Health Canada Santé Canada

Final Report

Audit of the Implementation of the Chemicals Management Plan – Existing Substances

September 2013

Canada

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Executive summary

The focus of this audit was the implementation of the Chemicals Management Plan (CMP) as it relates to 4,300 existing chemical substances. In December 2006, the Government of Canada launched the CMP initiative to strategically address these priority substances. The Government is managing the work in three phases over a 14 year period which started in 2006-07 and will be ending in 2020-21. The CMP is a jointly managed initiative between Health Canada and Environment Canada and brings together existing federal chemical programs related to the *Canadian Environmental Protection Act* under a single strategy.

The objective of the audit was to assess the effectiveness of the management control framework for the implementation of the CMP for existing substances as it relates to governance, risk and internal controls designed to support the Department in meeting its commitment to risk assess and risk manage 4,300 existing substances by 2020-21. The audit was conducted in accordance with the Treasury Board *Policy on Internal Audit* and the *International Standards for the Professional Practices of Internal Auditing*. Sufficient and appropriate procedures were performed and evidence gathered to support the audit conclusion.

Health Canada undertook an extensive exercise (with its partner department) and categorized the 4,300 chemical substances as high, medium or low priorities and established an ambitious timeline to conduct the risk assessment and risk management work. The initiative was well planned and remains well governed, however the progress to date has been slower than forecasted posing future challenges to meet the established 2020 timeline. It will be important for the Department to define a mid-term strategy that will address the current implementation challenges to support the long-term goal and to support renewal of the Program in 2015-16. Moreover, since the Program has not been tracking its use of financial and human resources specifically related to the assessment and management of the 4,300 existing substances, the Department could be investing valuable resources, time and effort without being certain that these efforts will bring it closer to achieving its goal of completing the assessment and risk management of the chemicals by 2020. Finally, the Program is monitoring and reporting on this multi-million dollar initiative using at least 10 different Excel spreadsheets and at least six different databases, all with limited interaction between them. This has reduced the Program's operational efficiency and weakened its ability to provide consistent information for monitoring purposes.

The audit report has four recommendations which are related to: updating the governance structure; developing a mid-term strategy to address current implementation challenges; developing and implementing an information system; and implementing a performance measurement strategy that includes enhancing existing tools. Management has agreed with the four recommendations and has prepared an action plan which will serve to strengthen the overall program management.

A - Introduction

1. Background

Chemical substances enter our air, water, land and food from many sources and consequently Canadians rely on the Government to take actions to minimize the risks to their health and the environment, posed by chemicals in the Canadian market. The Federal Government's main responsibilities in managing chemical substances are to identify which substances pose a risk to human health or the environment and to determine what must be done to prevent or minimize exposure to a toxic substance.

Over 25 years ago, the 1988 *Canadian Environmental Protection Act* came into force and required that new substances manufactured or imported into Canada, above certain thresholds, undergo a pre-market notification and government-led health and environmental risk assessment. Prior to the legislation and regulations being implemented more than 23,000 substances were manufactured, imported or used in Canada without full knowledge of their toxicity. These 23,000 substances are included on the Domestic Substances List.

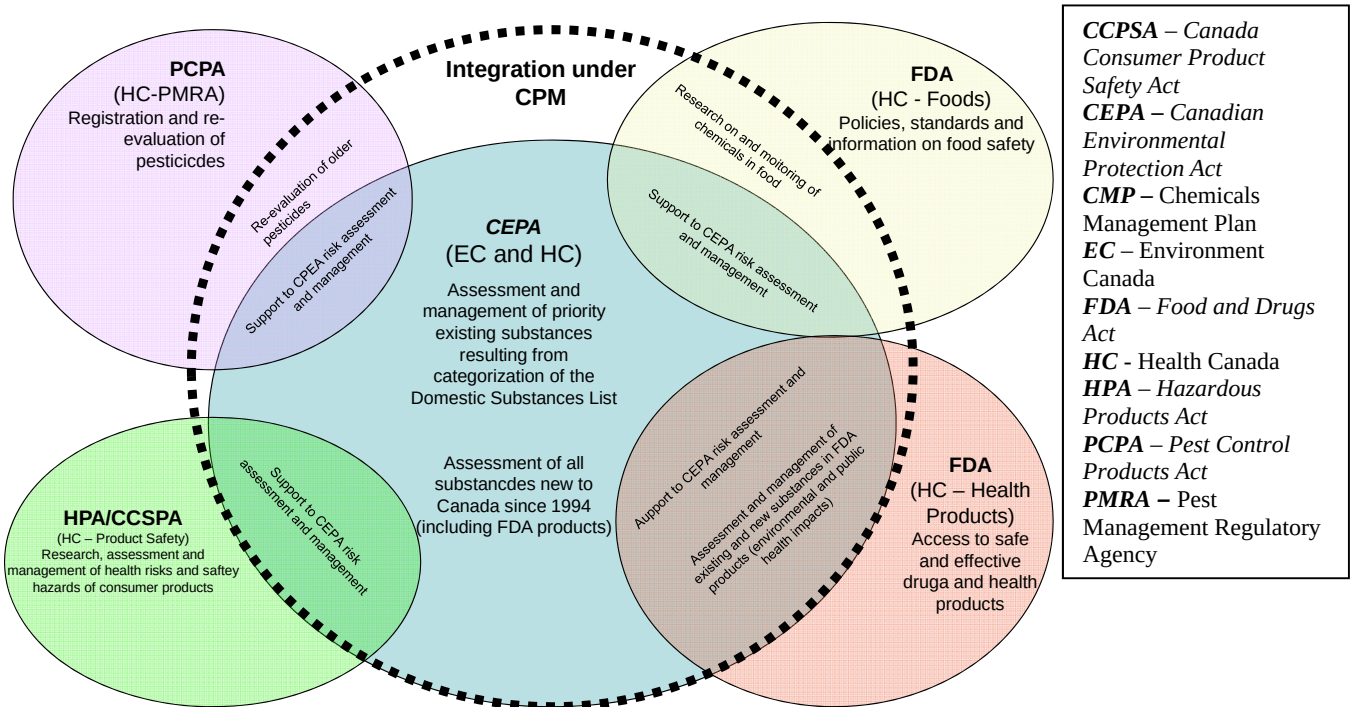
The revised *Canadian Environmental Protection Act* (1999) is the cornerstone of Canada's regulatory system for controlling exposure to toxic substances. Among other things, the Act requires the ministers of Health and of Environment to identify and determine which existing chemical substances in Canada pose a risk to human health and to the environment. The two departments undertook a large scale exercise to prioritize the listed domestic substances. The departments conducted this work by identifying high, medium and low priority substances based on the criteria specified in the Act (that is to say persistence, bioaccumulation and inherent toxicity to human health and to the environment and/or greatest potential for exposure to Canadians). The Act allowed 7 years for the completion of the categorization. In September 2006 the Government declared that approximately 4,300 (19 percent) of the legacy substances would undergo assessment.

Canadian Environmental Protection Act Highlights

- Sets out processes to assess the risks to the environment and human health posed by substances in commerce.
- Imposes timeframes for managing toxic substances.
- Provides a wide range of tools to manage toxic substances.
- Ensures the most harmful substances are phased out or not released into the environment in any measurable quantity.

