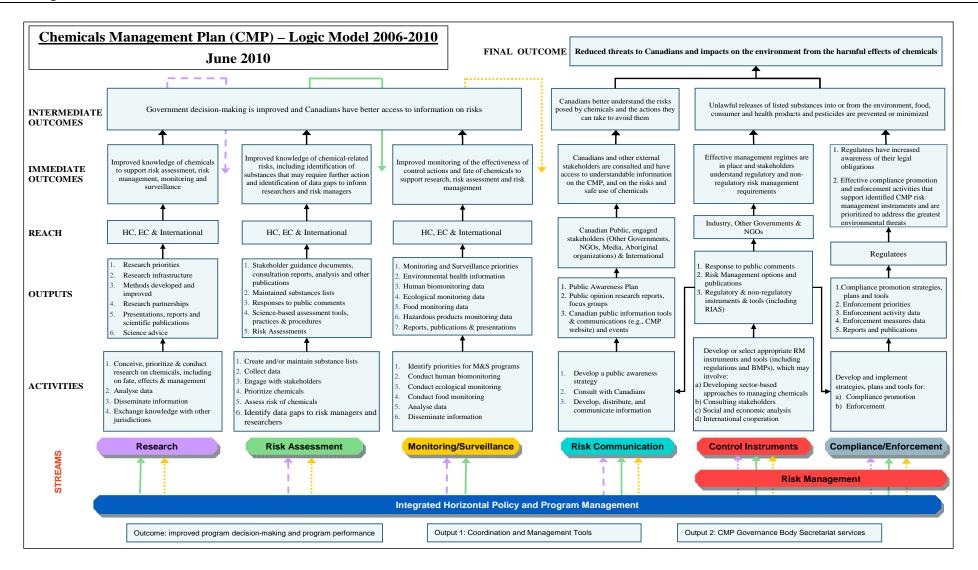
The current logic model for the CMP is shown in Exhibit V-1. The core focus in the design of the CMP is concerned with the assessment of approximately 4,300 substances that the Categorization process identified as potentially persistent and/or bioaccumulative and inherently toxic to humans and the environment, and to which people might have the greatest potential for exposure. Risks posed by these substances were to be assessed to determine if they should be added to Schedule 1 of CEPA 1999, starting with the high priority substances described in section C.1 of chapter III. As previously noted, under S.64 a substance is added to Schedule 1 if it is or may be entering the environment and may be harmful to the environment or biological diversity, constitutes a danger to the environment on which life depends or constitutes a danger to human life or health.

The CMP includes a range of other risk assessment and/or risk management actions under the PCPA, F&DA and HPA, relating to the regulation of pesticides, labelling of cosmetic ingredients, regulation of environmental risks of new substances in pharmaceuticals and personal care products, and strengthening the regulation of contaminants in the food supply. Parallel actions to update information on the use of ICL substances and medium priority substances on the DSL are expected to contribute to improved knowledge of the extent to which these substances are in commercial use and basic usage characteristics.

Mechanisms for stakeholder and public consultation and input to proposed risk assessment and risk management decisions for these substances have been strengthened as part of the CMP's design. Industry cooperation and sound stewardship are also a necessary condition for the successful management of existing substance risks and EC and HC will work with industry sectors and other stakeholders to facilitate this participation. Longer-term monitoring of the environmental and human presence of these substances (or, more accurately, a cross-section of substances that is representative of the range and types of substances subject to risk management measures) is necessary to measure and assess the impact of the control measures put in place.

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CMP RMAF, March 2007, p.4.



The design of the CMP shares similarities with approaches taken to manage the risks posed by other chemical substances in both Canada and internationally. For example, under the federal Building Public Confidence in Pesticide Regulation initiative implemented in 2002/03 actions were taken to increase transparency by providing additional public and stakeholder consultation mechanisms, strengthen research and monitoring of the environmental effects of pesticides, re-evaluate older pesticides, and implement post-market monitoring requirements. Internationally, the Stockholm Convention on Persistent Organic Pollutants (POPs), which aims to protect human health and the environment by eliminating or reducing the release of POPs into the environment, includes measures relating to stakeholder and public awareness and education, and the performance of research and monitoring activities pertaining to POPs and their alternatives.

The principal outputs from each of the activity streams of the CMP are:

- ➤ Risk assessment identification of data gaps, and draft and final assessments of the environmental and human health hazards posed by substances and potential exposure of the population to these hazards. With regard to the Challenge process and petroleum sector streams, the purpose of these assessments is to determine if existing substances are toxic, within the definition provided in CEPA 1999, and should be added to Schedule 1 and made subject to risk management. The formal outputs from this work are draft and final risk assessments for the substances in the Challenge process and petroleum sector stream as well as proposed and final re-evaluation decisions for pesticide active ingredients.
- ➤ Risk management –identification, evaluation, selection and implementation of proposed and final instruments and tools for substances determined to pose risks to human health or the environment. Risk management tools include regulations, pollution prevention plans, addition of substances to the environmental emergency regulations and preparation of environmental emergency plans, administrative agreements, codes of practice, environmental quality objectives or guidelines, release guidelines, deposit-refund systems and tradable permits. Risk management actions are also taken under the PCPA, HPA and F&DA. Under the F&DA, some of these tools include a number of non-regulatory strategies such as setting migration targets for substances in food packaging materials, increased scrutiny of submissions for specific substances (e.g. for pre-market assessment of food packaging materials) and targeted monitoring of potential sources.
- ➤ Risk communication dissemination of information to stakeholders and interested members of the public on the nature and extent of risks posed by existing substances, and advice and input to CMP management by stakeholders on the delivery of the initiative and proposed risk assessment and risk management decisions. The principal risk communication outputs are stakeholder contact mechanisms (focusing on but not limited to industry associations, manufacturers, importers and users in industry; public health and environmental advocacy organizations, and Aboriginal organizations), and communications tools (such as the CMP web site, fact sheets, Frequently Asked Questions (FAQs) and press releases).
- **Compliance promotion** actions to establish or maintain awareness of regulated substances and risk management measures among entities subject to these controls (regulatees).
- ➤ **Enforcement** monitoring and verification to confirm that regulatees are complying with risk management measures, and actions to compel compliance where necessary.

About the Convention: Stockholm Convention on POPs, accessed at: chm.pops.int/Convention/tabid/54/language/en-US/Default.aspx

- ➤ Research research projects conducted by HC and EC scientists that investigate possible hazards of substances or groups of substances, the toxicological mechanisms of the substances and how Canadians may be exposed to these substances, to inform risk assessment and management decision-making, and to aid the development and validation of assessment models and tools. Appendix C contains a list of CMP-funded research projects.
- > Monitoring and surveillance projects and activities investigating the incidence of, and trends in, the environmental and human presence of selected substances, to inform risk assessment and risk management decision-making and, in the longer-term, track trends in the health and environmental presence of Schedule 1 and other substances of concern. The principal outputs from these studies will be environmental and human health monitoring data, and the findings from analyses of these data.

Amongst the internal and external key informants, the design of the key CMP streams implemented during the initial phase of the CMP (information collection, risk assessment, risk management, risk communication, research, and monitoring and surveillance) was generally perceived as appropriate and effective, in terms of enabling the assessment of risks posed by existing substances and identification of appropriate risk management actions. One concern noted by most of the external key informants related to the extent to which the CMP's approach to communications to Canadians could be expected to increase general levels of understanding of the risks posed by chemicals and means of avoiding these risks.

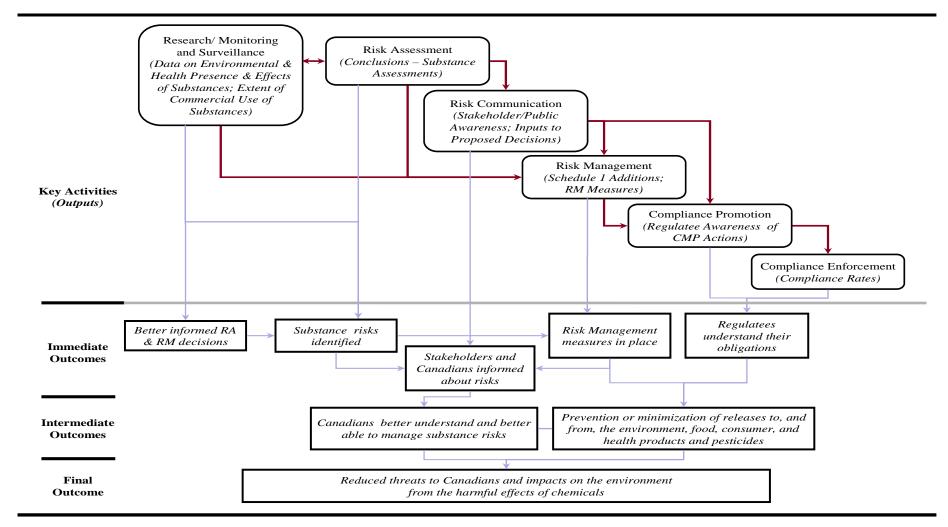
3. Specification of clear deliverables and expected results

In conducting the evaluation we reviewed the clarity of the CMP's outputs (deliverables) and outcomes (results) as presented in the CMP logic model and performance reports, such as the outcome and results statements contained in horizontal reporting documents for the CMP on the Treasury Board Secretariat's Horizontal Initiatives Database. This analysis showed that the CMP logic model contains separate sets of outputs and immediate outcomes for each of the six main activity streams of the CMP (risk assessment, risk management, risk communication, compliance promotion and enforcement, research and monitoring and surveillance). These outputs are consistent with those listed in the previous section, above.

In the current logic model, each stream of activity has a separate immediate outcome which feeds into three intermediate outcomes (as shown previously in Exhibit V-1) and one final outcome. Examination of these outcomes, and the linkages to and between the supporting outputs and activities, suggests that the logic model could be simplified to more clearly identify the most central expected results relating to substance use and releases, public understanding and behaviour, and reduced health and environmental effects; and recognize the highly inter-dependent nature of the various activity streams. A possible form of this more streamlined outcomes structure is shown in Exhibit V-2.

In this structure the enabling or supporting roles of the risk assessment, research and monitoring and surveillance streams, feed into the risk management and compliance/enforcement streams and their associated outcomes rather than being assigned separate immediate and intermediate outcomes. Another feature of this structure is that outcomes are clearly demarcated from activities or outputs, which is not the case with the current logic model. For example, the current immediate outcome for monitoring and surveillance refers to "monitoring" (an activity), the immediate outcome for risk assessment refers to the "identification of data gaps" (an output), the immediate risk communication outcome refers to Canadians being consulted (an activity), and the immediate outcome for compliance/enforcement refers to "compliance promotion and enforcement activities".

Exhibit V-2
Sequencing and linkages of CMP activities and outputs to intended outcomes



Source: KPMG analysis.

On a more specific point, the current intermediate outcome for compliance/enforcement and risk management – "Unlawful releases of listed substances into or from the environment, ..." – does not provide for the impact of non-regulatory measures that do not have the force of law behind them but do result in the prevention or minimization of substance releases. In particular, "release" is beyond the authority of the F&DA, which regulates the sale of specific types of products, such as food.

4. Overall appropriateness of the CMP's program theory and design

The program design and logic for the CMP is basically sound and responds to a legislated need, which is linked to societal expectations regarding the protection of health and the environment. In essence, the CMP is expected to reduce threats to the health of Canadians and impacts on the environment by collecting information on the hazards and patterns of use of existing substances, including the conduct of research by HC and EC scientists; assessing the risks to health and the environment of these substances; selecting appropriate risk management measures; and, requiring compliance with these measures. In parallel, information on the risks posed by existing chemicals and end-use products will be made available to Canadians and guidance on their safe use provided. Industry cooperation and sound stewardship is also a necessary condition for the successful management of existing substance risks and EC and HC will work with industry sectors and other stakeholders to facilitate this participation. Longer-term monitoring of the environmental and human presence of these substances will be undertaken to measure and assess the impact of the control measures applied.

However, the current specification of program outputs and outcomes, as defined in the CMP logic model, could be simplified to clarify and identify the most central expected results of the CMP and demonstrate the inter-dependencies among the various activity streams. These central outcomes are to fill gaps in HC's and EC's knowledge of the hazards posed by priority substances and possible exposure scenarios; to determine if substances should be added to Schedule 1 and prevent or minimize releases of such substances; increase Canadians' understanding and management of risks posed by chemical substances; and ultimately, to reduce threats to Canadians and the impacts of chemical substances on the environment.

B. Is the CMP delivered as designed and intended? (EQ5)

Evaluation Issue: Design and Delivery	Indicator(s)	Rating
5. Is the CMP delivered as designed and intended?	Extent to which outputs are produced and delivered to target audiences, as specified in the CMP logic model. Extent to which CMP activities are leading to harmful and potentially harmful legacy chemicals being managed in accordance with regulatory and other established timelines, and in a manner that takes due consideration of opportunities, risks and the regulatory burden on government and industry.	Progress made; attention needed

Most CMP areas of activity have been implemented as planned with only the approach to the DSL Inventory Update being substantially revised. Delays have occurred in four areas – the petroleum sector stream, new targeted regulations to manage the environmental risks of new substances in pharmaceutical and personal care products, production of the revised ICL, and the re-evaluation of older pesticides. These delays may potentially mean the continuation of risks to the environment and human health posed by substances in these areas. Delays in the DSL Inventory Update and production of the revised ICL may also result in data gaps for the medium priority substances that would otherwise have been addressed.

The question as to whether the CMP has been delivered as designed and intended has two aspects. Firstly, whether the various elements have been (or are being) delivered as originally intended, and secondly, whether they have been (or are being) delivered within intended timeframes. This timeliness aspect is particularly important because of the timelines required for the core risk assessment and risk management

processes as well as the importance of some activities in the current phase in generating data that may be useful for the assessment of risks associated with medium priority substances in later phases of the CMP between 2011 and 2020. The intended scope and timing of CMP activities and their current status (as of December 2010) is summarised in Exhibit V-4.

Exhibit V-4 Intended scope, timing and current status of CMP activities (as of December 2010)

K	ey CMP Activities	Target Outputs	Intended Timing	Status
1.	Challenge Process	Risk assessment of 195 high priority substances between 2007/08 and 2010/11. Risk management measures implemented for substances added to Schedule 1.	RA: 2007/08 – 2010/11 RM: 2007/08 – 2014/15	Implemented as intended and largely on schedule. Final risk assessments and proposed risk management scope documents issued for Batches 1 to 9 (151 substances (84%)). Of these, 38 substances met one or more criteria in S.64 of CEPA 1999 and were added (or proposed for addition) to Schedule 1. Draft risk assessments and risk management scope documents issued for Batches 10, 11 and 12 (44 substances (23%)). Final risk assessments and proposed risk management documents projected to be issued in January, April and July, 2011, respectively. (See Exhibit V-5 and VI-1 for progress information.)
2.	Petroleum Sector Stream	Risk assessment and risk management of 164 high priority substances primarily used in the petroleum sector.	RA: 2006/07 – 2010/11 RM: 2006/07 – 2014/15	Delayed due to the complexities involved in assessing the risks of substance mixtures. Draft risk assessments and risk management scope documents issued for 70 of 164 substances (43%) between May 2010 and January 2011.
3.	Rapid Screening of Substances of Lower Ecological Concern	Screening of ~1200 substances of low ecological concern to identify those to be subject to risk assessment as medium priority substances. (Initial CMP planning estimated ~1,200 substances; the actual number was 1,066.)	2007/08	Completed as planned. 1,066 substances were screened and 312 (29%) identified as requiring further screening assessment, and added to the list of medium priority substances.
4.	Domestic Substances List Inventory Update	Cyclical updates of the DSL to identify substances still in commerce and collect information on the usage characteristics focusing on the ~3,000 medium priority substances to be assessed post-2011.	Complete first cyclical update by the end of 2010/11	Delayed. Approach revised in 2010 to focus on medium priority substances to be assessed post-2015. Information gathering process for an initial cross-section of 500 DSL substances from October 2009 to May 2010.
5.	Re-evaluation of Older Pesticides	Accelerate the re-evaluation of 401 older pesticides first registered prior to 1995.	Completion in 2008/09	Delayed. Final decisions issued for 270 (67%) and proposed/pending decisions for another 90 (22%) of the 401 by the end of 2009/10. Completion expected in 2011/12.
6.	Pesticide Incident Reporting	Implement PCPA requirements for reporting of environmental and health incidents believed to be due to pesticides.	2006/07	Regulations took effect in April 2007. Initial annual report on 2007/08 incidents issued, and risk management actions taken as needed.
7.	Pesticide Sales Reporting	Implement PCPA requirements for registrants to report annual pesticide sales volumes.	2006/07	Implementation of PCPA incident reporting requirements announced as part of the CMP's launch. Regulations took effect in Oct. 2006, prior to the launch of the CMP, with initial data submission (for 2007) by June 2008. Some issues encountered with quality, completeness and comparability of data in initial years.
8.	Evaluation of New Reduced Risk Pesticides	Strengthen current regulatory activities for registration of new pesticides and facilitate access to new and safer pesticide products.	Ongoing	Implemented as planned. Rate of evaluation and registration of new pesticides is determined by registrants.

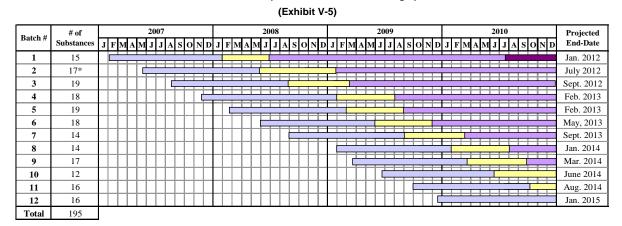
Key CMP Activities	Target Outputs	Intended Timing	Status
9. Mandatory Labelling of Cosmetic Ingredients	Implement requirements for ingredients to be listed on labels of cosmetic products.	2006/07	Implementation of labelling requirements announced as part of the CMP's launch. Regulations took effect in November 2006, prior to the launch of the CMP.
10. Environmental Regulations for New Substances in Pharmaceutical and Personal Care Products Subject to the F&DA	Develop and implement regulations to promote best practices for the proper assessment and management of new substances in pharmaceutical and personal care products to reduce the burden on the environment.	2006/07 – 2010/11	Delayed. Draft regulations expected to be published in 2011/12.
11. Revised In Commerce List (ICL)	Identification of ICL substances that are still in commerce from the ~9,000 substances in pharmaceutical, veterinary drug, biologic and generic therapy, cosmetic, medical device and food additive products on the current ICL.	2006/07 – 2010/11	Delayed. Notice of Intent published in <i>Canada Gazette I</i> in September 2010 regarding the process for nominating substances to the revised ICL. This process was initially expected to run to July 2011, and subsequently, was extended to October 2011.
12. CMP Research	Select and fund research projects to increase knowledge of the risks of toxic chemical substances.	2006/07 – 2010/11	Implemented and proceeding as planned. Joint research fund established; 26 research projects in process at the start of 2010/11. Final results to be published in 2011/12. Project list in Appendix C.
13. CMP Monitoring and Surveillance	Strengthen environmental and human biomonitoring programs to identify and track exposure to hazards in the environment and associated health implications.	2006/07 – 2010/11	Implemented and proceeding as planned. National monitoring projects implemented. Initial data and results generated for 91 substances in 11 groups in the CHMS; data collection for 13 groups of substances for MIREC. Targeted biomonitoring and supporting research projects in progress. Some bisphenol A studies completed. Studies include 83 substances in indoor air, 60 substances in drinking water and 45 substances in house dust. Total Diet Study strengthened and targeted dietary surveillance programs based on CMP priorities initiated. EC's national environmental monitoring system strengthened, covering air, water, sediment, non-human biota (fish and wildlife) media as well as source monitoring at wastewater plants and landfills.

- 1. Draft risk assessment and risk management scope documents for Batch 12 are for 12 of the 16 substances in the batch. Assessments for the remaining four are still in progress.
- 2. The final risk assessments for Batch 10 substances were issued in January 2011, as planned. Release of the final risk assessments for Batches 11 and 12 was delayed due to the federal election and are now projected to be released in August and October 2011, respectively.

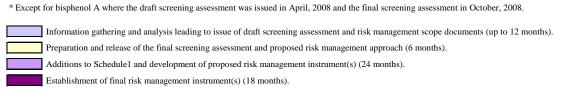
Exhibit V-5 demonstrates the sequencing of actions relating to the Challenge batches and key time frames for completion of intermediate and final steps for each batch. The launch of each of the 12 batches of Challenge substances was staggered at intervals of approximately three months between January 2007 and December 2009. The nature of the timelines for each of the four major steps – up to 18 months for information gathering by HC and EC from published research, industry, other jurisdictions and other stakeholders, and preparation of draft and final risk assessments and proposed risk management approaches; 24 months for additions to Schedule 1 and development of proposed risk management instruments for these substances; and 18 months to establish the final risk management instruments – means that the risk assessments for the final batch will be issued in mid-2011. This timing is marginally behind the target completion date of end-2010/11 (three months in a four-year process). Establishment of

the final risk management instruments for Batch 1 commenced in July 2010 and will be finalized by January 2012; establishment of the final instruments for subsequent batches will occur at regular intervals, running until January 2015.

Exhibit V-5
Sequencing of batches of substances in the Challenge process



Current status and outputs from the CMP Challenge process



Source: Sub-sites for each batch in the Challenge process on CMP website and linked documents, accessed from www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php.

The approach to one area of activity – the DSL Inventory Update – has been revised. Implementation of the DSL Inventory Update was modified in 2010 to focus the DSL data collection activities on the commercial status and use characteristics of medium priority substances expected to be assessed post-2015. In making this decision it was decided that the substances to be assessed in the next phase of the CMP, between 2011/12 and 2015/16, that were previously the principal focus are less in need of the substance use information collected through the DSL update process than the substances slated for later assessment.

Four other areas of activity were initiated but incurred significant delays compared to the anticipated completion dates established in the original design of the CMP. These areas and the reasons for their delays are as follows:

Assessment of petroleum sector stream substances. Initially, HC and EC expected that the timeframe for information collection and risk assessment of the petroleum sector stream substances would be similar to that set for the Challenge process (18 months). Mandatory (S.71) requests for information relating to substances included in the petroleum sector stream were issued in March 2008 and July 2009. Findings from the 2008 request were used to conduct an initial triage of the substances to identify those that were no longer in commerce, substances that are site-limited and substances

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Substances that are not expected to be transported off petroleum refinery, upgrader and natural gas processing facility sites, and are often used in petroleum facilities or are further refined or blended into other products.

that leave the site (that is, products that are sold, or intermediates that are transferred elsewhere). The 2009 request sought further information on the "industry limited" substances that were identified as potentially leaving petroleum sector facilities for transport to other industrial facilities (inside or outside of the petroleum sector) where they are consumed as fuels or feedstocks. Draft risk assessments for the 70 site-restricted substances in Stream 1 (of four streams in total) were issued in three lots between May 2010 and January 2011.

Key informants who were involved in the petroleum sector stream indicated that the longer time frame for preparation of the draft risk assessments and risk management scope documents (compared to the Challenge substances) is due to the presence of complex mixtures of substances involving much more demanding risk assessments compared to what was originally anticipated as well as needs for supplementary follow-ups with industry participants to clarify or obtain additional data. Documentation on the petroleum sector stream also highlighted that the presence of complex mixtures in the stream could require different approaches compared to the discrete substances in the Challenge process. In addition, one of the external key informants representing a petroleum sector organization indicated that firms that are required to respond to the mandatory information request issued by HC and EC (a S.71 request) may not possess the requested information and it is challenging to obtain the necessary data on a timely basis.