To strategically address these 4,300 priority existing substances in an expedited manner, the Government launched the Chemicals Management Plan (CMP) in December 2006 as a large horizontal initiative. The CMP is a jointly managed initiative between Health Canada and Environment Canada and brings together all existing federal chemicals programs under a single strategy to address environmental and health risks. The diagram on the following page illustrates the inter-relationships of the 1999 *Canadian Environmental Protection Act*, the CMP Program, Health Canada and Environment Canada, and some of the various acts that are more closely related to the Program.

Interrelation Between Chemicals Programs



Primary Goal of the Initiative

A primary goal of CMP is to complete the assessments of the 4,300 existing substances by 2020 and to take any appropriate risk management action. This timeline results from an international commitment under the Strategic Approach to International Chemicals Management (SAICM) which has an overall objective for the achievement of sound management of chemicals throughout their life cycle so that, by 2020, chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. The 2020 goal was adopted internationally at the World Summit on Sustainable Development in 2002 as part of the Johannesburg Plan of Implementation.

The first phase of the CMP started in 2007-08 and lasted for four years. In the last year of CMP1 Health Canada had a total budget of $91.9M for work related to chemicals assessment and management (see Table 1). The CMP provided Health Canada with $66.9M and the one-year extension to Budget 2005 provided an additional $25M. CMP1 was to focus on approximately the 200 highest priority chemicals, 164 petroleum stream substances, and on the rapid screening triage of some 1,100 substances of lower concern. During that time, 195 of the high priority substances were examined, with 161 completed, and over 1,100 of the low priority substances were examined, with 533 determined not to be harmful with the remainder requiring further assessment. The petroleum stream substances were carried forward into CMP2 along with other substances examined but not completed resulting in a total carry forward of approximately 824 substances.

Health Canada is currently mid-way into CMP2, (2011-12 to 2015-16). This phase focuses on addressing substances carried forward from CMP1 (approximately 824) and 1,500 of the remaining priority (medium risk substances). Health Canada was allocated a total of $70.6M per year for five years or approximately 72 percent of the total funding from the second funding agreement. The funding agreement allocated approximately 225 full-time-equivalents in the Branch working on the CMP. The Safe Environments Directorate (the lead directorate) was allocated approximately 148 full-time-equivalents for all of its CMP activities.

Table 1: Total Health Canada Funding (CMP1, Budget 2005 and CMP2)

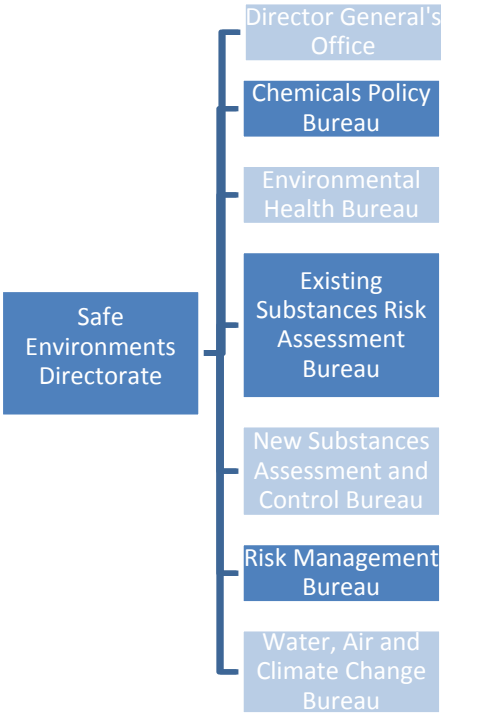
Activity	CMP1 (2010-11)	Budget 2005 * extension (2010-11)	CMP1 + Budget 2005	CMP2 (annual funding)
Risk Assessment	9.7	10.0	19.7	21.7
Risk Management	32.7	4.7	37.4	23.8
Research	8.6	2.1	10.7	9.5
Monitoring and Surveillance	14.4	5.7	20.1	10.5
Stakeholder Engagement	-	-	-	2.5
Program Management	1.5	2.5	4.0	2.6
Total:	**66.9**	25.0	**91.9**	**70.6**

* Budget 2005 one year extension was a top up of the CMP1 funding agreement, in addition to the funding provided under CMP1 and CMP2, excluding capital requested in a separate funding agreement.

Healthy Environments and Consumer Safety Branch

HECSB's – Safe Environments Directorate (SED) is the lead branch for the CMP initiative. It received funds to: collect information on use patterns, conduct risk assessments; implement risk management strategies; conduct scientific research; conduct monitoring and surveillance related to chemicals; and for program management purposes. Specifically for 4,300 existing substances, the Branch was allocated approximately $21.0 M per year, for five year period including permanent budget and program dollars provided to the program areas involved (see Table 2).

Safe Environments Directorate



The **Chemicals Policy Bureau** plays the *program management* function for CMP. The Bureau promotes integration of all CMP program elements within and between Health Canada and Environment Canada, in order to promote informed, cost-effective and timely action on health and environmental risks. For example, the Bureau acts as the secretariat to numerous CMP Health Canada/Environment Canada governance structures, leads the development of CMP performance measures, coordinates business planning (including linking human and financial resources to CMP activities), coordinates the development of

risk assessment and risk management packages for senior management or ministerial approval and is the key contact on international activities.

The **Existing Substances Risk Assessment Bureau** is involved in assessing and providing expert advice on the health risks posed by 4,300 existing chemicals. The risk assessment activity is a science-based evaluation of substances to determine if and how they may pose threats to human health. The Bureau houses the secretariat for the CMP Science Committee and coordinates external peer review of assessments and works internationally to develop common methods for assessing risk. This Bureau is the lead for a number of sub-activities such as: the Challenge Process; the Rapid Screening Approach; the Petroleum Sector Stream Approach; the Substance Groupings Initiative for nine groups of substances; and the development of the Polymer Approach, as well as assessment of legacy substances. The Bureau also coordinates participation of other programs in Health Canada in these assessments when uses of the substances are within the legislative and regulatory authority of those other programs.

The **Risk Management Bureau** is responsible for risk management for both CMP1 and CMP2 substances as well as legacy substances; for information gathering prior to the risk assessment stage and after the risk assessment phase; for cost-benefit analysis, such as regulatory impact assessment; and for stakeholder engagement and communication. Under the Act, control instruments can include: Significant New Activity provisions; regulations; pollution prevention plans; administrative agreements; and codes of practice. Many instruments are developed by Environment Canada or by Health Canada, in collaboration with Environment Canada.

The **Environmental Health Science and Research Bureau** conducts scientific research to identify 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. The Safe Environments Directorate is a key client who works closely with this Bureau in developing priorities and knowledge transfer following research. Research is also done in Health Products and Food Branch (see below).

The **Chemicals Surveillance Bureau** is responsible for delivering the biomonitoring component of the CMP and providing overall coordination of the CMP monitoring and surveillance program. This work involves leading and coordinating the development, collection, interpretation and reporting of biomonitoring and other environmental monitoring data in order to obtain better exposure information regarding Canadians, to protect health and to inform policies.

The Branch's CMP total budget includes programs such as: the New Substances Assessment Program, the assessment and management of the In Commerce List substances, Research, Bio-monitoring, the Water Program, and the Travelling Public Program on Passenger Conveyances. The table below shows the portion of the funding received by the Branch for the risk assessment, risk management and program management activities which were the

focus of the audit. In addition, HECSB uses approximately $9 million per year of its permanent salary funding for existing substances.