- Re-evaluation of older pesticides. Re-evaluation of active ingredients in older pesticides has also taken longer than anticipated with 131 outstanding at the time work on these pesticides was expected to be completed by the end of 2008/09. Of these, 90 were at the point where proposed decisions had been issued for public comment or issuance for public comment was pending. Re-evaluation of the 41 (10%) outstanding active ingredients is continuing through into 2011/12.
 - HC-PMRA does not have a prescribed or target timeframe for the completion of re-evaluations. The elapsed time required is a function of such factors as the scientific complexity of active ingredients, the complexity of potential environmental and health effects, the number of end-use products that incorporate the active ingredient, availability of review documents and data from other jurisdictions, whether HC-PMRA requires new data to be generated by industry, and the timeliness of industry responses to data requests. The median elapsed time for the re-evaluations finalized during 2007/08 and 2008/09 was 35 months, with the range going from zero to 121 months.
- Personal care products. According to an internal key informant working in this area, delays in the development of these regulations were encountered due to the complexity of the consultations required on the proposed regulations and the large number of industry sectors and commodity groups that will be subject to the regulations. HC initially entered into separate consultations with each of the different commodity groups involved but then found it would be more effective to consult more broadly on just two categories of substances active and non-active ingredients which required some "retooling" and a restart to the consultations. There has also been some uncertainty and some resistance to changing the regulatory requirements amongst the various sectors and commodity groups, due to the nature of the proposed changes and how the proposed requirements differ from current US and European requirements. Additional time had to be invested in explaining the rationale and need for regulations more responsive to the environmental effects of pharmaceutical and personal care products, and gaining buy-in. HC now expects to publish the draft regulations in Canada Gazette I in 2011/12.

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Stakeholder briefing, Addressing High Priority Petroleum Substances under the Chemicals Management Plan: Information session on the Petroleum Sector Stream Approach, March 5, 2008.

These comments draw on the findings from the re-evaluation section of the Summative Evaluation of the Building Public Confidence in Pesticide Regulation Horizontal Initiative, completed in 2010.

➤ Preparation of the revised ICL. Initial work on the identification and nomination of substances to the revised ICL to confirm which are still in commerce and not on other lists, such as the DSL, is in progress. A nomination process requesting manufacturers, importers, distributors and users to provide key details of substances in use was instigated in July 2010 and is currently expected to run to October 2011.

In addition, data collected through the CMP risk assessment processes have been used to inform environmental emergencies (E2) assessments under Section 200 of CEPA 1999. These E2 assessments are concerned with the potential effects that an uncontrolled, unplanned or accidental release of a substance may have on the environment or human health, and go beyond the scope of CMP risk assessments under S.64 to include assessments of the flammability, combustibility and aquatic toxicity of substances. As a result, EC's E2 Program may propose addition of CMP substances to the E2 Regulations and preparation of environmental emergency plans for sites subject to the Regulations. This work received funding from the risk management stream in the first phase of the CMP.

E2 risk assessments were not integrated into the risk assessment and risk management processes for the Challenge substances and petroleum sector stream. The E2 Program proposed to add 27 Challenge substances (15 Schedule 1 additions and 12 determined to be non-toxic by CMP risk assessors) from Challenges Batches 1 through 9 to the E2 Regulations, in addition to the seven proposed for addition by CMP risk managers. The proposed addition of these 27 substances to the E2 regulations was distinct from the CMP risk management and stakeholder consultation activities for these substances. Opportunities exist to further integrate the work of the E2 Program and CMP risk assessment and risk management and will be pursued in the next phase of the CMP. Areas for such integration include ensuring that information concerning risks during emergencies is considered as appropriate in CMP risk assessments, ensuring that CMP risk assessments inform prioritization of actions by the E2 Program, and identifying appropriate linkages to or between actions under the E2 Program and CMP risk management actions.

EC utilized grants and contributions to support CMP activities related to risk assessment, risk communication and risk management. Over a period of three years from 2007/08 to 2009/10, nine contribution agreements were established with two domestic NGOs and two multilateral organizations, with expenditures totalling \$753,250. A review of the files for these nine contributions indicated that the purpose and expected activities, outputs and outcomes of the projects were in most cases reasonably well specified and were generally aligned with CMP activities and intended outcomes. Moreover, most projects were successfully delivered as intended and achieved their expected outcomes to at least some extent, though the latter issue could not be assessed for three projects because reporting on outcomes was either inadequate or unavailable. Also, the specification of CMP-related performance indicators in the contribution agreements was either weak (for example, referring only to a report on outcomes rather than an indicator) or absent for all of these projects.

A majority of the participants in the internal key informant interviews agreed that the CMP is being delivered as intended or has evolved in the light of experience. Areas where improvements have been incorporated include strengthening processes for coordinating activities between the two departments and between program areas within HC and EC; improving the information exchange between researchers and risk assessors, and between risk assessors and risk managers; and, progressively refining risk communication methods and making information posted on the CMP website more understandable for non-technical readers. Stakeholder communications are regarded as being quite effective but outreach to the public less so. Almost all external key informants – who had all participated in stakeholder consultation and engagement activities or were involved in CMP advisory bodies – agreed that the implementation of the CMP was going either reasonably or very well.

Most of the internal key informants who commented on the risk assessment and risk management streams of the CMP noted that there was a strong commitment to meeting the timelines for batches in the Challenge process and the majority of the interim milestones were achieved. This view is also supported by the data on the progress of the Challenge batches summarized in Exhibits V-4 and V-5, and is consistent with the evolution of approaches to risk assessment in other jurisdictions. A number of internal key informants noted that the commitment to meeting the Challenge timelines represented a significant cultural shift, to conduct risk assessments more quickly using less hazard and/or exposure data than would have been the case prior to the CMP, with greater reliance on data modelling. These key informants saw this change as a positive factor in that decisions to better manage the risks of substances currently in use are being made faster. Some also noted that the design of the Challenge process and application of the precautionary approach shifts the emphasis from the regulator having to demonstrate that substance risks exist, to industry having to demonstrate that the substances in use are safe. Some key informants did, however, highlight the presence of data gaps as a challenge to the risk assessment and risk management analyses during the first phase of the CMP or to future work on medium priority substances.

Others noted that research projects and monitoring activities are on track, and are now reaching the point where most data and findings (published in peer reviewed journals) are expected to be available for use in risk assessment and risk management work in 2011/12. Longer term, the monitoring stream is expected to provide valuable data for the validation and updating of risk assessment conclusions and choices of risk management instruments.

Participants in the international interviews (involving a small number of representatives from chemicals regulators in the EU, US and Australia) were also positive about the implementation of the CMP. The CMP approach was described as pragmatic and effective and Canada was described as a trail blazer in tackling the inventory of existing substances. They noted that substantial efforts were devoted to gathering information and establishing priorities prior to the Challenge. Other jurisdictions with related systems reported doing Challenge-type activities first without an initial priority setting exercise, as was done with the DSL in Canada, and noted that this approach does not work as well. The overall strategy of sequencing releasing batches made the process function more effectively and the timelines for batches provided certainty. These interviewees who were more familiar with the overall approach to the CMP but less familiar with the design of specific activity streams believed, based on this perspective, that the outputs that they were familiar with implied effective delivery.

These findings from the review of CMP documents, key informant interviews and international interviews indicate that most areas of activity that comprise the CMP have been implemented largely as initially planned, with the exception of the DSL Inventory Update, which has been revised to focus on data collection activities on the commercial status and use characteristics of medium priority substances expected to be assessed post-2015. Delays have occurred in four areas – the petroleum sector stream substances, regulations to manage the environmental risks of new substances in pharmaceutical and personal care products, production of the revised ICL and the re-evaluation of older pesticides. These delays may potentially mean the continuation of risks to the environment and human health posed by substances in these areas. Delays in the DSL Inventory Update and production of the revised ICL may also result in data gaps for the medium priority substances that would otherwise have been addressed.

through the OECD's Environment Directorate. See, for example, the OECD's website for hazard/risk assessment: www.oecd.org/department/0,3355,en_2649_34373_1_1_1_1_1_0.0.html

Work on the development and evolution of approaches to risk assessment is fostered by and shared among jurisdictions

C. Is appropriate performance information collected against CMP outputs and outcomes? (EQ6)

Evaluation Issue: Design and Delivery	Indicator(s)	Rating
6. Is appropriate performance information collected against CMP outputs and outcomes? If so, is the collected information used to inform senior management/decision makers?	Presence/absence of a populated performance data system(s) with performance targets, baselines where appropriate, and reliable data. Demonstrated use of performance information by senior management/ decision makers. Views on strengths, weaknesses and needed improvements to CMP Performance Measurement Strategy.	Little progress; priority for attention

Performance information collected or available for the various CMP activity streams is almost exclusively focused on activities and outputs. These data, which are often in disaggregated form, have been sufficient to inform management decision-making at the operational level.

However, provision and use of performance information to inform more strategic decision-making, planning, direction setting and performance reporting for the CMP is weak. Actions are needed to:

- Establish a more integrated and systematic performance reporting system that keeps CMP management informed as to the status and progress of the key activities in each stream, identifies where issues or delays are being encountered and the responses to these issues, and tracks progress in producing key outputs and outcomes.
- Determine how the intended CMP outcomes will be measured and methods to collect and report this outcome data implemented.

1. Program managers' perspectives on the state of performance measurement and reporting

Many of the key informants noted that data on the progress of, and outputs from, the main areas of activity under the CMP are available and used to inform HC and EC's operational management and planning. Systematic aggregation or summarization and reporting of these data are limited, however. The need for information on the achievement of outcomes is recognized but the necessary data are not currently available, for the most part. The main reasons for this are the limited extent to which risk management outputs have been finalized and implemented, the timeframes involved in collecting and reporting monitoring and surveillance findings, and the difficulty of measuring longer-term outcomes and determining the contribution of the CMP to their achievement.

Supporting points made by key informants regarding performance measurement for each of the CMP streams were as follows:

- ➤ Risk assessment and risk management. Performance data and reporting for the RA and RM streams is output based and largely focused on the progress of batches against the Challenge timelines, number of substance risk assessments completed and risk management instruments and tools in development. Measurement and reporting of risk management outcomes is only now starting to matter as proposed risk management instruments under CEPA 1999 are developed, released for public comment and finalized. Some non-regulatory risk management strategies have already been implemented under other Acts, such as additions to the cosmetic ingredients hot list. Data on the outputs from pesticide re-evaluations, new pesticide evaluations and pesticide incidents are also compiled and reported at regular intervals.
- **Risk communications**. Consultation participation, correspondence, inquiries, media coverage of stories, hits to the website, etc., are tracked by the risk communication function with the level of web site activity being a major area of interest. A baseline study of public awareness and opinion regarding the management of chemical risks was also commissioned. Interviewees also noted that the ability of the function to measure the effectiveness of risk communications is constrained by the level of funding available for research into the reach and effectiveness of risk communications.

- ➤ Compliance promotion and enforcement. Compliance promotion and enforcement measures under CEPA 1999 will commence when risk management measures for substances added to Schedule 1 are finalized and implemented, starting in 2012. Risk management measures under the PCPA, HPA and F&DA may be implemented prior to this date, as was the case with the prohibition on polycarbonate baby bottles containing bisphenol A under the HPA and changes to the conditions of use for older pesticides due to re-evaluation under the PCPA. Compliance promotion and enforcement activities for these measures fall within the mandates of HC's programs under each of these Acts. Information on all compliance promotion and enforcement activities by EC and HC-PMRA under CEPA 1999 and the PCPA, respectively, is included in the CEPA 1999 and HC-PMRA annual reports. The small number of internal key informants who commented on this stream noted that some discussions have taken place regarding the identification of suitable performance indicators and that measurement of regulatee awareness will be important as compliance promotion and enforcement under CEPA 1999 gets underway.
- ➤ Research. Measurement of outcomes in research is difficult given the extended time periods required to establish and conduct the selected projects and challenges associated with identifying and measuring impacts attributable to the research. A more immediate focus for measuring performance is whether the projects are well managed, on track and produce results within the funded time periods. In this regard, renewal of multi-year project funding is contingent on the submission of annual reports to the HC/EC CMP Research Network by the project leads demonstrating satisfactory progress of their projects. All interviewees who responded to this question indicated that they are able to report on whether performance is on track and identify early research results.
- ➤ Monitoring and surveillance. Similar to the research stream, project-level performance data for the monitoring and surveillance stream status reports on projects and publications and presentations on findings are compiled. In turn, these outputs are, or will be as they become available, used as inputs to the risk assessment and risk management work, and as one source of information on substance risks and the longer-term outcomes of risk management measures. Renewal of multi-year funding for monitoring and surveillance studies is contingent on the submission of annual reports to the CMP Monitoring and Surveillance Review Committee by the project leads demonstrating satisfactory progress of their studies.
- ➤ Horizontal management. Key informants who are involved with the horizontal management and coordination of the CMP agreed that to date they have had sufficient information to inform or facilitate their activities. Another area of interest for the two senior governance levels for the CMP CMEC and the ADM Committee is that of lessons learned with the design and delivery of the CMP and associated changes in processes and methods. Looking ahead they will require more outcome based information on the efficacy of CMP streams, particularly with respect to risk management.

Many of the internal key informants interviewed expect that monitoring and surveillance data will be a key source of information on the effectiveness of CMP risk management measures that aim to reduce environmental and/or human exposure levels through the removal or restricted use of substances in the longer term. Some representatives of the monitoring and surveillance function cautioned, however, that monitoring and surveillance data are only one possible source for measuring these outcomes, and only a sub-set of the existing substances can be tracked and monitored using environmental and biomonitoring methods. Other anticipated sources of information on the effectiveness of risk management measures include time series data from the National Pollutant Release Inventory (NPRI) and EC's National Enforcement Management Information System and Intelligence System (NEMISIS).

2. Evidence of performance reporting in CMP documents

A review of CMP documents provided for the evaluation indicates that a wide variety of activity and output data is compiled or available to CMP program managers for operational management and tracking purposes but little of this data is assembled and presented in more aggregated form that constitutes a "performance measurement system". The extent to which output and outcome data is available also depends on the varying rates of progress of the different activity streams, as noted elsewhere in this report.

The extent to which performance information against outputs and outcomes is collected or available, as suggested by the documents made available for the evaluation, is summarized in Exhibit V-6. This information suggests that a wide array of raw output information is available to CMP managers. Some performance information is available against each of the intended immediate outcomes or the available output data enables inferences to be drawn regarding progress to date against the intended immediate outcomes. This is primarily the case for the initial risk assessment outcomes that are pre-cursors for the achievement of later, dependent outcomes, such as those for risk management and compliance promotion and enforcement.

Exhibit V-6
Performance information collected or available against CMP outputs and outcomes

CMP Stream	Primary Outputs and Immediate Outcomes	Performance Information Collected/Available
1. Risk Asses	sment	
Outputs	Draft and final screening assessment reports Substances proposed for addition to Schedule 1	Draft and final screening assessment reports for each batch in the Challenge process. Draft screening assessment reports for stream 1 of the petroleum sector stream substances. Proposed Schedule 1 additions for Challenge substances.
Outcomes	Identification of data gaps	Data gaps considered/factored into establishment of research and monitoring priorities and selection of projects.
	Identification of substance risks and risk management issues	Substance risks and risk management issues identified in: Risk assessments and proposed risk management measures for batch substances Proposed and final pesticide re-evaluation decisions.
2. Risk Mana	ngement – Control Instruments	
Outputs	Proposed and final risk instruments and tools	Risk management measures in development for Challenge substances proposed for addition to Schedule 1 under CEPA 1999. Risk management measures implemented under PCPA, HPA and F&DA.
Outcomes	Risk management measures in place	Risk management measures in development for proposed Schedule 1 additions under CEPA 1999. Risk management measures for Challenge substances implemented under PCPA, HPA and F&DA. Risk management requirements for re-evaluated and new pesticides.
3. Risk Com	nunication	
Outputs	Information dissemination to stakeholders and the public Advice to CMP by stakeholders	SAC advice to CMP. Stakeholder comments on proposed risk assessment and management decisions. Baseline public opinion research on public awareness. Analysis of web traffic patterns.

CMP Stream	Primary Outputs and Immediate Outcomes	Performance Information Collected/Available
Outcomes	External stakeholders and Canadians informed about the risks posed by chemical substances and their management	Baseline data on public awareness and understanding. (No data on awareness/understanding among stakeholders, particularly regulatees.)
4. Compliance	Promotion and Enforcement	
Monitoring and verification results Enforcement actions Outcomes Regulatees understand and comply with applicable risk management requirements		CMP insufficiently advanced for CEPA 1999 compliance promotion and enforcement activities to be implemented. (Actions under PCPA, HPA and F&DA for CMP substances are
		not separately tracked and reported. HC-PMRA reports on compliance promotion and enforcement for all pesticides in its annual report.)
5. Research		
Outputs	Completed research projects, and associated publications and presentations	Some (peer reviewed) research published (most findings will be published post-2010/11).
Outcomes	Better informed risk assessment and risk management decisions	Timing of research projects means that most research findings will be used in the next phase of the CMP and/or considered in risk management stages of the Challenge process.
6. Monitoring a	and Surveillance	
Outputs	Monitoring and surveillance data on the health and environmental presence of representative substances	Status of monitoring and surveillance activities. Baseline CHMS data and initial analysis. Findings from some surveillance projects.
Outcomes	Better informed risk assessment and risk management decisions Knowledge of the effectiveness of risk management measures	Some baseline data available (e.g., Cycle 1 of CHMS). Extended time period required to compile trend data on human and environmental presence of selected substances.

Some CMP output information is included in public reports such as the HC-PMRA and *CEPA Annual Reports* and, to a lesser extent, the annual DPRs and RPPs. For example, the 2009-2010 and 2008-2009 *CEPA 1999 Annual Reports* include summary information on the progress of CMP research and monitoring and surveillance work, the results of the risk assessments of Challenge batches (numbers identified for addition to Schedule 1), and numbers of SNAc notices issued. The HC-PMRA Annual Report includes data on the numbers of re-evaluations and evaluations of new active ingredients and their end-use products completed. This point was also made by some of the internal key informants, who identified the *CEPA Annual Reports* and DPRs and RPPs as key sources of public reporting on the performance of the CMP as well as the posting of information on the CMP website. They noted that the majority of this information related to the Challenge activities and outputs and that only limited information on the activities of other streams (e.g., research results) is readily available to external stakeholders and the public.

Environment Canada, Canadian Environmental Protection Act, 1999: Annual Report for April 2009 to March 2010 and Canadian Environmental Protection Act, 1999: Annual Report for April 2008 to March 2009, Ottawa, 2010 and 2009, respectively, accessed at: www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=39419FFB-1 and www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=477203E8-1

Health Canada, *Pest Management Regulatory Agency: Annual Report 2008–2009*, Ottawa, 2010, accessed at www.hc-sc.gc.ca/cps-spc/pubs/pest/ corp-plan/ann-pest-para-ann/index-eng.php

3. Use of performance information in management decision-making

Comments made by many of the internal key informants indicated that operational management and decision-making is informed by, or takes into account, the rate of performance and progress of directly applicable activities and pending outputs. Examples of these types of management activities referred to in these interviews included the regular "four corners" meetings/calls of the four directors of risk assessment and risk management at EC and HC to review the progress of Challenge batches, HC and EC meetings to review the progress and findings from research and monitoring activities, and pre-release meetings of directors to review and confirm details of the substance assessments for each batch.

At the governance level of the CMP, the minutes of and presentations to the ADM Committee and CMEC show that information on the performance of various activities and emerging issues is presented to the two committees. However, there is no regular reporting summarizing the overall progress of the CMP streams or attention to the reasons for delays or changes to activities, for example, factors contributing to the delay in the petroleum sector stream, and remedial actions being taken.

Development of a performance measurement strategy to provide ongoing program performance management and reporting across all CMP activities has been ongoing since the inception of the CMP. The most recent version of the framework for this system was released in mid-2010 and, according to internal key informants, is now being implemented.

A review of the outcome and output measures proposed in the most recent framework suggests that it has a number of shortcomings that reduce its effectiveness in supporting ongoing monitoring and the periodic evaluation of impacts, as noted below.

- Implementation of many of the CMP activities and production of related outputs involves interdependent and sequential steps both within and between activity streams, often with several years elapsing between initial implementation and final outputs, and even longer before evidence of outcomes can be determined. However, there is no provision for reporting on the extent to which interim milestones are on track and the potential effects of any delays on the subsequent production of outputs. Examples of these long-term interdependencies include the design, implementation, data compilation, analysis and reporting of long-term national biomonitoring activities and the progression from risk management to compliance promotion and enforcement.
- Some of the proposed measures count activities and outputs rather than measuring outputs or outcomes, respectively, that matter most in terms of informing assessments of progress against targeted outputs and intended outcomes. As such, these types of measures are likely to be of limited value in informing management decision-making or demonstrating progress to external stakeholders and other interested parties. Examples of this misalignment include using the percentage of planned research priorities met within prescribed timelines, and some of the monitoring outcome indicators are counts of outputs, such as the number and type of new monitoring and surveillance tools or the number of biomonitoring and environmental monitoring projects completed as planned.
- Proposed output indicators for the risk assessment stream include several that are either outside the scope of the current phase of the CMP (relating to new substance notifications)²⁸ or measure risk management (number of Schedule 1 additions) or compliance promotion and enforcement outputs.

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Other B-base funding for HC (CEPA 2005) included funding for new substance activities, and new substances work is expected to be integrated more fully into future phases of the CMP. As such, the performance measurement framework has been designed to enable monitoring of both existing and new substances.

A number of proposed measures may be difficult or expensive to measure, or the actual definition of the measure and methodology has not been determined. Examples include the reported levels of behaviour change in decision-making by the general Canadian population on the use of potentially harmful chemicals as the proposed measure of the intermediate outcome for risk communication; and the percentage of external stakeholders having effective management regimes in place for a representative sector and/or instrument and percentage complying with regulatory requirements as immediate risk management outcome measures.

A further factor affecting the application of the framework is the long-term nature of many elements of the CMP and their effects, which means that some performance data on the achievement of outcomes will only become available towards the end of (or beyond) the anticipated term of the CMP (2020). Other outcome data will only be reported at intervals of two, three or more years depending on the reporting cycles for monitoring and surveillance studies.

A second level of performance measurement proposed for the CMP is that of monitoring and assessing the impacts of risk management measures for selected substances added to Schedule 1. Guidelines for the development of these substance-specific performance measures are in development, in response to recommendations from the Commissioner of the Environment and Sustainable Development (CESD) report on the *Risks of Toxic Substances* (2009) and Treasury Board's *Handbook for Regulatory Proposals: Performance Measurement and Evaluation Plan* (2009). Data collected on the achievement of these risk management outcomes should also be useful as a source of information for the measurement of overall CMP outcomes.

The EU approach to measuring outcomes from REACH differs markedly from that proposed for the CMP. The EU approach is highly structured and dependent on the collection of an extensive amount of data. Under the EU approach Eurostat, the statistical office of the EU, developed a methodology to monitor the success of the REACH policy. This methodology was used to prepare a pre-REACH baseline of risk for a sample of 237 of the more than 30,000 chemicals covered under REACH. This ongoing project will then attempt to assess the post-REACH data to infer the REACH impact at 5-year intervals, starting in 2012-13.