Table 2: Branch Budgets versus Expenditures for activities related to the 4,300 Existing Substances (in $M)

Directorate	Activity	FY 2011-12			FY 2012-13		
		Planned Budget	Expenditure	Variance	Planned Budget	Expenditure	Variance
Safe Environments	Risk Assessment	8.5	7.7	0.8	8.2	8.4	-0.2
	Risk Management	7.1	4.6	2.5	5.7	4.6	1.1
	Program Management	1.6	1.6	0.0	1.6	1.4	0.2
Consumer Product Safety	Risk Assessment	2.2	1.5	0.7	2.2	1.9	0.3
	Risk Management	1.5	2.0	-0.5	1.5	1.5	0.0
Total:		**20.9**	**17.4**	**3.5**	**19.2**	**17.8**	**1.4**

Note: Figures confirmed by the Chief Financial Officer's Branch and do not include items such as employee benefits, corporate support, or accommodations. Unaudited.

2. Audit objective

The objective of the audit was to assess the effectiveness of the management control framework for the implementation of the CMP for existing substances as it relates to governance, risk and internal controls designed to support the Department in meeting its commitment.

3. Audit scope

The audit focused on the management control framework in support of the implementation of the CMP for 4,300 existing chemical substances. HECSB is the lead for the Department and approximately 21 percent of the Branch's budget is devoted to this activity. While other Branches are implicated in the CMP2 work (Health Products and Food Branch, Pest Management Regulatory Agency, Regions and Programs Bureau, and Corporate Services Branch) they were excluded from the scope of the audit as the relative size of the funding and full-time equivalents conducting CMP2 work forms a significantly smaller proportion of the total funding.

Also not included within the scope of the audit is the retrofit project underway for the Sir Frederick Banting building. This began in 2011-12 and is expected to finish in 2015-16. As well, the scientific research related to CMP was not examined as a recent horizontal audit was completed on the management of scientific research. As well, the surveillance and monitoring was not examined as it will be the subject of an upcoming Health Canada audit. Lastly, the CMP funds received by PMRA to re-examine certain pesticides was also not included.

4. Audit approach

The audit criteria are designed to provide assurance that the CMP initiative as it relates to the work on existing substances is well governed, risk managed and has good internal controls to ensure that the Department is successful in meeting its commitments within the allotted timeframe.

The audit methodologies included the analysis of corporate and program documentation, interviews, focus groups, examination of the www.chemicalsubstanceschimiques.gc.ca website, analysis of the financial and non-financial information in the Integrated Planning and Performance Reporting System, and detailed analysis of financial records from Health Canada's financial system.

The audit was conducted in accordance with the *Internal Auditing Standards for the Government of Canada* and the *International Standards for the Professional Practice of Internal Audit*. The audit criteria, outlined in Appendix A were derived from the *Government of Canada's Horizontal Initiatives Database for the Chemicals Management Plan* and from CMP funding requests.

5. Statement of conformance

In the professional judgment of the Chief Audit Executive, sufficient and appropriate procedures were performed and evidence gathered to support the accuracy of the audit conclusion. The audit findings and conclusion are based on a comparison of the conditions that existed as of the date of the audit, against established criteria that were agreed upon with management. Further, the evidence was gathered in accordance with the *Internal Auditing Standards for the Government of Canada* and the *International Standards for the Professional Practice of Internal Auditing*. The audit conforms to the *Internal Auditing Standards for the Government of Canada*, as supported by the results of the quality assurance and improvement program.

B - Findings, recommendations and management responses

1. Governance

1.1 Governance framework

Audit criterion: *The lead branch delivers its Chemicals Management Plan responsibilities through an established governance structure with clear roles and responsibilities.*

Governance decisions should play a fundamental role in strategically directing the Chemicals Management Plan (CMP) initiative. The funding agreements for the first phase of the CMP (CMP1) and the second phase of the CMP (CMP2) were clear in defining a governance structure. CMP1 established an interdepartmental horizontal governance structure at the Assistant Deputy Minister, Director General, Director and Analyst level.

The **Chemicals Policy Bureau** acts as the secretariat to the CMP Health Canada/Environment Canada governance structures with horizontal departmental committees at different levels. At the highest level, the **Assistant Deputy Minister CMP Committee** provides strategic direction, coordination and a challenge function for the overall implementation and review of results and resource utilization on CMP initiatives. It also serves as a high-level forum for making recommendations on chemicals management to Deputy Ministers.

The **Chemicals Management Executive Committee** is the key management committee at the Director General level to support the development of joint Health Canada and Environment Canada strategic directions. It is also a formal body for joint consultations and cooperation to support timely and coordinated actions in implementing the CMP work activities in an integrated fashion. The Chemicals Management Executive Committee reports to the ADM Committee, providing recommendations on program implementation, results and resource utilization. However, recent meetings of the Chemicals Management Executive Committee have been less frequent.

The terms of references for the ADM Committee and the Executive Committee were last published in 2009 during the final years of CMP1. There are other committees in the governance structure, including “Four Corners”, for risk assessment and risk management teleconferences between Health Canada and Environment Canada (which make up the four corners) and the CMP Steering Committee. These meetings consist of risk assessment and risk management managers from both departments who deal with a broad range of operational policy matters. With an increased number of committees at the Director and Director General levels, some of the roles and responsibilities for committees as a whole may have changed. Also included in the updated governance structure is the CMP *Canadian Environmental Protection Act* Director General Committee. These committees currently do not have terms of reference to guide their work.

At the operational level, the **Existing Substances Risk Assessment Bureau** has a detailed consultation framework with several active committees used to provide input in the

assessment of chemical substances. This Bureau also functions as the secretariat for the CMP Science Committee whose members are appointed based on their expertise in regulatory science. The Bureau works with representatives from other countries, sharing knowledge to assist in developing regulations, environmental health assessments and risk assessment processes.

Documentation related to the internal governance structure resides in several different documents, including terms of references, agendas and records of decisions for individual committees; and the CMP funding agreement. Given the complexity of the CMP Program, various bureaus within the Safe Environments Directorate (SED) are involved, including the Chemicals Policy Bureau, the Existing Substances Risk Assessment Bureau, the Risk Management Bureau and others. Likewise, other partner organizations within Health Canada may also be involved, for their expertise, such as the Health Products and Food Branch and the Pest Management Regulatory Agency. Most importantly, an internal approvals structure exists for decision-making purposes.

It was noted that some of the governance committees have varying degrees of activity at this time. As more committees are formed in a governance structure, the potential for mandate overlap can increase. With the third phase of the CMP approaching, it would be beneficial to review the current governance structure and any associated guidance documentation and update them to align with current practices.

Recommendation 1

It is recommended that the Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch review and update the governance structure.

Management response

Management agrees with this recommendation.

The Chemicals Management Plan (CMP) is jointly delivered by Environment Canada (EC) and Health Canada (HC). The main obligations and authorities for existing substances under Part 5 of the *Canadian Environmental Protection Act*, 1999 (CEPA 1999) are assigned to both the Ministers of Health and the Environment, including conducting risk assessments and making recommendations to Governor in Council on Orders to add a substance to Schedule 1 and on proposed regulations to manage substances on Schedule 1.

Governance, risk management, planning and reporting for the Chemicals Management Plan are jointly undertaken. Successful delivery of the program requires the close cooperation and approvals of both departments.

Elements of this recommendation are beyond the sole control of the Assistant Deputy Minister of HECS. As such, the deliverables related to governance will be implemented by the ADM of HECSB to the extent possible, given the shared obligations and authorities under the CMP. In consultation with program partners, the Safe Environments Directorate within the Healthy Environment Consumer Safety Branch will review the Chemicals Management Plan (CMP) governance structure and will assess the organizational roles and responsibilities to reduce duplication if needed and implement streamlined operations where required.

In addition, the current CMP Governance document will be updated to include all the main committees outlined in the CMP Governance Structure.

2. Risk management

2.1 Risk profile

Audit criterion: *Chemicals Management Plan risks are assessed, profiled and reported to senior management.*

For a large scale initiative such as CMP, it would be expected that management would identify overall program risks; that the risks would be assessed for likelihood of occurrence and magnitude of impact; and that a roll up of the individual risks would be conducted to form a complete program risk analysis.

In the development of the funding agreement, a risk assessment was conducted in February 2011 which identified 30 risks. The risks were ranked and the higher priority risks were assessed with mitigation strategies. Some of the risks identified and assessed include the scientific validity of CMP information; increased industry burden; risk assessment; risk perceptions of Canadians; delivery of CMP outcomes; and capacity to address emerging issues.

In addition to this exercise, the Healthy Environments and Consumer Safety Branch (HECSB) uses the Integrated Planning and Performance Reporting System (IPPRS), a business intelligence tool, for branch operational plans and departmental roll-ups, in order to report risks. Using the categories outlined by the Corporate Risk Profile, the Program, Directorate and Branch roll up their risk information. The data entered into the IPPRS is used to create a directorate and a branch risk register. Currently, the risks related to CMP2 are aligned with the *2013-14 Corporate Risk Profile*. These include information management, legislative framework and public and stakeholder expectations/need for information.

Senior management has been briefed on updated CMP corporate risks. In addition there are meetings that take place on a regular basis where CMP risks are presented and discussed. Lastly, the annual *Health Canada Report on Plans and Priorities* is linked to CMP high level risks.

While critical risks have been identified, assessed and have mitigating strategies, it will be important to re-evaluate the risks in preparation for the drafting of the next funding agreement. Given the CMP is such a large initiative the Department would benefit from an individualized approach for identifying and controlling cost and scheduling risks (see recommendation 2).

In relation to the audit criteria, the audit found a process for assessing profiling and reporting risks to senior management.

3. Internal control

3.1 Program management

Audit criterion: *There are clear objectives, priorities and timelines to deliver on commitments regulated under the Canadian Environmental Protection Act for existing substances. Resource requirements for existing substances are identified and managed.*

The **Chemicals Policy Bureau** plays the program management function for CMP. The Bureau promotes the integration of all CMP program elements within and between Health Canada and Environment Canada, in order to promote informed, cost-effective and timely action on health and environmental risks. Health Canada received funding for the program management function (planned budget of $1.6 million per year, over the five year period of CMP2) given the greater degree of coordination required between Health Canada programs and for its overall Government of Canada coordinating role.

CMP planning objectives for each fiscal year are clearly detailed in various documents as well as in the Treasury Board of Canada Secretariat's database for horizontal initiatives. The Department is clear that for CMP2, it will continue to assess and manage the potential health risks from the remaining high priority substances from CMP1, including the ongoing assessment of substances in the Petroleum Sector Stream. The Department committed to continuing the assessment and the management of the potential health risks associated with approximately 1,500 medium risk substances by 2016 through the Substance Groupings Initiative, the Rapid Screening Approach and other approaches. During 2013-14, the

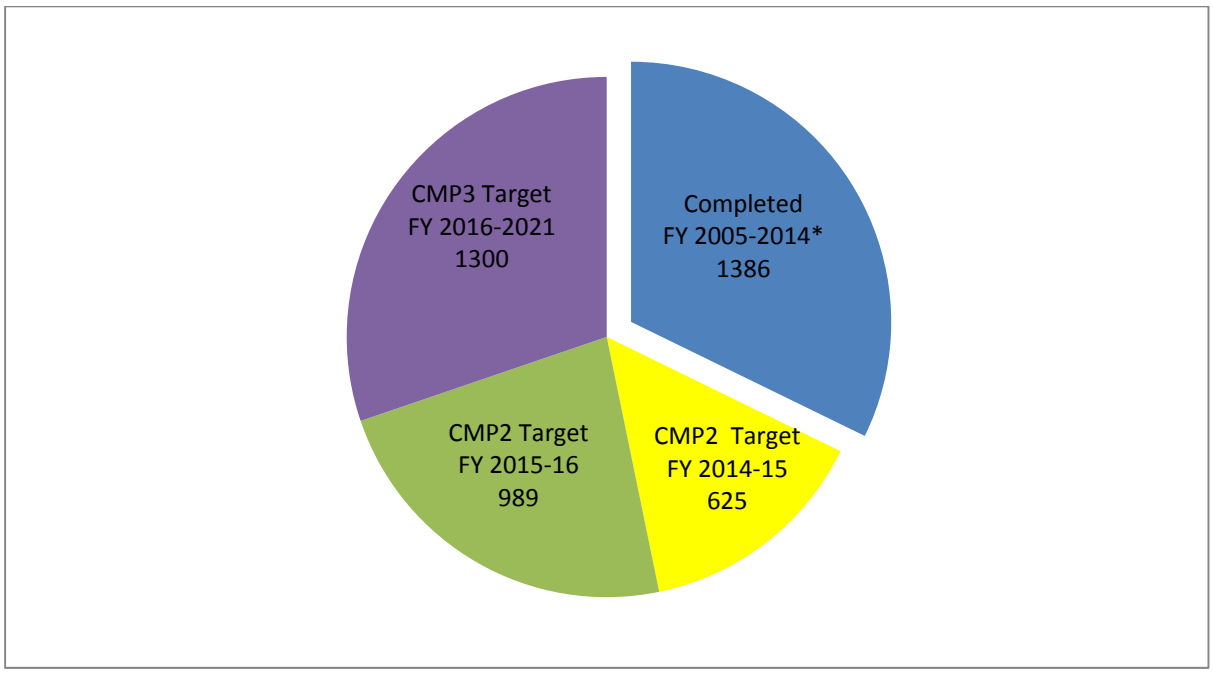
Department reports that data collection activities will also take place for the final three Groupings of the Substance Groupings Initiative. It notes that risk management measures will continue to be developed, implemented, tracked and monitored.

In order to advance the risk assessment and risk management work, substances are often packaged together based on like scientific properties. For example, one petroleum stream publication (petroleum and refinery gases) included 40 substances. Once a package is assessed, it is prepared for publication. The Program uses a master spreadsheet to track the progress according to the number of publications. While packaging chemicals for completing the risk assessment and risk management work may be an effective means to conduct the work, tracking the package publication dates does not provide information on the progress towards completion on the 4,300 substances. The audit found that the Branch has a variety of tools to support the overall project management however they are not being used as effectively as possible for project management purposes.