The Eurostat methodology proposes to track exposure and toxicity changes to calculate "risk characterization ratios" to monitor the impact of the REACH program. The expectation is that periodic "snapshots" can be calculated for a sample of substances spanning differing production and/or import tonnages and risk categories (based on toxicity and exposure levels) and compared to identify REACH impacts on workers, consumers, the environment and the impacts on humans via the environment. These expected impacts are:

- > Increased knowledge of properties of existing chemicals.
- > Increased knowledge of uses of substances and related exposures.
- > Improvement of data in extended safety data sheets as the key communication tool.
- > Direct communication of uses which are not supported by the manufacturer/importer.
- Increased involvement of downstream users in the communication and assessment of safe uses.

Based on information contained in the draft Risk Management Bureau Performance Measurement Framework, November, 2010.

Eurostat (2009), The REACH Baseline Study, Luxembourg, Office of Official Publications of the European Commission.

- Cessation of production of substances if no standard set of data is available by the required deadline ("no data, no market").
- > Cessation of the use of substances of very high concern (unless specifically authorized).
- Reduced risks related to chemicals resulting from changed use requirements and/or better risk management measures.
- Enhanced substitution of less dangerous for more dangerous chemicals.

This approach to measuring the impact of REACH goes well beyond what is currently planned for the CMP.

4. Overall assessment of CMP performance measurement and reporting

Performance information collected or available for the various CMP streams is almost exclusively focused on activities and outputs. According to the program managers interviewed this information has been sufficient to inform management decision-making at the operational level, which reflects the focus of many of the activity streams on establishing and maintaining "production systems" that coordinate the compilation and integration of various inputs to produce required outputs in accord with targeted timeframes.

Provision and use of performance information to inform overall decision-making and direction setting for the CMP and to include in external performance reporting, has also relied on this disaggregated information collection and reporting. What is lacking is a more integrated and systematic performance reporting system that keeps CMP managers informed as to the status and progress of the key activities in each stream, identifies where issues or delays are being encountered and the responses to these issues and tracks progress in producing key outputs.

The long-term nature of the CMP activities and the chain of effects involved in achieving the intended outcomes means that there will be a significant lag before the effects on the intended outcomes may be identified. Data to inform assessments of the CMP's effectiveness will need to come from multiple sources and be integrated to provide cohesive assessments of performance. While some steps have been taken to generate needed data, such as the monitoring and surveillance activities and baseline public opinion research, further work will be necessary to establish how all outcomes will be measured and to implement appropriate data collection methods and activities.

D. Clarity of HC and EC roles and responsibilities (EQ7, EQ8)

Evaluation Issue: Do	esign and Delivery	Indicator(s)	Rating		
clearly defined and specified? (b) Is there any duplica	HC and EC for the CMP implemented as tion in the roles and HC and EC that causes	Defined governance structure, including clearly articulated roles, responsibilities and accountabilities. Evidence of extent to which roles, responsibilities and accountabilities are implemented as defined, and any duplication. Views on the clarity and implementation of HC and EC roles, responsibilities and accountabilities, and any duplication.	Achieved Progress made; attention needed		
8. Are HC and EC role for the CMP clearly internal and externa		Degree of understanding of HC and EC roles and responsibilities, and any areas of confusion.	Achieved		

Indicator(s)

Rating

A formal governance structure is in place, with a DG-level committee providing for joint consultations and cooperation and an ADM Committee providing strategic direction and management oversight for the integrated delivery and management of the CMP. Coordinating and information exchange mechanisms have been established at the operational level and minimize unnecessary duplication. A majority of the internal key informants indicated that roles and responsibilities are clear and generally well-understood. Most external key informants also believed the EC and HC roles and responsibilities to be clear. Efficiency could be improved through better coordination between HC and EC regarding work on the revised ICL and development of regulations for new substances in pharmaceutical and personal care products subject to the F&DA.

A majority of the internal key informants indicated that the roles and responsibilities at the two departments were clear and the roles of the different programs and participants are generally well-understood. A number of these key informants also noted that the establishment of a formal governance structure with a DG-level committee (to provide a body for joint consultations and cooperation to ensure timely, concerted and integrated actions to deliver the CMP) and an ADM Committee (to provide strategic direction and management oversight for the integrated delivery and management of the CMP) had been very good at bringing the various programs and pieces together.

At the operational level many of the key informants highlighted the roles of various key coordinating and information exchange structures that facilitated coordination and minimized the amount of overlap in activities. Commonly mentioned examples of these structures included the regular "four corners" meetings/calls of the four directors of risk assessment and risk management at EC and HC; pre-release meetings of directors to review and confirm details of the substance assessments for each batch; and the application of the best placed Act approach to determine which Act(s) can be used to optimally manage substance risks and identify the lead programs for risk management actions.

Several interviewees noted that the process for coordinating work at HC is more challenging than at EC due to the potential for action under the HPA, PCPA and F&DA as well as CEPA 1999 and involvement of multiple program groups responsible for actions under these Acts. They also noted that coordination among the HC programs benefits from the establishment of designated CMP contacts in each of the programs as well as points of contact at EC.

Some internal key informants also noted that the nature of the Challenge process and timelines means that work on the development of proposed risk management measures must proceed in parallel with the finalization of risk assessments for batch substances, which may result in some necessary duplication. One participant in the Challenge process described the approach in the following terms:

Generally things are divided up so there's unlikely to be a lot of duplication. ... (But) risk managers have to begin their own research into exposure rather than waiting for the risk assessment to be completed. Sometimes this complements the work of the risk assessors and sometimes it results in (some) duplication.

Most of the external key informants who commented on the clarity of the HC and EC roles and responsibilities believed that the roles and responsibilities of HC and EC with regard to the CMP are clearly defined and minimize or avoid duplication. Two areas identified by one external key informant that appeared to be inefficient or unclear were the work on the revised ICL and the development of environmental regulations for new substances in products regulated under the F&DA. This key informant noted that there appeared to be too much overlap between HC and EC and approaches were not well-integrated. The external key informants, who were mostly involved with various aspects of the Challenge process, all appeared to have a good understanding of the HC and EC roles and responsibilities that are directly related to the areas where they interact with the CMP.

E. Effectiveness of the CMP's integrated horizontal management and governance structure (EQ9)

Evaluation Issue: Design and Delivery	Indicator(s)	Rating
 9(a) How effective is the integrated horizontal management and governance structure of the CMP? (b) To what extent are the various HC and EC groups within the CMP working together in an integrated manner? (c) To what degree are efforts at integrated horizontal management resulting in improved decision-making processes and efficiencies? (d) Are any improvements needed to the CMP's integrated horizontal management or governance structure? 	Extent to which HC and EC groups within the CMP are active in joint efforts at horizontal management. Extent to which there are efficiency and effectiveness improvements in managing chemicals through the integrated horizontal CMP functional teams. Extent to which opportunities for CMP delivery improvement are identified, reported and promptly implemented by CMP decision-making bodies. Views on the effectiveness of CMP integrated horizontal management and governance and areas in need of improvement.	Progress made; attention needed

Horizontal management and coordination of CMP activities is reasonably effective, particularly relating to the core risk assessment, risk management and supporting research and monitoring activities undertaken by HC and EC. At the governance level, the ADM Committee and DG-level CMEC provide joint HC and EC guidance and direction for the management and delivery of the CMP. Key areas for improvement are:

- Establishment of a common IT system to enable efficient information sharing and document preparation.
- Simplification and streamlining of the approvals process for Challenge substances.
- Establishment of a financial management and tracking system to support CMP planning and reporting.
- Establishment of a performance measurement and reporting system for the CMP.

Horizontal management and governance of the CMP is intended to work at two levels – overall horizontal policy and program management and the operational integration and coordination of key activities that involve multiple program groups in HC and/or EC. At the overall strategic management level the original design of the CMP anticipated that a single policy and program management group would be established and HC and EC would implement a fully integrated MAF (Management Accountability Framework) involving an integrated approach to governance, strategic directions and priorities, and human resource management strategy.

CMP documents and comments made by internal key informants indicate that the initial focus of horizontal management and governance activities was on ramping up capacity and initiating the various activity streams of the CMP. Implementation of the governance structure became more of a priority following the initial establishment and delivery of operational activities. The key steps and actions taken with regard to the governance of the CMP identified in presentations to, and minutes of, the two joint HC and EC oversight committees were as follows.

- ➤ In April 2008 (approximately one year after the CMP's launch) a "Status Check" of the CMP's Horizontal Management presented to CMEC noted that:
 - HC and EC had implemented coordinated approaches to many of the operational aspects of the CMP, particularly relating to research and monitoring activities, the Challenge process and associated stakeholder engagement activities.

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CMP RMAF, March 2007, p.7.

Integration of key strategic management mechanisms needed to be strengthened. Areas
identified included formalizing the terms of reference for and functioning of CMEC and the
ADM Committee; strengthening policy and program coordination, research planning and
selection; integration of F&DA, HPA and PCPA actions with CEPA 1999; and, to "move
beyond framing to implementation of the management approach across agenda of the whole".

The Record of Decision from this CMEC meeting noted that more effort was needed to meet management oversight commitments for the CMP, particularly relating to governance, strategic planning and performance measurement/evaluation.

- A proposed approach to the establishment and implementation of an Integrated Management Accountability Framework for the CMP was also presented to CMEC in April 2008.
- ➤ The proposed Accountability Framework was further developed between April and December 2008, and approved at the first formal meeting of the ADM Committee. Four key governance roles were defined in the final framework:
 - ADM Committee provides strategic direction, coordination and a challenge function for the overall implementation and review of results and resource utilization.
 - CMEC a DG-level committee that supports coordination of overall implementation of the CMP, including integrated program delivery and management accountability. The Committee provides advice to the ADM Committee and direction to CMP program groups.
 - Integrated Program Management Office provides secretariat support to the ADM Committee and CMEC; oversees and monitors performance, resources and risks across the CMP; and, facilitates and coordinates horizontal management activities.
 - Supporting sub-committees and working groups facilitate the sharing of information, coordination of activities and achievement of results, particularly where complex coordination and integration is required across organizational boundaries, and as needs arise. 33

Both committees meet on a regular basis with regular and consistent participation by the applicable DGs and ADMs, and provide direction for the delivery of the CMP and guidance on emerging policy issues.

- Activities relating to strategic directions and priorities initially focused on the development of an HC-EC Strategic Plan for the CMP in 2007/08. The Record of Decision for the September 2007 meeting of CMEC noted that the strategic plan would be written from the original CMP design documents and timelines. More recently, the committees have been actively engaged in planning for the proposed second phase of the CMP, building on lessons learned with the design and delivery of the CMP between 2007/08 and 2010/11.
- As noted in the previous section C, above, several rounds of work on developing a performance measurement and reporting framework for the CMP have been undertaken but a definitive framework to better inform decision-making and facilitate performance reporting has yet to be implemented.
- ➤ Human resource management appears to have been a key priority during the initial start-up and establishment period of the CMP, primarily to ensure adequate resources were available to handle the significant expansion in risk assessment and risk management work required by the CMP and meet the Challenge timelines. Starting in 2008/09, the view amongst senior managers appears to have

Horizontal Management of CMP: Status Check, presentation to CMEC, April 2008.

Integrated Program Management Office, Governance of the Chemicals Management Plan, CMEC presentation, April 2009.

Integrated Management Accountability Framework (IMAF), presentation to CMEC, April 2008.

shifted, with presentations to CMEC noting that progress had been made in building capacity. Thereafter, human resource management has not been included in items discussed by the ADM Committee or CMEC. Comments made by some internal key informants suggest that, while human resource capacity is generally adequate, some specific skill sets are difficult to recruit or retain, particularly experienced risk assessors who are in high demand both within government and in the private sector.

At the operational level, a majority of internal key informants indicated that the CMP's management is well integrated and coordinated. Most of the external key informants also noted that the horizontal management and integration of the CMP's delivery was working reasonably effectively and efficiently, aided by clear communications to and transparent engagement with stakeholders. Many of these key informants also highlighted the value of applying timelines for the completion of interim and final stages in the Challenge process, and HC and EC's commitment to meeting these timelines. A similar view was expressed by the representatives of the international regulatory agencies.

The internal key informants believed there to be good coordination between HC and EC on risk assessment and risk management matters and this coordination is believed to have improved steadily since the inception of the CMP. The quality of this integration and coordination was reported to be a function of good leadership within CMP; establishment of designated CMP contacts in each of the HC programs and at EC, the development of ongoing relationships and communications among key staff; and co-location of EC and HC staff in similar functions, such as risk communicators, where feasible. Coordination is generally perceived as being more complex and challenging at HC due to involvement of multiple programs with responsibilities under the F&DA, HPA or PCPA.

The approach to research management was perceived to work relatively well, but could be improved through better alignment of the respective HC and EC priorities to the extent possible, given the differing substances of interest to the two departments and thus, possibly differing information needs. Location of the research and monitoring functions within the same directorate was seen to have improved linkages between the two functions, aided by the establishment of a common secretariat to support the work of both functions.

Monitoring and surveillance activities were generally perceived to be well coordinated and effectively managed. This alignment and coordination was reported to benefit from regular meetings where representatives from EC and HC present and discuss the progress of projects and cross-representation of the directors on the respective HC and EC monitoring and surveillance management committees. Some of the key informants who were involved with the monitoring and surveillance or risk assessment and risk management functions noted that it was necessary for the monitoring and surveillance function to identify and promote the use (or potential use) of their monitoring activities as a source of data for risk assessments and, longer term, as a means of assessing the effectiveness of risk management to the risk assessment and risk management functions. This need was a function of the differing time perspectives of the two functions; risk assessors and risk managers are concerned with the immediate timelines for Challenge batches whereas the monitoring and surveillance function has to work with a much longer time horizon.

Examples of horizontal integration and coordination mechanisms implemented at the operational level that were identified by key informants or referred to in CMP documents included:

Development and application of the best placed Act approach, which aids the determination of which Act(s) (CEPA 1999, HPA, F&DA, PCPA) is (are) most appropriate for managing the identified risks of Schedule 1 substances. The approach is used as a tool to weigh the specifics of each substance and knowledge relating to hazards, exposure, and patterns of use against the powers available under each

of the Acts. Participants in case study interviews conducted for the evaluation indicated that the key to successfully applying the approach has been the establishment of solid working relationships between groups and increasing knowledge and understanding of programs' mandates and sector coverage as well as knowing who to contact, ask and/or involve in the discussion.

- Coordinated preparation and release of risk assessment and risk management documents and integration of HC and EC stakeholder engagement activities for the Challenge batches. This approach means that there is a single source for the various risk assessment and risk management documents (through the CMP website) and a single point of contact for submission of comments on proposed and final risk conclusions and proposed risk management measures.
- Establishment of a single fund for CMP research and coordinated assessment and selection of research projects in accord with a single set of CMP research priorities. According to the internal key informants who commented on the approach to research coordination, the approach taken has worked relatively well and has been improved as the work has progressed.

Three areas for improvement in the horizontal management of the CMP were highlighted by a number of the internal key informants. The first of these was the lack of a common IT system for the CMP with common software and shared servers for the HC and EC personnel working on the CMP, to improve the ease and efficiency of information sharing and preparation of documents. In this regard several noted that reliance on different word processing and email software makes scheduling and other tasks difficult and frustrating. The second area identified by some internal key informants was to simplify or streamline the approvals process for batch documents by reducing the number of people who need to review and approve documents, drawing on the experience with approvals for the Challenge process to date. The challenge here is to ensure that all programs that may need to provide input or that may be affected by a possible risk assessment conclusion or risk management decision are aware and have sufficient time to respond. The third area was that of financial management and tracking in support of governance and operational and strategic planning, which is addressed in section F, below.

The interpretation of the CMP material relating to the horizontal management and governance of the CMP and synthesis of findings from key informant interviews indicates that the horizontal management and coordination of CMP activities is reasonably effective, particularly relating to the core risk assessment, risk management and supporting research and monitoring activities undertaken by HC and EC. At the governance level, the ADM Committee and DG-level CMEC provide joint HC and EC guidance and direction for the management and delivery of the CMP. Development and implementation of a performance measurement and reporting framework for the CMP is an area of weakness, however, within the governance structure (as was noted and described in section C, above).

F. Adequacy of financial and human resources and their allocations to CMP activities (EQ10)

Evaluation Issue: Design and Delivery		Indicator(s)	Rating
10(a) (b)	human resources to achieve its intended outcomes? Are resources allocated appropriately among the major areas of CMP activity?	Program resources and capacity are commensurate with expected program results. Extent to which the HR plan appropriately identifies numbers of managers and scientists required by CMP activity area, and extent to which these positions have been filled with the expertise and skills required. Extent to which financial resources are budgeted and being expended in accordance with research, monitoring and surveillance and other CMP plans. Extent to which levels of CMP resources are consistent with those of comparable initiatives in other jurisdictions. Views on the adequacy and appropriateness of resource allocation.	Progress made; attention needed

The CMP has adequate capacity to complete most of its key activities.

Some re-allocation of funding has been necessary as the CMP has progressed, largely due to differences between actual and anticipated workloads for a number of activities and program areas. Progress in a number of areas has been affected by resource limits, such as the petroleum sector stream and risk assessment and risk management of legacy substances.

The ability of CMP managers to break down and analyze the allocation and appropriateness of CMP funding is limited by the fact that HC and EC's CMP activities are funded using a combination of A-base and B-base funding with operational planning and management guided by the total budgets available rather than looking at the CMP funding separately.

Funding for the CMP involves a combination of A-base funding and resources available to the program areas and functions that are central to the delivery of the various CMP activity streams plus two sources of fixed term funding (B-base) approved by Treasury Board. According to CMP planning documents relating to the delivery of the first phase of the CMP and planning for the second phase, this funding is composed of:

- A-base funding at HC and EC of approximately \$29 million and \$45.6 million per year, respectively. In both cases this funding supports a range of activities that includes, but is not limited to, work on the various CMP activity streams.
- ➤ CMP funding (B-base) allocated for the period from 2007/08 to 2010/11. A total of \$299.2 million was provided with \$192.7 million going to HC and \$106.5 million to EC. This funding started from a relatively low base in 2007/08 (\$23.5 and \$16.2 million, respectively) and was progressively ramped up over the period of the CMP. Exhibit V-7 shows the breakdown of this funding by department, activity stream and year as well as the projected numbers of FTEs that were to be added by HC and EC to undertake the increased throughput of work envisaged under the CMP. This information shows that CMP activities at both HC and EC were expected to progressively grow over the period of the CMP as staff was brought on line and core activities in each of the streams were established and, in the case of the Challenge, progressively expanded.

Exhibit V-7 CMP funding and resource allocations

CMP Funding Allocations	2007/08	2008/09	2009/10	2010/11	Total		
CMF Funding Anocations	(\$ mill.)	(%)					
Health Canada	İ						
Risk Assessment	3.21	6.52	7.60	9.64	26.97	9%	
Risk Management/ Communications	12.66	21.83	27.78	32.65	94.93	32%	
Research	3.25	6.64	11.67	8.65	30.21	10%	
Monitoring/ Surveillance	3.45	5.53	11.76	14.42	35.15	12%	
Performance Measurement/ Program	0.93	1.48	1.49	1.54	5.44	2%	
Management							
Sub-Total	23.50	42.00	60.30	66.90	192.70	64%	
CMP – Environment Canada							
Risk Assessment	2.13	3.10	3.10	4.80	13.13	4%	
Risk Management/ Communications	9.10	12.10	19.30	24.40	64.90	22%	
Research	0.63	1.50	-	-	2.13	1%	
Monitoring / Surveillance	4.35	6.90	7.30	7.80	26.35	9%	
Sub-Total	16.20	23.60	29.70	37.00	106.50	36%	
TOTAL	39.70	65.60	90.00	103.90	299.20	100%	

CMP FTEs	2007/08	2008/09	2009/10	2010/11	Total		
(Approved year-end strength)	2007/08	2000/03	2003/10	2010/11	#	(%)	
CMP – Health Canada							
Risk Assessment	16.3	33.6	36.0	39.1	39.1	10%	
Risk Management/ Communications	47.5	76.0	102.2	116.2	116.2	29%	
Research	9.1	9.9	11.6	11.7	11.7	3%	
Monitoring/ Surveillance	4.6	7.3	12.8	15.6	15.6	4%	
Performance Measurement/ Program	3.4	5.2	4.9	5.1	5.1	1%	
Management							
Sub-Total	80.9	132.0	167.5	187.7	187.7	47%	
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CMP – Environment Canada							
Risk Assessment	13.4	19.0	20.0	20.8	20.8	5%	
Risk Management/ Communications	52.6	87.0	121.7	163.3	163.3	41%	
Research	0.2	0.5	0.0	0.0	0.0	0%	
Monitoring / Surveillance	11.1	24.8	25.1	24.3	24.3	6%	
Sub-Total	77.3	131.3	166.8	208.4	208.4	53%	
TOTAL	158.2	263.3	334.3	396.1	396.1	100%	

Source: Figure 2: Approved CMP Resources, by Fiscal Year, CMP RMAF, March 2007, p.12.

CEPA funding (B-base) for HC of \$89.9 million for the period from 2005/06 to 2009/10, which was allocated to enable HC to meet the anticipated workload anticipated prior to the implementation of the CMP. Another \$25 million was subsequently allocated for 2010/11. This funding supported work on new substances and federal work on air and drinking water quality in addition to risk assessment, risk management, research and monitoring under CEPA 1999.

Various presentations to the ADM Committee and CMEC over the 2007/08 to 2009/10 period of the CMP that included references to the management of financial and human resources noted that HC has experienced difficulties in identifying and tracking CMP expenditures due to the combination of A-base and B-base funding sources; and, HC's financial reporting system has limited ability to differentiate between CMP and non-CMP activities within program groups. 35 Records of decisions from these meetings include references to action and support for improving financial tracking but little or no progress appears to have been achieved. Information provided by the CMP horizontal management and coordination group indicates that requests for assistance have been made to the finance working group within the Healthy Environments and Consumer Safety Branch at HC and work is apparently in progress to improve financial coding to better track financial performance.

Given this evidence, data comparing actual expenditures to planned allocations, as shown in Exhibit V-8, should be viewed as indicative rather than definitive. Estimated total CMP expenditures were slightly below planned allocations in each of 2007/08 (4% below), 2008/09 (5% below) and 2009/10 (3% below). Patterns at HC and EC were similar with the exception of 2008/09 where the actual expenditures at HC were 9% below the planned allocation and 1% above at EC.

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³⁵ CMP Finances: Current Status, presentation to ADM Committee, February 2009, p.5. CMP Status Report, presentation to CMEC, October 2008, p.16.