During the audit, the Chemicals Policy Bureau recognized this shortcoming relating to overall project management and has recently begun to use a new tool to track the flow of individual substances over the course of the assessment and risk management process (see Appendix C – flow chart). This change in progress tracking should allow for greater project management on the remaining 3,000 substances.

Once the Bureau completed the tracking exercise and provided the information for analysis, it became evident that based on current and future targets, there is a significant amount of outstanding work to be completed to meet the CMP2 published timelines as well as to reach the 2020 timelines. Risk assessment work, as a part of CMP2, was set out in an initial work plan, however since that time work within the second phase has been re-organized due to short-term unplanned issues. The specific details supporting the re-profiling of the work was not evident nor was there information on the impact related to existing workloads and timelines. The following pie chart shows the work completed (blue section) vis-à-vis the targets for future fiscal years (various colours):

Primary Goal for Chemicals Management Plan
4,300 Existing Substances
2005-2021



* Includes all completed assessments through to June 3, 2013 as well as 25 substances expected to be completed by March 31, 2014.

To support the CMP initiative, a request has been made from industry for information regarding several thousand medium priority substances. This information is expected to arrive in the fall of 2013. Some of these substances are to be addressed in CMP2 (1,500) and some are earmarked for the third phase of the Chemicals Management Plan (CMP3) (approximately 1,300). If industry provides the information by the established deadline, the Branch will only have 31 months to risk assess, where necessary, the remainder of the CMP2 commitments. In the interim, the Branch has started publishing drafts for the groupings initiative as well as more rapid screenings.

In 2008, the Department reported to the Office of the Auditor General that substances would be assessed at a pace of about 110 assessments completed per year. If this estimate is accurate, the pace will need to increase to approximately 450 assessments per year to meet the CMP commitment. Management reports that different types of assessments require different amounts of time to complete. For example, a rapid screening assessment requires less time to complete than a screening level risk assessment. They note that a number of draft assessments have already been published and more will be reported this fiscal year and point out that the drafting stage is the most time consuming part of the risk assessment process. However because of limited project management, the Branch is unable to identify the exact level of effort required. The carry forward from CMP1 combined with the fact that the Program has not yet completed any risk assessments targeted for CMP2, increases the risk that the established timeline may not be met (see Recommendation 2).

Resource management

The full cost of delivering a program within established timeframes is fundamental information for overall project management. Costing information assists in controlling expenditures against performance expectations. Since the Health Canada financial system does not provide the level of granularity at the activity level, it would have been expected that the Program would have tracked the costs and level of effort required to assess and risk manage the existing substances. While the Program was able to provide some costing information near the end of the audit, it was not something that was readily available. This type of resource information will be valuable in planning for the upcoming funding arrangement related to CMP3.

As well, the Program would benefit from having better information related to human resource planning. In the funding agreement, full-time equivalents were assigned to the different CMP activities. However it is difficult to determine whether this number of full-time equivalent staff is in fact correct. This may be due to the fact that each director is responsible for human resources planning. Without a Branch-wide perspective of the staff required and the resources used, the Program will have difficulty determining the costs associated to CMP2 or to know the effectiveness of the various initiatives. The 2010-11 evaluation of the CMP also identified the tracking and reporting of financial and human resources engaged in CMP activities as an area for improvement.

To more effectively manage the CMP initiative, and in preparation for the CMP3 funding agreement, it would be important to monitor the usage of financial and non-financial resources to better understand the overall requirements to meet the planned commitments.

Recommendation 2

It is recommended that the Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch develop a mid-term strategy (including an analysis on the efficiency and economy of the CMP activity) that will address the current implementation challenges.

Management response

Management agrees with the recommendation.

Elements of this recommendation are beyond the sole control of the Assistant Deputy Minister of HECS. As such, the deliverables related to program management will be implemented by the ADM of HECSB to the extent possible, given the shared obligations and authorities under the CMP. In consultation with with Environment Canada program management partners, the Safe Environments Directorate will develop a mid-term strategy to address the current CMP implementation challenges. This mid-term strategy will include an analysis of the efficiency and the economy of the CMP, setting up a sub-committee within existing governance structure to continually review progress towards the CMP 2 commitments.

3.2 Assessment of chemicals

Audit criterion: *There is a process for effectively prioritizing existing substances for risk assessment purposes. Risk assessments for existing substances are completed within established timelines.*

The **Existing Substances Risk Assessment Bureau** is responsible for the risk assessment process for identified substances. The Bureau's mandate is to protect the health of Canadians by assessing and providing expert advice on, the health risks posed by chemicals in commerce in Canada, including the development of approaches and strategies for risk assessment. As a part of CMP2 funding, the risk assessment activity had a planned budget of approximately $8.4M per year, for a five year period.

The Bureau has developed a number of approaches and strategies for the risk assessment workload such as: Rapid Screening (the most commonly used method for assessing substances of low concern); the Challenge initiative; sectoral approaches (such as petroleum); and the Substance Groupings Initiative (9 groups of substances identified based on structural or functional similarities). Some of its more prominent work includes the risk assessment conducted on *bisphenol A*, a high priority substance.

Risk assessment process

The risk assessment process is grounded in the *Canadian Environmental Protection Act* 1999. The process starts with information collection which may include publication of a notice to industry to gather mandatory information. Industry and interested stakeholders are invited to submit additional information that may be used to inform each risk assessment. Notices about the substances are posted on the chemical substances website as well as the *Canada Gazette*. Once information is collected, screening level assessments are conducted to determine whether substances are toxic or capable of becoming toxic. After the data is submitted, the draft screening assessment takes place followed by a 60 day period for public consultation on the draft conclusions of the assessment. Upon receipt of public comments the assessment is finalized and this process continues with risk management measures, if required. Due to the *Canadian Environmental Protection Act* requirements, there is a lot of timeline management as well as deadlines for the different types of notices (see Appendix C). Risk managers are embedded into the risk assessment process to ensure early awareness of issues and to confirm any additional data needs.

Health Canada's risk assessment of bisphenol A

Bisphenol A, along with approximately 200 other chemicals, was identified as a high priority under the Government's Chemicals Management Plan. Specifically, Bisphenol A was identified as a chemical that could affect reproduction. Health Canada analyzed the scientific literature, as well as recent assessments by other organizations, and confirmed that the potential health effects were reproductive and developmental.

The final risk assessment confirmed exposure levels are below those that could cause health effects; however, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of newborns and infants.

Source: Horizontal Initiatives Database

The audit found a process for prioritizing existing substances for risk assessment purposes and the risk assessments comply with the legislated timelines.

3.3 Management of chemicals

Audit criterion: *Risk management strategies, scope documents and instruments for existing substances are developed and implemented. Risk management measures for existing substances are developed, implemented, tracked and monitored.*

The Risk Management Bureau's mandate is to promote and protect the health of Canadians by developing, implementing, communicating and evaluating strategies to manage risks to human health associated with exposure to existing substances that are in use in Canada. Under certain conditions, exposure can have harmful short and/or long-term effects. Protection involves controlling these conditions and risk management is the process that sets out the control conditions. As a part of the CMP2 funding, the Risk Management Bureau received a planned budget of approximately $6.4M per year, for a five year period.

If a substance meets one or more of the criteria under section 64 of the *Canadian Environmental Protection Act* 1999, the ministers can propose to take no further action with respect to the substance, to add the substance to the Priority Substances List for further assessment, or to recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the *Act*.

A risk management scope is produced when a draft assessment is published with a potential concern requiring risk management. It summarizes the issue, including draft screening assessment report conclusions and current uses and exposure sources/pathways of concern, an overview of existing risk management, both Canadian and international, proposed risk management and next steps. Industry and other interested stakeholders are invited to submit comments on the contents of the scope document or other information that could inform decision-making. From this, a risk management approach is produced at the time of the final screening assessment report, providing another opportunity for consultation on the proposed risk management strategy. Following this consultation period, the Government of Canada initiates the development of the specific risk management instrument(s) and/or regulation(s), where necessary. Risk management scope and approach documents are not mandated in the Act, but are published to encourage early dialogue with stakeholders.

Currently, none of the substances specifically identified for CMP2 have been assessed to the point where risk management scope and approach documents would be produced as many of them are still in the information gathering/risk assessment stage. Within the Petroleum Sector Stream Approach for example, two risk management scope documents were completed (one in April 2012 and the other in June 2013). The contents of these documents were consistent with each other, providing information on the risk management issue, as well as existing and proposed risk management. One risk management approach was also released in June 2013, containing: current use; industrial sectors; presence in the Canadian environment; exposure sources; the consultation approach; and next steps with a proposed timeline. Moreover,

several substances initiated from CMP1 were completed during the timeframe of CMP2 due to the complex scientific issues involved. Many instruments may be utilized to mitigate risks.

Risk management measures

The "best-placed program" decision-making process is used to inform departmental discussions and to coordinate the appropriate use of relevant federal acts, including the *Canadian Environmental Protection Act* 1999, the *Food and Drugs Act*, *Pest Control Products Act*, and the *Canada Consumer Product Safety Act*. Risk management tools can include regulations, pollution prevention plans, environmental emergency plans, administrative agreements and codes of practice. These tools are not always necessary, as many substances may not require risk management. A process is in place for risk management with many steps including opportunities for public comment (see Appendix C).

Overall, risk management strategies, scope documents and instruments for existing substances are developed and implemented. As well, in instances where risk management measures for existing substances are required they are developed and implemented.

3.4 Information systems

Audit criterion: *Information systems support the management of the Chemicals Management Plan as it relates to existing substances.*

As a science-based department, Health Canada needs applications, tools and infrastructure to house data and facilitate the delivery of its regulatory and policy mandate. The funding agreement for CMP2 outlines the need for an information management and information technology system to assist in managing the volumes of information related to the chemical risk assessments and risk management strategies and to assist in overall project management.

The CMP is a multi-million dollar program that is being managed on various spreadsheets and several different databases, with limited interaction between them reducing operational efficiency. It is anticipated that operational efficiency could be further reduced into the future as the amount of data to be captured will increase significantly as the department collects data on the remaining 3,000 chemicals. It has become increasingly important that a system solution is identified and implemented to support the management of the initiative.

Since 2009-10, the Healthy Environments and Consumer Safety Branch (HECSB) has been working with the Corporate Services Branch, Information Management Services Directorate (IMSD) to find a solution. IMSD has a service delivery model for application development and maintenance and has engaged the Branch in this process to work on developing a risk assessment/risk management application. Once the application was approved for development, the Branch developed business requirements and worked with IMSD to meet departmental architectural standards.

Within the Branch, the Policy Planning and Integration Directorate, Office of Regulatory Process Improvement, is the project manager responsible for mapping "as is" business processes and the "to be" business processes and user requirements documentation, test plans,

training documentation, delivery of training, and change management plans, while Safe Environments Directorate is the ultimate client and subject matter expert. IMSD, on behalf of the program, has been involved with the options analysis.

Starting in 2009, the Branch focused on project management support, the modernization of the business processes and the business requirements document for the new application. The Branch worked on releases 1 and 2 of the system which included continued project management support, business analysis, test plans, training, user documentation and requirements. From 2011-12 to 2012-13, IMSD concentrated on the development of releases 1 and 2. Each of those releases was reviewed and subsequently reduced in scope.

Although the Branch and IMSD continue to work cooperatively to develop a solution to meet the Program's needs there have been challenges. In the spring of 2013, senior management agreed to continue with the development of the application's second release.

The project was funded through a combination of Branch permanent funding and the Deputy Minister's reserve (approximately $1.8M from the Branch and approximately $7.1M from the Deputy Minister's reserve). Between 2009-10 and 2012-13 approximately $6.5M was spent whereas approximately $2.4M will be spent in 2013-14 to complete release two. In total, almost $9M will have been spent on the identification of business requirements, business analysis, and the two project releases.

While the project has made significant progress, the originally identified requirements may have been overly ambitious as only one third of originally identified requirements will have been delivered with the completion of release two.

It will be important for the two partners to continue working together to complete the further development and ultimate implementation of a well-designed information system that can support the productivity related to CMP in a cost effective manner.

Recommendation 3

It is recommended that the Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch continue to work with the Assistant Deputy Minister, Corporate Services Branch to complete the development and implementation of an information system to support productivity related to CMP business needs.

Management response

Management agrees with this recommendation.

Healthy Environment Consumer Safety Branch, in consultation with Corporate Services Branch, will evaluate the viability and path forward of the *Risk Assessment Risk Management* IT project to support the productivity needs related to the CMP program requirements.

3.5 Measuring Performance

Audit criterion: *Progress for existing substances is regularly measured and reported to inform overall program effectiveness.*

A performance measurement strategy for CMP is an integral part of managing for results. The funding agreement committed the Program to revise the Performance Measurement Strategy by December 2013 and to implement the revised performance measurement framework by March 2014. It also provides for resources to be allocated to performance measurement to cover work in further refining the performance measurement framework developed for CMP1 and to develop tools for measurement and data capture. Approximately three full-time equivalents and $0.3 million in operating funds per year have been allocated to performance management. A further 0.5 full-time equivalent and $0.1 million will be used to develop performance measurements for specific risk management instruments. In total, approximately $1 million per year are to be dedicated to performance measurement and monitoring. However, the performance measurement strategy has not yet been fully updated and implemented.

Although there is not yet an updated performance measurement framework, particularly for higher level outcomes, the Program intends on piloting some performance indicators related to risk scores and quality indicators. Other international bodies have developed mathematically-based performance measurement standards. Health Canada and its partner department agree that a similar standard of incorporating mathematically-derived risk scores and quality indicators would be foundational in developing a CMP performance measurement framework; however, they note that the development of such a framework could be costly. Funds were already allocated in the funding arrangement for performance management, but the Program has done a preliminary analysis but needs to be piloted in order to validate projected cost data for the development of risk scores and quality indicators. CMP intends to pilot the collection of monitoring and other performance information for a subset of chemicals with an index being utilized. The pilot is expected to be undertaken in 2013-14, with results reported in the spring of 2014.

Given that the Chemicals Policy Bureau is responsible for program management, there is an expectation that the Bureau would provide for strategic management in such areas as performance measurement and reporting, strategic planning, financial tracking and provision of tools to support the project management of CMP2. While the Branch has various organizational tools such as monthly variance reporting, quarterly reporting through the Integrated Planning and Performance Reporting System, year-end reporting and departmental

performance reporting (including the CMP horizontal initiatives table), the Program recognizes these reports are at too high of a level and too general. Therefore, these reports have not been sufficient in clearly capturing detailed information on how many substances have been assessed to date and what still remains to be assessed.