Exhibit V-8
Comparison of estimated actual and planned CMP expenditures

	2007/08			2008/09			2009/10		
CMP Activity Streams	Planned (\$ mill.)	Actual (\$ mill.)	Difference	Planned (\$ mill.)	Actual (\$ mill.)	Difference		Actual (\$ mill.)	Difference
Health Canada									
Risk Assessment	3.2	3.0	-0.2	6.6	7.4	0.8	7.6	7.9	0.3
Risk Management	12.7	12.1	-0.6	20.8	19.4	-1.4	27.8	24.3	-3.5
Research	3.3	3.3	0.0	6.6	3.0	-3.6	11.7	12.2	0.5
Monitoring/Surveillance	3.4	3.4	0.0	6.5	7.0	0.5	11.8	13.9	2.1
Program Management	0.9	0.8	-0.1	1.5	1.5	0.0	1.5	1.4	-0.1
	\$23.5	\$22.6	-0.9	\$42.0	\$38.3	-3.7	\$60.4	\$59.7	-0.7
Environment Canada									
Risk Assessment	2.1	2.1	0.0	3.1	3.1	0.0	3.1	3.1	0.0
Risk Management	9.1	8.4	-0.7	16.1	15.2	-0.9	19.3	17.0	-2.3
Research	0.6	0.6	0.0	1.5	2.7	1.2	0.0	0.0	0.0
Monitoring/Surveillance	4.4	4.4	0.0	6.9	6.9	0.0	7.3	7.3	0.0
	\$16.2	\$15.5	-0.7	\$27.6	\$27.9	0.3	\$29.7	\$27.4	-2.3
TOTAL									
Risk Assessment	5.3	5.1	-0.2	9.7	10.5	0.8	10.7	11.0	0.3
Risk Management	21.8	20.5	-1.3	36.9	34.6	-2.3	47.1	41.3	-5.8
Research	3.9	3.9	0.0	8.1	5.7	-2.4	11.7	12.2	0.5
Monitoring/Surveillance	7.8	7.8	0.0	13.4	13.9	0.5	19.1	21.2	2.1
Program Management	0.9	0.8	-0.1	1.5	1.5	0.0	1.5	1.4	-0.1
	\$39.7	\$38.1	-1.6	\$69.6	\$66.2	-3.4	\$90.1	\$87.1	-3.0

Source: Health Canada, DPRs: Supplementary Tables - Horizontal Initiatives Reporting, 2007/08, 2008/09 and 2009/10.

Differences between estimated actual and planned expenditures for the different component activities are due to internal transfers between activities to better respond to actual workload patterns as well as such factors as delays in the initial ramping up of staffing in 2007/08 and lower than anticipated requirements for operating and maintenance expenditures (versus salary costs) in other years. Major reasons for internal re-allocations related to:

- Transfer of \$2 million in each of 2008/09 and 2009/10 from the risk management function in HC to the Food Directorate to handle higher than anticipated risk assessment, risk management and monitoring workloads. Under initial CMP planning scenarios, few substances were expected to have food or food packaging implications. The reality, according to the Food Directorate, has been that screening of food implications has been necessary for as many as 80-85% of Challenge substances, that 60% of the Challenge substances proposed for addition to Schedule 1 have food or food packaging implications and that consultations with food industry stakeholders have been necessary for 35% of Challenge substances.
- > Transfer of \$1.2 million from HC to EC each year to meet research funding commitments as part of a joint HC and EC approach to managing the selection and funding of research projects, supported by a single pooled research fund.
- Carryover of \$2.5 million in major capital funding to 2009/10 by HC.
- ➤ Transfer of \$0.1 million per year from the CMP program management to the Health Products and Food Branch to fund a CMP coordinator position in 2007/08, 2008/09 and 2009/10.

A re-profiling of resources and spending at EC, which reduced risk management expenditures by \$2.3 million in 2009/10. 36

Common themes in the comments by internal key informants regarding the allocation and management of financial and human resources were generally consistent with the patterns observed in reported expenditures.

- Many of the internal key informants indicated that funding allocations for their respective activities were generally adequate to meet commitments and deadlines. Some noted that:
 - At times, staff are stretched to the limit with little or no capacity to respond to emerging issues.
 - Work on the risk assessment and risk management of the Challenge batches received first
 priority, due to the commitment to meeting the timelines, and work on other, legacy substances
 was given a lower priority.
- A number of the internal key informants also highlighted challenges in managing with a combination of A-base and B-base funding. In particular, they noted the nature of B-base funding limits, which limited the ability of some programs to hire indeterminate (permanent) staff and thus the ability to develop and retain experienced people, and an associated imbalance between approved funding for salaries versus other operating expenditures. Some of these key informants suggested that the absolute funding levels were not an issue but the inability to re-allocate funds between salaries and other operating costs constrained the rate of work in some groups.
- ➤ Key informants working in program areas responsible for Acts other than CEPA indicated that their groups did not receive funding, or did not receive sufficient funding, to respond to the volume of risk assessment and risk management work required by the Challenge process. Most have been able to accommodate this work from their existing resource bases with the exception of the Food Directorate, as noted above, where the higher than anticipated workload necessitated a re-allocation of funding within HC.
- ➤ Key informants who commented on the petroleum sector stream indicated that staffing levels limited the rate at which the risk assessment of petroleum substances could be performed in combination with the difficulties encountered in assessing complex mixtures of the substances involved.

In summary, the breakdowns of actual versus planned financial and human resources, and supporting findings from key informant interviews, indicate that the CMP has adequate capacity to complete most of its key activities. However, the ability to break down and analyze the allocation and appropriateness of CMP funding is limited by the fact that HC and EC's CMP activities are funded using a combination of A-base and B-base funding with operational planning and management guided by the total budgets available rather than looking at the CMP separately. The inability of HC's financial reporting system to reliably identify and track CMP expenditures, and differentiate between CMP and non-CMP expenditures within program groups adds to the difficulty of tracking and managing financial expenditures for the CMP.

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Data on re-allocations is from the Treasury Board Secretariat's website for Health Canada's Supplementary Information (Tables) for Horizontal Initiatives to its Departmental Performance Reports for 2007/08 (www.tbs-sct.gc.ca/dpr-rmr/2007-2008/index-eng.asp?acr=39), 2008/09 (www.tbs-sct.gc.ca/dpr-rmr/2008-2009/index-eng.asp?acr=1485) and 2009/10 (www.tbs-sct.gc.ca/dpr-rmr/2009-2010/index-eng.asp?acr=1676).

Some re-allocation of funding has been necessary as the CMP has progressed, largely due to differences between actual and anticipated workloads for a number of activities and program areas. Re-allocation of funding within HC enabled one program area to cope with a much higher than anticipated level of risk assessment and risk management work, and other HC programs have been able to accommodate the risk assessment demands on their groups from within existing resources. However, in a number of areas the rate of progress has been affected by resource limits, such as the petroleum sector stream and risk assessment and risk management of legacy substances.

A number of internal key informants indicated that allocations between salary and other operating costs were often a greater constraint than the absolute levels of CMP funding, and that greater flexibility to reallocate between these two funding areas would allow for closer matching of resource capacity to workload demands. They also noted that the nature of B-base funding for the CMP created a long-term liability for programs involved in the CMP that rely on scientific knowledge and experience, and need to hire indeterminate (permanent) staff and develop and retain experienced people.

G. What are the best practices and lessons learned (both strengths and weaknesses) from the CMP? (EQ11)

Evaluation Issue: Design and Delivery	Indicator(s)	Rating
learned (both strengths and weaknesses) from the CMP?	Identified strengths, best practices, weaknesses and needed improvements to CMP design and delivery, and best practices of comparable programs in other jurisdictions. Views on strengths, weaknesses and needed improvements to CMP design and delivery.	Progress made; attention needed

CMP management practices include deliberate efforts to identify best practices and lessons learned, and the application of these practices and lessons to improve the effectiveness and efficiency of CMP activities. Key best practices and lessons learned identified by key informants were:

- Establishment of an effective horizontal governance mechanism.
- · Establishment of clear timelines and transparent processes for risk assessment and risk management.
- Implementation of coordinating mechanisms to ensure the timely progress of risk assessments at EC and HC.
- Allocation of substances to batches and establishment of a sequential process to assess the risks posed by substances in each batch as a means of optimally managing workflows.
- Scientifically-defensible decision-making is possible with less than complete data.
- · Application of the best placed Act approach as a tool to identify the most appropriate Acts for managing substance risks.
- Industry and other stakeholder engagement.

A number of areas for focus in the next phase of the CMP were also highlighted by key informants:

- Further development and refinement of approaches to the assessment of medium priority substances to enable the greater volume of such substances to be assessed and managed within mandated timelines.
- Application of comparative risk assessments of possible substitute or alternative substances rather than the substance-by-substance approach taken during the first phase of the CMP.
- Consideration of the scale of the response burden on industry generated by CMP data requests.
- Clarification of the CMP's role in occupational health and safety.

Industry members have ceased using many high priority substances prior to their assessment. Media coverage and consumer pressure/expectations also contributed to "pre-emptive" risk management actions.

In the context of the evaluation "best practices and lessons learned" refer to those activities and processes that are viewed or accepted as contributing to improved performance and/or efficiency of the CMP, as well as opportunities for improvement in the design and delivery of policies and programs. Our analysis of the findings from the various lines of enquiry, particularly the comments made by internal and external key informants, and supporting documents, suggests the following practices have played a central role in the success of the CMP since its inception in 2007/08.

- Establishment of an effective horizontal governance mechanism that involves senior CMP managers from participating branches and programs at HC and EC with the authority and accountability to direct the delivery of the CMP, including guiding the evolution of its policies and processes. This approach enabled the CMP to meet the expectation in the design of the initiative of taking an integrated approach to the selection and implementation of risk management measures using appropriate combinations of applicable Acts and usage characteristics of substances of concern.
- Establishment of clear timelines and transparent processes for risk assessment and risk management, including opportunities for stakeholder feedback, in combination with a strong commitment to meeting these timelines, provides predictability and certainty for all participants. The self-committed target of up to twelve months for initial information collection and preparation of draft risk assessments and risk management scope documents and six months for the preparation of final risk assessments and proposed risk management approach documents is particularly important in this process. Once the final risk assessment is issued mandatory timelines set in CEPA 1999 then apply. Future phases of the CMP may not be able to apply a single "hard and fast" timeline for data collection and analysis to enable significant data gaps that may be encountered with medium priority substances to be addressed. In cases where industry is requested to generate new data (versus providing existing data) or CMP chooses to undertake research or monitoring work to address key gaps longer timeframes may be necessary. Clear deadlines for the completion of these activities will still be necessary to provide needed transparency and predictability.
- ▶ Implementation of coordinating mechanisms to ensure the timely progress of risk assessments at EC and HC, including provision of input from programs affected by or involved with substances in each Challenge batch and sign-offs on conclusions and decisions at appropriate points. Early sharing of emerging risk assessment findings with risk managers was also identified as a necessary practice to facilitate the timely identification, assessment and development of risk management measures.
- Allocation of Challenge substances to batches and establishment of a sequential process to assess the risks posed by substances in each batch as a means of optimally managing workflows. This approach is generally regarded as working effectively by both internal and external key informants. This approach facilitated resource planning and management, and in combination with the publication of the expected scheduling of batches, provided predictability and certainty for the process. Many external key informants as well as the participants in international interviews from other jurisdictions both commented positively on this aspect of the Challenge process.
- Decisions are being made faster but with less than complete data. Prior to the CMP, timeframes for risk assessments for potentially toxic substances were often well in excess of the time periods applied to risk assessments under the CMP. With the Challenge process, risk assessments rely on a combination of available data (from literature searches, industry, other jurisdictions) and data modelling methods, and application of the precautionary principle when selecting prospective risk management measures. This type of approach is consistent with practices using a "weight of evidence" approach that is also applied in other jurisdictions, with the development and sharing of methods facilitated through the Organization for Economic Co-operation and Development (OECD). Most of the internal key informants involved in the CMP risk assessment and risk management functions noted that the lack of data for some substances posed challenges. However, most also noted that, while the maximum time frame of 18 months for risk assessments in the Challenge process is very demanding, it means that actions to manage the risks posed by substances that are currently in unregulated commercial use can be implemented sooner than would otherwise be the case.

- ➤ Application of the best placed Act approach as a tool to identify which Act is, or more frequently, which combinations of Acts are, best placed to manage the risks posed by Schedule 1 substances. In doing so, this process considers exposure patterns and characteristics of substance use for example, if risks are prevalent at the point of production or in downstream product sectors that use the substance of concern in a final product or process as well as the powers available to regulators under the different Acts available to the CMP. This approach also responds to the government's commitment in the Cabinet Directive on Streamlining Regulation to advancing the efficiency and effectiveness of regulation by focusing resources and actions where they can do the most good and minimizing duplication and complexity.³⁷
- ▶ Industry and other stakeholder engagement. In this regard the CMP goes well beyond the publication of proposed risk assessments and risk management measures in the *Canada Gazette* by using a variety of risk communication activities and tools to reach stakeholders and facilitate their participation. This approach is consistent with the best practices identified in the literature relating to the use of "participatory-transparent" approaches to science-based risk management where trust in, and the credibility of, a regulatory system depends on a high degree of transparency and external engagement. Key amongst these are:
 - Operation of the Stakeholder Advisory Council as a means of bringing representatives of key stakeholders together to provide guidance and feedback to HC and EC on the implementation of the CMP as well as fostering dialogue among the various types of stakeholders.
 - Funding capacity building among NGO stakeholders to facilitate their active participation in the Stakeholder Advisory Council and ongoing consultation activity related to proposed decisions and conclusions for the full range of CMP risk assessment and/or risk management activities undertaken.
 - Coordinating the preparation and release of risk assessment and risk management documents for Challenge substances between HC and EC, and using a single window approach to soliciting stakeholder input to and comments on these materials and a single website for public access to CMP materials and information.
 - A transparent and predictable process for issuing proposed Challenge decisions and activities, and seeking stakeholder feedback, including publication of summaries of comments received and responses to these comments for each Challenge batch.
 - Supporting communication and engagement activities to increase awareness and understanding
 of key CMP activities and the nature of risk assessments and risk management proposals for
 each Challenge batch. These activities include stakeholder briefings, workshops and webinars
 as well as complementary communication and engagement activities by the different program
 areas involved with the CMP to consult with representatives of the industry and product sectors
 they regulate.
- ➤ Media coverage of substances proposed for addition to Schedule 1 can lead to consumer and/or industry making their own decisions to avoid using certain substances. In some instances, risk assessments that determine that substances used in various consumer products should be added to Schedule 1, such as products used by children or food packaging products, may attract wide media coverage and result in strong reactions to the perceived hazards and reduced demand for these products prior to the development of risk management measures. Bisphenol A is a prominent example of this effect. Publicity relating to the use of the

Government of Canada, *Cabinet Directive on Streamlining Regulation*, Regulatory Affairs Sector, Treasury Board Secretariat, 2007, p.1 and p.7.

substance in polycarbonate containers following the release of the draft risk assessment in April 2008 apparently resulted in a number of key manufacturers, including the leading manufacturer of reusable polycarbonate drinking water bottles, Nalgene, ceasing to use bisphenol A in their products. Similarly, a number of leading retailers, including Wal-Mart and Hudson's Bay Company, stopped stocking reusable water bottles containing bisphenol A as well as baby bottles.³⁸

Opportunities to strengthen key approaches and processes were also apparent in the analysis of lessons learned, as follows:

- Need to clarify CMP's role in occupational health and safety. A number of NGOs expected that occupational health and safety risks of chemical substances would be addressed as part of the risk assessment and risk management process for Challenge substances. HC and EC have had to clarify that occupational health and safety is primarily under provincial jurisdiction to stakeholders, including representatives on the Stakeholder Advisory Council, whereas the focus of the CMP is on protecting the general (non-occupational) population. A related challenge is that even if a particular substance is found to be non-toxic for the general population there may still be occupational risks and safety issues. The CMP is working with federal Workplace Hazardous Materials Information System staff to share the findings from CMP risk assessments with the provinces and thereby facilitate occupational health and safety management.
- Need to consider the scale of the response burden on industry generated by CMP data requests. The rate at which Challenge batches are launched and progress means that companies may be responding to a series of mandatory information requests for different batches and substances at any one time, and responding to these requests requires an extensive amount of time and effort. While industry representatives recognized that it was in their best interest to actively participate in the process, some noted that economic pressures were placing limits on the ability of companies to respond to the full range of information requests. Planning for the much higher volume of medium priority substances to be assessed in the next phase of the CMP will also need to consider the ability of industry to comply with information requests or how to streamline such requests when defining substance groupings and developing approaches and processes.

Several industry representatives also indicated that companies using Challenge substances in their products or processes may encounter difficulties in obtaining information requested under mandatory S.71 notices, particularly when they have to obtain information from international suppliers, for example, regarding substance use in food packaging materials. A number of key informants, both internal and external, indicated that the design of questions in S.71 notices and voluntary questionnaires can be problematic, in terms of producing appropriate and complete information for risk assessment and risk management. The ability to obtain information on the characteristics of substance use in final products and industry processes, and thereby inform the analysis of exposures was also highlighted as a particular challenge in the current information collection processes.

➤ Design and delivery of the next phase of the CMP – addressing data gaps and grouping the medium priority substances. CMP managers expect many of the substances to be assessed in the second phase of the CMP to suffer from significant data gaps, particularly, but not only, relating to their effects on human health, compared to the data availability for the high priority substances currently being assessed. The development of risk assessment methods and tools to support expedited assessments of substances during the initial phase of the CMP provides a useful starting point for planning for the next phase. However, further development of the approach to risk

[&]quot;Bottle Maker to Stop Using Plastic Linked to Health Concerns", New York Times, April 18 2008.

[&]quot;Wal-Mart to pull baby bottles made with chemical BPA", Washington Post, April 18 2008.

assessment and management will be necessary to accommodate the approximately 3,000 substances to be assessed by 2020. This future risk assessment work will likely need to rely on a more tightly aligned combination of:

- Appropriate groupings of substances. Possible approaches to grouping medium priority substances include chemical class, chemical structure, mode of action, sector, and use profile.
- Engagement between risk assessors, risk managers and researchers to set research priorities that respond to anticipated information needs and data gaps, and taking into account the lead times involved in designing, performing and reporting on findings.
- Timely completion of the DSL Inventory Update and revised ICL to provide up-to-date information on the extent to which substances are still in commerce and, if so, their use characteristics.
- Requests to industry to generate new data, where appropriate, and also recognizing the lead times required for such work.
- Reliance on data available through similar regulatory review initiatives in other jurisdictions, such as REACH, where timelines and data collection processes can be aligned.
- Continuing development and refinement of data modelling tools to support the risk assessment of substance groupings.

Industry stakeholders also indicated that early notification of the groupings to be used and the scheduling of batch releases will be important to facilitate their planning and data compilation activities.

Application of comparative risk assessments to facilitate the identification and assessment of substitute substances. The current substance-by-substance approach to assessing and managing substance risks can be restrictive and limits time and opportunities to assess the availability and risks of possible alternatives and/or similar substances. Approaches to grouping substances in the second phase of the CMP may permit greater consideration of substitutes and alternatives as part of the risk assessment and risk management process.

H. Progress in mitigating key threats to Canadians' health and the environment (EQ12)

Evaluation Issue: Design and	Delivery	Indicator(s)	Rating
12(a) In addressing the legacy of assessed substances under 1999 by 2020, the CMP's objective is to mitigate kee to Canadians' health and the environment. Is the CMP, currently designed and designed and designed for 2020? (b) In order to facilitate the attempt of this objective, are any refinements to the CMP in now to address key challe and/or take advantage of keep opportunities?	CEPA managed other est takes due risks, and governm ivered, applish this tainment refinement refinement regeded ages	e that harmful chemicals are being in accordance with regulatory and ablished timelines in a manner that e consideration of opportunities, in the regulatory burden on the ent and industry. In the extent to which the CMP is to accomplish its objectives by disuggestions for any needed ents.	Too early to observe achievement Progress made; attention needed

Initial outputs from CMP risk assessments, proposed risk management measures and implementation of some risk management instruments as well as updated conditions of use for older pesticides suggest that a foundation for managing the health and environmental effects posed by high priority substances has been established.

Future assessment of the approximately 3,000 medium priority substances will depend on the continuing refinement and streamlining of risk assessment and risk management processes to enable their assessment to be completed by 2020. Implementation of compliance promotion and enforcement activities for the CMP substances will also be a necessary precondition for the achievement of the 2020 objective.

Analysis and interpretation of the findings from internal and external key informant interviews and content of documents relating to the progress of the CMP, lessons learned and considerations for the renewal of the CMP suggest the following insights regarding progress toward the long-term objective to mitigate key (chemicals-related) threats to Canadians' health and the environment.

The first four years of the CMP (2007/08 to 2010/11), established processes, tools and timelines for assessing the risks posed by high priority substances as well as actions under the PCPA to strengthen the regulatory management of pesticides and products subject to the F&DA or HPA that use chemical substances. The initial outputs from these activities – such as risk assessments, proposed risk management measures and implementation of some risk management instruments as well as updated conditions of use for older pesticides – suggest that a foundation for managing the health and environmental effects of high priority substances has been established. In turn, implementation of the risk management measures now flowing from the Challenge process and the re-evaluation of older pesticides should, by inference, be expected to contribute to the mitigation of chemicals-related threats to human health and the environment.

Supporting research projects have been initiated (and, in the case of some bisphenol A projects, completed, such as research on the migration of bisphenol A in packaged drinks and foods³⁹) and are expected to address some gaps in the knowledge of hazards and exposure for particular substances of concern. Findings from other research projects will be considered in the risk assessments of medium priority substances in the next phase of the CMP as well as the development of proposed and final risk management instruments for high priority substances included in the first phase of the CMP, as applicable.

Similarly, a range of ongoing national environmental studies, and national and targeted biomonitoring and surveillance studies, such as the CHMS and MIREC, have been initiated or strengthened and are expected to provide data on exposure to hazards and associated health implications, and contribute to the measurement of the efficacy of risk management measures. Until such time as reliable trend data are available from these sources as well as other sources such as the NPRI it will not be possible to draw robust conclusions about the impact of CMP control measures and their contribution to reducing human health and environmental risks posed by chemical substances.

Looking to the future phases of the CMP between 2011 and 2020 it is clear that the approach to risk assessment and risk management used for the 195 high priority Challenge substances assessed in the initial phase of the CMP will need to be further refined and streamlined to enable assessment of the

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Kubwabo C., et al, "Migration of bisphenol A from plastic bottles, baby bottle liners and reusable polycarbonate drinking bottles", Food Additives & Contaminants: Part A: *Chemistry, Analysis, Control, Exposure & Risk Assessment,* 1944-0057, Volume 26, Issue 6, 2009, pp.928 – 937.

Health Canada has also published the findings of a series of surveys of the incidence of bisphenol A in packaged drinks, canned foods, canned infant formula, and packaged baby foods between August 2008 and August 2010. The proposed risk management approach for bisphenol A also drew upon preliminary data from Phase 1 of the Canadian House Dust Study being conducted by Health Canada.

approximately 3,000 medium priority substances (that is, an approximately six-fold increase in the average annual volume) by 2020. Equally, the CMP and stakeholders have been aware of the need to further develop the design and delivery of the CMP to respond to this situation for quite some time and work is currently underway to define needed changes and approaches to their application. Additionally, several activities that were initiated during the first phase of the CMP – the DSL Inventory Update, in particular, as well as the production of the revised ICL – will need to be completed on a timely basis during the second phase of the CMP to provide up-to-date data on the extent to which medium priority substances are in commerce and, if so, their usage characteristics.

A final area of activity that will be important to the overall success of the CMP is that of compliance promotion and enforcement, to ensure that target entities for risk management measures are aware of their obligations and non-compliance is prevented or limited to the maximum extent possible. In the first phase of the CMP compliance promotion and enforcement had a very limited role and funding due to the fact that risk management measures under CEPA 1999 were in development and most will not be implemented until the second phase of the CMP. Going forward, the need to plan for and implement compliance promotion and enforcement activities linked to the completion of risk management measures for Challenge and petroleum sector stream substances will progressively become more prominent.

At EC, a Chemicals Standing Compliance Promotion and Enforcement Steering Committee was established in 2009 to provide broad strategic advice on policy, operational and technical issues related to chemicals risk management, compliance promotion and enforcement. Membership of the committee is predominantly from EC with only one HC member, from the Risk Management Bureau, which is consistent with the primary role of EC in CEPA 1999 compliance promotion and enforcement anticipated in the original design of the CMP. Summary documentation on the work of this Steering Committee suggests that the focus of much of its work to date has been on operational and enforceability issues involved in consistently applying CMP risk management instruments and recommending changes to improve the development and application of these instruments.

While attention to these aspects is necessary for successful implementation of CMP the experience with the selection of proposed risk management actions for Challenge substances suggests there may be a need for greater coordination between EC and HC compliance promotion and enforcement functions than may have been anticipated when the CMP was designed. This need would appear to derive from the greater than expected focus on downstream products and processes that use chemical substances and greater reliance on multiple risk management measures across various combinations of CEPA 1999, F&DA, PCPA and HPA in the proposed risk management measures for Challenge substances. As such, coordinated approaches to compliance promotion and enforcement for substances subject to risk management measures under CEPA 1999 and one or more of the F&DA, PCPA and HPA, and sharing of information on results and best practices may be beneficial.

Looked at in their entirety, these conclusions drawn from the analysis of CMP design, delivery and outputs to date suggest that a sound foundation for achieving the long-term objective of mitigating key threats to Canadians' health and the environment has been established. The actions taken in the first phase of the CMP as well as the planning underway to adapt the design and delivery of the CMP to assess approximately 3,000 medium priority substances by 2020 mean that HC and EC should be well-placed to ultimately improve the management of substance risks and contribute to improved mitigation of chemicals-related threats to Canadians' health and the environment.

VI. Effectiveness

A. To what extent have the intended immediate outcomes been achieved as a result of the CMP? (EQ13)

Evaluation Issue: Effectiveness	Indicator(s)	Rating
13. To what extent have the intended immediate outcomes been achieved as a result of the CMP?	Evidence in documentation/data of the degree of progress toward outcomes. Views on the extent to which intended outcome has been achieved as a result of the program.	
The CMP research activity stream is	als to support risk assessment, risk management, and monitoring and surveillance. generally on track to achieve this outcome. However, most of the research projects rity of published findings will only start to become available in 2011/12.	Too early to observe achievement
(b) Improved knowledge of chemic and identification of data gaps The CMP is generally perceived to b date in assessing high priority substa- stream, the DSL Inventory Update ar capability to better identify data gaps	Progress made; attention needed	
(c) Improved monitoring of the effect assessment and risk manageme Monitoring and surveillance actions a baseline data on the environmental amonitoring and surveillance stream wassessed and refined.	Too early to observe achievement	
(d) Canadians and other external s CMP and on the risks and safe Stakeholder engagement and consult. Less progress has been made in commactions they can take to manage these	Achieved – external stakeholders Little progress; priority for attention – Canadians	
(e) Effective management regimes management requirements. Judgements as to the extent to which that the majority of risk management	Too early to observe achievement	
(g) Effective compliance promotion instruments and are prioritized Compliance promotion and enforcem	treness of their legal obligations. In and enforcement activities that support identified CMP risk management I to address the greatest environmental threats. In an activities under CEPA 1999 will only come into play in the next phase of the draw conclusions regarding the achievement of these two outcomes.	Too early to observe achievement
This outcome is generally perceived Opportunities for improvement exist	aking and program performance. as being achieved. – development of the performance measurement system, establishment of a common ing CMP planning and financial tracking and management.	Progress made; attention needed

In answering this evaluation question it is important to understand that the CMP is four years into what is expected to be at least a fourteen year life cycle (that is, from 2007/08 to 2020/21). Most activity streams are only at the point where initial outputs and some outcome data are becoming available, and one stream – compliance promotion and enforcement under CEPA 1999 – will only be fully instigated in the next phase of the CMP as risk management measures are finalized and implemented. Baseline data on the environmental and human presence of selected substances is, however, being collected through the monitoring and surveillance stream. The discussion in the following sections on these outcomes is concerned with the pre-conditions for achieving these outcomes and the extent to which they are recognized in the CMP's current planning activities.

1. Research – Improved knowledge of chemicals to support risk assessment, risk management, monitoring and surveillance

Priorities for the research stream were identified in discussions between HC and EC researchers, risk assessors and, to a lesser extent, risk managers during the initial year of the CMP and a single funding pool for CMP research by HC and EC established. A joint HC and EC Research Network was established to manage the selection and funding of projects, and monitor their progress. These projects are long-term in nature, requiring two to three years for design, data collection and analysis plus additional time for preparation and publication of findings. Within the overall mix, funding was allocated for more focused studies on various aspects of bisphenol A with the findings from these studies becoming available from late-2008 onwards. Findings from other projects have been shared to the extent possible, via presentations and more informal contacts between researchers and risk assessors.

Internal key informants involved in the management of CMP research activities believe that the CMP research activity stream is generally on track to achieve this immediate outcome. Reasons given for believing the research stream was on track related to the way in which the research, risk assessment and (to a lesser extent) risk management functions had been brought together, common priorities determined, and a single funding pool established between EC and HC, all of which resulted in progressively better alignment of research to support risk assessment. However, most of the research projects undertaken are on a three-year cycle so the majority of published findings (which will be externally peer-reviewed) will only start to become available in 2011/12.

Some projects have had shorter lifecycles and researchers have shared early findings where possible so there has been some use of research results in support of risk assessment and risk management. Internal key informants from the risk assessment and risk management functions noted that only a small amount of information had been generated from the various research projects to date, due to the timeframes involved. A number commented that when research data is available it can be very useful in filling (some) gaps. The example cited most frequently was the use of findings from bisphenol A research, specifically, the investigation of exposure of young children to indoor dust and the investigation of migration from polycarbonate baby bottles, to facilitate the risk assessment in 2008. More recently, research on exposure to bisphenol A from canned and bottled foods and beverages is being used to investigate requirements for risk management measures.

Findings and other outputs from the CMP research, such as new or improved assessment models and tools, are expected to be applied to the conduct of risk assessments for medium priority substances as well as the development of risk management measures for the Challenge and petroleum sector stream substances, which runs through to January 2015. This means that, if new data or understanding of substance risks comes to light the risk assessment and risk management approaches for the high priority substances can be re-visited.

2. Risk assessment – Improved knowledge of chemical-related risks, including identification of substances that may require further action and identification of data gaps to inform researchers and risk managers

Internal key informants with risk assessment and risk management responsibilities and external key informants familiar with the CMP (mainly the Challenge process) generally perceive the CMP to be on track to achieve this immediate outcome, primarily as a result of the progress to date in assessing high priority substances covered by the Challenge process. Several external key informants also highlighted that stakeholder engagement and consultation activities during the risk assessment and risk management processes also contributed to increased knowledge among HC and EC's risk assessors and risk managers of sectors using substances of concern and the patterns of use of these substances.

However, progress in two other areas – the DSL Inventory Update and revised ICL – has been slower than planned and may have an adverse impact on the CMP's future capability to better identify data gaps and determine if substances require risk management. Other data gaps have been identified in consultation with the research and monitoring functions and used as input to the planning and conduct of biomonitoring and environmental monitoring actions, and selection of research projects. Once generated, this information will be used to inform assessments of environmental exposure, accumulation in humans, and the overall lifecycle analysis of chemical substances.

Evidence of the extent to which the Challenge process has identified substances that may require risk management actions, and the measures proposed to manage the risks so identified are summarized in Exhibit VI-1, which summarizes the results of the final risk assessments for the nine batches that have reached this milestone. These results, for Batches 1 to 9 of the Challenge process, show that:

- A total of 38 of 151 (25%) Challenge substances from Batches 1 to 9 were determined to meet the criteria in S.64 of CEPA 1999 that is, identified to be substances that may need risk management action and were added to, or proposed for addition to, Schedule 1. This incidence rate is lower than was anticipated at the time of the CMP's design and implementation.
- ➤ Six of those 38 (16%) substances met the S.64 criteria for long-term harmful environmental effect or danger to the environment on which life depends (sub-sections (a) and/or (b)) whereas 32 (84%) were determined to constitute a danger to human health (sub-section (c)), including one that also met subsection (a).

Exhibit VI-1 Challenge process outputs for Batches 1 to 9

Challenge	Batch						Total			
Outputs	_ 1	2	3	4	5	6	7	8	9	Total
# of Substances	15	17	19	18	19	18	14	14	17	151
# Meeting S.64 Of which:	8	9	4	3	2	1	3	4	4	38
(a)/(b)	0	3	0	1	0	0	0	2	0	6
(a) & (c)	0	1	0	0	0	0	0	0	0	1
(c)	8	5	4	2	2	1	3	2	4	31
Risk Management Action	s and Prop	osed Action	s:			_				
CEPA:										
SNAcs	4	5	3	2	0	1	2	3	4	24
Other ¹	1	2	0	2	1	0	0	3	1	10
P2 Plans ²	1	3	0	0	0	0	0	0	0	4
E2 Regulations ³	0	1	0	1	1	1	1	1	1	7
Cosmetics Hotlist	4	3	5	2	1	1	1	0	1	18
F&DA	5	7	2	0	6	0	0	1	1	22
HPA	1	1	4	0	1	0	1	0	0	8
PCPA	1	1	0	0	0	0	0	0	1	3
Policy Decision ⁴	5 (F&DA)	2 (F&DA) 6 (CEPA)	0	1 (CEPA)	0	0	0	1 (CEPA)	0	15

- 1. Other: form of actions under CEPA to be determined
- 2. P2 Plans: Pollution Prevention Plans
- 3. E2 Regulations: Environmental Emergency Regulations.
- 4. Policy decisions usually involve the scrutiny of future pre-market submissions for products containing substances of concern by groups administering regulations under the authority of the F&DA or CEPA 1999, or future investigation actions.

Source: Data table, provided by CMP management, summarizes the Challenge outputs as of December, 2010.

- The majority of the Schedule 1 additions involve multiple risk management measures, as shown under the Proposed RM actions in Exhibit VI-1, with an average of 2.9 measures or proposed measures per substance. The most frequently proposed measures were risk management Significant New Activity notifications under CEPA 1999, mostly for substances determined to be non-threshold carcinogens (24 of the 38 (63%) substances); additions to the F&DA Cosmetics Hotlist (18 / 47%); actions under the F&DA (22 / 58%); actions under the HPA (8 / 21%); and, other actions under CEPA 1999 (21 / 55%). These proposed other CEPA actions span environmental emergency regulations (7), pollution prevention plans (4), and a range of other actions (10), including environmental release guidelines, additions to the VE List, regulations and information gathering.
- In addition to the seven substances proposed for addition to the E2 Regulations by CMP risk managers, the E2 Program has identified another 27 Challenge substances that they propose to add to the E2 Regulations or that are already listed. Under these regulations, sites that store or use the listed substances above the specified thresholds, or are handling containers of the listed substances in excess of the assigned thresholds, are required to prepare and implement an environmental emergency plan and notify EC accordingly. The breakdown of the proposed additions to the E2 Regulations from the substances in Batches 1 to 9 of the Challenge is shown in Exhibit VI-2.

Exhibit VI-2
Proposed additions of Challenge substances to the E2 Regulations

	Proposed Ad	Proposed Additions to the E2 Regulations			Already Listed on the E2	
CMP Batch	Proposed by CMP Proposed by the I		E2 Program Regulati		tions	Total
CHAI Zatton	Risk Managers	CEPA-Toxic (Sched. 1)	Non-CEPA Toxic	CEPA-Toxic (Sched. 1)	Non-CEPA Toxic	20002
1	-	4	-	4	-	8
2	1	4	-	2	1	8
3	-	-	1	-	-	1
4	1	-	1	-	-	2
5	1	-	1	-	2	4
6	1	-	-	-	2	3
7	1	-	1	-	-	2
8	1	1	1	-	-	3
9	1	-	2	-	-	3
Total	7	9	7	6	5	34

Source: Data provided by CMP and E2 Program managers.

Delays in the progress of the petroleum sector stream mean that draft risk assessments have been issued for only 70 of the 164 substances in this stream.

Re-evaluations of older pesticides by the HC-PMRA integrate risk assessment and risk management into a single process and decision. Re-evaluation of the 401 older pesticides targeted is running behind the targeted completion date (end-2008/09). At the end of 2009/10, final or proposed/ pending decisions had been reached for 360 (90%) of these substances. In 63% of the re-evaluation decisions to date, PMRA has made changes to the conditions of use to bring them into line with current registration requirements, 4% resulted in no changes and the remaining 34% were withdrawn from the market at either PMRA's request or by registrants.

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Health Canada, Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products
 Horizontal Initiative — Summative Evaluation, 2010, p.62.

3. Monitoring and surveillance – Improved monitoring of the effectiveness of control actions and fate of chemicals to support research, risk assessment and risk management

Internal key informants responsible for the monitoring and surveillance activities believed that this CMP stream was generally on track to achieve this immediate outcome. These perceptions are based on the progress during the initial years of the CMP in determining, with input from the risk assessment and risk management functions, which substances should be monitored using biomonitoring and/or monitoring in various environmental media (air, sediment, water, aquatic biota, wildlife) and foods, and implementing systems and methods for collecting and compiling these data. Work was also undertaken, or is in progress, to develop methods for measuring and interpreting the health and environmental presence of substances of interest.

Under the CMP:

- EC strengthened its national systems to monitor the presence of chemicals in multiple environmental media: air, water, sediment, non-human biota (fish and wildlife); and established source monitoring (wastewater treatment plant effluents and sludge; landfill leachate and biogas) systems. Data collected through EC's environmental monitoring activities is used to quantify exposure levels and generate science-based information to identify risks and inform risk management, improve understanding of the environmental fate and behaviour of chemical substances, and, longer term, inform assessments of the effectiveness of risk management controls. The following substances are currently monitored by EC in at least one environmental media: bisphenol A, siloxanes, chlorinated paraffins, metals (including platinum group elements), perfluorinated compounds (PFCs), polybrominated diphenyl ethers (PBDEs) and other flame retardants.
- ➤ HC has implemented a range of national and targeted biomonitoring initiatives as well as research projects to develop methodologies and tools to enable biomonitoring data collection, interpretation and communication, and monitoring of substances in environmental media and foods to assess human exposures. Key national monitoring actions supported by the CMP are:
 - Canadian Health Measures Survey (CHMS) data on 91 substances included in cycle 1 was released for analysis in August 2010 along with an initial analysis of the presence of lead and bisphenol A⁴¹; cycle 2 data collection is in process and expected to be completed in 2012.
 - Maternal-Infant Research on Environmental Chemicals (MIREC) data collection for 13 groups of substances between 2007 and 2012; early results expected in 2013.
 - Northern Contaminants Program biomonitoring and health outcomes studies to characterize human exposures to and the health impacts of environmental chemicals in the northern population.
 - Total Diet Study monitoring to estimate the levels of chemicals to which Canadians in different age-gender groups are exposed through the food supply.
 - First Nations Biomonitoring Initiative (in development).

Health Canada, Report on Human Biomonitoring of Environmental Chemicals in Canada: Results of the Canadian Health Measures Survey Cycle 1 (2007–2009), Ottawa, August 2010. Bushnik T, Haines D, Levallois P, Levesque J, Van Oostdam J and Viau C, "Lead and Bisphenol A Concentrations in the Canadian Population", Health Reports, Vol. 21, no. 3, September 2010, Statistics Canada, Catalogue no. 82-003-XPE.

These national studies are complemented by a range of targeted biomonitoring and environmental monitoring studies that focus on sub-populations of interest and the presence of substances in particular types of locations.

These monitoring and surveillance actions are in process and are only at the point where they are providing HC and EC with baseline data on the environmental and human presence of various substances. CMP managers expect that, over time, the monitoring and surveillance stream will prove to be a rich stream of trend data that enables the effectiveness of risk management actions to be assessed and refined. However, it will be quite some time before conclusions can be drawn about trends because of the need for multiple cycles of consistent data collection over extended time periods.

4. Risk communication – Canadians and other stakeholders are consulted and have access to understandable information on the CMP, and on the risks and safe use of chemicals

In order to assess the extent to which the immediate outcome for risk communication is on track for achievement it is necessary to split it into its two component parts – stakeholder consultation and access to information, and consultation with and availability of information to Canadians.

The small number of internal key informants involved in the risk communications stream believed that stakeholder engagement was effective but that less progress had been achieved in reaching and informing Canadians about the risks posed by chemical substances. As noted by one of these key informants, establishment and development of stakeholder engagement and consultation activities in support of risk assessment and risk management activities was (and continues to be) an immediate priority during the formative years of the CMP, by virtue of the need to establish and maintain the transparency of the CMP's work with, and feedback channels for, high priority substances. External key informants expressed similar views, with most noting that stakeholder communications, engagement and consultation are effective but outreach to Canadians should be stronger. These key informants also referred to a lack of public information to counter alternative positions and claims regarding the risks of chemical substances that can be found on the internet, the difficulty of explaining risks and communicating technical information, a need for (or value of) "boiled down" assessment conclusions, and the confusion caused by use of the term "toxic" in CEPA 1999 in explaining their views on progress against this outcome.

In regard to communications with Canadians, information on the CMP and the Challenge substances (in particular) is available on the CMP website, and linked sites on the HC and EC websites. However, proactive communications targeting Canadians or population sub-groups and intermediaries of interest is limited. Examples of these include the issuance of press releases regarding the results of risk assessments for the Challenge batches and the distribution of fact sheets on the CMP and managing chemical risks. Substances of particular interest, such as bisphenol A, do attract a lot of public interest and the CMP has responded by adding a special section on bisphenol A to its website, including a more extensive set of Q&As relating to the risks and management of this substance. An analysis of search patterns on the CMP website by the Risk Communication function shows that bisphenol A was the most frequently searched chemical name between November 2009 and August 2010.

Baseline public opinion research conducted for the CMP in 2009 drew the following conclusion before going on to note that Canadians are interested in learning more about chemical risks and their management but the issues involved are complex and (by inference) difficult to communicate.

The knowledge of many Canadians about chemical risks is fairly superficial. Beyond certain cleaning products and pesticides, the range of consumer products that could potentially cause health or environmental problems is not well known, nor is the nature or severity of the possible effects. Chemical hazards are not a major priority for many, and some citizens underestimate

the extent to which chemicals inside their home can be harmful, choosing instead to distance themselves and believe that chemicals outside in the environment pose a higher level of risk. There is limited understanding about the extent to which consumer product and food chemicals are tested, regulated and legislated.

The public opinion research conducted in 2009 also found that confidence in the federal government as a source of consumer product and food safety information was relatively limited. Only 29% of those surveyed had a "great deal of confidence" in the federal government as a source of such information, and the federal government lagged behind health groups, such as the Canadian Cancer Society (59%), health professionals such as doctors and public health nurses (51%), and environmental groups (29%). A minority of those surveyed (24%) rated information about chemicals that they had seen to be "very helpful" in determining the safety of such products, and another 58% rated it as "somewhat helpful". The most common reasons for rating this information as unhelpful were insufficient detail, too much detail and too technical or confusing, suggesting there is scope to improve the content and presentation of such information. Amongst those who claimed to have checked federal government sources of information on the health and environmental effects of chemicals (27% of those surveyed), only 20% found that information to be "very helpful" and another 68% found it to be "somewhat helpful".

A number of presentations to CMEC and the ADM Committee have noted that the communication to non-traditional stakeholders and the public could be improved, consistent with the findings of the public opinion research, and largely relies on relatively passive communications approaches, such as making information available on the CMP website. Internal key informants involved in the management of communications as well as a number of the external key informants noted that it is often a challenge for the CMP to reach Canadians and successfully communicate the technical aspects of risk assessments and risk management measures in competition with competing messages from interest groups and misinformation circulating on the internet.

A number of key informants also suggested that additional public opinion research to supplement the past baseline work is required in order to understand and measure the nature of any shifts in public understanding. In doing so, some suggested that the value of building understanding of the ways chemical risks are being managed for Canadians versus building awareness of the regulatory system for chemicals and trust that the system is managing risks to the public should be assessed.

Findings from the literature review relating to risk communication show that building trust and confidence in regulatory systems is not a simple matter and needs to understand and build on the way members of the public subjectively perceive and manage the applicable risks. A public that has become less trustful of risk regulators will become more risk averse, and in an environment in which risk regulators are not trusted, public fears are amplified relative to statistical or "objective" measures of the same risk. As such, risk managers should not expect that it will be straightforward to convince the public of the adequacy of expanded and more effective risk management frameworks such as the CMP. The literature also highlights the difficulty of improving trust relationships and the substantial impacts that well-publicized risk issues can have on public perceptions.

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Environics, Chemicals Management and Environmental Health Issues: Baseline Survey, prepared for Health Canada, 2009, p.53.

Ibid, pp.36-40.

These findings draw on the review of risk communication research findings in work by Löfstedt, op cit, 2004 as well as Slovic, P. (1987), "Perception of Risk" Science, v. 236, pp. 280-285, and Slovic, P. (1993), "Perceived Risk, Trust and Democracy", *Risk Analysis*, v. 13, pp. 675-685.

5. Risk management—control instruments – Effective management regimes are in place and stakeholders understand regulatory and non-regulatory risk management requirements

Judgements as to the extent to which the CMP is on track to achieve this immediate outcome are largely premature at this stage given that the majority of risk management instruments under the CMP will only take effect post-2010/11 due to the timeframes involved in risk assessment and development of risk management instruments. At the end of 2010, risk management actions under CEPA 1999 were in development for 38 of 151 substances in Challenge Batches 1 to 9 (with Batches 10, 11 and 12 and petroleum sector stream substances still in the risk assessment stage). As was noted in Exhibit VI-1, SNAc requirements for the future uses have been implemented or proposed for 24 substances and under CEPA 1999, pollution prevention plans proposed for four substances, and environmental emergency regulations proposed for seven substances, and a range of other actions proposed for another 10, including additions to the VE List and environmental release guidelines. Actions under the PCPA, HPA and F&DA have been implemented by HC for a subset of the proposed/actual Schedule 1 additions. Examples of these actions include changes to the conditions of use of older pesticides, a ban on the importation, sale and advertising of polycarbonate baby bottles that contain bisphenol A, additions to the Cosmetics Hotlist which prohibits or restricts their use in consumer products, review of presence of specific substances in future submissions (for example, in food packaging), and market surveillance and further investigation of the presence of specific substances in products in use.

The extent to which stakeholders, particularly substance manufacturers, importers and users, are aware of and understand proposed regulatory actions has not been formally assessed. However, the CMP's stakeholder engagement and consultation process involves an extensive amount of effort obtaining information from industry groups and consulting on proposed risk management measures. In parallel, industry associations representing the interests of businesses affected by the CMP also undertake communications activities to keep their members aware of CMP activities and proposals. This level of activity suggests that major industry participants are aware of the scope and implications of proposed and actual risk management measures. A tailored survey would be necessary to obtain a more definitive measurement of the level of awareness and understanding among industry participants and other stakeholders.