A second issue that makes performance measurement challenging relates to the way the Bureau interprets the word "addressed" in the funding agreement. For the purposes of measuring performance, the Bureau interpreted "addressed" to be when a screening assessment was drafted – step 3 of 8 in the *Canadian Environmental Protection Act* 1999 process – rather than when an assessment has been finalized (step 4 of 8 - see Appendix C). Final assessments are typically published in the *Canada Gazette* up to 11 months after the draft assessment. Alternatively, a substance could be considered "addressed" when the substance's control measures have been implemented for example, a risk assessment has been finalized and the risk management control measures have been implemented. Without a consistent definition, information can be interpreted in a variety of ways, which can result in the Program overstating actual progress.

Lastly, the Chemical Substances Website is a Government of Canada site managed by Health Canada that is a central point of information for stakeholders and the public about the CMP. The CMP website (www.chemicalsubstanceschimiques.gc.ca) contains a substantial amount of information on many topics, including the approaches, information specific to businesses and organizations, individuals and families and the latest news about chemical substances. Among this information are links to Environment Canada sites hosting spreadsheets containing listings of substances that form the Domestic Substances List, as well as substances in the various assessment initiatives (the challenge, substance groupings, rapid screening etc.). An examination of the website found that some posted information is inconsistent with attached spreadsheets providing data posted or linked at different times, making reconciliation of data between the spreadsheets difficult. To provide users with consistent and timely information, website data should be updated consistently and at regular intervals. Discussions regarding the content on the website should be discussed with government partners at one of the governing committees. Currently, website information is being reviewed and updated in accordance with the Web Renewal Action Plan and web accessibility standards. The program should continue to work with its partners to ensure that materials linked to the CMP website are up to date and consistent.

By enhancing existing tools to better track the use of human and financial resources, the Program will better be able to determine progress in achieving its goals. This will further assist the Program in implementing its performance measurement strategy.

Recommendation 4

It is recommended that the Assistant Deputy Minister, Healthy Environments and Consumer Safety Branch

- *review and update the performance measurement strategy;*
- *enhance existing tools to better track program management data such as human and financial resources.*

Management response

Management agrees with this recommendation.

Elements of this recommendation are beyond the sole control of the Assistant Deputy Minister of HECS. As such, the deliverables related to performance measurement will be implemented by the ADM of HECSB to the extent possible, given the shared obligations and authorities under the CMP. The Safe Environments Directorate within the Healthy Environment Consumer Safety Branch will review the existing performance measurement strategy and assess existing indicators. Any gaps identified will be addressed by adding relevant indicators and removing those not measureable. The program will develop and implement a data collection strategy. The Performance Measurement Strategy will be reported quarterly through a dashboard to the CEPA DGs.

The Safe Environments Directorate within the Healthy Environment Consumer Safety Branch will also work with the Director, HECS Financial Services to develop a comprehensive and consistent approach to coding the financial expenditures for CMP in the financial system (SAP).

C - Conclusion

Health Canada's ability to continue to protect public health depends on credible and timely assessments of the risk posed by 4,300 existing chemicals. The department and its partner have the authority to obtain more information on those existing chemicals and to regulate those chemicals they determine pose an impact on the health of Canadians or the environment. Health Canada and its partners work with industry and other stakeholders to make information on chemicals publicly available. In this way, Canadians can actively participate in consultations with the Government of Canada and make informed decisions. As mentioned in the most recent funding agreement, Canada will continue to be a world leader in the assessment and management of chemicals.

The audit found that the Chemicals Management Plan initiative was well planned using a risk-based approach and remains well governed. As the Department plans for renewal of resources in 2015-16, there is an opportunity to develop strategies for addressing challenges that are currently impeding the Department's ability to meet its goal including challenges associated with the timeliness of obtaining data and identifying resources needed to conduct risk assessments and implement risk management decisions. As well, identifying and implementing an information technology solution will assist the Program in better managing the data collected, the risk assessment/risk management process and will provide a more sophisticated ability to performance monitor and report.

Management has agreed with the four recommendations and has developed a management action plan that serves to strengthen the governance, risk management and internal controls for the Chemicals Management Plan initiative as it relates to Health Canada's work for existing substances.

Appendix A –Lines of enquiry and criteria

Lines of enquiry and criteria

Line of Enquiry 1: Governance	
1.1 Governance framework[1]	The lead branch delivers its Chemicals Management Plan responsibilities through an established governance structure with clear roles and responsibilities.
Line of Enquiry 2: Risk Management	
2.1 Risk profile[1]	Chemicals Management Plan risks are assessed, profiled and reported to senior management.
Line of Enquiry 3: Internal Control	
3.1 Program management[2]	There are clear objectives, priorities and timelines to deliver on commitments regulated under the *Canadian Environmental Protection Act* for existing substances.
	Resource requirements for existing substances are identified and managed.
3.2 Assessment of chemicals[2]	There is a process for effectively prioritizing existing substances for risk assessment purposes. Risk assessments for existing substances are completed within established timelines.
3.3 Management of chemicals[2]	Risk management strategies, scope documents and instruments for existing substances are developed and implemented.
	Risk management measures for existing substances are developed, implemented, tracked and monitored.
3.4 Information systems[1]	Information systems support the management of the Chemicals Management Plan as it relates to existing substances.
3.5 Measuring performance[1]	Progress for existing substances is regularly measured and reported to inform overall program effectiveness.

[1] Office of the Comptroller General – Core Controls
[2] *Government of Canada's Horizontal Initiatives Database for the Chemical Management Plan* and *Chemicals Treasury Board Submissions*