6. Risk management—compliance promotion and enforcement – Regulatees have increased awareness of their legal obligations, and effective compliance promotion and enforcement activities that support identified CMP risk management instruments are prioritized to address the greatest environmental threats

As noted in regard to the previous outcome, most risk management measures under the CMP will only take effect during the next phase of the CMP. This also means that compliance promotion and enforcement is more of a future priority of the CMP and it is premature to draw conclusions about the achievement of compliance promotion and enforcement outcomes. Compliance promotion and enforcement under CEPA 1999 is an EC responsibility while responsibility for actions under the PCPA, HPA and F&DA rests with HC, supported by the Canadian Food Inspection Agency. The application of the best placed Act approach to risk management under the CMP suggests that approaches by the compliance promotion and enforcement functions at HC and EC will require a greater degree of coordination than may currently be the case to achieve an optimal level of coverage of industry sectors.

7. Integrated horizontal policy and program management – Improved program decision-making and program performance

There was a general consensus among internal key informants with horizontal management responsibilities as well as those with responsibilities to deliver the various activity streams of the CMP, that this outcome is being achieved. As an example of these views, two jointly interviewed participants from one of the non-CEPA programs at HC (who managed both CMP and non-CMP program demands) noted, "Overall, a good process, probably the best example of linking and integrating (they have seen)." As was noted under the discussion regarding the effectiveness of the horizontal management and governance structure (EQ9), majorities of internal and external key informants indicated that the CMP's operational management is generally well integrated and coordinated within and between HC and EC. Governance structures – principally CMEC and the ADM Committee – are also considered to be effective.

Opportunities exist to further improve horizontal policy and program management, through such actions as the establishment of a common IT system to support cross-program and cross-department activities, development of performance measurement and reporting for the CMP, and strengthening financial tracking and management, operational performance monitoring, strategic and operational planning and budgeting.

B. To what extent has progress been made toward the intended intermediate and final outcomes of the CMP? (EQ14)

Evaluation Issue: Effectiveness	Indicator(s)	Rating			
14. To what extent has progress been made toward intended intermediate and final outcomes?	Evidence in documentation/data of the degree of progress toward outcomes. Views on the extent to which intended outcome has been achieved as a result of the program.	Too early to observe achievement			
Judgements as to the extent to which the CMP is on track to achieve these outcomes are largely premature at this stage of the CMP's lifecycle.					

A common theme in key informants' responses to questions regarding progress toward the achievement of the CMP's intended intermediate and final outcomes was that it was too early to draw conclusions but that at least some pre-conditions for progress had been addressed or were in progress.

1. Government decision-making is improved and Canadians have better access to information on risks

This intended outcome actually contains two unrelated expectations – government decision-making and better access to risk information for Canadians. The first of these may be viewed from two perspectives. Firstly, if decision-making may be improved as a result of increased availability of data to inform analysis and decision-making and/or more timely availability of data then it may be concluded that decision-making is, or is likely to be, improved. That is, under the CMP the resource capacity to assess the risks posed by chemical substances and develop appropriate risk management measures where needed has expanded significantly while reducing the timeframe in which such decisions are made. In parallel, steps have been taken to develop new tools and methods for assessing substance risks, consistent with emerging best practices in assessing substances risks in jurisdictions with well-established regulatory programs. Longer term, findings from CMP-funded research and monitoring and surveillance studies are expected to expand the availability of data to fill high priority gaps thus potentially improving the

availability and quality of data for use in risk assessment and risk management work. Most of the external key informants perceived the CMP to be making progress against this outcome, in so far as a structured process with clear timelines has been established and it is possible to follow the logic behind decisions (for the Challenge substances). The second perspective on "government decision-making is improved" – whether the efficacy of decisions and actions (that is, are CMP decisions on substances good decisions) – cannot be assessed until data on the effectiveness of risk management actions becomes available.

The second expectation in this outcome statement – "Canadians have better access to information on risks" – overlaps with the immediate outcome for risk communication examined in the previous section as well as the second intermediate outcome, examined in section B.2 below.

2. Canadians better understand the risks posed by chemicals and the actions they can take to avoid them

Access to and understanding of information on the risks posed by chemicals and their management are best considered together, in that access to information is a necessary initial step in changing the level of understanding and bringing about changes in behaviour.

As was noted in section A.4 of this chapter, above, information on the CMP and the Challenge substances (in particular) is available on the CMP website, and linked sites on the HC and EC websites, but proactive communications targeting Canadians or population sub-groups and intermediaries of interest, are limited. Many key informants noted that it is difficult to communicate information on complex technical issues involved with chemical hazards, exposures and their management, and to capture and retain the attention of Canadians, many of whom do not appear to see chemical hazards as a major priority in their lives. Without research into trends in levels of awareness and understanding of CMP information on the management of chemical risks and how such information is perceived and applied by Canadians it will not be possible to determine if this intended outcome is being achieved.

3. Unlawful releases of listed substances into or from the environment, food, consumer, and health products and pesticides are prevented or minimized

According to the program theory underlying the CMP's design, achievement of this intended intermediate outcome is expected to flow from the development and implementation of risk management measures for substances determined to pose risks to human health or the environment. With regard to actions under CEPA 1999, the development and implementation of risk management measures is insufficiently advanced and, as an extension of this, compliance promotion and enforcement actions are yet to be initiated, and this means that it is not possible to draw a conclusion regarding the extent to which the CMP is on track to achieve this outcome. Risk management measures have been implemented under the PCPA, F&DA and HPA to limit the availability of some substances used in the range of products or the use of such products mentioned in the outcome statement, which suggests that some initial progress in achieving the outcome has been made. Data on trends in the presence of substances of concern in the environment or humans required to measure achievement of this intermediate outcome will only become available in the longer term, drawing on findings from the various monitoring and surveillance activities supported by the CMP as well as such sources as the NPRI. In addition, not all risk management measures for chemical substances under these Acts have the power of law so it is inappropriate to consider only "unlawful releases" in the context of this outcome.

4. Reduced threats to Canadians and impacts on the environment from the harmful effects of chemicals

At this point in the life cycle of the CMP it is not possible to make judgements about the extent of progress toward this intended final outcome. However, it may be inferred that the first phase of the CMP has provided a starting point for reducing the human health hazards and environmental impacts of chemicals in that 25% of the high priority Challenge substances assessed to date have been determined to pose risks to the environment and human health, and actions are in progress to remove or restrict their use. Continuation of the research and monitoring, risk assessment, and risk management activities initiated during the first phase, plus the development and application of effective risk assessment and risk management approaches for medium priority substances and initiation of the CMP compliance promotion and enforcement activity stream, may reasonably be expected to lead to reduced threats to human health and the environment. Identification of clear changes in the exposure of humans and the environment to chemical substances of concern that may be attributable to the CMP will require multiple cycles of CMP-related monitoring and surveillance studies and supporting analyses to assess the reasons for identified patterns and trends, and as such, will not be available until the end of the CMP in 2020 or later.

C. Are there any external factors outside of the CMP that influence (positively or negatively) the success of the program? (EQ16)

Evaluation Issue: Effectiveness	Indicator(s)	Rating
the CMP that influence (positively or negatively) the success of the program?	Evidence of factors outside the program which have influenced the achievement of intended outcomes. Views on whether there are any external factors that help or hinder the achievement of intended CMP outcomes.	Not applicable

External factors identified that fall outside of the CMP's direct control or influence:

- Willingness of stakeholders, particularly industry, to participate in CMP consultation activities and provide input to proposed and final
 risk assessments and proposed risk management measures.
- A lower than expected incidence of high priority substances continuing to be used in commerce.
- High priority substances that were still in commerce were more likely to pose risks related to their presence in downstream products and processes and to require multiple risk management actions. In turn, risk assessment and risk management workloads for sector oriented programs with knowledge of such product applications increased as a result.

A small number of external factors outside of the CMP's direct control or influence that affect its success were identified by key informants:

- The willingness of stakeholders, particularly industry, to participate in CMP consultation activities and provide input to proposed and final risk assessments and proposed risk management measures. Comments made by industry stakeholders in key informant interviews suggest that the level of participation was positively influenced by the transparency and predictability of the CMP's processes. Other factors that appear to influence willingness to participate include the nature of the precautionary approach applied under CEPA 1999, which means that it is in the best interests of industry to demonstrate what it believes is an appropriate level of risk management, and recognition that strengthened regulatory management of existing chemical substances is increasing around the world and is not a "Canada-only" phenomenon.
- The extent to which substances identified as high priorities for risk assessment (and medium priority substances in the next phase of the CMP) are still in commerce, which in turn, determines the number of Challenge substances that require the development of risk management measures. Data on levels and characteristics of use used in the Categorization process was often quite dated (stemming from

the 1980s and early 1990s when the DSL was created). Data made available by industry during the information collection stage of the Challenge process demonstrated a higher than expected incidence of substances that were no longer in commercial use. Substances that are not in commerce do not require the same level of risk assessment or risk management, other than the issuance of a SNAc notice if there is a chance that a substance may re-enter commerce, and thus influence the risk assessment workloads at HC and EC.

While the incidence of potential Schedule 1 substances was lower than anticipated when the CMP was being designed, those that were identified were more likely to pose risks related to their presence in downstream products and processes (versus their initial production) and to require multiple risk management actions (an average of 2.9 per substance in Batches 1 to 9). For example, a recent summary of the experience with data collection for the Challenge process noted:

Based on recent S.71 surveys (mandatory information collection requests) the following can probably be extrapolated to the 3,000 (medium priority) substances:

- ~40% not in commerce
- Most substances are reported as present in "products"
- ~20% of the reported substances account for ~80% (of the) total quantities reported with a smaller subset of substances responsible for a large portion of commercial activity
- Initial data collection is key to success to ensure efforts are first directed towards the substances, or group of substances, with greater risk for exposure or release 45.

The greater incidence of substance use in products resulted in greater than anticipated workloads for sector oriented programs (for example, the Food Directorate at HC). The need to target substance use in products means that the success of the CMP will depend on the success of compliance promotion and enforcement activities in targeting industry sectors that, in many instances, may not be accustomed to being subject to chemicals regulation.

D. Have there been any unintended outcomes, either positive or negative, that can be attributed to the CMP? (EQ17)

	Evaluation Issue: Effectiveness	Indicator(s)	Rating
17	outcomes, either positive or negative, that can be attributed to the CMP? If	Where appropriate, documented management actions and/or lessons learned from unintended outcomes.	Not applicable
		Views on whether unintended outcomes occurred and appropriateness of any associated actions taken.	

Two possible unintended outcomes that may be attributed to the CMP were suggested:

- Removal of high priority substances from commercial use in Canada prior to their assessment under the Challenge process.
- Actions by consumers to avoid using products containing certain substances even though the CMP risk assessments concluded that the particular uses did not pose unacceptable risks, for example, avoiding repeat-use polycarbonate water bottles made with bisphenol A.

Two possible unintended outcomes of the CMP were identified. The first of these was the possible action by industry to remove or reduce their use of substances expected to be added to Schedule 1 in advance of the risk assessment of these substances under the Challenge process. That is, companies may have reviewed the list of high priority substances to be assessed during the first phase of the CMP and decided

Chemicals Management Plan — Horizontal Evaluation Health Canada / Environment Canada — July 2011

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Overview of Considerations for the Next Phase of the Chemicals Management Plan, presentation to the HC/EC Workshop on Selecting the Next Round of Substances, November 2010, p.8.

to remove some of these substances from production or end-use products because of the expected likelihood of the substances being added to Schedule 1. Alternatively, economic forces may have resulted in the cessation of production of substances in Canada or the introduction of substitutes, for example, higher costs of production in Canada versus other jurisdictions. In either event, the result is that fewer substances that may be of concern are in commercial use in Canada and, by extension, the exposure of Canadians to their attendant risks has been reduced.

A second possible unintended outcome is the previously noted potential for consumers to avoid using products identified as containing or using proposed Schedule 1 substances. In these situations consumers may choose to make their own decisions on avoiding the risks posed by certain substances, with bisphenol A being the best example, without necessarily considering and acting upon the full range of information made available by HC and EC. Actions of this nature may result in the removal or reduction of substances prior to final risk management decisions and possibly without considering the relative risks of using alternative or substitute substances.

VII. Efficiency and Economy

The demonstration of efficiency and economy is one of five core issues to be addressed in evaluations, according to the 2009 Directive on the Evaluation Function, which it defines as the "assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes".

The CMP involves multiple actions, outputs and outcomes distributed across multiple programs at HC and EC, many of which involve time periods of several years for completion, funded through a combination of A-base and B-base resources that have been difficult to allocate to the various outputs. Consequently, the analysis in this section is more qualitative and examines the extent to which the CMP provides a more efficient approach to identifying and regulating the risks posed by existing chemical substances and the extent to which resources have been allocated to best effect. A more fulsome assessment of efficiency would require more detailed breakdowns of the costs of each of the streams and areas of activity within the CMP and a full benefit-cost analysis when outcome data is available to assess value-for-money.

A. Efficiency of CMP activities and delivery (EQ18)

Evaluation Issue: Efficiency and Economy		Indicator(s)	Rating
18(a)	E	Views on whether the cost of producing program outputs is as low as possible. Views on how the efficiency of program activities	Progress made; action needed
(b)	achieving the objectives of the CMP?	could be improved. Views on whether there are alternative, more efficient, ways of achieving the objectives of the	
(c)		program.	

The CMP incorporates a number of measures to improve its efficiency and timeliness compared to the approach in place previously. Implementation of the CMP increased the capacity to assess substance risks and develop risk management measures. Application of a mix of self-imposed and mandatory timeframes for the Challenge process provided predictability and certainty that was previously lacking.

Significant increase in the number of substances to be assessed in the next phase of the CMP means that additional improvements in the productivity and efficiency of CMP risk assessment and risk management processes will be necessary.

Prior to the CMP, the approach to data collection and generation to assess risks posed by existing chemical substances was open-ended and without clear targets or deadlines for completion. Compared to this approach, the CMP incorporates a number of measures to improve the overall efficiency and timeliness of risk assessment activities:

- A risk-based approach that concentrated initial risk assessment and risk management work on substances categorized as high priority by the Categorization process. This approach concentrates on substances where the risks were anticipated to be the greatest rather than taking a uniform approach to assessing all substances on the DSL. By extension, actions to regulate the currently unregulated use of these high priority substances, and thereby reduce associated threats to Canadians and the environment will be implemented ahead of actions involving lower priority substances.
- > Strengthening of the core capacity for risk assessment and risk management work and a projected reduction in the timeframe to complete the assessment of priority substances from 2050 to 2020.
- Establishment of processes and methods to ensure timely progression of substances through the Challenge process, linked to the sequential issuance of batches of substances. A clear commitment to meeting the timelines by CMP managers reinforced the expectation that the Challenge would be completed as planned.
- Establishment of clear timelines for the assessment of batch substances and development of risk management instruments for Schedule 1 substances. As was shown previously in section B of chapter V, the core Challenge process has been implemented as planned with only minor slippage in the timing of risk assessments for each batch. Timelines for the development and finalization of risk management measures for substances proposed or added to Schedule 1 are proceeding in line with the timelines mandated in CEPA 1999.
- A higher degree of alignment of research and monitoring activities to the priorities and needs of the risk assessment functions at HC and EC. Outputs from these activities are expected to contribute to improvements in the effectiveness and efficiency of risk assessment and risk management in the longer term. Pooling of HC and EC research funding provides the basis for a shared approach to priority setting and project selection and funding.
- ➤ Horizontal coordination and integration of activities within and between HC and EC to ensure timely assessment of health and environmental risks and selection of the most appropriate Act and instruments for managing identified risks.

The net impact of the above design features of the CMP was twofold, compared to the approaches in place prior to the CMP. First of all, the capacity to assess substance risks was increased to a level that allows for approximately 100 substances to be assessed at any time, compared to a capacity to assess about 10 substances per year prior to the CMP, plus the development of risk management measures for the approximately 25% of substances added to Schedule 1. This increased capacity was achieved with an increase in annual funding for CMP activities of approximately 72% (from about \$118 million prior to the CMP's introduction to about \$204 million in 2010/11). Secondly, the establishment of a fixed maximum time to conduct the initial data collection and preparation of draft risk assessment documents, in combination with the time limits mandated in CEPA 1999 for final screening assessments and selection of risk management instruments, provided a level of certainty and predictability to the process that was previously lacking. Longer term, the closer alignment of research and monitoring actions to risk assessment and risk management needs and priorities is expected to further enhance the CMP's capability to measure the effects of risk management actions.

Participants in the international interviews conducted for the evaluation also highlighted many of these same aspects of the CMP as evidence of the efficiency and effectiveness of Canada's approach. As noted previously, these interviewees perceived the CMP to be pragmatic and effective in that substantial efforts were devoted to gathering information and establishing priorities prior to the Challenge, and described Canada as a trail blazer in tackling the inventory of existing substances. They also noted that the overall strategy of sequencing and scheduling batches made the process function more effectively and the timelines for batches provided certainty.

Compared to REACH (the only other similarly advanced chemicals regulatory system), the CMP sets priorities based on risk levels identified through the initial Categorization process whereas priorities under REACH are based on the volume of production and importation plus identification and inclusion of a subset of Substances of Very High Concern (SVCH). One consequence of the REACH approach is that industry had to submit data on a very large volume of substances for the first submission deadline (November 30, 2010) for substances produced or imported in high volume and/or identified as most hazardous substances. The European Chemicals Agency received over 24,000 registration dossiers relating to nearly 3,400 different substances.

Going forward, a number of possible opportunities to improve the efficiency of CMP delivery were identified in the analysis of key informants' responses:

- > Streamlining of HC and EC reviews and approvals of key risk assessment, management and communications documents, to increase the time available for risk assessment and risk management work.
- Development of approaches to the grouping and batching of medium priority substances for the next phase of the CMP and communicating details of the proposed approach to stakeholders.
- Maximizing the use, where possible, of a mix of approaches to filling data gaps for substances, to enable HC and EC to respond to the much higher volume of medium priority substances to be assessed in the next phase of the CMP. The suggested approaches comprise:
 - The use of data available from international sources and, to the extent possible, coordination of CMP risk assessment schedules with other key regulatory agencies' schedules.
 - Requiring industry to conduct testing and generate additional data on substances subject to assessment by HC and EC in addition to providing currently available data.
 - Identifying research and monitoring needs for the medium priority substances as early as possible to enable data to be produced in time to inform risk assessments and development of risk management measures to the maximum extent possible.
 - Further development and refinement of data modelling methods.
 - Timely completion of the DSL Inventory Update and revised ICL to facilitate identification of medium priority substances that are no longer in commerce.
- Provision for some flexibility in the timelines for initial information collection and preparation of draft risk assessments for medium priority substances, taking identified data gaps into account.

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Substances manufactured or imported at or above 1000 tonnes/year as well as Carcinogenic Mutagenic or Reprotoxic substances category 1 and 2 manufactured or imported at or above 1 tonne/year, and substances classified as dangerous for the aquatic environment and manufactured or imported at or above 100 tonnes/year.

Flexibility in funding structures for the next phase to enable re-allocation of funding among program areas to better respond to workload demands within HC and EC for risk assessment and risk management work that differ markedly from forecasts.

B. Is the CMP achieving its intended outcomes in the most economical manner and provided value for the federal dollars spent? (EQ19)

Evaluation Issue: Efficiency and Economy	Indicator(s)	Rating
 19(a) Is the CMP achieving its intended outcomes in the most economical manner? (b) Has the CMP provided value for the federal dollars spent? 	Extent to which program intended outcomes have been achieved at the least possible program cost. Views on whether good value is being obtained with respect to the use of public funds. Evidence of/views on whether there are alternative program models that would achieve the same expected outcomes at a lower cost.	Too early to observe achievement

Given that the CMP is at a relatively early stage of its lifecycle, it was not feasible to conduct a detailed analysis of the value for money achieved. Qualitative observations by key informants suggest that the CMP is believed to be on track to achieve its intended outcomes in an economical manner and providing value for the federal dollars spent.

At this stage of the CMP's implementation, with only limited outcome data available, it is not feasible to conduct a detailed analysis of the value-for-money of the CMP. Qualitative observations, largely drawn from the observations of internal key informants involved in the CMP's management and external key informants who have participated in stakeholder consultation and engagement activities, suggest that the CMP is seen to be on track to achieving its intended outcomes in an economical manner and is providing value for money in its design and delivery.

The key attributes of this perceived value for money are:

- Conformity with the principles for smart regulation established by the federal Cabinet, in particular, setting clear timelines for regulatory processes and coordinating the implementation and management of regulatory activities across HC and EC, and across multiple Acts applicable to the operations of prospective regulatees.
- As noted in the previous section:
 - Establishment of clear goals and timelines for risk assessment and risk management of high priority Challenge substances.
 - Supporting coordination and integration processes to enable timely progression of batches of substances and sign-off and approval of key outputs.
 - Alignment of research and monitoring with risk assessment to address priority data gaps and provide future insights into the effectiveness of risk management instruments.
 - Horizontal governance, coordination and integration mechanisms.

In addition, and as described in more detail in section F of chapter V, many of the internal key informants noted that resource allocations for their CMP activities were generally adequate to meet commitments and deadlines. Some noted, however, that actual CMP-related workloads were higher than anticipated but they

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Government of Canada, op cit, p.1.

were able to accommodate these additional demands through careful balancing of staff allocations and workloads. The Food Directorate in HC was an exception to this and required funding to be re-allocated within HC to enable it to handle the workload demands generated by the CMP. Delays have occurred with a number of core activities due, in part, to resource constraints such as the petroleum sector stream; development of environmental regulations for pharmaceutical and personal care products subject to the F&DA regulations; and revisions to the ICL. All told, this pattern of resource demands and workloads suggests that any reduction in resources would likely delay the completion of CMP screening assessments beyond the targeted 2020 completion date and the achievement of its intended outcomes.

VIII. Conclusions

A. Relevance of the CMP

Provisions in CEPA 1999 required HC and EC to screen and categorize the approximately 23,000 substances on the DSL and to assess the risks posed by those that were potentially toxic under S.64 of the Act. The CMP is a response to that requirement and was implemented to accelerate the rate at which the approximately 4,300 priority substances identified by the Categorization process would be assessed, reducing the expected end-date from 2050 to 2020. The first phase of the CMP was intended to assess the approximately 500 high priority substances and implement appropriate risk management measures for those determined to be toxic (that is, added to Schedule 1 of CEPA 1999). As such, there is a clearly established need for the CMP and this need will extend to at least 2020 in order to satisfy the legislated requirements of CEPA 1999.

The presence of these risks to human health and the environment is a function of a market failure to adequately recognize the social costs stemming from the health and environmental effects arising from the use of hazardous substances in the supply and pricing of these substances. As such, there is a clear rationale for public intervention to regulate the availability and use of potentially risky chemical substances.

The objectives set for the CMP – to take timely action to reduce or eliminate the risks posed by existing chemical substances to the health of Canadians and the environment – are also clearly aligned with the federal government's priorities in that the CMP is central to its environmental agenda and aligned with HC's and EC's Strategic Outcomes related to protecting Canadians from the health and environmental risks of hazardous chemicals. Finally, the assessment and management of toxic substances is a role that falls under various federal heads of power, including primarily the Criminal Law, that enables the federal government to take action that complements provincial and territorial authority to regulate industries that produce and use chemicals, to regulate the release of effluents and emissions, and to regulate occupational health and safety.

B. Design and delivery

The CMP is a long-term initiative of the federal government that is expected to run until at least 2020. The initial phase of the CMP from 2007/08 to 2010/11 involved the establishment and initial delivery of six of the seven core activity streams. The seventh stream, compliance promotion and enforcement, will become a priority during the second phase as final risk management measures are implemented.

The establishment and initial delivery of the CMP appears to be effective. However, there are a number of opportunities to refine and strengthen its design and delivery.

The program design and logic for the CMP is basically sound and focuses on a legislated need to identify, assess and manage risks to human health and the environment. In this regard, CEPA 1999 is a response to societal expectations that governments should intervene to protect human health and the environment from the hazardous effects of chemical substances. However, the current specification and ordering of program outputs and outcomes in the CMP logic model could be simplified to more clearly identify the most central expected results of the CMP and recognize the highly inter-dependent nature of the various activity streams. These core outcomes are:

- Fill gaps in HC's and EC's knowledge of the hazards posed by priority substances and possible exposure scenarios.
- ➤ Determine if substances should be added to Schedule 1 of CEPA 1999 and implement risk management strategies to prevent or minimize releases of such substances.
- > Increase Canadians' understanding and management of risks posed by chemical substances.
- ➤ Ultimately, to reduce health threats to Canadians and the negative impacts of chemical substances on the environment.

Most CMP areas of activity have been implemented as planned. The Challenge process has been implemented as intended and is largely on schedule; as of December 2010, final risk assessments had been issued for 151 of the 195 high priority substances in the Challenge process and final assessments of the balance are expected to be issued during 2011/12. Other key actions – rapid screening of 1,066 substances of lower ecological concern, introduction of pesticide incident and pesticide sales reporting, ongoing evaluation of new reduced risk pesticides, and mandatory labelling of cosmetic ingredients – have been implemented since the launch of the CMP.

Implementation of the DSL Inventory Update was modified in 2010 to focus data collection activities on the commercial status and use characteristics of medium priority substances expected to be assessed after 2015/16. Substances to be assessed between 2011/12 and 2015/16 were determined to be less in need of the substance use information collected through the DSL update process than those slated for later assessment.

Four other areas of activity have been implemented as intended but are running behind the original schedule. These are the assessment of 164 high priority substances in the petroleum sector stream, reevaluation of older pesticides, development and implementation of regulations to address environmental risks of new substances in pharmaceutical and personal care products, and preparation of the revised ICL of substances contained in products regulated under the F&DA. Further delays in these areas may potentially mean the continuation of risks to the environment and human health and have an impact on the ability of the CMP to achieve its intended risk assessment and risk management outcomes.

Environmental emergencies assessments under Section 200 of CEPA 1999 of the potential environmental or human health effects of the uncontrolled, unplanned or accidental release of a substance were not integrated into the risk assessment and risk management processes for the Challenge substances and petroleum sector stream. Opportunities exist to further integrate the work of the E2 Program and CMP risk assessment and risk management and will be pursued in the next phase of the CMP. Areas for such integration include ensuring that information concerning risks during emergencies is considered as appropriate in CMP risk assessments, ensuring that CMP risk assessments inform prioritization of actions by the E2 Program, and identifying appropriate linkages to or between actions under the E2 Program and CMP risk management actions.

Horizontal management and coordination of CMP activities is reasonably effective, particularly relating to the risk assessment, risk management and supporting research and monitoring activity streams undertaken by HC and EC. At the operational management level, the majority of internal key informants involved in the delivery of the CMP noted that the management and delivery of the CMP is generally well integrated and coordinated, and has improved steadily since the inception of the CMP.

At the governance level, the ADM Committee and DG-level CMEC provide joint HC and EC guidance and direction for the management and delivery of the CMP. Four areas in need of strengthening were identified:

- Performance information collected or available for the various CMP activity streams is almost exclusively focused on activities and outputs. These data, which are often in disaggregated form, have been sufficient to inform management decision-making at the operational level. However, provision and use of performance information to inform more strategic decision-making, planning, direction setting and performance reporting for the CMP is weak. A more integrated and systematic performance reporting system that keeps CMP managers informed as to the status and progress of the key activities in each stream, identifies where issues or delays are being encountered and the responses to these issues, and tracks progress in producing key outputs and outcomes, is needed to address this weakness.
- Strategic planning to translate thinking on the renewal of the CMP into direction setting and coordination of HC and EC activities in the next phase of the CMP.
- ➤ Provision of a common IT system with common software and shared servers for activities that are undertaken jointly by HC and EC personnel to improve the ease and efficiency of information sharing and preparation of key documents.
- Improving systems to track and report on CMP (B-base) and A-base expenditures and human resources involved in CMP activities to support financial reporting, operational management and strategic planning.

The future success of the CMP will also depend on the effectiveness of compliance promotion and enforcement activities by EC and HC, to ensure that target entities for risk management measures are aware of their obligations and non-compliance is prevented or limited. CMP compliance promotion and enforcement only comes into play once risk management measures are developed and implemented which meant that this activity stream had a very limited role during the first phase of the CMP. Going forward, the need to plan for and implement compliance promotion and enforcement activities linked to the completion of risk management measures for Challenge and petroleum sector stream substances will become progressively more prominent. The experience with the selection of risk management actions for Challenge substances – with combinations of pre- and post-market measures under combinations of Acts – suggests there may be a need for greater coordination between the EC and HC compliance promotion and enforcement functions than was anticipated at the time of the CMP's initial design.

Financial and human resources available to HC and EC for the first phase of the CMP appear to have been adequate for the majority of work undertaken although the delays in some areas of activity were somewhat affected by resource shortages and other areas indicated that they have very limited "surge capacity" to manage short term increases in workload demands. Some problems were encountered with the allocations among program areas and necessitated sustained re-allocation within HC. Allocations between salary and other operating costs were often a greater constraint than the absolute levels of CMP funding, and greater flexibility to re-allocate between these two funding areas would have permitted closer matching of human resource levels to workload demands.

C. Effectiveness

The CMP is four years into what is expected to be at least a fourteen year life cycle (that is, from 2007/08 to 2020/21), and consequently, has made only limited progress toward the achievement of its intended immediate outcomes. Each of the activity streams for the CMP has an associated immediate outcome. The status of progress and achievement in each of these areas is as follows:

- Risk assessment Improved knowledge of chemical-related risks, including identification of substances that may require further action and identification of data gaps to inform researchers and risk managers. The CMP's risk assessment process for high priority substances identified a range of substances that meet the criteria in S.64 of CEPA 1999 and were added to, or are proposed to be added to, Schedule 1 of the Act, and require risk management action. In particular, 38 of the 151 Challenge substances (25%) for which risk assessments were completed by the end of 2010 were determined to meet the criteria in Section 64. This incidence rate is lower than what was anticipated at the outset of the CMP, in part because a higher than expected proportion of the Challenge substances were found to be no longer in commerce in Canada. Additionally, the PMRA re-evaluated 360 of 401 pesticides first registered prior to 1995 by the end of 2009/10. Data gaps were identified by the risk assessment and research and monitoring functions and used in the planning and design of biomonitoring and environmental monitoring actions, and selection of research projects.
- Risk management—control instruments Effective management regimes are in place and stakeholders understand regulatory and non-regulatory risk management requirements. Judgements as to the extent to which the CMP is on track to achieve this immediate outcome are premature at this stage, given that the majority of risk management instruments under the CMP will only take effect in the next phase due to the timeframes involved in risk assessment and development of risk management instruments. At the end of 2010, risk management actions under CEPA 1999 were in development for 38 of 151 substances in Challenge Batches 1 to 9 (with Batches 10 to 12 and petroleum sector stream substances still in the risk assessment stage) or, in the case of actions under the PCPA, F&DA or HPA, implemented. The majority of the proposed risk management strategies for these substances involve multiple instruments, with an average of 2.9 different measures per substance under CEPA 1999, the PCPA, F&DA or HPA. With regard to the reevaluations of the 360 older pesticides, 34% were withdrawn, conditions of use were changed for 64% and left unchanged for the remaining 4%. In terms of stakeholder understanding, stakeholders who have participated in the engagement and consultation activities would be expected to have at least some understanding of proposed risk management measures by virtue of their involvement in consultation activities and receipt of supporting communications.
- ➤ Risk communication Canadians and other stakeholders are consulted and have access to understandable information on the CMP, and on the risks and safe use of chemicals. Stakeholder engagement is generally perceived to be a strength of the CMP by external stakeholders and program managers, with multiple opportunities for interested stakeholders to comment on, and provide input to, proposed decisions. Additionally, information on the CMP and many of its component activities (particularly the Challenge process) is available on the CMP website or EC and HC sites linked to the CMP website. Looking to the next phase of the CMP, many industry stakeholders emphasized that early notification of planned groupings of medium priority substances and the estimated scheduling of data call-ups would facilitate industry planning and data compilation.

Outreach to Canadians, however, has been limited, with only a limited amount of proactive communications targeting Canadians undertaken. Many of the key informants saw communications to Canadians as an area of weakness in the CMP. Baseline public opinion research conducted for the CMP in 2009 concluded that many Canadians have only a fairly superficial knowledge of chemical

risks. However, findings from the literature review conducted for the evaluation suggest that building trust and confidence in regulatory systems is not simply a function of the level of public communications by the regulators. Instead, the literature suggests that it is necessary to understand and build on the way members of the public subjectively perceive and manage the perceived risks, which may differ considerably from the "objective" risks identified by regulators.

- ➤ Research Improved knowledge of chemicals to support risk assessment, risk management, monitoring and surveillance. Most research projects are on a three-year cycle and the majority of the peer-reviewed results will only start to become available in 2011/12. In a limited number of instances, early findings have been shared with CMP risk assessors and risk managers, and there has been some use of research results in support of risk assessment and risk management, such as the risk assessment of bisphenol A.
- Monitoring and surveillance Improved monitoring of the effectiveness of control actions and fate of chemicals to support research, risk assessment and risk management. Monitoring and surveillance studies measuring the presence and effects of chemical substances in the environment and people are in progress. These studies are designed to increase knowledge of the fate of chemicals and understanding of the effectiveness of risk management actions will be improved as a result of the CMP. However, the need for multiple cycles of consistent data collection means that it will be quite some time before definitive conclusions can be drawn regarding the effectiveness of control measures.
- ➤ Risk management—compliance promotion and enforcement Regulatees have increased awareness of their legal obligations, and effective compliance promotion and enforcement activities that support identified CMP risk management instruments and are prioritized to address the greatest environmental threats. This activity stream will largely be implemented during the next phase of the CMP due to its dependence on the implementation of final risk management measures for Schedule 1 substances. As such, no conclusion regarding progress towards the achievement of this outcome can be drawn.
- ➤ Integrated horizontal policy and program management Improved program decision-making and program performance. Both internal and external key informants perceive that this outcome is being achieved. The CMP's operational management is generally well integrated and coordinated within and between HC and EC. Governance structures principally CMEC and the ADM Committee are also considered to be effective. Opportunities exist to improve support for strategic management in such areas as performance measurement and reporting, strategic planning, financial tracking and provision of supporting IT tools and systems.

At this stage of the CMP's life cycle it is too soon to be able to draw conclusions about progress toward the achievement of the CMP's intermediate and final CMP outcomes. These long-term outcomes involve the prevention or minimization of releases of hazardous substances, improving Canadians' access to and understanding of information on chemical risks and their management, improvements to government decision-making regarding chemical substances, and, ultimately, reduced threats to Canadians and the environment from the harmful effects of chemicals. Progress toward the achievement of the immediate outcomes suggests that the foundations and initial steps for their eventual achievement are in place except in regard to enabling Canadians to better understand the risks posed by chemicals and the actions they can take to avoid them.

D. Efficiency and economy

A detailed quantitative analysis of the efficiency and economy of the CMP was not feasible given the current state of data availability and stage of the CMP's implementation. Conduct of a more detailed analysis in the future will also require information on the cost and resource requirements (both A-base and B-base) of the main activities undertaken within the various streams of the CMP, which is not currently available. Efficiency and economy were examined using available program data and supporting qualitative assessments.

The CMP has adequate capacity to complete most of its key activities. Some re-allocation of funding has been necessary as the CMP has progressed, largely due to differences between actual and anticipated workloads for a number of activities and program areas. Progress in a number of areas has been affected by resource limits, such as the petroleum sector stream and risk assessment and risk management of legacy substances.

In terms of planned versus actual spending, the estimated total CMP expenditures were slightly below planned allocations in each of 2007/08 (4% below), 2008/09 (5% below) and 2009/10 (3% below). Patterns at HC and EC were similar with the exception of 2008/09 where the actual expenditures at HC were 9% below the planned allocation and 1% above at EC. Differences between estimated actual and planned expenditures for the different component activities are due to internal transfers between activities to better respond to actual workload patterns as well as such factors as delays in the initial ramping up of staffing in 2007/08 and lower than anticipated requirements for operating and maintenance expenditures (versus salary costs) in other years.

The CMP incorporates a number of measures to improve its efficiency and timeliness compared to the approach in place previously. Under the CMP, the capacity to undertake risk assessment and risk management work increased significantly to a level that allows for approximately 100 substances to be assessed at any time, compared to a capacity to assess about 10 substances per year prior to the CMP, plus the development of risk management measures for the approximately 25% of substances added to Schedule 1. This increased capacity was achieved with an increase in annual funding for CMP activities of approximately 72% (from about \$118 million prior to the CMP's introduction to about \$204 million in 2010/11). In addition, the application of clear and predictable timelines for the initial data collection and preparation of draft risk assessment documents, in combination with the time limits mandated in CEPA 1999 for final screening assessments and selection of risk management instruments, provided a level of certainty and predictability compared to the open-ended process applied previously. Longer term, the closer alignment of research and monitoring actions to risk assessment and risk management needs and priorities is expected to improve the availability of risk data and thereby strengthen the capacity of HC and EC to measure the effects of risk management actions. These changes, in combination with heightened horizontal management and coordination between and within HC and EC, suggest that the CMP is on track to achieve its intended outcomes in an economical manner and provide value for the federal dollars spent.

IX. Key Recommendations and Suggestions for Improvement

A. Key Recommendations

1. CMP logic model and outcomes

Revise the current number and definition of intended outcomes from the CMP, as captured in the logic model, to simplify the alignment and linkages between activities, outputs and outcomes. In doing so, clearly identify measurable results relating to preventing or minimizing health impacts and environmental releases of substances of concern, improving public understanding and management of chemical risks, and reducing threats to Canadians and the environment.

2. Performance Measurement Framework

- 2.1 Revise the proposed CMP Performance Measurement Framework to ensure that the indicators used clearly measure the production of key outputs and provide evidence of progress toward the intended outcomes. The Framework should also be used to track the status of key activities and identify areas where progress is diverging from plans and actions being taken in response to these emerging issues. This revised Framework should then be used to keep senior management responsible for the CMP at HC and EC informed as to the CMP's overall status and results, and as the basis for external reporting on the CMP's performance.
- 2.2 Define how and when the intended immediate, intermediate and final CMP outcomes will be measured, and implement the development and application of the necessary data collection methodologies at the most appropriate times.

3. Reassessment

Develop and implement a formal process and/or criteria for prompting reassessment of substances when new information becomes available.

B. Further Suggestions for Improvement

- 1. Tracking and reporting of financial and human resources engaged in CMP activities

 Develop and implement improvements to the tracking and reporting of actual A-base and CMP financial and human resources engaged in CMP activities to better inform the analysis and reporting of cost and resource requirements for the various CMP activities and outputs.
- 2. Coordinated planning and monitoring of compliance promotion and enforcement activities Establish a mechanism to provide advice to CMEC on the efficacy of CMP compliance promotion and enforcement activities and to support the coordinated delivery of those activities by EC and HC. The purpose of this role should be to provide a bridge between the management of the CMP and the conduct of compliance promotion and enforcement activities by the various compliance promotion and enforcement groups at EC and HC.

Areas of advice and support to CMEC should include:

Promoting information exchange, application of best practices, and where appropriate, policy coordination recognizing the different legal authorities and broader program mandates involved under CEPA 1999, the PCPA, the FDA and the HPA/CCPSA.

- Providing direction and guidance for the:
 - Establishment of compliance promotion and enforcement indicators and targets.
 - Collection of required performance data.
 - Reporting on CMP compliance promotion and enforcement outputs and outcomes.

This direction and guidance should form part of the development and implementation of the CMP Performance Measurement Framework.

Periodically reporting on CMP compliance promotion and enforcement approaches, outcomes and issues to CMEC and the ADM Committee.

In doing so, CMEC should consider adding EC's Chief Enforcement Officer and the DG of Environmental Protection Operations Directorate to its membership, and making best use of existing structures, including the EC Chemicals Standing Compliance Promotion and Enforcement Steering Committee.

3. Integration of supporting IT systems at HC and EC

Implement an appropriate IT system or tools to support HC and EC activities that require close collaboration and joint development of outputs.

4. Streamlining of approvals processes for batch documents

Review the documents approvals process for Challenge batches to determine if the process can be streamlined without posing risks to the overall integration and consistency of the various outputs, and implement improvement opportunities identified in the review.

5. Strategic planning for the next phase of the CMP

Develop and implement a strategic plan to guide the implementation of activities planned for phase two of the CMP to ensure interdependent areas of activity are appropriately coordinated and target outputs are produced within proposed timeframes, particularly activities that were delayed in the first CMP phase and carried over to the second, post-2010/11 phase.

6. Research into the understanding of chemical risks and their management among Canadians Conduct research into how Canadians perceive, interpret and use information on the risks posed by chemical substances to better inform the design of communications strategies and tracking of Canadians' levels of understanding.

Appendix A Bibliography

- 1. Bushnik T, Haines D, Levallois P, Levesque J, Van Oostdam J and Viau C, "Lead and Bisphenol A Concentrations in the Canadian Population", *Health Reports*, Vol. 21, no. 3, (September 2010), Statistics Canada, Catalogue no. 82-003-XPE.
- 2. CMEC and ADM Committee presentations and submissions:
 - Horizontal Management of CMP: Status Check, presentation to CMEC, (April 2008).
 - Integrated Management Accountability Framework (IMAF), (April 2008).
 - *CMP Status Report*, (October 2008).
 - *CMP Finances: Current Status*, (February 2009).
 - Integrated Program Management Office, Governance of the Chemicals Management Plan, (April 2009).
 - *Domestic Substances List Inventory Update* (DSL IU), (June 2009).
- 3. CMP presentations:
 - Canada's Chemicals Management Plan, (September 17, 2009).
 - An Overview of the Chemicals Management Plan and the Challenge, NICNAS briefing, (September 21, 2009).
 - Prioritization of Existing Substances under the Canadian Environmental Protection Act and Canada's Chemicals Management Plan, Briefing for NICNAS visit, no date.
- 4. CMP Integrated Program Management Office, Governance of the Chemicals Management Plan, April 2009,
- 5. Environics, Chemicals *Management and Environmental Health Issues: Baseline Survey*, prepared for Health Canada, (2009).
- 6. Environment Canada, *Canadian Environmental Protection Act, 1999*, accessed at: lawslois.justice.gc.ca
- 7. Environment Canada, 2009-2010 Estimates: Part III Departmental Performance Report, (2010).
- 8. Environment Canada, *Canadian Environmental Protection Act, 1999: Annual Report for April 2009 to March 2010*, Ottawa, (2010).
- 9. Environment Canada and Health Canada, Risk Management Strategy for Mercury, Ottawa (2010).
- 10. Eurostat, *The REACH Baseline Study*, Office of Official Publications of the European Commission, Luxembourg, (2009).
- 11. Government of Canada, *Cabinet Directive on Streamlining Regulation*, Regulatory Affairs Sector, Treasury Board Secretariat, (2007).
- 12. Health Canada and Environment Canada, *Results-based Management and Accountability Framework (RMAF): Chemicals Management Plan, (March 19, 2007).*
- 13. Health Canada and Environment Canada, *Canadian Environmental Protection Act, 1999 Review: The Interim Government Response*, (October 2007).
- 14. Health Canada and Environment Canada stakeholder briefing, *Addressing High Priority Petroleum Substances under the Chemicals Management Plan: Information session on the Petroleum Sector Stream Approach*, (March 5, 2008).
- 15. Health Canada and Environment Canada, *Overview of Considerations for the Next Phase of the Chemicals Management Plan*, presentation to the HC/EC Workshop on Selecting the Next Round of Substances, (November 2010).
- 16. Health Canada, Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products Horizontal Initiative Summative Evaluation, (2010).

- 17. Health Canada, *DPRs: Supplementary Tables Horizontal Initiatives Reporting*, 2007/08, 2008/09 and 2009/10.
- 18. Health Canada, Overview of the Report on Human Biomonitoring of Environmental Chemicals in Canada, Ottawa, (August 2010).
- 19. Health Canada, Pest Management Regulatory Agency: Annual Report 2008–2009, Ottawa, (2010).
- 20. Health Canada, Report on Human Biomonitoring of Environmental Chemicals in Canada: Results of the Canadian Health Measures Survey Cycle 1 (2007–2009), Ottawa, (August 2010).
- 21. Health Canada, 2009-2010 Estimates: Part III Departmental Performance Report, (2010).
- 22. Kubwabo C., et al, "Migration of bisphenol A from plastic bottles, baby bottle liners and reusable polycarbonate drinking bottles", *Food Additives & Contaminants: Part A: Chemistry, Analysis, Control, Exposure & Risk Assessment*, 1944-0057, Volume 26, Issue 6, (2009), Pages 928 937.
- 23. Lofstedt R., *How Can Better Risk Management Lead to Greater Public Trust in Canadian Institutions: Some Sobering Lessons from Europe*, paper prepared for the Privy Council Office as part of the Smart Regulation Initiative, Ottawa (2003).
- 24. Lofstedt R., *Risk Communication and Risk Management in the 21st Century*, Washington, AEI-Brookings Joint Center for Regulatory Studies (2004).
- 25. Lofstedt R., *Risk Management in Post-Trust Society*, London, England, Palgrave Macmillan Limited (2005).
- 26. New York Times, "Bottle Maker to Stop Using Plastic Linked to Health Concerns", (April 18 2008).
- 27. Slovic, P., "Perception of Risk" Science, v. 236, pp. 280-285, (1987).
- 28. Slovic, P., "Perceived Risk, Trust and Democracy", Risk Analysis, v. 13, pp. 675-685, (1993).
- 29. Washington Post, "Wal-Mart to pull baby bottles made with chemical BPA", (April 18 2008).