Appendix B – Scorecard

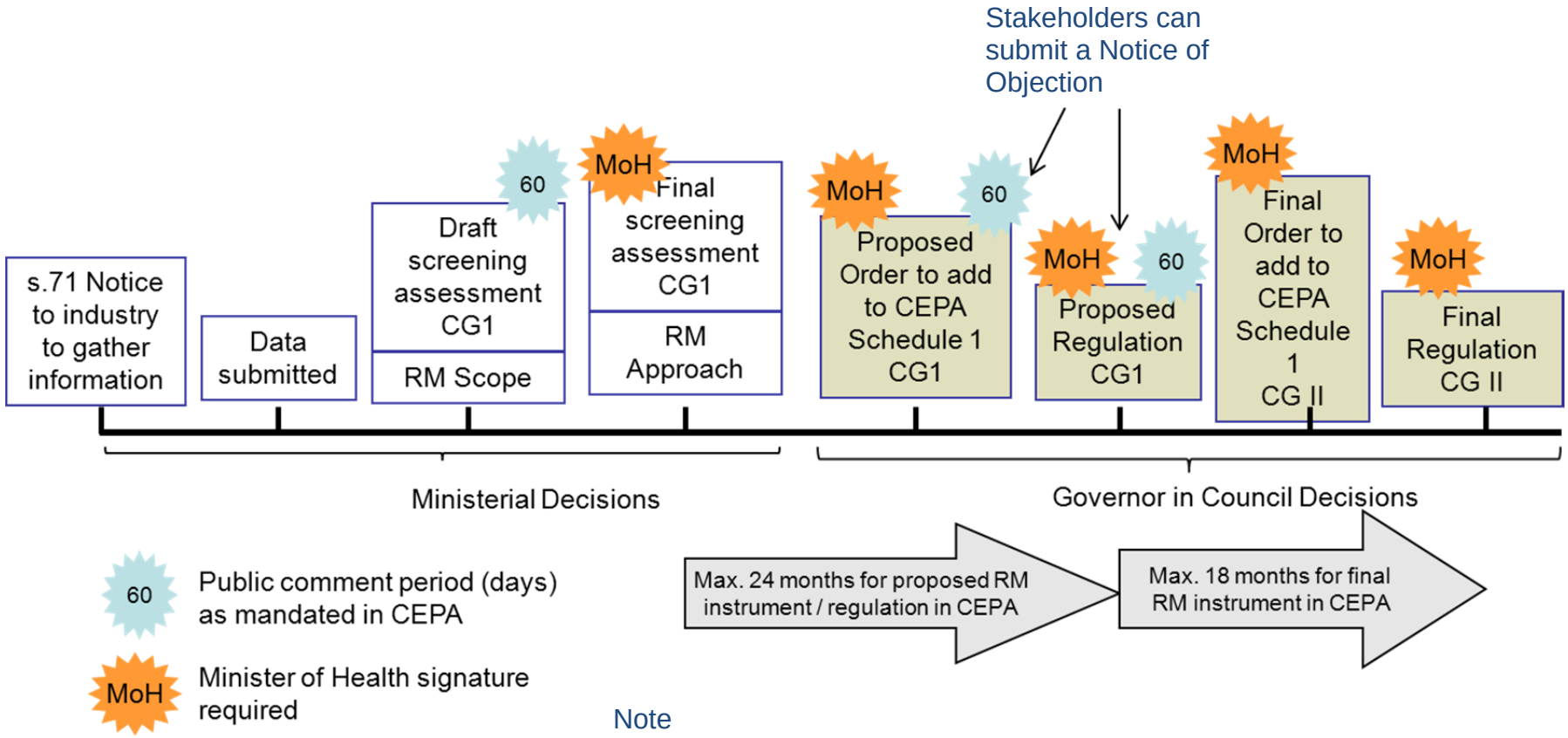
Scorecard

Criterion	Rating	Conclusion	Rec #
Governance			
1.1 Governance framework	**NMI**	A horizontal and internal governance structure exists. Additional committees have been included to update the governance structure required.	1
Risk Management			
2.1 Risk profile	**NMI**	Risk exposure related to the Chemicals Management Plan is assessed and profiled and reported. Scheduling and cost containment risks will need to be assessed for the third phase of the Chemicals Management Plan.	2
Internal Control			
3.1 Program management	**NMO**	Program management can be strengthened by tracking progress on individual substances and the better tracking of financial and human resource usage.	2
3.2 Assessment of chemicals	**NMI**	A process exists for prioritizing and assessing existing substances within the publication timeframes.	2
3.3 Management of chemicals	**NMI**	A risk management process is in place. Risk management tools are identified through the *Canadian Environmental Protection Act* 1999.	2
3.4 Information systems	**NMO**	The Chemicals Management Plan uses spreadsheets and manual data entry to monitor. This is currently reducing operational efficiency.	3
3.5 Measuring performance	**NMO**	The performance measurement strategy is to be implemented by March 2014.	4

S	NMI	NMO	NI	U	UKN
Satisfactory	Needs Minor Improvement	Needs Moderate Improvement	Needs Improvement	Unsatisfactory	Unknown; Cannot Be Measured

Appendix C – The *Canadian Environmental Protection Act* 1999 –Process for risk assessment and risk management

Process for risk assessment and risk management



Note

- Risk management scope and approach documents are not mandated in the *Canadian Environmental Protection Act* 1999 but are published to encourage early dialogue with stakeholders.
- Minister of the Environment signature is required where the MoH is required, and in addition for the section 71 notice and draft screening assessment.

Appendix D – Other branches participating in the Chemicals Management Plan

The following branches are also participants in the Chemicals Management Plan (CMP):

Health Products and Food Branch

The Health Products and Food Branch (HPFB) is the scientific and regulatory authority for health products and food. The directorates receiving these findings are the Food Directorate and Policy, Planning and International Affairs Directorate. This Branch has received funds to: conduct risk assessments; implement risk management strategies; conduct scientific research; conduct monitoring and surveillance; and for program management purposes (see the section on audit scope for funding and full-time equivalents). Specifically for existing substances, HPFB will receive approximately $14.2 million, or 11.6 percent of the total funding over the Program's five year term.

The *Canadian Environmental Protection Act* 1999 requires premarket notification and an assessment of risks to health and to the environment for substances new to Canada. Substances in the *Food and Drugs Act* regulated products undergo assessment (by Safe Environments Directorate) under the *Canadian Environmental Protection Act* 1999 for environmental and health risks due to environmental exposure. This Branch is leading the development of a regulatory framework that is more appropriate for these substances, and is supported by the Safe Environments Directorate and Environment Canada in this activity.

The food safety and nutrition program activity received funds to perform risk assessments, risk management, research, monitoring and surveillance and program management. The health products activity received funds for risk management activities. As part of the second phase of the CMP (CMP2), HPFB will continue to conduct risk assessments and to develop and implement risk management measures to address risks posed by harmful chemicals in foods.

HPFB also committed to continuing work related to the substances and products regulated under the *Food and Drugs Act*, including the re-evaluation of food additives and food packaging materials and assessment of food contaminants as indicated by CMP screening assessments and new scientific knowledge.

Regions and Programs Bureau

The Regions and Programs Bureau (RAPB) is an operational organization that manages the delivery of regulatory, scientific, and laboratory based programs and services across the country. Many of the regional programs are delivered in partnership with Health Canada's regulatory branches. The Bureau manages the laboratories across the country ensuring collaboration across business lines and providing broad based analytical and scientific support to all regions, and to the Department as a whole, as well as to external clients, including law enforcement agencies.

As part of CMP2, this Bureau receives a small amount of funding ($3 million per year) from HECSB for existing substances. The Bureau's work, as it relates to CMP, also involves supporting HPFB in its CMP activities through RAPB food laboratories, compliance promotion, and public outreach and awareness activities for CMP stakeholders, including engaging industry on mandatory surveys.

Corporate Services Branch

The Corporate Services Branch supports Health Canada branches by providing a variety of internal services, including policy and program management activities, human resources services, information/knowledge management services, planning, integration and management services, and real property and security. Some of the funds allotted were used to coordinate the horizontal management of human resources activities and other corporate service costs. The funds also support information technology systems and information management infrastructures, including integrated data collection for performance measurement purposes and financial tracking of CMP related expenditures across program areas (see section on scope). As resources are pooled, a precise figure for full-time equivalents is not available. Specifically for existing substances, CSB will receive approximately $14.2 million, or 11.6 percent of the total funding over the Program's five year term.

Pest Management Regulatory Agency

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

Primarily, PMRA will continue to work on the re-evaluation of approximately 400 previously approved pesticides according to legislated timelines and requirements under the *Pest Control Products Act*, as well as on continuing to monitor health and environmental incidents related to pesticides, analyzing trends and sales data and taking regulatory action as needed.