Appendix B Evaluation Matrix

Relevance Does the CMP continue to be consistent with and contribute to HC, EC and federal government priorities and does it address actual needs?				
Question	Indicators	Sources/Methods	TB Policy Issue Addressed	
1. Is there a continued need for the CMP?	Demonstration of societal/environmental need to ensure that legacy chemicals are managed and used in a safe and effective manner by industry and Canadians	 Literature Review Document Review (e.g., Canada Health Measures Survey (CHMS) results, environmental monitoring and surveillance reports) Key Informant Interviews with HC & EC representatives and external stakeholders 	Issue #1: Continued Need for Program	
	Presence/absence of other programs that complement or duplicate the objectives of the program	 Literature Review Document Review Key Informant Interviews with HC & EC representatives and external stakeholders 		
	Gaps would exist in addressing societal/ environmental need in absence of the program	 Document Review Key Informant Interviews with HC & EC representatives and external stakeholders 		
	Reach and activities are connected to societal/environmental needs	 Document Review Key Informant Interviews with HC & EC representatives and external stakeholders 		
	Views on connection of program objectives with societal/environmental needs	Key Informant Interviews with HC & EC representatives and external stakeholders		
2. Are the objectives of the CMP aligned with the	 Program's objectives correspond to recent/current federal government priorities 	Document Review (e.g., Treasury Board (TB) Submissions, Speech from the Throne, Budget Speech)	• Issue #2: Alignment with Government	
priorities of HC, EC and the Government of Canada?	Program's objectives are aligned to current HC and EC strategic outcomes	Document Review (e.g., HC & EC Departmental Performance Reports (DPR) and Reports on Plans and Priorities (RPP))	Priorities	
	 Views on the alignment of program objectives to recent/current federal government and departmental priorities 	Key Informant Interviews with HC & EC representatives and external stakeholders		
3. Is there a legitimate and necessary role for the federal	Program mandate aligned with federal government jurisdiction	Document Review (e.g., TB Submissions, Speech from the Throne, Budget Speech, HC & EC DPR and RPP)	• Issue #3: Alignment with Federal Roles and	
government in this program area?	Extent to which there is duplication or overlap with other jurisdictions, or opportunities to increase their roles in fulfilling this mandate	 Document Review Key Informant Interviews with HC & EC representatives and external stakeholders 	Responsibilities	
	Views on the appropriateness of federal involvement	Key Informant Interviews with HC & EC representatives and external stakeholders		

Has the Cl	Performance Has the CMP achieved its intended outcomes? Are the most appropriate, efficient and economic means being used to achieve outcomes?					
Question	Indicators	Sources/Methods	TB Policy Issue Addressed			
 a) Is the program design for the CMP appropriate for achieving expected program results? b) Is the program theory for the CMP (i.e., linkage of activities and outputs to intended outcomes, instruments (approaches used) 	Plausible link between program activities, outputs, and intended outcomes	 Literature Review (e.g., program theories in other jurisdictions) Document Review (e.g., CMP logic model and planning documents) Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives Case Studies 	• Issue #4: Achievement of Expected Outcomes / Design and Delivery			
instruments/approaches used) logically sound and does it realistically address the societal needs identified? c) Does the CMP identify clear deliverables and expected results?	Demonstration that the CMP has clear deliverables and expected results that are agreed to among CMP management	 Document Review (e.g., CMP planning documents, CMEC and ADM Committee meeting minutes) Key Informant Interviews with HC & EC representatives Case Studies 				
	Views on the appropriateness of program design, activities and processes	Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives				
5. Is the CMP delivered as designed and intended?	Extent to which outputs are produced and delivered to target audiences, as specified in CMP logic model (see output indicators in Performance Measurement Strategy)	 Document review (e.g., CMP Quarterly Reports) Performance Data Analysis Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives Case Studies 	• Issue #4: Achievement of Expected Outcomes / Design and Delivery			
	Extent to which CMP activities are leading to harmful and potentially harmful legacy chemicals being managed in accordance with regulatory and other established timelines, and in a manner that takes due consideration of opportunities, risks and the regulatory burden on government and industry	 Document review Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives Case Studies 				
6. Is appropriate performance information collected against CMP outputs and outcomes? If so, is the collected information used to inform	Presence/absence of a populated performance data system(s) with performance targets, baselines where appropriate, and reliable data	 Document review (performance reporting documents) Performance Data Analysis Literature Review (e.g., performance data in other jurisdictions) 	• Issue #4: Achievement of Expected Outcomes / Design and Delivery			
senior management/ decision makers?	Demonstrated use of performance information by senior management/ decision makers	Key Informant Interviews with HC and EC representatives Document Review (e.g., CMEC and ADM Committee meeting minutes)				
	Views on strengths, weaknesses and needed improvements to CMP Performance Measurement Strategy	Key Informant Interviews with HC and EC representatives, external stakeholders and international representatives				

Has the Cl	Performance MP achieved its intended outcomes? Are the most appropriate, effi	cient and economic means being used to achieve outcomes?	
Question	Indicators	Sources/Methods	TB Policy Issue Addressed
7. a) Are the roles, responsibilities and	Defined governance structure, including clearly articulated roles, responsibilities and accountabilities	Document Review (e.g., CMP Integrated MAF)	• Issue #4: Achievement of
accountabilities of HC and EC for the CMP clearly defined and implemented as specified? b) Is there any duplication in the roles	Evidence of extent to which roles, responsibilities and accountabilities are implemented as defined, and any duplication	 Document Review (e.g., HR plan, CMEC and ADM Committee meeting minutes) Case Studies 	Expected Outcomes / Design and Delivery
and responsibilities of HC and EC which causes unnecessary inefficiencies or delays?	Views on the clarity and implementation of HC and EC roles, responsibilities and accountabilities, and any duplication	Key Informant Interviews with HC & EC representatives	
8. Are HC and EC roles and responsibilities for the CMP clearly understood by key internal and external stakeholders?	Degree of understanding of HC and EC roles and responsibilities, and any areas of confusion	Key Informant Interviews with HC & EC representatives and external stakeholders	• Issue #4: Achievement of Expected Outcomes / Design and Delivery
 9. a) How effective are the integrated horizontal management and governance structure of the CMP? b) To what extent are the various HC and EC groups within the CMP working together in an integrated manner? c) To what degree are efforts at integrated horizontal management resulting in improved decisionmaking processes and efficiencies? d) Are any improvements needed to the CMP's integrated horizontal management or governance structure? 	 Extent to which HC and EC groups within the CMP are active in joint efforts at horizontal management Extent to which there are efficiency and effectiveness improvements in managing chemicals through the integrated horizontal CMP functional teams Extent to which opportunities for CMP delivery improvement are identified, reported and promptly implemented by CMP decision-making bodies Views on the effectiveness of CMP integrated horizontal management and governance and areas in need of improvement 	 Document review (e.g., CMP Quarterly Reports, CMEC and ADM Committee meeting minutes) Performance Data Analysis (internal databases (e.g., CANLINE) and other sources) Case studies Key Informant Interviews with HC & EC representatives 	• Issue #4: Achievement of Expected Outcomes / Design and Delivery
 10. a) Does the CMP have adequate capacity in terms of financial and human resources to achieve its intended outcomes? b) Are resources allocated appropriately among the major areas of CMP activity? 	 Program resources and capacity are commensurate with expected program results Extent to which the HR plan appropriately identifies numbers of managers and scientists required by CMP activity area, and extent to which these positions have been filled with the expertise and skills required Extent to which financial resources are budgeted and being expended in accordance with research, monitoring and surveillance and other CMP plans 	 Document review (e.g., HR plan, CMP financial information) Literature review (e.g., programs of other jurisdictions such as REACH in the EU and CHAMP in the US) 	• Issue #4: Achievement of Expected Outcomes / Design and Delivery

Has the CI	Performance MP achieved its intended outcomes? Are the most appropriate, effic	cient and economic means being used to achieve outcomes?		
Question	Indicators	Sources/Methods	TB Policy Issue Addressed	
	• Extent to which levels of CMP resources are consistent with those of comparable initiatives in other jurisdictions			
	Views on the adequacy and appropriateness of resource allocation	Key Informant Interviews with HC & EC representatives and international representatives		
11. What are the best practices and lessons learned (both strengths and weaknesses) from the CMP?	 Identified strengths, best practices, weaknesses and needed improvements to CMP design and delivery, and best practices of comparable programs in other jurisdictions 	 Document Review Literature Review Case Studies 	• Issue #4: Achievement of Expected Outcomes /	
	 Views on strengths, weaknesses and needed improvements to CMP design and delivery 	Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives	Design and Delivery	
12. a) In addressing the legacy of unassessed substances under CEPA 1999 by 2020, the CMP's long-term objective is to mitigate key threats to Canadians' health and the environment. Is the CMP, as currently designed and delivered, on the right track to accomplish this objective for 2020?	Evidence that harmful chemicals are being managed in accordance with regulatory and other established timelines in a manner that takes due consideration of opportunities, risks, and the regulatory burden on government and industry	 Document Review (e.g., substance-level PMEPs) Case Studies 	• Issue #4: Achievement of Expected Outcomes / Design and Delivery	
b) In order to facilitate the attainment of this objective, are any refinements to the CMP needed now to address key challenges and/or take advantage of key opportunities?	Views on the extent to which the CMP is on track to accomplish its objectives by 2020 and suggestions for any needed refinements	Key Informant Interviews with HC & EC representatives and external stakeholders		
 13.To what extent have the intended immediate outcomes been achieved as a result of the CMP? a) Improved knowledge of chemicals to support risk assessment, risk management, and monitoring and surveillance 	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis (e.g., internal databases and external sources) Case Studies Key Informant Interviews 	• Issue #4: Achievement of Expected Outcomes [Effectiveness]	

Performance Has the CMP achieved its intended outcomes? Are the most appropriate, efficient and economic means being used to achieve outcomes?						
Question	Indicators	Sources/Methods	TB Policy Issue Addressed			
b) Improved knowledge of chemical- related risks, including identification of substances that may require further action and identification of data gaps to inform researchers and risk managers	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				
c) Improved monitoring of the effectiveness of control actions and fate of chemicals to support research, risk assessment and risk management	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				
d) Canadians and other external stakeholders are consulted and have access to understandable information on the CMP and on the risks and safe use of chemicals	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				
e) Effective management regimes are in place and stakeholders understand regulatory and non-regulatory risk management requirements	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				
f) Regulatees have increased awareness of their legal obligations	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				
g) Effective compliance promotion and enforcement activities that support identified CMP risk management instruments and are prioritized to address the greatest environmental threats	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				
h) Improved program decision-making and program performance	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 				

Has the CI	Performance MP achieved its intended outcomes? Are the most appropriate, effi-	cient and economic means being used to achieve outcomes?	
Question	Indicators	Sources/Methods	TB Policy Issue Addressed
made toward the intended intermediate and final outcomes of the CMP?	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 	• Issue #4: Achievement of Expected Outcomes [Effectiveness]
 a) Government decision-making is improved and Canadians have better access to information on risks b) Canadians better understand the risks posed by chemicals and the 	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 	
actions they can take to avoid them c) Unlawful releases of listed substances into or from the environment, food, consumer and	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 	
health products and pesticides are prevented or minimized d) Reduced threats to Canadians and impacts on the environment from the harmful effects of chemicals	 Indicators in Performance Measurement Strategy (still to be finalised) Views on the extent to which intended outcome has been achieved as a result of the program 	 Document Review Performance Data Analysis Case Studies Key Informant Interviews 	
15. Have the objectives for CEPA 2005's air, water, new substances notification and research activities been achieved?	Extent to which the objectives set for the following CEPA 2005 activities have been met or significant progress achieved: Air and drinking water risk management New substances notification Priority research activities	Document Review Key Informant Interviews with HC & EC representatives and external stakeholders	• Issue #4: Achievement of Expected Outcomes [Effectiveness]
outside of the CMP which influence (positively or negatively) the success	Evidence of factors outside the program which have influenced the achievement of intended outcomes	Document Review (e.g., CMEC and ADM Committee meeting minutes) Case Studies	
of the program?	Views on whether there are any external factors that help or hinder the achievement of intended CMP outcomes	Key Informant Interviews with HC & EC representatives and external stakeholders	
negative, that can be attributed to	 Presence/absence of unintended outcomes Where appropriate, documented management actions and/or lessons learned from unintended outcomes 	Document Review Case Studies	
the CMP? If so, were any actions taken as a result of these outcomes?	Views on whether unintended outcomes occurred and appropriateness of any associated actions taken	Key Informant Interviews with HC & EC representatives and external stakeholders	

Has the Cl	Performance MP achieved its intended outcomes? Are the most appropriate, effi	cient and economic means being used to achieve outcomes?	
Question	Indicators	Sources/Methods	TB Policy Issue Addressed
 18. a) Is the CMP undertaking activities and delivering products in the most efficient manner? b) Are there alternative, more efficient ways of achieving the objectives of the CMPs. 	Comparison of program activities and products delivered to other similar programs	 Document Review Financial Analysis Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives Literature Review Case Studies 	• Issue #5: Demonstration of Efficiency and Economy [Efficiency]
the CMP? c) How could the efficiency of the CMP be improved?	Analysis of actual program operational costs in relation to the production of outputs	Document ReviewFinancial AnalysisCase Studies	
	• Views on whether the cost of producing program outputs is as low as possible	Key Informant Interviews with HC & EC representativesCase Studies	
	Views on how the efficiency of program activities could be improved	 Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives Case Studies 	
	Views on whether there are alternative, more efficient, ways of achieving the objectives of the program	 Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives Case Studies 	
a) Is the CMP achieving its intended outcomes in the most economical manner?	Extent to which program intended outcomes have been achieved at the least possible program cost	 Document Review Performance Data Analysis Financial Analysis Case Studies 	• Issue #5: Demonstration of Efficiency and Economy [Economy]
b) Has the CMP provided value for the federal dollars spent?	Views on whether good value is being obtained with respect to the use of public funds	Key Informant Interviews with HC & EC representatives and external stakeholders	
	Evidence of/views on whether there are alternative program models that would achieve the same expected outcomes at a lower cost	 Document review Literature review Key Informant Interviews with HC & EC representatives, external stakeholders and international representatives 	

^{*} Addressed in Phase I of the evaluation (evaluation of CEPA 2005).

Appendix C CMP Funded Research Projects

A. CMP Research fund projects

Health Canada projects

- 1. Maternal-Infant Research on Environmental Chemicals: Effects on Infant Development (MIREC-ID)
- 2. Development of the Screening Models and Biomarkers of Thyroid Disrupting Substances
- 3. Assessing the Utility of In Vitro Genetic Toxicity Tests for the Quantitative Prediction of In Vivo Effects for New and Existing Chemicals
- 4. Changes in DNA methylation as a predictive mode of action for effects of low dose exposure to mixtures and endocrine disrupters
- 5. Characterization of selected biomarkers and molecular mechanisms of toxicity following exposure to environmental contaminant mixtures and development of genomic tools to study neurotoxicity in animal model
- 6. The P4 Study: Plastics and Personal-care Product use in Pregnancy
- 7. Investigation of environmental fate of airborne CMP chemicals for the evaluation of human exposure to possible secondary pollutants
- 8. Investigation of Children's Exposure to Contaminants from Indoor Dust and Particulate Matter
- 9. Novel Approaches for Assessing Exposure to Phthalates

Bisphenol A projects

- 10. Developmental Mechanisms of BPA action: Role of cell surface receptors
- (2.) The P4 Study: Plastics and Personal-care Product use in Pregnancy (Bisphenol A component)
- 11. Investigation of the Genomic and Nongenomic Mechanisms Underlying the "Low Dose Effects" of Bisphenol A: The Role of Estrogen-Related Receptors (ERRs), Reactive Oxygen Specise (ROS)/Ca2+ Signalling, and Nuclear Factor Erythroid-Derived 2-Related Factor 2 (Nrf2)-Antioxidant Response Element (ARE)-Regulated Stress Response Pathway
- 12. Human Fetal Liver and Placenta: Metabolomic and Transcriptomic Responses in Foetuses with "High" and "Low" Exposures to Bisphenol A (BPA)
- 13. In utero Exposure to Bisphenol A

Environment Canada projects

- 14. Characterization and Effects of Substances found in Sewage Treatment Plant Effluent on Keybisp-Indicator Wildlife and Fish: Impacts of perfluorinated alkyl compounds, brominated flame retardants, various endocrine disrupting contaminants, and/or other medium-priority listed commercial chemicals of interest.
- 15. Screening CMP Chemicals for the Potential to be Persistent Organic Pollutants
- 16. EcoTOXScreen (ETOXS): Innovative biomarker platform to rapidly assess toxicity of priority chemicals in birds
- 17. Validating and using the amphibian toxicity test method system as a screening tool for the assessment of exposure and effects of priority chemicals and use of amphibians as biological indicators of environmental contamination in wetlands.
- 18. Exposure of avian species to atmospheric hydrocarbons: Evaluation of medium-priority listed aromatic hydrocarbons
- 19. Development of the zebra finch as an avian model for testing the effects of priority chemicals on early developmental effects
- 20. Assessing the fate and Impact of Dyes and Pigments in the Aquatic Environment
- 21. Effects of CMP Priority Chemicals in Mixtures
- 22. Development of a SED-TOX predictive model to assess risk to the aquatic environment based on chemical behaviour in sediment.
- 23. Effects of Chemicals Management Plan (CMP) Medium-Priority Compounds on Invertebrates and Fish
- 24. Determination of selected CMP metallic species in environmental media
- 25. Impact of Organosilicones on the Canadian Environment and the Health of Canadians
- 26. Estimating Chemical Bioavailability to soil organisms with CMP Substances from the Medium Priority List

B. F&DA research projects

- 1. Effects of municipal wastewater effluents on wild fish populations in Canada
- 2. On-farm fate of pharmaceuticals and personal care products: rates, mechanisms and rate-control
- 3. Canadianizing the European VetCalc model
- 4. In vitro toxicology of new nano formulations of pharmaceuticals to bacteria, algae, fish, and human cells
- 5. Effects of antibiotics, lipid regulators and mixtures on aquatic microbial community structure and function
- 6. Environmental fate of triclocarban during sludge digestion in Ontario sewage treatment plants
- 7. Evaluating the environmental fate and toxicity of sulphonamide antibiotics and their metabolites
- 8. Evaluating environmental exposure of selected plants and terrestrial organisms to veterinary pharmaceutical monesin
- 9. Analysis of the chemotherapy compounds methotrexate and cyclophosphamide in water
- Bioavailability of antidepressants released by municipal wastewaters and drug-related effects in fish and mussels
- 11. Identification of gene expression (toxicogenomic) indicators of ibuprofen exposure in critical life stages of native amphibian tadpoles
- 12. Long-term effects of municipal wastewater effluent (MWWE) and mixtures of pharmaceuticals and personal care products on fathead minnows and tree swallows

C. Foodborne contaminants research

Assessment of health effects of exposure to:

- 1. Flame retardants Polybrominated Diphenyl Ethers (PBDE's) A Developmental Immunotoxicity study
- 2. Emerging flame retardant HexabromocycloDodecane (HBCD) 28- and 90-day toxicity studies
- 3. Surfactants, stain/soil repellents Perfluoroalkyl acids (PFOS) 28-day toxicity study
- 4. Organo arsenic compounds during pregnancy and lactation
- 5. Acrylamide formed during food processing A colon cancer study.

Sources:

- "Health Canada & Environment Canada CMP Research Fund Allocations", April 2010.
- "CMP Research", presentation to ADM Committee, February 2009.

Appendix D Summary of Findings by Evaluation Question

Evaluation Questions	Achie	ieved	Progress Made; Attention Needed	Little Progress; Priority For Attention	Too Early to Observe Achievement	Not Applicable	
Relevance							
EQ1 Is there a continued need for the CMP?	✓	/					
EQ2 Are the objectives of the CMP aligned with the priorities of HC, EC and the Government	nt of Canada? ✓	/					
EQ3 Is there a legitimate and necessary role for the federal government in this program area	? ✓	/					
Performance – Design and Delivery				·			
 EQ4 (a) Is the program design appropriate for achieving expected program results? (b) Is the program theory for the CMP (i.e., linkage of activities and outputs to intend instruments/approaches used) logically sound and realistically addressing societal (c) Does the CMP identify clear deliverables and expected results? 			✓				
EQ5 Is the CMP delivered as designed and intended?			✓				
EQ6 Is appropriate performance information collected against CMP outputs and outcomes? information used to inform senior management/ decision makers?	If so, is the collected			✓			
 EQ7 (a) Are the roles and responsibilities of HC and EC for the CMP clearly defined and is specified? (b) Is there any duplication in the roles and responsibilities of HC and EC which cause inefficiencies or delays 			✓				
EQ8 Are HC and EC roles and responsibilities for the CMP clearly understood by key interstakeholders?	nal and external	/					
 EQ9 (a) How effective are the integrated horizontal management and governance structure (b) To what extent are the various HC and EC groups within the CMP working togeth manner? (c) To what degree are efforts at integrated horizontal management resulting in improprocesses and efficiencies? (d) Are any improvements needed to the CMP's integrated horizontal management or structure? 	er in an integrated ved decision-making		✓				
EQ10 (a) Does the CMP have adequate capacity in terms of financial and human resources outcomes? (b) Are resources allocated appropriately among the major areas of CMP activity?	o achieve its intended		√				
EQ11 What are the best practices and lessons learned (both strengths and weaknesses) from the strengths are the best practices and lessons learned (both strengths and weaknesses) from the strengths are the best practices and lessons learned (both strengths and weaknesses) from the strengths are the best practices and lessons learned (both strengths and weaknesses) from the strengths are the best practices and lessons learned (both strengths and weaknesses) from the strengths are the best practices and lessons learned (both strengths and weaknesses) from the strengths are the best practices and lessons learned (both strengths are the best practices).	ne CMP?		✓				

		Evaluation Questions	Achieved	Progress Made; Attention Needed	Little Progress; Priority For Attention	Too Early to Observe Achievement	Not Applicable
EQ12	(a)	In addressing the legacy of un-assessed substances under CEPA 1999 by 2020, the CMP's long-term objective is to mitigate key threats to Canadians' health and the environment. Is the CMP, as currently designed and delivered, on the right track to accomplish this objective for 2020?				✓	
	(b)	In order to facilitate the attainment of this objective, are any refinements to the CMP needed now to address key challenges and/or take advantage of key opportunities?		✓			
Perfor	rma	nce – Effectiveness					
EQ13	To	what extent have the intended immediate outcomes been achieved as a result of the CMP?					
	(a)	Improved knowledge of chemicals to support risk assessment, risk management, and monitoring and surveillance (Research)				✓	
	(b)	Improved knowledge of chemical-related risks, including identification of substances that may require further action and identification of data gaps to inform researchers and risk managers (Risk assessment)		✓			
	(c)	Improved monitoring of the effectiveness of control actions and fate of chemicals to support research, risk assessment and risk management (Monitoring and surveillance)				✓	
	(d)	Canadians and other external stakeholders are consulted and have access to understandable information on the CMP and on the risks and safe use of chemicals (Risk communication)	✓ (Stake-holders)		✓ (Canadians)		
	(e)	Effective management regimes are in place and stakeholders understand regulatory and non-regulatory risk management requirements (Risk management)				✓	
	(f)	Regulatees have increased awareness of their legal obligations (Compliance/ enforcement)				✓	
	(g)	Effective compliance promotion and enforcement activities that support identified CMP risk management instruments and are prioritized to address the greatest environmental threats. (Compliance/ enforcement)				✓	
	(h)	Improved program decision-making and program performance (Horizontal policy and program management)		✓			
EQ14	То	what extent has progress been made toward the intended intermediate and final outcomes of the CMP?					
	(a)	Government decision-making is improved and Canadians have better access to information on risks				✓	
	(b)	Canadians better understand the risks posed by chemicals and the actions they can take to avoid them				 	
	(c)	Unlawful releases of listed substances into or from the environment, food, consumer and health products and pesticides are prevented or minimized				✓	
	(d)	Reduced threats to Canadians and impacts on the environment from the harmful effects of chemicals				✓	
		there any external factors outside of the CMP which influence (positively or negatively) the success of program?					✓

Evaluation Questions	Achieved	Progress Made; Attention Needed		Too Early to Observe Achievement	Not Applicable
EQ17 Have there been any unintended outcomes, either positive or negative, that can be attributed to the CMP? If so, were any actions taken as a result of these outcomes?					✓
Performance – Efficiency and Economy					
EQ18 (a) Is the CMP undertaking activities and delivering products in the most efficient manner? (b) Are there alternative, more efficient ways of achieving the objectives of the CMP? (c) How could the efficiency of the CMP be improved		✓			
EQ19 (a) Is the CMP achieving its intended outcomes in the most economical manner? (b) Has the CMP provided value for the federal dollars spent?				✓	